No. 24-60227

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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 Final Action
by the United States Environmental Protection Agency

BRIEF OF RESPONDENTS

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Dated: December 13, 2024

CERTIFICATE OF INTERESTED PERSONS

Pursuant to the fourth sentence of Fifth Circuit Rule 28.2.1, Respondents United States Environmental Protection Agency ("EPA") and Michael S. Regan, in his official capacity as EPA Administrator (collectively Respondents), need not provide a certificate of interested parties as all parties are governmental entities.

Dated: December 13, 2024 */s/ Laura J. Brown*

REQUEST FOR ORAL ARGUMENT

Respondents request oral argument. The petitions involve the nuanced issues of compliance with the Toxic Substance Control Act ("TSCA"), a complex and technical statute. Adjudicating the merits of the petitions for review will require the Court to consider a substantial amount of complex information with significant impacts. The Court would therefore benefit from oral argument.

Dated: December 13, 2024 */s/ Laura J. Brown*

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INTRODUCTION

Methylene chloride is a toxic chemical that poses well-documented dangers to human health. When inhaled at high doses for even a few minutes, methylene chloride can kill. At medium doses, it can render a person unconscious. Even lower doses can cause vision loss, dizziness, and auditory-processing delays, all of which are especially dangerous when working with heavy machinery. And chronic exposure, even to low doses, can cause liver damage and cancer.

Methylene chloride, which is used in paint and coating removers, adhesives, and automotive products, is precisely the sort of chemical that the Toxic Substances Control Act ("TSCA") requires EPA to address. Troubled by the ever-more-prevalent risks from chemical exposure in American life, Congress gave EPA a clear directive: Starting with methylene chloride and nine other chemicals Congress singled out as the "worst offenders," EPA must continually prioritize and evaluate chemical substances to determine whether they pose an unreasonable risk to health or the environment; and then regulate to address risks that EPA determines are unreasonable.

That is what EPA did here. As mandated by TSCA, EPA thoroughly evaluated the reasonably available information using the best available science on risks posed by methylene chloride, paying particular attention to susceptible subpopulations. As mandated by TSCA, EPA made the science-based

determination that methylene chloride poses an unreasonable risk to human health. And as mandated by TSCA, EPA crafted a rule to address that unreasonable risk.

The various petitioners challenge the Rule from opposite directions. East Fork Enterprises, Epic Paint Company, and the American Chemistry Council (collectively "Industry Petitioners") argue that the Rule is too strict, while Sierra Club argues the Rule is too lax. But both Industry Petitioners and Sierra Club misread TSCA and effectively ask this Court to impose requirements on EPA that Congress declined to impose when it wrote the statute. And both Industry Petitioners and Sierra Club misstate the science around methylene chloride. Substantial evidence demonstrates that methylene chloride poses unreasonable risks to human health that EPA appropriately and necessarily managed with the Rule.

The crux of both petitioner groups' arguments is a disagreement with the scientific and technical judgments—judgments that Congress expressly assigned to EPA. Because those judgments are well-supported by the administrative record, the petitions should be denied.

STATEMENT OF JURISDICTION

Federal courts of appeals have jurisdiction over petitions to review final rules issued under TSCA. 15 U.S.C. § 2618(a)(1)(A). Petitioners timely petitioned

for review of EPA's final rule entitled *Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)*, 89 Fed. Reg. 39254 (May 8, 2024).

STATEMENT OF THE ISSUES

1. Whether substantial evidence supports EPA's determination that methylene chloride—a chemical known to cause neurotoxicity and liver damage—presents an unreasonable risk to human health.
2. Whether substantial evidence supports the Rule's existing-chemical exposure limit and short-term exposure limit, which are designed to protect workers from the adverse effects of methylene chloride and based on EPA's peer-reviewed comprehensive risk evaluation.
3. Whether substantial evidence supports the prohibition on certain uses of methylene chloride where EPA concluded the relevant industry sectors could not reliably comply with the exposure limits necessary to protect worker health.
4. Whether EPA considered alternatives to methylene chloride to account for the possibility that its prohibition would result in replacement use with a more toxic chemical.
5. Whether EPA reasonably defined "retailer" to ensure that methylene chloride is not sold to consumers.

