# No. 24-60227

# IN THE
# UNITED STATES COURT OF APPEALS
# FOR THE FIFTH CIRCUIT

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No. 24-60227

East Fork Enterprises, Incorporated; Epic Paint Company,

Petitioners

v.

United States Environmental Protection Agency; Michael S. Regan, 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

v.

United States Environmental Protection Agency; Michael S. Regan, Administrator, United States Environmental Protection Agency,

Respondents

**On Petition for Review of a Rule of the Environmental Protection Agency**
89 Fed. Reg. 39,254

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## CERTIFICATE OF INTERESTED PERSONS

**Case No. 24-60256,** *East Fork Enterprises v. EPA*

Pursuant to Fifth Circuit Rule 28.2, the undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

**Petitioners**

1. American Chemistry Council. It has no parent corporation and no publicly held corporation owns 10% or more of its stock.

2. East Fork Enterprises, Incorporated. It has no parent corporation and no publicly held corporation owns 10% or more of its stock.

3. Epic Paint Company. It has no parent corporation and no publicly held corporation owns 10% or more of its stock.

4. Sierra Club. So far as the undersigned petitioners are aware, the Sierra Club has no parent corporation and no publicly held corporation owns 10% or more of its stock.

**Respondents**

1. United States Environmental Protection Agency; and

2. Michael S. Regan, Administrator, United States Environmental Protection Agency.

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October 9, 2024

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## STATEMENT REGARDING ORAL ARGUMENT

Petitioners East Fork Enterprises, Inc., Epic Paint Company, and American Chemistry Council request oral argument. This petition presents important and complex questions about the validity of a major rule of the Environmental Protection Agency that effectively shuts down many existing markets for methylene chloride-based products. Oral argument will aid the Court in its consideration of the issues.

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## JURISDICTIONAL STATEMENT

This petition seeks review of a rule of the Environmental Protection Agency ("EPA") under section 6(a) of the Toxic Substances Control Act ("TSCA"), and of the risk determination embodied in the rule. ECF Doc. 1-1. Under TSCA section 6(i)(2), the rule is a final agency action, including the underlying risk evaluation and its "associated determination" of unreasonable risk; and section 19(a) confers exclusive jurisdiction for such review upon the circuit courts. 15 U.S.C. §§ 2605(i)(2), 2618(a). "[A]ny person may file a petition for judicial review," *id.* § 2618(a)(1)(A); such language allows a challenge regardless of whether the petitioner submitted comments in the rulemaking process, *Am. Forest & Paper Ass'n v. EPA*, 137 F.3d 291, 295 (5th Cir. 1998). This Court is an appropriate venue because petitioners East Fork Enterprises, Inc. ("East Fork") and Epic Paint Co. ("Epic") have their principal places of business within this circuit. 15 U.S.C. § 2618(a)(1)(A); Boyd Declaration, ¶ 4; Whaley Declaration, ¶ 4. The petition was timely filed 14 days after EPA's rule was published.

East Fork and Epic have standing to challenge EPA's rule, because the rule significantly restricts the manufacture and distribution of products containing methylene chloride. They manufacture and/or sell a range of products with methylene chloride as a key ingredient, particularly paint strippers. Each of them is subject to EPA's rule and the activities of each is newly restricted by EPA's

regulation: EPA is prohibiting manufacturing of methylene chloride products for a range of uses including those products which East Fork and Epic have made and would (absent the rule) continue making and/or selling. Boyd Declaration, ¶¶ 5-6; Whaley Declaration, ¶¶ 5-6; RE-44[1] (codified at 40 C.F.R. § 751.107(b)). "[T]here is ordinarily little question" that a directly regulated entity has standing to "challeng[e] the legality of government action or inaction." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62 (1992).

The American Chemistry Council ("ACC") has standing to challenge the rule, and to raise the questions herein presented to this Court, because its members include methylene chloride manufacturers and companies that use methylene chloride in various processes to make other chemicals, polymers, and products. *See* RE-309. Those members, such as Celanese Corp., The Chemours Company, Dow, DuPont deNemours, Inc., and SABIC Innovative Plastic, US LLC, *see* ECF Doc. 57 at 5-6 (ACC Motion to Intervene), are directly regulated by the challenged rule. *See Lujan*, 504 U.S. at 561-62.

Petitioners request *vacatur* of EPA's rule. Only that remedy would truly relieve East Fork and Epic, and ACC's affected members, of the severe restrictions on their manufacture, sale, and use of the covered products.

[1] "RE-" citations refer to the excerpts from the administrative record that will be filed within 21 days after EPA's brief, pursuant to Fifth Circuit Rule 30.2(a).

## STATEMENT OF THE ISSUES

1. Whether, given TSCA's mandate to determine whether a given "condition[] of use" of a substance presents an "unreasonable risk," EPA can legitimately determine an entire chemical to be unreasonably risky by concluding simply that there is some non-zero risk from some activities using the chemical, and by ignoring the actual conditions of use;
2. Whether EPA's exposure limits are not supported by substantial evidence and were arbitrary and capricious, given that EPA set the limits to prevent all risk, not just unreasonable risks, and ignored contrary data in the record;
3. Whether EPA is authorized to prohibit most uses of methylene chloride solely on the basis that certain users might not be able to comply with its stringent exposure limits; and
4. Whether EPA's regulation of methylene chloride is arbitrary and capricious for failure to consider whether purported alternatives are actually reasonable substitutes, and for failing to account fully for the costs of the rule particularly to small businesses.

## INTRODUCTION

TSCA enables EPA to regulate unreasonable risks that might otherwise escape control under other statutes. Given the statute's gap-filling role, EPA unsurprisingly issued few such regulations. After a 2016 amendment that instructed

EPA to undertake risk evaluations for priority chemicals, EPA finally sprang into action—but the agency has gone much too far. The rule at issue, the second under the new provisions, grabs sweeping authority, ignoring the restrictions that Congress placed on TSCA rules. EPA has issued an outright ban on most activities using a particular industrial chemical.

That chemical, methylene chloride, is central to a wide range of commercial and industrial processes. It is used as a solvent in adhesives, sealants, automotive products, paint strippers and coating removers, and far more. Methylene chloride is used in sectors involving refining, petroleum, batteries, electronics, and energy—and in many others that improve the American quality of life and the U.S. economy. In most of its uses, it is far superior to any other known chemical, and in many applications, there is no practical substitute. As just one example, methylene chloride-based paint removers work on virtually any coating (including to remove multiple layers) and on any surface without causing damage; they work quickly; and they are easy to use. Methylene chloride is so widely used because it has unique physical and chemical properties that cannot be matched by any known alternative.

The Occupational Safety and Health Administration ("OSHA") has long regulated the exposure of workers to methylene chloride, based on OSHA's assessment of the appropriate limits, and businesses nationwide use engineering

controls and personal protective equipment ("PPE") to manage employee exposure accordingly. Nevertheless, EPA banned most uses of methylene chloride.

Before EPA can exercise regulatory authority under TSCA section 6(a), it must first determine whether various uses of a chemical present unreasonable risk. EPA must make that determination about specific activities, on a use-by-use basis, considering the actual circumstances of use. EPA refused to follow that mandate. Rather, EPA assessed whether theoretical exposures to methylene chloride, without PPE, present *any* risk. Moreover, having found a risk in some uses, it said it could determine that methylene chloride as a whole presents unreasonable risks. EPA thereby asserted authority to regulate all uses of methylene chloride, even the ones where it had found risk was already well-managed.

EPA compounded these errors by regulating well beyond "the extent necessary" to address the supposed unreasonable risks, the statutory limit, 15 U.S.C. § 2605(a). Indeed, it mandated a 2 parts-per-million ("ppm") limitation on medium-term occupational exposure to methylene chloride, without any determination that exposures above that level present unreasonable risk to humans. It based that 2-ppm limit on a single study of a single health effect in rats, from which it extrapolated by a factor of roughly 100 to the different circumstance of humans at work, even though studies in *humans* find no such health effect at exposures far above 2 ppm. EPA also mandated a 16-ppm limit for short-term (15-minute) exposures, on the basis of yet

another single study at a single, far-higher concentration over a much longer time, from which EPA extrapolated what level would guarantee zero short-term risk. Zero is not the target under TSCA; Congress directed EPA to use the heavy weaponry of TSCA regulation only "to the extent necessary" to prevent "unreasonable" risks. 15 U.S.C. § 2605(a).

EPA blew past that boundary. Wide ranges of productive commercial activity must stop because EPA has prohibited use of a key substance. Stocks of methylene chloride and products containing it will not be recycled and reused, as they are in current practice, but will have to be discarded as waste. According to the statute, EPA must consider several other factors before it prohibits uses of a chemical. These include weighing the costs and benefits, and evaluating the economic consequences and cost-effectiveness of at least one alternative to the regulatory strategy it ultimately selects. Instead of taking that obligation seriously, EPA banned most uses of methylene chloride simply because EPA was not sure all users would be able to comply with the 2-ppm and 16-ppm limits.

TSCA is an important statute, but in the hands of an unconstrained and nonaccountable regulator, a dangerous tool. Under EPA's extreme (and incorrect) reading of TSCA, EPA can prohibit a wide range of commercial activities simply by saying a chemical substance poses unreasonable risk. This Court should require EPA to correct course and implement the statute as Congress wrote it.

The Court should vacate the Methylene Chloride Rule.

## STATEMENT OF THE CASE

### I. STATUTORY BACKGROUND

TSCA regulates the manufacture, sale, distribution, and use of chemical substances. Section 6(a) authorizes EPA to issue regulations "prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce" of existing chemicals that it determines "present[] an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a). These requirements are to be imposed only "to the extent necessary so that the chemical substance or mixture no longer presents such risk." *Id.*

In 2016, Congress amended TSCA, in part, to specify certain procedures for the determination of "unreasonable risk." Pub. L. No. 114-182, § 6, 130 Stat. 460 (2016). EPA was required to develop a "risk-based screening process" to prioritize substances for review that included public input and notice and comment. 15 U.S.C. § 2605(b)(1). EPA was also required to establish, by mid-2017, a process to "conduct risk evaluations" of the prioritized chemicals and then carry out risk evaluations in accordance with that process. *Id.* § 2605(b)(4). On the substance of those evaluations, EPA has to avoid "consideration of cost or other nonrisk factors," but must also "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical

substance." *Id.* §§ 2605(b)(1), (4)(F). EPA's instructions are to determine whether a substance "presents an unreasonable risk of injury … under the conditions of use." *Id.* § 2605(b)(4)(A).

Where EPA determines that a chemical presents an "unreasonable risk," Congress prescribed specifically how EPA must proceed. EPA is to "apply one or more" of several identified requirements, which range from notice and recordkeeping obligations to prohibitions on manufacture or sale. *Id.* § 2605(a). At this stage—selecting among regulatory options— EPA must "factor in" costs and feasibility. *Id.* § 2605(c)(2)(A), (B). So, too, must EPA consider "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). EPA must also compare its preferred measures to at least one alternative. *Id.* § 2605(c)(2)(A). EPA must publish a statement discussing those factors. *Id.* If a regulation would operate "in a manner that substantially prevents 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).

TSCA prescribes specific procedural requirements for section 6(a) risk-management rules. *Id.* § 2605(c)(3). In addition, "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," and EPA must consider a number of factors bearing on the reliability of the scientific evidence. *Id.* § 2625(h), (i).

The rule under review is only EPA's third rule adopted under TSCA section 6(a) since 1989. The 1989 rule banned asbestos products, and this Court vacated that rule in *Corrosion Proof Fittings. v. EPA*, 947 F.2d 1201 (5th Cir. 1991). Another asbestos prohibition is before this Court for review in *Texas Chemistry Council v. EPA*, No. 24-60193.

## II. PROCEEDINGS REGARDING METHYLENE CHLORIDE

In June 2020, EPA published its Risk Evaluation for Methylene Chloride. RE-131; *see also* RE-135. That Risk Evaluation concluded that methylene chloride does not present unreasonable risks to the environment, that it presents unreasonable risks to human health in certain specific uses, and does not present unreasonable risks in other uses. RE-67-70.