6. Whether the Rule adequately addresses methylene chloride's risks to potentially exposed or susceptible subpopulations.
7. Whether the Rule adequately accounts for any risk of ozone depletion posed by methylene chloride.

STATEMENT OF THE CASE

I. Statutory History

Congress originally enacted TSCA in 1976 "to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S. Rep. No. 94-698, at 1 (1976), as reprinted in 1976 U.S.C.C.A.N. 4491. To that end, Congress authorized EPA to regulate chemical substances whose "manufacture, processing, distribution in commerce, use, or disposal . . . present[] an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a).

But TSCA, as originally enacted, failed to deliver. Notably, the 1976 version of TSCA instructed EPA to address any "unreasonable risk" that it identified "using the least burdensome requirements" necessary. 15 U.S.C. § 2605(a) (1976). In 1991, this Court interpreted that statutory language as requiring EPA to consider each regulatory option, beginning with the least burdensome, and to evaluate the costs and benefits of regulation under each option. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1217 (5th Cir. 1991). EPA would then have to show that its

chosen regulation—in that case, a ban on almost all uses of asbestos—would reduce risk to an adequate level and that each alternative, less-burdensome regulatory option would be insufficient. *Id.* In the decades following, EPA promulgated very few new regulations under section 2605(a).

By 2016, it had "become clear that effective implementation of TSCA [had] been challenged by shortcomings in the statute itself, and by several key decisions of Federal Courts and the Agency's interpretation of those decisions." S. Rep. No. 114-67, at 2. Indeed, as Senator David Vitter (R-LA) noted at the time, "stakeholders across the political spectrum agreed for decades" that TSCA "needed to be updated . . . to fully protect public health and safety." 162 Cong. Rec. S3511-01, S3513 (daily ed. June 7, 2016). Senator Ed Markey (D-MA) agreed. Characterizing the original TSCA as a "failed law," Senator Markey noted that "[Americans] have been guinea pigs in a terrible chemical experiment. Told that all the advances in [chemistry] would make us healthier, happier, and safer, American[s] have had to suffer with decades of a law that did nothing to ensure that [this] was true." *Id.* at S3514.

In response, a near-unanimous Congress passed the bipartisan Frank R. Lautenberg Chemical Safety for the 21st Century Act in 2016 ("2016 Amendments"), which, for the first time, substantively amended TSCA. The 2016 Amendments "substantially increased EPA's obligation to evaluate and regulate

dangerous chemicals." *Lab. Council for Latin Am. Advancement v. EPA*, 12 F.4th 234, 243 (2d Cir. 2021). Congress expressly rejected *Corrosion Proof Fittings*, removing the old law's "least burdensome" standard and explaining that while "the old law require[d] that the EPA consider the costs and benefits of regulation when studying the safety of chemical," the new version of TSCA required EPA "to consider only the health and environmental impacts." 162 Cong. Rec. S3511-01, S3513.

The 2016 Amendments also imposed a series of aggressive deadlines and quotas on EPA. Among these, Congress required that within six months of the 2016 Amendments' effective date, EPA had to begin the process of evaluating risk and promulgating regulations for ten chemicals selected from a pre-determined list. 15 U.S.C. § 2605(b)(2)(A). Methylene chloride was one of the chemicals on that list. Congress also mandated that, by the end of 2019, EPA must at all times be engaged at least twenty ongoing risk evaluations for high-priority substances. *Id.* § 2605(b)(2)(B), (3)(C). As one Senator explained when the 2016 Amendments were enacted, these requirements reflected Congress' instruction that EPA "methodically review all existing chemicals for safety, starting with the worst offenders." 162 Cong. Rec. S3511-01, S3513.

II. Statutory Overview

TSCA, as amended, sets up a three-step process by which EPA identifies and regulates chemical substances. First, EPA designates a chemical substance as either a "high-priority substance" that may present an unreasonable risk or "low priority substance." 15 U.S.C. § 2605(b)(1)(B). For any chemical substance designated as high-priority, EPA must then conduct a "risk evaluation" to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the chemical's conditions of use. *Id.* § 2605(b)(3)–(4). If, through the risk evaluation, EPA determines that the chemical substance presents an unreasonable risk, EPA must engage in risk management, and ultimately regulate to address any unreasonable risks. *Id.* § 2605(a), (c)–(d).

A. Risk Evaluations

In conducting a risk evaluation, EPA must "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, [] under the conditions of use." 15 U.S.C. § 2605(b)(4)(A), (F)(iii). Congress explained that it had added "text that directs EPA to determine whether such risks exist 'without consideration of costs or other nonrisk factors'" to ensure that "the Agency may not apply the sort of 'balancing test'" between risks and benefits that courts, including in

Corrosion Proof Fittings, previously had read into section 2605(b). 162 Cong. Rec. S3511-01, S3516.

The statute does not define "unreasonable risk of injury to health or the environment," but instead provides requirements that EPA must undertake in conducting risk evaluations. EPA must assess available information on the chemical substance's hazards (the adverse human health and ecological effects) and exposures for the chemical substance's conditions of use. 15 U.S.C. § 2605(b)(4)(F)(i). The term "conditions of use" means "the circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* § 2602(4). In evaluating the hazards and exposures, EPA must consider risk to "potentially exposed or susceptible subpopulations," which are groups identified by EPA that, "due to either susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure." *Id.* §§ 2605(b)(4)(F)(i), 2602(12). Congress specifically noted that potentially exposed or susceptible subpopulations can include workers. *Id.* § 2602(12). EPA also must describe whether aggregate exposures or sentinel exposures—the plausible upper bound of exposure—were considered, and the basis for their consideration. *Id.* § 2605(b)(4)(F)(ii). The risk evaluation must consider the likely duration, intensity, frequency, and number of exposures under the conditions of use. *Id.*

§ 2605(b)(4)(F)(iv). Finally, the risk evaluation must describe the weight of the scientific evidence of the identified hazard and exposure. *Id.* § 2605(b)(4)(F)(v).

B. Risk Management

If EPA finds that a chemical substance presents an unreasonable risk, the Agency must proceed to the section 2605(a) risk management phase. *Id.* § 2605(a). Section 2605(a) instructs EPA to select among a menu of options in promulgating a rule that regulates the chemical substance "to the extent necessary so that the chemical substance . . . no longer presents such risk." *Id.* § 2605(a). This standard replaced the standard in the old version of TSCA, which instructed EPA to apply requirements "to the extent necessary to protect adequately against such risk using the least burdensome requirements." Pub. L. No. 94-469, § 6(a), 90 Stat. 2003, 2020 (1976).

In selecting among regulatory options that could satisfy Congress's commandment in section 2605(a) to "apply one or more . . . requirements . . . to the extent necessary so that the chemical substance . . . no longer presents such risk," section 2605(c) requires EPA to "factor in, *to the extent practicable*," several considerations, such as the economic consequences of a rule, including the costs and benefits of the proposed final regulatory action and one or more alternatives. 15 U.S.C. § 2605(a), (c)(2)(A)–(B) (emphasis added). While section 2605(c) does "require[] EPA to assess the costs, benefits, and feasibility of regulatory options

the Administrator has considered, and describe how that assessment influenced the choice of regulatory requirements," those assessments are "*not* intended to establish a least burdensome requirement." S. Rep. No. 114-67, at 18–19 (emphasis added). And the section 2605(c) requirements do not override section 2605(a)'s overarching requirement that EPA fully address the unreasonable risk. *See* 162 Cong. Rec. S3511-01, S3517 ("[Section 2605(c)(2)(A)] requires only that EPA take into account the specified considerations in deciding among restrictions to impose, which must be sufficient to ensure that the subject chemical substance no longer presents the unreasonable risk EPA has identified.").