In November 2022, EPA issued a revised risk determination. RE-162; RE-135. This Revised Risk Determination did not purport to amend any of EPA's underlying factual findings or scientific analysis. RE-139. Instead, EPA changed its policy approach in two key ways. First, instead of assessing the risks for each

use case, EPA used a "whole chemical" approach. RE-138. Second, EPA assumed that no person facing a potential methylene chloride exposure is using PPE, even though EPA's Risk Evaluation had relied on reasonably available information to conclude that workers routinely do use such protection. RE-139. After changing these two key policies, EPA determined that methylene chloride itself—regardless of the conditions of use—presents an unreasonable risk. RE-160.

Multiple commenters, including ACC, its members, and the Halogenated Solvents Industry Alliance, Inc. ("HSIA"), provided numerous submissions throughout the entire process. *See* ECF Doc. 92 (Revised Certified Index to the Administrative Record). TSCA does not permit judicial review of a finding of unreasonable risk; it specifically allows review of such a determination only as part of the review of a resulting section 6(a) rule. 15 U.S.C. § 2605(i).

EPA proposed the risk-management rule for methylene chloride in May 2023. RE-228. Multiple parties across many industries, including HSIA and ACC, submitted comments informing EPA how important methylene chloride is in many applications and contending the proposal was scientifically and legally defective. *See generally* ECF Doc. 92. In May 2024 EPA published the final rule under review (the "Methylene Chloride Rule" or "Rule"). RE-1.

The Rule identifies 53 conditions of use for methylene chloride and prohibits all but 13 of them. RE-3, RE-5. The 13 allowed uses involve manufacturing,

processing of methylene chloride, or a few specified industrial or commercial uses. RE-21-22 (codified at 40 C.F.R. § 751.109). The 13 allowed uses also include "[d]isposal" of methylene chloride itself. RE-21-23. The 13 uses are subject to Workplace Chemical Protection Program ("WCPP") requirements to be implemented by employers (referred to by EPA as "owners or operators"). *Id.*

New section 751.107(b)(3) prohibits "all persons" from "manufacturing" methylene chloride, after May 5, 2025, for any use listed in new section 751.107(a)(1) and (2), except for uses specified in subsections (b)(7) through (9). There are similar prohibitions, with staggered dates several months later, for "processing," "distributing," and then for "us[ing]" methylene chloride. 40 C.F.R. § 751.107(b)(4), (5), (6). Paragraph (a)(2), in turn, covers "[a]ll manufacturing," including import, "processing, and distribution … for industrial or commercial use," and "[a]ll commercial and industrial use," with both paragraphs excluding the 13 uses identified in section 751.109(a). Thus, upon these effective dates, the only allowed manufacturing, processing, distribution, or use will be for the 751.109(a) uses or for the (b)(7)-(9) applications. Paragraphs (b)(7) through (9) then identify three specific applications for which manufacturing, processing, distribution, and use will be prohibited, but with later effective dates, such as May 2029 for commercial stripping of paint from furniture.

The allowed uses must meet much lower exposure limits—Existing Chemical Exposure Limits ("ECELs") and Short-Term Exposure Limits ("STELs")—than those established by OSHA. 29 C.F.R. § 1910.1052. Specifically, the limits are:

| OSHA | EPA | (Reduction from OSHA) |
|---|---|---|
| **25 ppm PEL*** | 2 ppm ECEL* | (-92%) |
| **125 ppm STEL**** | 16 ppm EPA STEL** | (-87%) |

*8-Hour Time-Weighted Average (TWA)
**15-Minute Short-Term Exposure Limit

EPA's stated basis for the ECEL is an asserted precursor of liver toxicity, and for the STEL is temporary decreases in peripheral vision.

EPA said it prohibited the many banned uses of methylene chloride because it was not certain users in those applications can meet the ECEL and STEL. RE-8; *see also* RE-14. The prohibited uses include all consumer, and most industrial and commercial, uses of methylene chloride. RE-44-45. Methylene chloride is widely used and has important and valuable properties in many applications. RE-309. It is used to make other chemicals, polymers, and products, including uses as a reactant, and is also used as a catalyst, in processing or as a processing aid, and as a heat transfer fluid in systems designed to minimize fluid loss. *Id.* Methylene chloride is further used as a solvent in a variety of applications, including adhesives and sealants, automotive products, and paint and coating removers. RE-293. A vast

number of sectors use methylene chloride in chemicals, coatings, refining, petrochemicals, petroleum, forestry, wood products, batteries, electronics, electricity, and energy—to name a few. *Id.*

For some of these uses, including ones that are now banned, EPA acknowledged there are no viable alternatives. For example, EPA determined there is no technically and economically feasible alternative to methylene chloride for commercial furniture refinishing, RE-12-13, yet nevertheless adopted a prohibition of methylene chloride for furniture refinishing that will result in the closure of many of the 5,000 furniture refinishing firms that rely on methylene chloride, RE-34. That decision gravely impacts the antiques business, among others.

Petitioners seek vacatur of EPA's rule because it exceeds EPA's authority, is not based on sound science, and is arbitrary and capricious, among other reasons.

## SUMMARY OF THE ARGUMENT

TSCA commands EPA to assess whether specific uses of a chemical present unreasonable risks to human health or the environment. If they do, EPA must regulate those activities "to the extent necessary" to prevent the unreasonable risks. The Methylene Chloride Rule did the opposite. EPA determined that the substance itself presents risk, even though it had found some activities and uses are not risky; and EPA set the level of acceptable risk at zero, contrary to the statutory mandate to identify only "unreasonable" risks. Then, having asserted the authority to regulate

every aspect of methylene chloride products, EPA established exposure limits that are far more stringent than necessary for any sensible assessment of risk. EPA then prohibited the vast majority of uses of methylene chloride, solely on the grounds that EPA was uncertain whether those users would be able to comply with EPA's absurdly tight exposure limits. Methylene chloride is a unique and important substance with no adequate substitute in most of its applications, but EPA banned most uses of it anyway, for no sound reason.

Below, Petitioners show as follows:

EPA's Risk Evaluations treated any non-zero risk as unreasonable, contrary to the plain meaning of TSCA.

EPA determined risk for methylene chloride as a whole, and disregarded the widespread use of protective equipment, even though Congress required EPA to assess unreasonable risk for specific uses in the circumstances of actual use.

To regulate, EPA then established limits on permissible exposure, 2 ppm over 8 hours and 16 ppm over 15 minutes. Each of these was designed to achieve zero risk and each was based on extrapolation from thin evidence, in violation of the statutory requirement for substantial evidence. Worse, the 2-ppm limit was directly contrary to the evidence; EPA relied on studies in rats, which it then extrapolated to a different exposure level in humans, even though actual observations in humans at higher exposure levels showed no effect.

Having established these unfounded limits as the new standard for exposures, EPA prohibited the vast majority of uses of methylene chloride for no reason except that EPA was not sure users could meet its new limits. This strategy of banning activities just in case compliance is difficult is far from the measured approach that Congress required—of regulating only "to the extent necessary" to prevent unreasonable risks and of basing decisions on reasonably available information, not assumptions.

For any ban like what EPA has imposed, TSCA requires EPA to assess, first, whether there are alternatives to the prohibited substance that would be reasonable substitutes. EPA disregarded copious record evidence that, for many of the uses it banned, there are no reasonable substitutes. Consequently, EPA also vastly underestimated the costs of its draconian rule.

Finally, even for the uses that supposedly remain allowed, EPA carelessly erased most of the distribution network for methylene chloride products. It prohibited sales of the products through any distributor that ever, even on just a single occasion, provides or has provided any chemical substance to a single consumer. No distributor could achieve that perfect record, so sales of methylene chloride products are effectively barred even for the uses that EPA has nominally allowed.

## STANDARD OF REVIEW

The Court can "grant appropriate relief ... as provided in" the Administrative Procedure Act ("APA"), and generally "review[s] [a] rule ... in accordance with" the APA. 15 U.S.C. § 2618(c). "[T]he role of the reviewing court under the APA is to 'fix[] the boundaries of [the] delegated authority' and ensur[e] the agency has engaged in reasoned decisionmaking within those boundaries." *Tex. Med. Ass'n v. HHS*, 110 F.4th 762, 774 (5th Cir. 2024).

TSCA excludes a particular APA standard, with respect to a section 6(a) rule (and the "associated determination" of unreasonable risk), namely section 706(2)(E), and replaces it with a TSCA-specific requirement of "substantial evidence in the rulemaking record taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i)(I). That 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 at 1213 (alteration in original). "The substantial evidence standard mandated by [TSCA] is … more rigorous than the arbitrary and capricious standard normally applied to informal rulemaking." *Id*. at 1214 (quoting *Envt'l Defense Fund v. EPA*, 636 F.2d 1267, 1277 (D.C. Cir. 1980)) (alternation in original). "[T]his standard of review [i]s more demanding than the arbitrary and capricious test often applied to

administrative rulemaking." *Ausimont U.S.A., Inc. v. EPA*, 838 F.2d 93, 96 (3d Cir. 1988). Congress's choice to state this standard specifically in TSCA makes the standard of review "particularly demanding" for the agency. *Chem. Mfrs. Ass'n v. EPA*, 859 F.2d 977, 992 (D.C. Cir. 1988).[2]

Where interpretations of TSCA affect the analysis, the Court must "apply[] [its] own judgment," and EPA's interpretations are "*not* entitled to deference." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2261 (2024). Nothing in TSCA expressly delegates any interpretive authority to EPA.

## ARGUMENT

### I. THE RISK EVALUATION AND REVISED RISK DETERMINATION WERE UNLAWFUL AND IRRATIONAL.

EPA's task under section 6(b) was to evaluate whether methylene chloride "presents an unreasonable risk of injury to health ... under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). EPA flouted that mandate. First, it assessed only whether there are risks, and disregarded whether those risks are "unreasonable." Second, it openly ignored the "conditions of use."

[2] *Ausimont* and *Chemical Manufacturers* reviewed rules under section 4(a), regarding testing of certain types of chemicals. The standard of review was the same, under section 19(c), as for 6(a) rules such as the Methylene Chloride Rule.

### A. EPA improperly treated any health risk as unreasonable.

The details of how EPA evaluated potential risks are buried in layers of technical papers, jargon, and acronyms. But EPA's flawed path can ultimately be discerned from EPA's Revised Risk Determination.

In its Revised Risk Determination, EPA estimated risk by comparing the "margin of exposure" to the "benchmark [margin of exposure]." RE-142. To determine the "margin of exposure," EPA first identified the highest exposure level possible without ***any*** health consequences in studies—as EPA put it, the "point of departure" or "POD," an "approximation of the *no-observed* adverse effect level." *Id.* The "margin of exposure" is that highest exposure for zero risk, divided by the actual exposure level experienced in a "specific scenario"—paint-stripping, rubber manufacture, etc. *Id.* In some applications that EPA studied, the margin of exposure in typical operations was as great as 795, meaning typical exposures are nearly 800 times below the level with ***zero*** health consequences. RE-105.

Meanwhile, the "benchmark [margin of exposure]," as opposed to a specific condition of use margin of exposure, "accounts for the total uncertainty in a POD." RE-142. A low benchmark margin of exposure means EPA has "greater certainty in the data," and is therefore willing to tolerate a less-protective ratio between exposures and the point at which health effects *might* be a risk. *Id.*

EPA concluded that a particular application of methylene chloride presents an unreasonable risk if the margin of exposure is less than the benchmark. RE-125 ("EPA's determination that the import of methylene chloride presents unreasonable risk is based on the comparison of the risk estimates … to the benchmarks (Table 4-2).").[3] Consider, for example, the use of methylene chloride in recycling. Even a worker without protective equipment had, at the high end of EPA's estimates, a margin of exposure of 15 (for acute exposure; an of 4 for chronic exposure). RE-107-108. This means typical acute exposure for such a worker could be 15 times higher (and 4 times higher for long-term exposure) and *still* have zero health consequences. One might think this application presents no perceptible risk. But EPA considered it a risk because the benchmark margin of exposure is 30, meaning that EPA's uncertainty about the risk estimates is such that it cannot be confident that an acute exposure *15 times below the zero-effect limit* presents truly zero risk.

The result is that EPA treated a use as risky if there was even a theoretical *possibility* of health risks. EPA did not find that workers are exposed at levels that put them at risk, but rather that given ordinary uncertainties in data, EPA is not confident they have zero risk. Instead of determining the various uses of methylene

[3] EPA asserted the determination was also based on "other considerations," RE-125, but did not elaborate. That there were other "considerations" does not, at any rate, change the reality that EPA considered any non-zero potential risk to be an "unreasonable risk."

chloride actually pose unreasonable risk, EPA concluded that even with minuscule exposures, there is a non-zero *possibility* (a risk?) of a non-zero risk. On that basis, EPA ultimately ended up prohibiting a wide swath of commercial activity.

To be clear, EPA also noted that there have been deaths from methylene chloride exposure. But there have also been deaths—many more of them—from exposure to alcohol, gasoline, automobile exhaust, and Tylenol.[4] Past deaths involving methylene chloride have been overexposure situations not in accordance with instructions and far exceeding the OSHA limit. RE-566, RE-594. Death in such circumstances was not the basis for the Rule; EPA determined unreasonable risk on the grounds that the much lower exposures occurring in ordinary circumstances might theoretically present some non-zero risk of *some* health effects.

EPA's analytical strategy is contrary to the statutory text and Congress's regulatory structure. Congress did not instruct EPA to ensure there are no risks. RE-564 (comment raising this objection). It tasked EPA to determine whether a given use of a substance presents an "*unreasonable* risk" to human health or the

[4] *E.g.* Nat'l Library of Medicine, MedlinePlus, "Acetaminophen overdose," at https://medlineplus.gov/ency/article/002598.htm (Jan. 2, 2023) ("Acetaminophen overdose is one of the most common poisonings. ... [I]t can be deadly if taken in large doses."). Here and below, *infra* n.11, petitioners recite generally known information from incontestable government sources, which are proper matters for judicial notice. Fed. R. Evid. 201; *e.g. City of Houston v. FAA*, 679 F.2d 1184, 1191 (5th Cir. 1982) (in APA review, taking judicial notice of "under- and over-use" at Houston's airport).

environment. 15 U.S.C. § 2605(b)(4)(A). That word "unreasonable" must be given real significance; it is the Court's "duty to give effect ... to every clause and word of a statute." *TRW, Inc. v. Andrews*, 534 U.S. 19, 31 (2001). Given the obvious role of "unreasonable" as a modifier of "risk," that significance must mean that not every risk can warrant a negative determination; some risks must be reasonable or acceptable ones. The Supreme Court dealt with a comparable interpretive matter in *Groff v. DeJoy*, which addressed the phrase "undue hardship." 600 U.S. 447 (2023). "[A]dding the modifier 'undue' means that the requisite burden ... must rise to an 'excessive' or 'unjustifiable' level." *Id.* at 469. Similarly here, the modifier "unreasonable" means a risk must "exceed[] the bounds of reason or moderation" before it justifies regulation. *Unreasonable*, MERRIAM-WEBSTER DICTIONARY, https://www.merriam-webster.com/dictionary/unreasonable (last visited Oct. 8, 2024). EPA, by contrast, made an unreasonable risk determination whenever there was even the possibility of a non-zero risk, and therefore made no assessment of which risks warrant the "unreasonable" designation. To be sure, EPA repeatedly intoned the phrase "unreasonable risk." But it nowhere explained why the risks it identified were "unreasonable," and EPA's analysis makes clear it drew the line at the presence of *any non-zero* potential risk. But, "Congress did not enact TSCA as a zero-risk statute." *Corrosion Proof Fittings*, 947 F.2d at 1215.

Congress's two-stage setup highlights the importance of the "unreasonable" standard. EPA is required to apply that standard for a use of a chemical, without regard to the economic costs. 15 U.S.C. § 2605(b)(4)(A). Then, once it has identified an "unreasonable" risk, EPA is to impose restrictions (taking account of costs, benefits, and economic consequences) on the use "to the extent necessary" that the substance "no longer presents such risk," *i.e.*, the "unreasonable risk." *Id.* § 2605(a). The gating function of the risk determination is hugely significant, both in triggering regulation and in establishing what degree of restriction is permissible. Mandating regulation whenever a use creates some potential risk, and then requiring regulation to eliminate all that potential risk, is very different from regulating only more significant, "unreasonable" risks (and allowing regulation only to the extent necessary to prevent the particular risks that are "unreasonable"). The sweep of the former would be massively broader, and the economic costs far higher.

### B. EPA's "whole chemical" approach ignores the mandate to assess each chemical in its "conditions of use."

The Revised Risk Determination departed from TSCA in yet another way, and at the same time violated EPA's own regulation about risk evaluations. Whereas the Risk Evaluation had, appropriately, assessed each application of methylene chloride, finding an unreasonable risk for some uses and not for others, in 2022, EPA recharacterized methylene chloride as presenting an unreasonable risk "as a whole chemical substance," regardless of the application. *Compare* RE-127-128 *with* RE-

160. EPA made that revised determination while insisting it was not changing any of its factual analysis and findings from the 2020 evaluation. RE-139. In other words, for the variety of uses where EPA had previously found there was no unreasonable risk, EPA maintained the accuracy of those findings. But it deemed methylene chloride to pose an unreasonable risk in those circumstances anyway, simply because the chemical presents (according to EPA) an unreasonable risk in *other* uses.

That conclusion is arbitrary and capricious on its face, because an agency must "articulate a ... rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Having found that activities such as manufacturing with methylene chloride do not present unreasonable risk, RE-127-128, EPA then deemed them unreasonably risky anyway, RE-160—the opposite of "the facts found." EPA's rationale was that "a substantial amount of the conditions of use drive the unreasonable risk." RE-140. That explanation confirms the point: EPA has assigned "unreasonable risk" status to all uses of methylene chloride even through only a "substantial amount" of the uses actually present such risks.

EPA's justification also ignores the statutory mandate. TSCA section 6(b) does not allow a "whole chemical substance" determination. The statute is explicit: EPA is to "determine whether a chemical substance presents an unreasonable risk ...

under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). The sentence is long, but the "unreasonable risk" clause is followed by a comma, introducing a dependent clause, followed by another comma before "under the conditions of use." The interpretation of this text must "heed[] the commands of its punctuation," and a "qualifying phrase separated from antecedents by a comma is evidence that the qualifier is supposed to apply to all the antecedents." *Facebook, Inc. v. Duguid*, 592 U.S. 395, 403 (2021). Following that grammatical principle, the phrase "under the conditions of use" must modify "determine ... unreasonable risk." A freestanding determination that the chemical itself presents such a risk, without reference to particular conditions of use, is not permitted.

Other provisions in TSCA confirm that reading. At the outset of a risk evaluation, EPA is required to "publish the scope of the risk evaluation to be conducted, including the ... conditions of use ... [EPA] expects to consider." 15 U.S.C. § 2605(b)(4)(D). Thus, EPA cannot perform a risk evaluation without identifying the particular conditions of use at issue. That requirement would be meaningless if EPA could determine a chemical is itself an unreasonable risk without regard to the particular uses. EPA's determination must "assess available information on hazards and exposures for the conditions of use" that EPA included in the scope and must account for "the likely ... exposures under the conditions of use." *Id.* § 2604(b)(4)(F). EPA's resulting decisions have potent preemptive force

over state law, but only with respect to the "conditions of use ... included in the scope of the risk evaluation." *Id.* § 2617(d)(1)(A)(iii)(II)(aa).

Congress clearly contemplated that risk determinations would be made with respect to specific conditions of use. Section 6(a), mandating restrictions on chemicals after unreasonable-risk determinations, does not ask whether EPA has determined that "a chemical substance ... presents an unreasonable risk." *Id.* § 2605(a). Rather, the precondition is a determination that "manufacture, processing, distribution, ... use, or disposal of a chemical substance ... or ... any combination of such activities, presents an unreasonable risk." *Id.* Yet again, Congress asked whether given activities present unreasonable risks, not whether a chemical poses a risk. "Conditions of use" is defined to mean "the circumstances under which ... a chemical substance is ... manufactured, [etc.]" *Id.* § 2602(4). This definition aligns the section 6(a) precondition (that a given activity presents an unreasonable risk) with the risk evaluation—that there is an unreasonable risk in the "circumstances under which" that activity takes place. Nothing permits EPA to decide that a chemical itself presents a risk without regard to particular activities involving it.

This is not just petitioners' interpretation of the statute. It was EPA's own interpretation, set forth in the rule that governs risk evaluations. Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82

Fed. Reg. 33,726 (July 20, 2017) (codified at 40 C.F.R. part 702, subpart B (Sept. 18, 2017)) ("Risk Evaluation Rule"). EPA had said it "will determine whether the chemical substance presents an unreasonable risk under each condition of uses [sic] within the scope of the risk evaluation." *Id.* at 33,752. "EPA will make *individual risk determinations* for all uses identified in the scope," EPA said, and it "clarif[ied]" that "each condition of use covered by the risk evaluation" will "receive[] a risk determination." *Id.* (emphasis added).[5]

That determination about a given condition of use would obligate EPA to issue a section 6(a) rule, and EPA said "[a]ny rule would apply only to the condition(s) of use that present an unreasonable risk." 82 Fed. Reg. 33,744. "[T]hose [conditions of use] that do not present an unreasonable risk will not be subject to risk management." *Id.*[6]

EPA's derogation from its own expressed interpretation of TSCA is not just arbitrary and capricious, but outright unlawful. The Court has "long held that federal

[5] "[T]he preamble to a regulation is evidence of an agency's contemporaneous understanding of its proposed rules." *Wyo. Outdoor Council v. USFS*, 165 F.3d 43, 53 (D.C. Cir. 1999).

[6] EPA changed its policy in a revision to the Risk Evaluation Rule published just days before the Methylene Chloride Rule. Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA) 89 Fed. Reg. 37,028 (May 3, 2024). But the revision took effect only on July 2, 2024, after the Methylene Chloride Rule was adopted. *See id.* at 37,028 (effective date). In the revision, EPA stated that the changes would not "apply retroactively." *Id.* at 37,049.

agencies must abide by their own regulations." *DOJ v. FLRA*, 992 F.2d 285, 291 n.4 (5th Cir. 1993); *see also United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954) (similar). And Congress specifically required EPA to abide by the Risk Evaluation Rule, which was issued to fulfill EPA's obligation to set the process for risk evaluations. 15 U.S.C. § 2605(b)(4)(B); Risk Evaluation Rule, 82 Fed. Reg. at 33,748 ("This subpart establishes the EPA process for conducting a risk evaluation ... as required under TSCA section 6(b)(4)(B)."). Thereupon, TSCA required that risk evaluations be conducted "in accordance with" the rule. 15 U.S.C. § 2605(b)(4)(C). The operative rule said risk determinations would be on a use-by-use basis, yet the risk determination for methylene chloride openly did the opposite.[7]

This violation has real-world consequences. Indeed, that is apparent from EPA's taking the trouble to revise its risk determination, with an attendant (and quite contentious) notice and comment process, to issue the "whole chemical" determination. And the consequences are evident. When EPA determines unreasonable risks from specific use activities, section 6(a) empowers it to impose restrictions to reduce only those risks; restrictions would not apply to other use activities that do not present unreasonable risks. By determining, instead, an

[7] As noted above, EPA subsequently revised its Risk Evaluation Rule to assert that "whole chemical" evaluations are permissible. That new policy is unlawful, and ACC is challenging it in litigation elsewhere. Pet'n, *Tex. Chem. Council v. EPA*, No. 24-1185 (D.C. Cir. June 6, 2024). The revised Risk Evaluation Rule is not at issue here because it postdated the methylene chloride risk evaluation by *two years*.

unreasonable risk for methylene chloride as a whole, EPA asserted authority to regulate *all* activities with the chemical. Its 2024 revision to the procedures for risk evaluation makes this consequence clear. Whereas the version operative when EPA adopted the Methylene Chloride Rule said "[a]ny [6(a)] rule would apply only to the condition(s) of use that present an unreasonable risk," 82 Fed. Reg. at 33,744, EPA now insists that "[t]he determination itself ... has *no bearing* on which conditions of use EPA will focus on during the risk management phase," Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. at 37,036 (emphasis added). Though that later pronouncement should have no application here, for a risk determination and a 6(a) risk-management rule two years/ two months earlier (respectively), this regime is precisely what EPA asserted by making a determination for the "whole chemical substance."