In connection with issuing a risk management rule, EPA must publish a statement explaining its consideration of various factors, including the chemical substance's effects on health and the environment, its benefits for various uses, and "the reasonably ascertainable economic consequences of the rule." 15 U.S.C. § 2605(c)(2)(A). The statement must address "the costs and benefits of the proposed and final regulatory action and of the . . . primary alternative regulatory actions considered by the Administrator." *Id.* § 2605(c)(2)(A)(iv)(II). TSCA then directs EPA to "factor in, to the extent practicable," those considerations when "selecting among prohibitions and other restrictions." *Id.* § 2605(c)(2)(B). Additionally, in deciding whether to prohibit or restrict a condition of use of a chemical substance (and in setting an appropriate transition period, 15 U.S.C.

§ 2605(d)), EPA must "consider, to the extent practicable, 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 when the proposed prohibition or other restriction takes effect." *Id.* § 2605(c)(2)(C). In other words, section 2605(c)(2)(C), requires EPA to account for the possibility of regrettable substitutions (i.e., replacement of the regulated chemical with another chemical that is more hazardous) when prohibiting or effectively prohibiting a condition of use. *See id.*

In conducting risk evaluations and promulgating risk management rules under TSCA, Congress directed EPA to use scientific information "in a manner consistent with the best available science." *Id.* § 2625(h). To that end, the statute requires that in using scientific information, procedures, measures, methods, or models, EPA consider whether (1) they "are reasonable for and consistent with the intended use of the information" (2) they are "relevant for [EPA's] use in making a decision about a chemical substance or mixture"; (3) the "clarity and completeness" with which the methods employed to generate them are documented; (4) any variability and uncertainty in them has been evaluated and characterized; and (5) they have been independently verified or peer reviewed. *Id.* EPA must also consider reasonably available information and base its decisions about risk evaluations and risk management on the weight of the scientific

evidence. *Id.* § 2625(i), (k). A risk management rule, including the preceding unreasonable risk determination, is a final agency action subject to judicial review. *Id.* §§ 2605(i)(2), 2618(a)(1)(A).

C. TSCA's Relationship to Other Laws

In amending TSCA in 2016, Congress made clear that TSCA was the primary statute for the regulation of toxic substances, explaining that "TSCA can no longer be construed as a 'gap-filler' statutory authority of last resort." 162 Cong. Rec. S3511-01, S3517.

Although TSCA requires EPA to regulate unreasonable risk presented by chemical substances, TSCA section 9, 15 U.S.C. § 2608, gives EPA discretion to consider if the unreasonable risk can be prevented, eliminated, or "reduced to a sufficient extent" by another federal law after conducting a risk evaluation for that chemical substance. However, Congress was as clear as the text itself: this decision is "completely discretionary . . . and not subject to judicial review in any manner." 162 Cong. Rec. S3511-01, S3517.

Section 2608(a) states that if EPA finds that a chemical substance presents unreasonable risk, and also determines ("in the Administrator's discretion") that the unreasonable risk "may be prevented or reduced to a sufficient extent" by an action taken by another Federal agency, then EPA shall submit a report to that agency describing the activities and the risk associated with those activities. 15

U.S.C. § 2608(a). Section 2608(b) further states that if EPA determines that a chemical substance presents risk to health or the environment, and that risk "could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained" in other federal laws administered by EPA, EPA shall use those authorities to protect against the risk, unless EPA determines ("in the Administrator's discretion") that it is in the public interest to protect against such risk using TSCA. 15 U.S.C. § 2608(b)(1).

III. Procedural Background

A. The 2019 Final Rule Restricting Consumer Use of Methylene Chloride for Consumer Paint and Coating Removal.

For the few chemical substances listed in the 2014 update to the TSCA Work Plan where EPA had published a completed risk assessment before 2016, Congress gave EPA the authority to promulgate risk management rules outside the usual three-stage prioritization, risk evaluation, and risk management process by "publish[ing] proposed and final rules under section 2605(a) . . . that are consistent with the scope of the completed risk assessment . . . and consistent with other applicable requirements of section 2605." 15 U.S.C. § 2625(*l*)(4).