The Methylene Chloride Rule bears this out in dramatic fashion. For example, EPA imposed an exposure limit of 2 parts-per-million for the uses of methylene chloride that are allowed to continue, such as manufacturing. RE-45 (codified at 40 C.F.R. § 751.109(c) (July 8, 2024)). That limit is more than 10 times lower than the existing occupational-exposure limit under OSHA regulations and may be difficult for an employer to achieve. (Indeed, EPA acknowledged that the OSHA standard was driven by OSHA's assessment that a tighter requirement would be unduly costly. RE-233.) Yet manufacturing is an activity that EPA's Risk Evaluation had

found not to be risky (a finding the Revised Risk Determination reaffirmed). RE-127; RE-139 ("EPA did not amend . . . underlying scientific analysis of the risk evaluation"). EPA did not suggest that a 2-ppm limit was necessary for manufacturing operations in order to reduce risks faced in other applications. For good reason; the exposures in a plant manufacturing methylene chloride-containing products have no bearing on the exposures of a person who later uses the products out in the field. Thus, the ECEL for the allowed uses could only be justified, if at all (actually it cannot be, *see infra* Section II), by EPA's illegitimate determination that the "whole chemical" presents unreasonable risks. That violation had serious consequences, in that EPA used this maneuver to assert authority that Congress never intended to confer.

### C. EPA assessed risks under unrealistic conditions rather than the actual "conditions of use."

EPA's Revised Risk Determination violated TSCA in yet another way, by refusing to account for PPE that workers routinely use when dealing with potentially hazardous substances. PPE includes, for example, things like respirators with filters or adsorbents that prevent vapors from reaching the wearer's mouth, nose, and lungs; gloves to prevent hand contact; aprons or outerwear that prevent other skin contact; and safety glasses preventing contact of the chemical with a wearer's eyes. Unsurprisingly, EPA's 2020 risk evaluation estimated substantially lower risk possibilities for workers wearing appropriate PPE. Workers do wear this equipment,

in part because OSHA rules require an employer to provide appropriate PPE and verify its use. 29 C.F.R. § 1910.1052(h).

Yet in 2022, EPA insisted on reevaluating methylene chloride risks on the new assumption that workers are not wearing PPE. RE-139. The implications of that change are obvious: Any given use of methylene chloride in the workplace would appear riskier if one assumes the workers are not using PPE.

This about-face was contrary to TSCA, which expressly requires EPA to evaluate the risks presented "under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). As noted above, "conditions of use" means "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be ... used." *Id.* § 2602(4). It is fairly obvious that, in the wide range of commercial applications that EPA considered for methylene chloride products, the products are "intended" to be used with PPE and that usage is at least reasonably foreseeable. RE-612-613; 29 C.F.R. § 1910.1052.

In fact, EPA explicitly found, in 2020, that PPE use is an appropriate "condition of use" for the various commercial and industrial applications. EPA 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, and therefore existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE in a manner that achieves the stated APF or PF.... 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.

RE-66. Thus, in line with the statutory definition of "conditions of use," EPA found that for many applications, it was *known* from the comments that workers were using PPE. EPA acknowledged it was not known for each application but given the statutory definition that the "conditions" include the circumstances that are "reasonably foreseen," EPA found that it is reasonable to expect that workers in all applications are "us[ing] ... appropriate PPE." And EPA provided a sound basis for that expectation, namely the applicable OSHA regulations.

EPA cannot, under the APA, simply ignore that finding. "[A] reasoned explanation is needed for disregarding facts and circumstances that underlay ... [a] prior policy." *BNSF Ry. Co. v. Fed. Ry. Admin.*, 105 F.4th 691, 700 (5th Cir. 2024) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515-16 (2009)). Moreover, EPA said it was not "amending ... the underlying scientific analysis." RE-139. EPA's 2022 revision cited no evidence supporting any finding about PPE different from its 2020 finding and did not attempt to make a different finding. In fact, EPA disavowed such a change: It said its revised approach "should not be

viewed as an indication that EPA believes ... there is widespread noncompliance with applicable OSHA standards." *Id*. Thus, it remains EPA's finding that in many conditions of use, employers are providing PPE and workers are using it; and that in the other applications, "reasonably available information" supports an assumption that employers and workers are operating in compliance with OSHA's PPE requirements.

Instead, EPA decided as a matter of policy that it would not treat PPE usage as part of the "conditions of use" and would instead have PPE "considered during risk management." RE-138-139. The impact on industries that use methylene chloride is obvious. Every exposure looks larger if one ignores the PPE, and every risk looks more serious if the agency can ignore reality and discount the measures already in place to reduce the risk. And, as discussed above, determining "unreasonable risk" under section 6(b) for a given use unlocks EPA's section 6(a) authority. But Congress required EPA to evaluate the risks "under the conditions of use," and it specified that the "conditions" means the circumstances that are "intended, known, or reasonably foreseen." Usage of PPE in accordance with OSHA standards is what any reasonable person would expect, and EPA had itself acknowledged that PPE usage is both foreseeable and foreseen. EPA does not have discretion, under section 6(b), to disregard a genuine "condition of use" just because EPA wants to move the goalposts closer.

EPA's other explanation is equally unlawful. EPA noted, without supporting evidence, that some subpopulations of workers "may be ... not covered by OSHA standards," and that some employers "may be ... out of compliance with OSHA standards." RE-139. But this cannot justify disregarding the actual, widespread usage of PPE—particularly given the documentation that, in the 2020 evaluation, EPA had said shows actual compliance in many sectors. EPA's TSCA decisions must be based on "substantial evidence" in the record as a whole. 15 U.S.C. § 2618(c)(1)(B)(i). Under that standard, non-use of PPE cannot count as "reasonably foreseen" if EPA has no evidence supporting the hypothesis. Congress mandated a "rigorous," "particularly demanding" standard of evidence for EPA's TSCA decision making. *Corrosion Proof Fittings*, 947 F.2d at 1213-14; *Chem. Mfrs. Ass'n*, 859 F.2d at 991-92. Speculation that some workers "may be" not covered by OSHA regulations or some employers "may be" noncompliant is not evidence at all.

Further, the legislative history of the 2016 amendments expressed Congress's understanding that "conditions of use" would not include "intentional misuse."[8] That category would surely include an employer's failure (as EPA hypothesizes) to

[8] *See* U.S. Congress (2015), Frank R. Lautenberg Chemical Safety for the 21st Century Act, Report together with Minority Views, 114th Congress, 1st Session, Report 114-67, at 7 (emphasis added), available at https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf.

comply with an applicable regulation from OSHA, and the concomitant disregard of Congress's command that every employer "comply with occupational safety and health standards" from OSHA. 29 U.S.C. § 654(a)(2). Given OSHA standards mandating PPE, that protection must be "intended" by all pertinent parties and "reasonably foreseen," and EPA cannot ignore those realities by suggesting some employers might choose to violate the OSHA regulations.

### D. This Court should interpret the statutory phrase "unreasonable risk" in a reasonably narrow way, rather than defer to EPA's overbroad view of its authority.

Per *Loper Bright*, it is up to this Court, not EPA, to determine the best interpretation of the statutory phrase "unreasonable risk of injury to health." 144 S. Ct. at 2261. The government has, in other cases, suggested that statutory language nonetheless indicates Congress's intent to delegate to the agency and that courts then "must respect the delegation"—here, defer to EPA. Br. for Respondents, *Ohio Telecom Ass'n v. FCC*, No. 24-7000, p.22 (6th Cir. Sept. 11, 2024) ("[W]hen a statute … [uses] a term or phrase that leaves agencies with flexibility,'" ... "'courts must respect the delegation.'"). To the extent there is any merit to such a suggestion after the Supreme Court's clear mandate in *Loper Bright* that courts must retake the reins when it comes to questions of statutory interpretation, "unreasonable risk of injury to health," as used in TSCA sections 6(a) and (b), is not a phrase that can or should be construed to give EPA broad authority to regulate as it sees fit, including

to avoid any risk and essentially ban the use of common, necessary chemicals. Such an interpretation would raise serious nondelegation questions, which this Court should avoid by interpreting those provisions more reasonably and narrowly.

If EPA's view of its authority prevailed, it would have sweeping power to regulate in ways that could dramatically impact the entire U.S. economy. EPA's purview encompasses any "chemical substance," which is defined as "any organic or inorganic substance of a particular molecular identity," 15 U.S.C. § 2602(2), and any "combination of such substances," *id*.[9] Upon identifying an "unreasonable risk" in a "use" of a chemical substance, EPA is empowered to "regulat[e] any manner or method of commercial use of such substance or mixture." *Id.* § 2605(a)(5). This scope of authority extends to nearly the entire economy,[10] and potentially allows EPA to regulate any type of conduct in commerce so long as it involves use of a "chemical substance or mixture" that EPA has, by means of a risk determination, ushered into section 6(a). EPA can claim that authority about any given substance

[9] The vast majority of matter is a chemical substance under that definition, or a mixture. *See* Nuclear Regulatory Comm'n, "What is a Chemical?", at https://www.nrc.gov/reading-rm/basic-ref/students/science-101/what-is-a-chemical.html (last visited Oct. 9, 2024) ("Chemicals are all around you: the food you eat, the clothes you wear. You, in fact, are made up of a wide variety of chemicals.").

[10] TSCA exempts specific, narrow categories, such as tobacco, pesticides, food, and ammunition. 15 U.S.C. § 2602(2)(B).

by issuing a determination that the substance poses "unreasonable risk of injury to health."

Consequently, the meaning of the phrase "unreasonable risk of injury to health" as used in TSCA is "an issue of great economic and political significance." *Texas v. NRC*, 78 F.4th 827, 844 (5th Cir. 2023), *cert. granted*, No. 23-1312, 2024 WL 4394130 (Oct. 5, 2024). As such, it triggers the major questions doctrine, under which courts must reject a statutory interpretation that would give an agency expansive, transformative authority in favor of a more reasonable, limited reading of the provision. *See West Virginia v. EPA*, 597 U.S. 697, 723-25 (2022).

This Court has said any of three circumstances triggers the "major questions" doctrine, including "when the agency claims the power to resolve a matter of great political significance" or "when the agency seeks to regulate a significant portion of the American economy or require billions of dollars in spending by private persons or entities." *Mayfield v. Dep't of Labor*, No. 23-50724, 2024 WL 4142760, *2 (5th Cir. Sept. 11, 2024). The issue here presents both those circumstances. First, the meaning of "unreasonable risk" is indeed a matter of "great political significance." Congress itself demonstrated that significance by legislating a careful compromise on this very topic just eight years ago. Pub. L. No. 114-182, 130 Stat. 448. Second, the issue implicates EPA regulation that does, indeed, sweep across the economy. The Methylene Chloride Rule itself touches on the activities of over 900,000

workers, RE-414; But EPA's assertion that any non-zero risk is unreasonable affects vastly more than that. Multiple proposals are already pending at EPA for multiple other chemicals, *e.g.* 89 Fed. Reg. 65,066 (Aug. 8, 2024) (bromopropane); 88 Fed. Reg. 49,180 (July 28, 2023) (carbon tetrachloride); 88 Fed. Reg. 39,652 (June 16, 2023) (perchloroethylene), covering far more activities than those at issue here. And even with respect to methylene chloride, the impact is not just about the workers themselves. Large swaths of economic activity will be more expensive or impossible now that EPA has prohibited many uses of methylene chloride.

Meanwhile, the structure of TSCA does not convey a congressional intent to delegate to EPA broad authority to determine that any level of risk is unreasonable. To the contrary, Congress prescribed specific processes for risk evaluations, and then for the ensuing risk-management rules; and it specified factors that EPA must consider and factors it must not consider. 15 U.S.C. § 2605(a), (b). Congress required, in multiple provisions, that EPA consider the best science, the weight of the evidence, and all reasonably available information. *Id.* §§ 2605(b)-(c), 2625(h). Congress mandated that EPA must issue a rule describing its "process to conduct risk evaluations." *Id.* § 2605(b)(4)(B). These sorts of limits on rulemaking authority are exactly what the Supreme Court has traditionally considered to be signals that Congress did not mean to confer broad regulatory authority on an agency.

Moreover, if Congress had empowered EPA to interpret "unreasonable risk," as broadly as the agency seeks to do here—*i.e.*, as allowing it to determine that any risk is unacceptable and bar uses of a chemical on that basis—that delegation would be unconstitutional. In *Industrial Union Department, AFL-CIO v. America Petroleum Institute* (the *Benzene* case), the Supreme Court held that a delegation instructing OSHA to set health and safety standards would be a nondelegation concern had Congress not mandated the agency to balance the "benefits" to be gained from a given standard. 448 U.S. 607, 646 (1980). EPA's authority under TSCA sweeps even more broadly than OSHA's, given that regulation under TSCA is not limited to workplaces. And EPA's ability to weigh benefits when issuing rules under TSCA is constrained because in 2016 Congress prohibited it from considering "cost or other nonrisk factors." 15 U.S.C. § 2605(b)(4)(F)(iii). If EPA had the authority to interpret "unreasonable risk" broadly despite the withdrawal of guiding principles like cost-benefit balancing, the nondelegation concern that *Benzene* identified would become manifest in TSCA. This Court should interpret the statutory phrase "unreasonable risk" in a more restrained, limited way that avoids that constitutional issue. *See Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 173 (2001) ("[W]here an otherwise acceptable construction of a statute would raise serious constitutional problems, the Court will construe the

statute to avoid such problems unless such construction is plainly contrary to the intent of Congress.'") (internal quotation marks and citation omitted).

## II. EPA'S EXPOSURE LIMITS WERE ARBITRARY AND CAPRICIOUS AND LACKED SUBSTANTIAL EVIDENCE.

Having claimed its authority to regulate methylene chloride, wherever it appears, by means of an unlawful and arbitrary risk determination, EPA then issued draconian regulations prohibiting the use of this important chemical for most of its applications, and sharply restricting it in the few uses that remain allowed. But this disregards a primary limit on EPA's authority to issue section 6(a) risk-management regulations—it may only regulate "to the extent necessary" for a substance to no longer present the unreasonable risk. 15 U.S.C. § 2605(a).

EPA far exceeded that authority by selecting two limits based on exposure concentrations, 2 ppm (average over 8 hours) and 16 ppm (short-term), which lack substantial evidence, and actually contradict the best evidence in the record. These thresholds are central to the rule. For the limited uses that remain allowed, "an owner or operator must ensure that no person is exposed to an airborne concentration of methylene chloride in excess of ... 2 ppm." RE-45 (codified at 40 C.F.R. § 751.109(c)). For the uses that EPA prohibited—the vast majority—EPA's rationale was:

> Because both EPA's 8-hour ECEL [2 ppm exposure, averaged over 8 hours] and 15-minute EPA STEL [16 ppm as the maximum exposure in any 15-minute period] are significantly lower than the OSHA PEL

> and STEL, 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. As discussed earlier in this Unit, this uncertainty ... has led EPA to propose prohibitions, rather than compliance with the WCPP, for most industrial and commercial uses of methylene chloride.

RE-266. Thus, had EPA not established those 2-ppm (over the day) and 16-ppm (short-term) standards, it would not have had any reason to fully *prohibit* all those uses of methylene chloride products.

### A. EPA's 2-ppm limit directly contradicts the best evidence on human health risk.

EPA based the 2-ppm limit, the foundation for all its prohibitions and restrictions, on a particular health risk, "liver effects." It identified these as "the most sensitive endpoint of the non-cancer adverse effects from chronic inhalation and dermal exposures for all conditions of use." RE-5; RE-245.[11] This approach in itself is irrational, as discussed below, because it means EPA designed its restrictions to eliminate every last potential risk, thus going far beyond what might be necessary to prevent "unreasonable" risks. But even on its own terms, EPA's rationale was unfounded because the record does not support the conclusion that exposures above 2 ppm actually generate liver effects in humans.

[11] EPA adopted "an ECEL under TSCA section 6(a) of 2 ppm (8 mg/m3) as an 8-hour TWA based on the chronic non-cancer human equivalent concentration for liver toxicity." RE-245.

The only studies in the record that directly investigated liver toxicity in humans from methylene exposure were three studies submitted by commenters. Each of these studies, by qualified, expert researchers, conducted medical surveillance of workers at U.S. plants who were exposed regularly to methylene chloride.[12] The investigators conducted health histories, clinical chemical testing, and physical examinations, comparable to annual physical exams by doctors. RE-568. For two of the studies, the median exposures were as high as 475 ppm—240 times the level of EPA's ECEL. *Id.* The results? These researchers found *no* evidence of increased liver toxicity at such levels of methylene chloride exposure. *Id.*

Such evidence is damning for any conclusion that an exposure limit of 2 ppm is necessary to prevent liver damage. In its Risk Evaluation, EPA rated the three studies as having "medium data quality." RE-82. That status is not unusual; most of the studies that EPA used in its risk evaluation had "medium" quality. Indeed, EPA's limit of 16 ppm for short-term exposures was based entirely on a study that

[12] The studies include: Ott, MG, Skory, LK, Holder, BB, Bronson, JM, Williams, PR, *Health Evaluation Of Employees Occupationally Exposed To Methylene Chloride*, SCAND. J. WORK ENVIRON. HEALTH 9: 1-38 (1983); Soden, KJ, *An Evaluation Of Chronic Methylene Chloride Exposure*, J. OCCUP. MED. 35: 282-286 (1993); Kolodner, K, Cameron, L, Gittlesohn, A, Berney, B, Emmett, EA, *Morbidity Study of Occupational Exposure to Methylene Chloride Using a Computerized Surveillance System (Final Report) With Cover Sheets and Letter Dated 041190, OTS 0522984*., THE CENTER FOR OCCUPATIONAL & ENVIRONMENTAL HEALTH, THE JOHNS HOPKINS SCHOOL OF HYGIENE & PUBLIC HEALTH (1990).). *See* RE-568.

EPA had given a "medium confidence rating." RE-235-236 ("The EPA STEL is based on decreased visual performance identified in an acute inhalation study on human subjects. Putz ... is a well-conducted study."); *see also* RE-88 (assessing the Putz study as "medium"). Had EPA disregarded the three human liver studies simply because of their "medium" quality, that would have been arbitrary and capricious; "internal inconsistency [is] characteristic of arbitrary and unreasonable agency action," *Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1014 (5th Cir. 2019). But EPA did not reject the three studies on that ground.

In the Risk Evaluation, EPA chose not to rely on the studies to show adverse liver effects "because these data don't provide clear evidence of adverse liver effects." RE-82. Indeed, they do not.[13] In fact they provide evidence that at the concentrations tested, there were *not* adverse liver effects.

Consequently, these studies fundamentally undermine EPA's conclusion (in its section 6(a) rule) that it was "necessary" to limit exposures to 2 ppm. After EPA proposed *that* limitation, commenters submitted an analysis of the three studies by

[13] The human studies assessed liver health by monitoring the blood levels of key liver enzymes. EPA's Risk Evaluation said that "increased bilirubin is of concern" but does not provide "clear evidence of adverse liver effects." RE-82. As commenters explained during the subsequent section 6(a) rulemaking, even though increased bilirubin does not necessarily mean an adverse liver effect, the *absence* of increased bilirubin shows the absence of adverse effect. RE-569. And the human studies also used physical examinations to check for symptoms of potential liver harm.

Dr. Jonathon Borak, a highly experienced scholar of occupational health and medicine. RE-635-668. Borak reported that the studies "provide *no evidence* of adverse hepatic [*i.e.*, liver] effects ... even at exposures for longer than 10 years at levels nearly 20-fold greater than the current OSHA [standard]," and "no evidence of dose-related hepatic effects of exposures." RE-640 (emphasis in original). He concluded that there was "no evidence, based on reported studies of liver function in workers, that the current OSHA [standard] is not adequately protective." *Id.* EPA's new limitation, recall, is more than 10 times lower than the OSHA standard.

EPA did not respond to these comments. Nor did it explain why it insisted on imposing a limitation of 2 ppm for the sake of avoiding adverse liver effects in the face of studies, in humans, showing that humans with sustained exposures more than 200 times higher do not suffer adverse liver effects.

Instead, EPA focused on experiments in rats. Its key input was a study by Nitschke and colleagues which found that in rats exposed to 500 ppm of methylene chloride, there was an increase in "liver vacuolation." RE-537. "Vacuolation" is not, itself, necessarily harmful, but EPA has regarded it as a "precursor of toxicity." RE56-57. Rats exposed to 200 ppm did not have any meaningful increase. RE-537. Those numbers, 200 ppm for no effect and 500 ppm for a "precursor" of harm, are of course much higher than EPA's 2-ppm limit. The difference comes from multiple levels of extrapolation. First, EPA used a "physiological-based pharmacokinetic

model" to estimate what exposure of a human would be comparable to the exposure levels for a rat. RE-235; RE-98. Second, EPA evaluated the exposure level that would generate just a 10% increase in the risk of the "precursor of toxicity." RE-98-99. Third, EPA then used the 1st percentile of rat exposures from the Nitschke study, not the mean. RE-99. That is, rather than setting the standard at the exposure level that was typically necessary to generate a 10% increase in the risk of the precursor of harm, EPA chose the exposure level at which the earliest 1% of rats in the study showed hints of vacuolation.[14] EPA made that choice "to account for ... variability among humans related to differences in metabolism." *Id.* In sum, to derive a 2 ppm limit for humans from a study that found 200 ppm exposures do not cause problems in rats, EPA piled assumption upon assumption upon uncertainty. The final tiers of that teetering tower were added not because EPA determined that humans have risks at the pertinent concentrations, but simply because it was uncertain whether they do. This is not the application of best available science; it is the misuse of science.

An analysis like that is a shockingly thin basis for shutting down entire industries. It is well-established that "[a]n agency must consider and respond to significant comments received during the period for public comment." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015); *see also Chamber of Comm. of U.S.*

[14] The average value was roughly three times higher than what EPA used. RE-99.

*v. SEC*, 85 F.4th 760, 774 (5th Cir. 2023). But EPA did not do so here, and instead, EPA chose to rely on the evidence from rats, extrapolated one-hundred-fold downwards, even though research in actual humans showed that exposures much higher than EPA's limit were not producing any actual harm.

This disregard of the most directly relevant data, which is contrary to EPA's preferred policy outcome, in favor of extrapolation from experiments that are obviously less significant, is disturbingly contrary to EPA's mission under TSCA. Congress told EPA to use "scientific information ... in a manner consistent with the best available science." 15 U.S.C. § 2625(h). That is not what EPA did here. Moreover, EPA must make its section 6 decisions "based on the weight of the scientific evidence." *Id.* § 2625(i). Even if the rat study has some relevance, the "scientific evidence" must also include the studies in humans; and, involving humans under real-world exposures, those studies must have significant weight. This Court has "recognized the 'very limited usefulness of animal studies when confronted with questions of toxicity' ... for human beings." *Johnson v. Arkema, Inc.*, 685 F.3d 452, 463 (5th Cir. 2012). By contrast, nothing in the record suggests that EPA weighed the rat study against the data from humans at all.

Courts routinely disapprove agency decisions that ignore relevant data. For example, the Ninth Circuit found an agency's decision arbitrary and capricious because it "ignore[d] a comprehensive data base that is the product of many years'

effort by trained research personnel." *Am. Tunaboat Ass'n v. Baldrige*, 738 F.2d 1013, 1016 (9th Cir. 1984). That characterization holds true for the multiple studies searching for liver effects in humans that EPA ignored. "[W]here other evidence in the record detracts from that relied upon by the agency we may properly find that the agency rule was arbitrary and capricious." *Id.* The Ninth Circuit invalidated a decision not to list a particular species as endangered because the agency "failed to account for" a particular study. *Ctr. for Biological Diversity v. Zinke*, 900 F.3d 1053, 1068 (9th Cir. 2018). An agency "cannot," the court held, "ignore available biological data." *Id.*

In *Corrosion Proof Fittings*, this Court rejected EPA's conclusion that the product it was banning caused greater cancer risk than the substitutes that would replace it. EPA had speculated that the risk estimates for those other products "is most likely an overestimate," but the Court said EPA must "present something more concrete than its own speculation to refute these earlier ... cancer studies." 947 F.2d at 1227. Here, EPA has not even offered "speculation" to overcome the studies showing no liver harm in humans exposed far above the 2-ppm limit. EPA simply ignored them.

As a final example, *Gulf South Insulation v. Consumer Product Safety Comm'n* vacated a rule precisely because the agency had ignored an epidemiological study in humans, and instead placed "exclusive reliance" on a study in rats. 701

F.2d 1137, 1146 (5th Cir. 1983). This Court observed that while the rat study might legitimately show the product could pose a cancer risk to humans, that did not "authenticate the use of the study's results, and only those results, to predict exactly the cancer risk UFFI poses to man." *Id.* In that case, just like here, the agency "extrapolate[d] from the high exposure rat data"—recall, the study EPA used here found no liver effects at 200 ppm in rats—"to humans at the low levels of ... exposure" realistic for the product. *Id.* at 1141. Given the extrapolation, the Court concluded, the agency "could not properly use the study as it did." *Id.* at 1146. EPA's insistence on a 100-fold extrapolation from rat data instead of actual observations in humans is equally unsound.

### B. EPA set its 16-ppm limit by extrapolating and inferring what level would present zero risk.

The 16-ppm limit for short-term exposures (over 15-minute periods) similarly lacked substantial evidence, because EPA had no evidence that methylene chloride presents an unreasonable risk at exposures above that level. Rather, EPA reasoned that 16 ppm is the level at which, for 15-minute exposures, no person would experience any risk. That "precautionary principle" approach fundamentally contradicts TSCA.

EPA derived the 16-ppm limit from a single study, conducted by Putz and collaborators. RE-235-236 ("The EPA STEL is based on decreased visual performance identified in an acute inhalation study on human subjects."). In that

study, 12 volunteers were exposed to 195 ppm of methylene chloride vapor for 4 hours; after 1.5 hours the volunteers showed a 7% decrease in peripheral vision. RE-74. The Putz study did not measure any different concentration to show EPA how performance might change at lower exposure levels, so EPA treated 195 ppm as the "LOAEC," meaning the lowest concentration producing any adverse effect. RE-94, RE-65. That level, 195 ppm, is obviously much higher than 16 ppm. EPA produced the latter by making multiple unfounded extrapolations from the former.

First, EPA extrapolated from 1.5 hours back to 15 minutes by assuming a given concentration over a long time is equivalent to a particular higher concentration over a short time. It concluded that 478 ppm over 15 minutes is equivalent to 195 ppm over 1.5 hours. RE-94-95.

Next, EPA divided that concentration by a factor of 3, to produce the "NOAEL," meaning the hypothetical highest concentration at which there would be no adverse effects. RE-95-97; AO98. This step is startling for a statutory regime in which Congress "reject[ed] a no-risk policy," *Corrosion Proof Fittings*, 947 F.2d at 1215. "Reducing risk to zero ... was not the task that Congress set for the EPA in enacting TSCA," *id.* at 1217, but that is exactly the task EPA assumed for itself by estimating the "no adverse effects" level.

Third, exacerbating that disregard of its mandate, EPA divided by another factor of ***10***, to account for variability among individuals. RE-95-97.[15] Some people might experience the visual impairment effect at lower concentrations than others, EPA suggested, such as smokers, workers engaged in vigorous activity, and people with heart disease. RE-95-96. An exposure limit 10 times lower than the "no adverse effects" level would ensure that nobody, not even individuals with those extra sensitivities, would face any risk of the adverse effect reported in the Putz study.

Thus, EPA's 16-ppm short-term cap resulted by extrapolating a single data point from 1.5 hours back to 15 minutes, and then dividing by 30 to eliminate all conceivable risks. That analysis is directly contrary to the mandate in TSCA, as this Court explained years ago: EPA must "determine[] what an acceptable level of non-zero risk is," *Corrosion Proof Fittings*, 947 F.2d at 1215, and regulate only "to the extent necessary" to achieve that level, 15 U.S.C. § 2605(a). Worse yet, the Putz "adverse effect" was itself "of a small magnitude," as even EPA admitted. RE-97. There was just a 7% decrease in peripheral vision. *Id.* EPA does not suggest the effect was long-lasting, and never made any assessment that such a small, brief effect was an unreasonable risk warranting TSCA intervention. Had EPA drawn that

[15] EPA's final short-term exposure limit, 16 ppm, represents 480 ppm (the extrapolated 15-minute equivalent of the 1.5-hour observation in the Putz study) divided by these factors of 3 and then 10 as discussed here.

conclusion, it would be dubious at best: The Putz researchers, after observing the 7% decrease, continued to expose their human volunteers for another 2.5 hours (more than doubling the exposure), so they cannot have perceived any serious health risks.[16] RE-524 (Putz researchers noting they followed ethical guidelines; describing the effects as "temporary" and "small").

As the Court contemplates EPA's rough estimation and its highly protective avoidance of any risk, it should bear in mind the scale of regulation that depends on the resulting 16-ppm number. For uses that supposedly remain allowed, the owner or operator "must ensure that no person is exposed" to more than 16 ppm of methylene chloride over 15 minutes. RE-45 (codified at 40 C.F.R. § 751.109(c)(2)). Violating this rule exposes a company to civil penalties up to $37,500 a day. 15 U.S.C. § 2615(a), and knowingly violating it is a crime, *id.* § 2615(b). For uses that are now prohibited, EPA's justification for the ban was its uncertainty whether users would be able to meet that 16-ppm limit (and the 2-ppm limit, discussed above). If EPA had recognized the Putz effect as an "acceptable level of non-zero risk," rather than insisting on regulating to eliminate even the hypothetical possibility of a

[16] A different study from the same time by Winneke, used 500 ppm for over 24 hours and found zero effect on multiple measures. RE-76. EPA chose to disregard Winneke's paper and use only Putz's for deriving the short-term exposure limit, RE-88, precisely because the Putz paper used a lower concentration (195 ppm instead of 500 ppm) and thus would lead to a more protective exposure limit, *id.* EPA did not, in that choice, address the fact that Winneke had reported multiple experiments with zero effect at the higher concentration. *Id.*

person's experiencing that "small," temporary effect, the short-term exposure limit could easily have been 50 ppm or higher. EPA has imposed a massive amount of cost and economic disruption based on an improper inference. The Occupational Safety and Health Act requires OSHA to use the "best available evidence," and this Court found that a mandate to "regulate on the basis of knowledge rather than on the unknown." *Am. Petroleum Inst. v. OSHA*, 581 F.2d 493, 504 (5th Cir. 1978), *aff'd, The Benzene Case*, 448 U.S. 607.

## III. EPA RESTRICTED METHYLENE CHLORIDE FAR BEYOND WHAT TSCA ALLOWS.

Even assuming EPA had legitimately determined unreasonable risks for various activities with methylene chloride, TSCA section 6(a) authorizes the agency to restrict those activities only "to the extent necessary" so that they no longer present the unreasonable risk. 15 U.S.C. § 2605(a). EPA transgressed, indeed leaped over, the statutory bounds. Its entire analysis was fundamentally defective because it depended on EPA's assignment of 2 ppm as the limit for continuing exposure to methylene chloride, and that limit was contrary to the scientific evidence (as discussed just above). But even if 2 ppm were an appropriate limit with foundation in scientific reality, that still cannot justify prohibiting nearly all sales and use of methylene chloride products.

For the few uses that remain allowed, EPA mandated WCPPs, with limitations on methylene chloride exposure as well as requirements for equipment, training,

recordkeeping, etc. RE-44-50. This was unlawful on its own, because these were generally uses that EPA's Risk Evaluation had found do *not* present unreasonable risk. RE-67. EPA's sole claim of authority to regulate these activities was its decision to declare methylene chloride itself an unreasonable risk, regardless of use conditions. As discussed above, *supra* Section I.B, TSCA does not permit such a blanket determination for a substance, and does not authorize EPA to regulate uses of a given chemical that do not present unreasonable risk.

### A. EPA did not have evidence that businesses cannot meet its 2-ppm (continued exposure) and 16-ppm (short-term exposure) limits.

The vast majority of uses are not subject to WCPPs; they are now simply prohibited. That prohibition is also beyond EPA's authority.

EPA only ever gave, so far as petitioners can find, one supposed justification[17] for its sweeping ban:

> Because both EPA's 8-hour ECEL and 15-minute EPA STEL are significantly lower than the OSHA PEL and STEL, 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. ... [T]his uncertainty, combined with the severity of the risks of methylene chloride and the prevalence of cost-effective alternative processes and products (Ref. 3), has led

[17] EPA also at one point asserted that, without the prohibitions, there could be "the potential for use of methylene chloride to increase in a sector that has already moved away from it." RE-266. That is manifestly no justification for any regulation at all, because TSCA section 6(a) only allows regulation for the purposes of addressing the identified risks.

> EPA to propose prohibitions, rather than compliance with the WCPP, for most industrial and commercial uses of methylene chloride.

RE-266. Thus, EPA chose to prohibit use of this substance, in a vast array of applications where it is currently crucial, with all the attendant economic upheaval, simply because EPA was *uncertain* whether businesses would be able to comply with EPA's new exposure limits.

The 2-ppm limit itself, recall, was chosen to achieve zero risk. *Supra* Section II.A. There is nothing in the record and no determination by EPA that continued exposure to, say, 3 ppm would create an unreasonable risk. Meanwhile there is nothing in the record and no determination by EPA suggesting that, if businesses are unable to meet the arbitrary 2-ppm standard, by how much they might fail. It is not as though EPA prohibited use of methylene chloride only by companies that fail to protect their workers from extreme exposures. It is the opposite: EPA made up an arbitrary 2-ppm standard that bears little relationship to unreasonable risk, and then prohibited nearly all uses of methylene chloride because it *did not know* whether businesses would be able strictly to comply with that arbitrary number.

EPA thus relied not on substantial evidence, but on the absence of evidence. To be sure, EPA's proposal asked the public to provide evidence that various industries would be able to comply with the new limits, and some industries did provide such evidence. RE-267. Besides the practical reality that such data might be challenging to gather on the short timescale of a 60-day comment period, users

might not want to be in the position of demonstrating the feasibility of an unreasonable 2-ppm limit they objected to. EPA's strategy proposed one unreasonable regulation (the tight exposure limits) and then threatened to impose an even more unreasonable full prohibition unless users gave it data that could indicate that the first proposal was feasible. *Id.* But EPA, not the users of methylene chloride, had the "initial burden of promulgating and explaining a non-arbitrary, non-capricious rule." *Corrosion Proof Fittings*, 947 F.2d at 1214.

Moreover, EPA acknowledged that "for some of the occupational uses that it is proposing to prohibit, there may be some activities or facilities that *could* implement workplace protection requirements necessary to ensure that exposures remain below the ECEL and EPA STEL." RE-267. "In some cases," EPA admitted, "they may be able to undertake more extensive risk reduction measures than EPA currently anticipates." *Id.* EPA's final rule cited no evidence refuting those possibilities or showing that users across the range of prohibited activities would actually be unable to achieve the new limits. Instead, given the absence of evidence, EPA banned methylene chloride because of its hypothesis that companies *might* not be able to reach the ECEL and STEL. "Musings and conjecture are not the stuff of which substantial evidence is made." *Corrosion Proof Fittings*, 947 F.2d at 1227.

This Court held that EPA "bears a heavier burden when it seeks a partial or total ban of a substance than when it merely seeks to regulate that product." *Id.* at

1214. That holding was based in part on language in the original statute that restricted EPA to the "least burdensome alternative." 15 U.S.C. § 2605(a) (1980). The 2016 amendments eliminated that phrase, and apparently EPA feels emboldened now to issue widespread bans on the basis of no more than guesswork. But *Corrosion Proof Fittings* relied only partly on the "least burdensome alternative" restriction.[18] It drew its holding also from the mandate that EPA regulate uses only "to the extent necessary" to mitigate "unreasonable risk"; from the reality that product bans are more intrusive than other forms of regulation (and thus may be a greater "extent" than "necessary"); and from EPA's obligation to "carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action." *Id.* at 1214-15 (quoting 15 U.S.C. §§ 2605(a) & 2601(c); alteration in original). "The very language of TSCA"—namely the provision to regulate only "to the extent necessary" to eliminate the "unreasonable risk"—requires ... the EPA ... [to] determine[] what an acceptable level of non-zero risk is," and regulate only to that point. *Corrosion Proof Fittings*, 947 F.2d at 1215.

[18] The chief import of "least burdensome alternative" was that EPA had to step its analysis up a "hierarchy" of potential regulatory approaches before it could find a product ban appropriate. 947 F.2d at 1216-17. That EPA no longer has to engage in that specific "least-to-most" analysis does not mean it can arbitrarily impose whatever burden it pleases.

Those features of the statute remain in place. 15 U.S.C. §§ 2605(a), 2601(c) (2020). And they require far more from EPA than a total ban on most uses of methylene chloride when the agency itself had already found exposure levels it deemed safe. "[E]xtent" means "the point, degree, or limit to which something extends"," and "necessary" means "absolutely needed." *Extent*, MERRIAM-WEBSTER DICTIONARY, https://www.merriam-webster.com/dictionary/extent (last visited Oct. 8, 2024); *Necessary*, MERRIAM-WEBSTER DICTIONARY, https://www.merriam-webster.com/ dictionary/necessary (last visited Oct. 8, 2024). Consequently, the obvious meaning of "to the extent necessary" is that EPA can only regulate "no more than was necessary to achieve" the stated goal, here the elimination of "such risk," meaning the previously determined "unreasonable risk." *See High Sierra Hikers Ass'n v. Blackwell*, 390 F.3d 630, 647 (9th Cir. 2004) (interpreting a "to the extent necessary" clause in the National Wilderness Act, 16 U.S.C. § 1133(d)(5)).

EPA itself "emphasize[d] that implementation of the WCPP can fully address the unreasonable risk from methylene chloride for the conditions of use allowed to continue." RE-9. Surely such compliance in any other business, if it occurred, would also sufficiently eliminate the risks; and EPA made no suggestion otherwise.

Banning various uses of methylene chloride is a greater "extent" of regulation.[19] So to impose those bans, EPA must reasonably determine, on the basis of evidence, that these further actions beyond the WCPP requirements are truly "necessary." Instead of that determination, and instead of that evidence, EPA expressed only its uncertainty.

### B. EPA failed to refer the matter to OSHA, principal workplace safety regulator.

Moreover, EPA's Rule is unlawful because EPA duplicated the work of OSHA without referring the matter to OSHA as it should have done under TSCA section 9(a), 15 U.S.C. § 2608(a). Under that provision if EPA "determines, in [EPA]'s discretion," that an identified unreasonable risk "may be prevented or reduced to a sufficient extent by action taken under a Federal law" administered by a different agency, EPA "shall submit to the agency which administers such law a report" on the risk and "a specification of the activity ... which ... presents such risk."[20] *Id.* EPA must then ask the other agency to determine whether actions under its authorities could reduce the risk and respond accordingly. *Id.*

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[19] *Corrosion Proof Fittings* observed that Congress listed potential regulatory actions "in order of how burdensome they are." 947 F.2d at 1215. The 2016 amendment did not change that list.

[20] Yet again, Congress showed that "activities," not whole chemicals, can present risk. *See supra* Section I.B.

If this statutory language were not sufficient to express the limitations on EPA's authority, the legislative history leaves no doubt. The House Energy and Commerce Committee Report states: "H.R. 2576 reinforces TSCA's original purpose of filling gaps in Federal law that otherwise did not protect against the unreasonable risks presented by chemicals," and further clarifies that "while section 5 makes no amendment to TSCA section 9(a), the Committee believes that the Administrator should respect the experience of, and defer to other agencies that have relevant responsibility such as the Department of Labor in cases involving occupational safety." H. R. Rep. No. 114-176 (114th Cong., 1st Sess.) at 28-29 (2015). "Specifically, the Committee d[id] not intend for the implementation of TSCA to conflict with or disregard Occupational Safety and Health Administration's hierarchy of controls." *Id.* at 29. Similarly, Representative James Broyhill of North Carolina indicated that "it was the intent of the conferees that the Toxic Substance [Control] Act not be used, when another act is sufficient to regulate a particular risk." 122 Cong. Rec. H11344, 11344 (Sept. 28, 1976). EPA originally understood this point quite well. Its General Counsel said of section 9, "Congress expected EPA—particularly where the Occupational Safety and Health Act was concerned—to err on the side of making referrals rather than withholding them." EPA, *Memorandum to Lee M. Thomas from Gerald H. Yamada* 2, (June 7, 1985) (available at 1985 WL 71788).

In the Methylene Chloride Rule, EPA declined to involve OSHA, because the agency concluded OSHA would not address the unreasonable risk. *See* RE-35.[21] But the Rule is highly duplicative of OSHA's Methylene Chloride Standard. Both aim to protect workers from unsafe exposure to methylene chloride, and both apply to the same classes of industry. *See generally* 29 C.F.R. § 1910.1052. EPA's Rule conflicts with the OSHA Standard by imposing different regulatory requirements on the same employers; besides much lower exposure limits, EPA adopted additional requirements for user notification, recordkeeping, periodic monitoring, and respirator selection criteria. RE-44-50; 40 C.F.R. §§ 751.111, 751.109(d), 751.109(f). EPA acknowledged that entities currently in compliance with the OSHA Standard may have to increase the frequency and scope of their compliance activities, such as through the implementation of engineering controls to reduce exposures to the extent feasible, periodic exposure monitoring frequency, establishment of regulated areas, use of respiratory protection, and notification of monitoring results. RE-24.

OSHA has regulated occupational exposure to methylene chloride for many years and has responsibly adjusted its limits to take account of evolving science. *See* 40 C.F.R. § 1910.1052 (1997). Given the overlap and conflicts between EPA's Rule

[21] It is apparent that EPA did not issue a 9(a) referral, because the referral document must be published in the Federal Register. 15 U.S.C. § 2608(a).

and OSHA's regulations, OSHA should have been given an opportunity to consider whether a lower workplace standard would be appropriate. OSHA's existing limits remain in place, regardless of EPA's action, and OSHA's enforcement of its own standards is mandatory.

EPA's explanation for its refusal to confer with OSHA was that before the Rule—and with only OSHA's existing Standard—there are still unreasonable risks. RE-35. That explanation cannot be sufficient, because on any occasion that EPA issues a section 6(a) rule, there will have to be unreasonable risks to be addressed; the existence of those risks is a required precondition for a 6(a) risk-management regulation. Those unreasonable risks would exist despite whatever other agencies' regulations had achieved. Consequently, the justification that other agencies have left unreasonable risks unaddressed would mean EPA never needs to engage in a section 9(a) conferral. That provision would be meaningless. But Congress, sensibly, did not mandate section 9(a) conferral only when another agency *has* addressed the unreasonable risks. The question is whether another agency's statutory authority "may" address the risks. 15 U.S.C. § 2608(a). The point must be to give the other agency—here, OSHA—the opportunity to exercise that authority, if it can achieve the goal, rather than resorting immediately to TSCA regulation. A finding that OSHA has not yet addressed the risks of concern, and a

conclusion that therefore EPA should immediately proceed with a section 6(a) prohibition, is quite contrary to what Congress prescribed.

### C. EPA failed to consider whether there are technically and economically feasible alternatives to methylene chloride.

The duty to assess such potential alternatives arises under section 6(c) if EPA issues a regulation that "substantially prevents a specific condition of use of a chemical." 15 U.S.C. § 2605(c). No nuance about "substantially prevents" is necessary here, where EPA outright prohibited most uses of methylene chloride, including many that originated decades ago and continue to be critical for American manufacturing. Given those bans, EPA was required to assess "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.*

EPA prepared a narrative it characterized as an Alternatives Analysis. But it was deeply deficient, because it did not consider whether any particular alternative will actually work effectively in a given use. *See generally* RE-363. That question is central to whether a hypothetical alternative is "reasonably available" as a "substitute." Instead, EPA looked for "alternative chemical ingredients performing the same or similar functions as methylene chloride," and then, given those substances, analyzed whether they are "beneficial to health or the environment relative to methylene chloride." RE-369. The sole goal of EPA's Alternatives

Analysis was "to characterize the landscape of potential chemical alternatives in order to ensure that the alternatives that benefit health or the environment of potential alternatives are considered as part of regulations under TSCA section 6(a) for methylene chloride." RE-371. In no instance did the Alternatives Analysis address the key question of whether its supposed alternatives are actually reasonable substitutes for methylene chloride in its various uses.

EPA acknowledged openly it had not performed that analysis:

> EPA did not find it practicable to consider alternative processes that may be reasonably available as a substitute for processes involving methylene chloride when the proposed prohibitions or restrictions would take effect. This is due to considerable uncertainties about alternative processes that may be reasonably available, and the limited time to conduct research on alternative processes in light of the statutory timeframe for completing the TSCA section 6(a) risk management rule for methylene chloride, the difficulty of ascertaining whether any alternative processes may be technically and economically feasible, the challenges of comparing the benefits of alternative processes to the benefits of the methylene chloride-containing processes, and other relevant considerations.

RE-370. Rather, the analysis was intended "to enable EPA to compare the human health hazards, environmental hazards, potential persistence, and bioaccumulative properties of each chemical for each product in each product category," *id.*—a pointless exercise if the supposed alternatives do not actually work for the necessary applications.

Some additional discussion appeared in EPA's "Economic Analysis of the Final Regulation of Methylene Chloride under TSCA Section 6(a) ("Economic

Analysis"). *See generally* RE-419-508, but it did not remedy the shortcomings of the Alternatives Analysis. For example, regarding use for automotive wheel-stripping and refinishing, the Economic Analysis is silent. The automotive wheel and parts refinishing industry uses millions of pounds of various metals each year, and wheel remanufacturers need methylene chloride to strip the wheels to bare substrate, which they then straighten, repair, and re-powder. RE-587-588. Methylene chloride is dominant in stripping aluminum and magnesium wheels because it is effective in removing coatings without damaging the metal substrate. RE-588. There is no known, viable alternative that will not destroy the integrity of the substrate. *Id.* If this industry, alone, is unable to recycle, refurbish, and re-use these parts, millions more pounds of substrate material will have to be mined and processed to address the market demand. *Id.* Commenters told EPA that 100,000 workers would be affected by this prohibition alone. RE-587-588. EPA estimated just over 34,000 workers, which is still a massive amount of disruption. RE-414.

Automotive parts are actually only part of a larger powder-coating market valued at $2.37 billion. RE-588. One commenter estimated that 10-15% of that sector is refinishers and re-manufacturers that rely on methylene chloride-based strippers, as these are the only products that remove coatings safely from automotive wheels and parts. *Id.* They are also used to strip hooks and racks and spray booths that are used in the powder coating process. *Id.* The only alternative is to incinerate,

which can damage or weaken the hooks and racks and is not viable for larger items. *Id.* If these items had to be disposed of rather than re-painted/powdered, there would be a large increase in waste as well as a significant increase in cost of manufacturing to be passed on to consumers. *Id.* EPA's analyses ignore all these issues; to the extent EPA said anything, it concluded methylene chloride can fully be substituted but did not acknowledge these serious problems and consequences.

As another glaring example, the Economic Analysis did not discuss the widespread use by paint-stripper formulators of recycled methylene chloride from pharmaceutical manufacturing. *See generally* RE-412; *see also* RE-588. This use has economic value not only by enabling the products that these formulators make, but also by consuming and reusing material from drug manufacturers that would otherwise be waste. RE-588. After EPA's ban on this recycled use prevents drug manufacturers from selling this material, they will have to dispose of it as hazardous waste. The only effective means of disposal is incineration, and the cost to incinerate methylene chloride is approximately $5/lb. *Id.* For just one formulator, Benco Sales, the cost to incinerate the recycled methylene chloride that it purchases would be $11 million to $15 million. *Id.* Any assessment that an alternative is a reasonable "substitute" would have to take account of these features and functions. EPA ignored them.

As in the Alternatives Analysis, the Economic Analysis is mostly limited to a comparison of hazards and physical properties, not an evaluation of the actual feasibility of replacement. *See generally* RE-419-508. It compares physical characteristics and health effects of potential alternatives but does not consider the physical/chemical and *economic* properties of methylene chloride that a reasonable substitute would have to match. *See, e.g.*, RE-416-417 (noting that the economic analysis "does not include quantified cost estimates for all costs" which include "labor time and wait time" costs); *see also generally* RE-419-508 (discussing customer satisfaction for potential alternatives).

The Economic Analysis also ignores key points in its comparisons between methylene chloride products and alternatives. For example, for brake cleaning products, because the EPA identified one alternative with a price level "in the range" of methylene chloride products, it concluded that "there does not appear to be a price barrier." RE-446. But that one alternative is also identified as having a 96% volatile organic compound content and has a flammability rating of "Extremely Flammable." RE-439-440. For adhesive caulk remover, EPA acknowledged that it used customer reviews to determine the importance of coating removal time, even though it acknowledged that reviews were largely do-it-yourself consumers who might not place much weight on this characteristic, whereas "removal time could potentially be more of a concern for commercial users." RE-468. Thus, EPA concluded the

alternatives are appropriate without actually assessing whether they can match methylene chloride on the feature that is most important to commercial users. For adhesives, restricting methylene chloride could "potentially limit non-flammable adhesive options currently on the market," but EPA did not identify any alternatives that would satisfy California regulations regarding volatile emissions, or safety concerns about flammability. RE-491.

The list goes on and on. For one use after another, EPA concluded that the alternatives it identified were equivalent, even though its own discussion showed they are inferior. Its prohibitions on methylene chloride have massive real-world consequences, making all sorts of applications work far less well than they do with methylene chloride, and EPA did not begin to grapple with that cost. In fact, it openly declined to assess "incremental costs for product users that must switch to alternatives" because it glibly assumed that "alternative products with similar costs and efficacy are generally available." RE-511. EPA's own statements, and comments in the record, belie that assumption.

### D. EPA ignored the heavy cost of its rule for small businesses.

EPA was required, under the Regulatory Flexibility Act, 5 U.S.C. § 603, to specifically account for the costs of its regulation for small businesses. And EPA must give weight to the "benefits of the chemical substance ... for various uses." 15 U.S.C. § 2605(c)(2)(A)(iv)(I). Many small business participants in the rulemaking

told EPA, and submitted evidence, that methylene chloride-based formulations are the most efficient and cost-effective paint-remover products available to them. RE-542. Many also submitted information showing that the supposed alternative paint strippers currently available do not work effectively. RE-531; *see also generally* RE-170.

EPA concluded that most small businesses will see impacts of less than 1 percent of annual revenue. RE-514. That conclusion was arbitrary and capricious because EPA ignored the information put before it by small businesses that methylene chloride products and alternatives are not suitable. The record includes 56 pages of comments submitted by small businesses representing several use sectors. *See* RE-170. Several small entity representatives ("SERs") provided compelling arguments that purported alternatives are not technically or economically feasible. *Id.* The SERs that formulate both methylene chloride-based products and non-methylene chloride-based alternatives reported that, though they have marketed the latter for years, customers do not accept them. Commercial customers continue buying methylene chloride products despite being offered alternatives because those alternatives simply do not effectively remove coatings from many substrates. *Id.*[22] Yet, ignoring these concerns, EPA asserted that the

[22] W.M. Barr & Company, Inc. noted that chemical solvent alternatives such as toluene, acetone, methanol and benzyl alcohol did not completely remove alkyd or epoxy paints in fewer than four hours and in some cases not at all. RE-550-551. In

costs of its rule for small businesses would only arise from reformulating their products, plus the compliance work to become familiar with the Rule. RE-512-513. The real costs are much greater, because small businesses must contend with the significantly lower effectiveness of alternative paint-stripping products—costing more time and money to complete a given project if it can be done at all—and the loss of business on projects that cannot be done effectively at all without methylene chloride products.

In sum, given the information EPA received from small businesses, the alternatives on the market constitute neither technically nor economically feasible alternatives. Nowhere in the record did EPA acknowledge or discuss these comments.

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contrast, methylene chloride-based products removed both kinds of coatings from substrates within five minutes on all painted surfaces tested, and within 15 minutes on cured coatings. RE-551. Similarly, Benco Sales Inc. disagreed with EPA's assessment that there would be cost savings by switching from a methylene chloride-based product, in particular that less product is required because of lower volatility, noting that this does not take into account the reduced effectiveness of other formulations, the need for multiple coatings, the increase in cost, the increase in labor, or the increase in costs for waste removal. RE-556. Benco stated that costs would increase substantially for every industry sector, and that increased costs and reduced effectiveness would be substantial enough to cause closure of many small businesses. *Id.* SERs pointed out that, due to the longer duration necessary to remove coatings, exposure time necessarily increases, as does the risk of flammability. RE-545.

## IV. EPA EFFECTIVELY PREVENTED SMALL COMMERCIAL USERS FROM ACCESSING METHYLENE CHLORIDE EVEN FOR USES THAT ARE STILL ALLOWED.

Many products formulated with methylene chloride are sold through big box stores and hardware stores. In an abundance of caution, EPA "prohibit[ed] retailers from distributing in commerce methylene chloride and all methylene chloride-containing products, in order to prevent products intended for industrial and commercial use under the WCPP outlined in Unit IV.A.1 from being purchased by consumers." RE-30. That prohibition sweeps far more broadly than at first appears, because EPA defined "retailer" to include any company that "distributes or makes available products to at least one consumer." 40 C.F.R. § 751.5. Given that definition, a methylene chloride product that in theory can be sold for an allowed use, to a user that maintains a robust WCPP compliant with the regulation, can only be sold by and through a specialty distributor that sells only to commercial users.

The restriction is even more stringent yet. A specialty distributor that intends to sell only to commercial users, and does sell only to commercial users for the vast majority of its sales, becomes a retailer if it sells to a *single consumer*. The regulation says so explicitly: "If a person or business entity distributes or makes available any product to at least one consumer, then it is considered a retailer." RE-30 (codified at 40 CFR § 751.5). Worse, there is no apparent time limit, and no apparent defense for good-faith errors. A single inadvertent sale to a consumer today

makes a company a "retailer," and thus excluded from selling (and receiving for sale) methylene chloride products for the foreseeable future. Worse yet, the regulation does not limit this "retailer" category to businesses that sell methylene chloride products to consumers. A company becomes a retailer by selling any "product" to just one consumer. *See* 40 C.F.R. § 751.5. "Product" is defined to mean a "chemical substance" or "mixture," plus a range of objects that contain a substance," *id.*; but the vast majority of stuff is chemical substances, and the regulation does not limit "product" to any particular chemical substance (such as the substance being regulated, here methylene chloride). Bleach is a "chemical substance or mixture," and so is paint. Thus, under EPA's radical definition, any company that sells paint, an innocuous material, just once to a consumer, even if only accidentally, qualifies as a "retailer" excluded from selling methylene chloride. The restriction on supply chains is severe. Petitioners East Fork and Epic Paint will be unable to find any distributor for their products that is reliably not a "retailer." There may be no store, even one focusing on commercial buyers, that has never sold any chemical product to a single consumer.

While in theory businesses are still allowed to use some methylene chloride products for the allowed uses, the "retailer" restriction will make it practically impossible to obtain the products. This can be a more severe restriction than having to comply with a WCPP, and a greater "extent" of regulation.

EPA made no attempt to justify this additional burden of regulation as "necessary" to eliminate unreasonable risk. Instead, it pretended the additional regulation is not happening. "Small businesses that are non-retail distributors exist," EPA asserted, "and even participated as small entity representatives consulted" during the early phases of the rulemaking. RE-253. Even on its face that assertion was inadequate; as multiple commenters pointed out, "one or two bulk distributors cannot serve a geographically dispersed nation of tens of thousands of small businesses desiring to purchase small containers for allowed uses." RE-602. Moreover, these few distributors are "non-retail" in the ordinary English sense. EPA never assessed whether any of them could avoid being classed as "retailers" under EPA's regulatory definition in which any single consumer sale of any "product" seals a distributor's fate. Instead of addressing that obvious problem, EPA hypothesized that "this restriction on sales to and by retailers will create a new marketspace for wholesalers" who "may be able to sell similar products to commercial users who previously purchased them from retail stores." RE-357-358. There is no evidence in the record that any "new marketspace for wholesalers" will be created. The assertion that "wholesalers may be able" to take the place of the existing nationwide product distribution system is entirely speculative and defies common sense. And EPA did not bother to contemplate what scale of compliance system—and at what cost—its hypothetical new wholesalers would need to ensure

they never, never sell anything to a *single* consumer. EPA certainly did not consider what would happen in the market for methylene chloride products if one of those hypothetical wholesalers slipped up, sold something to a consumer one time, and thereby (under EPA's definition of "retailer") excluded itself from the market.

Several commenters pointed out other ways to keep methylene chloride products out of consumers' hands without cutting off access for commercial users. For example, it could "eliminate the incredibly broad definition of 'retailer,'" while requiring any sales to be "restricted to individuals with commercial accounts or those who can show tax IDs or other verification methods to establish that they are businesses." RE-603. As commenters observed, sales restrictions implemented this way are common, such as the laws limiting sales of drugs to customers with prescriptions, or barring sales of alcohol to minors. *Id.* EPA dismissed these suggestions off-handedly, saying "the prohibition on distribution in commerce to and by retailers is a more reliable risk management tool." RE-359. (EPA also stated that "making the retailers responsible for determining who can meet the ECEL and the WCPP would not be appropriate or practical." RE-360-361. But that is simply a *non sequitur*, because the commenter's alternative would not ask a seller to assess the compliance of its buyers—just whether they are commercial users or consumers.) That response is woefully inadequate, because reliability alone is not the only consideration. The most reliable way to avoid cybersecurity risks is simply not to

use a computer, but that approach forgoes important benefits. Even if barring sales to "retailers" using EPA's incredibly broad definition of the term is more reliable than requiring verification of a buyer's commercial status, EPA has ignored the plain reality that its draconian approach has major costs. Overlooking "an important aspect of the problem" is arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43.

## V. THE COURT SHOULD VACATE THE ENTIRE METHYLENE CHLORIDE RULE AND RISK DETERMINATION.

### A. EPA's errors are not harmless.

An APA error "is harmful unless it had no bearing on the procedure used or the substance of decision reached." *Wages & White Lion Investments, LLC v. FDA*, 90 F.4th 357, 389 (5th Cir. 2024) (*en banc*). Each of the errors identified above was harmful. EPA's use of the wrong standard for risk, assessing for any non-zero risk rather than for unreasonable risks, certainly affected the substance of its risk determination and the resulting regulation. Its choice to determine risk on a "whole chemical" basis asserted authority to regulate activities that EPA's own findings said were not risky. By ignoring PPE at the risk determination stage, EPA asserted authority to prohibit uses where PPE is in use and effectively mitigates risk. Then, EPA's erroneous and arbitrary choices of exposure limits were central to its mandated workplace chemical protection programs. They were also necessary predicates for EPA's prohibitions on most uses of the substances, because EPA's

sole rationale for the prohibitions was that users might not be able to meet the exposure limits.

EPA's defective assessment of alternatives and economic analysis were also harmful. Congress required EPA to consider whether there are reasonable substitutes before it prohibits a given use of a chemical, 15 U.S.C. § 2605(c)(2)(C), and to consider the costs of its regulation, *id.* § 2605(c)(2)(A), because EPA has choices about how to regulate to prevent unreasonable risks. Had EPA recognized the full costs and consequences of its bans, particularly for uses where there are no reasonable substitutes for methylene chloride, it might well have selected different forms of regulation.

**B. Vacatur is the proper remedy.**

"When an agency action is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,' the APA directs the reviewing court to 'hold unlawful and set aside [that] agency action.' 5 U.S.C. § 706(2). In such circumstances, our court's 'default rule is that vacatur is the appropriate remedy.'" *Restaurant Law Ctr. v. U.S. Dep't of Labor*, 115 F.4th 396, 410 (5th Cir. 2024). Given the deficiencies described above, infecting every stage of EPA's process, vacatur is certainly the right remedy.

"Departing from that default rule is justifiable only in rare cases satisfying two conditions: *First*, there must be a serious possibility that the agency will be able

to correct the rule's defects on remand. ... Remand without vacatur is therefore inappropriate for agency action suffering from one or more serious procedural or substantive deficiencies. *Second*, vacating the challenged action would produce disruptive consequences." *Chamber of Comm. of U.S. v. SEC*, 88 F.4th 1115, 1118 (5th Cir. 2023) (internal quotation marks and citations omitted).

There is no serious possibility that EPA can correct the deficiencies in the Methylene Chloride Rule as it stands. As discussed above, the risk determination did not respect the mandate to identify only "unreasonable" risks. The restrictions and prohibitions in the rule were calibrated to eliminate all risk from methylene chloride, not just unreasonable risk. Assuming that EPA persists in thinking methylene chloride must be regulated under TSCA, those regulations will have to be different from and less restrictive than the Methylene Chloride Rule—not just with respect to the prohibitions on use, but also for the maximum exposure levels for workplace chemical protection programs.

Meanwhile, there would be no disruptive consequences from vacatur. Users of methylene chloride products would be able to continue, but that is not disruption. Manufacturers and distributors would also be able to continue, but that is not disruption either. And commercial users would still be subject to OSHA regulations with their maximum exposure levels. Non-commercial users would not be significantly exposed, because EPA already, before the Rule at issue, prohibited

consumer access to paint strippers, which were the methylene chloride product that they used most. That other rule would remain in place.

"[R]emand without vacatur is available only rarely." *Tex. Med. Ass'n v. HHS*, 110 F.4th 762, 779 (5th Cir. 2024). This is not that rare case.

## CONCLUSION

For these reasons, the Court should grant the petitions and vacate the Methylene Chloride Rule.

Dated this 9th day of October, 2024.

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## CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

1. This brief complies with the type-volume of the Court's briefing order because this brief contains 17,992 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman.

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