In March 2019 EPA issued a such a rule prohibiting the manufacture, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal based on its 2014 final risk assessment for methylene chloride, determining that this use of methylene chloride presented an

unreasonable risk of injury to health due to acute human lethality. 84 Fed. Reg. 11420 (Mar. 27, 2019) ("2019 Consumer Paint Rule"). Industry and environmental groups filed petitions for review of that rule, which the Court of Appeals for the Second Circuit denied in *Labor Council for Latin American Advancement v. EPA*, 12 F.4th 234 (2d Cir. 2021).

B. EPA's Risk Evaluation for Methylene Chloride.

Separately, in December 2016, EPA published a list of the first 10 chemical substances for risk evaluations in accordance with section 2605(b)(2)(A). 15 U.S.C. § 2605(b)(2)(A); *see* 81 Fed. Reg. 91927 (Dec. 19, 2016). Methylene chloride was one of those chemicals.[1] *See Scope of the Risk Evaluation for Methylene Chloride* ("Scope"), AR 30, JA ___. The methylene chloride risk evaluation would cover the dozens of conditions of use for methylene chloride that were not assessed in EPA's 2014 final risk assessment.

After identifying the relevant conditions of use, EPA conducted its risk evaluation by conducting a risk assessment and then making a risk determination. *See 2020 Risk Evaluation for Methylene Chloride* ("RE"), AR 275, JA ___; *see*

[1] The Scope, published in June 2017, noted that consumer and commercial methylene chloride paint and coating removal uses were assessed in the 2014 Risk Assessment. Scope at 29, JA ___. However, following publication of the 2019 Consumer Paint Rule, which regulated only consumer paint and coating removal uses (not commercial as initially proposed), EPA published a draft risk evaluation pursuant to 15 U.S.C. § 2605(b)(4), that included methylene chloride use in commercial paint and coating removal.

also 40 C.F.R. § 702.41(a)(1) (2017). Consistent with TSCA section 2605(b)(4)(F) and EPA's risk evaluation procedures,[2] the risk assessment included three parts: (1) a hazard assessment, *see* 40 C.F.R. § 702.41(a)(1)(ii), (d) (2017); (2) an exposure assessment, *see id.* § 702.41(a)(1)(iii), (e) (2017); and (3) a risk characterization, *see id.* §§ 702.41(a)(1)(iv), 702.43 (2017).

1. EPA's Human Health Hazard Assessment

In the hazard assessment, EPA (a) evaluated reasonably available information and identified the potential adverse effects methylene chloride has on human health and the environment; (b) weighed the scientific evidence to describe the evidence in more detail for each health outcome; and (c) performed a dose-response assessment (for human health) and determined a concentration of concern (for environment), by analyzing the relationship between the dose or level of a chemical and the presence and severity of observed adverse effects, using data from scientific studies. RE at 227–313, JA ___–___; *see also* 40 C.F.R. § 702.41(d) (2017).

[2] Congress required EPA to "establish, by rule, a process to conduct risk evaluations." 15 U.S.C. § 2605(b)(4)(B). EPA conducted the risk evaluation for methylene chloride consistent with the 2017 version of this rule, which lays out the components of a risk evaluation and EPA's approach to risk assessments. 40 C.F.R. pt. 702, subpt. B (2017); *see also* 82 Fed. Reg. 33726 (July 20, 2017). EPA has since replaced the 2017 rule but did not alter the fundamentals of how the Agency approaches risk assessments. *See* 89 Fed. Reg. 37028 (May 3, 2024).

EPA systematically reviewed existing hazard assessments for methylene chloride that had previously been conducted by EPA, and other federal and state agencies.[3] RE at 240-41, JA ___–___. EPA also reviewed the primary literature cited in those hazard assessments, as well as additional peer-reviewed studies. *Id.* The peer-reviewed studies included controlled human clinical studies, human epidemiological studies, animal studies, and in vitro studies.[4] From those sources, EPA identified the health effects associated with methylene chloride, which include neurotoxicity, liver toxicity, immunotoxicity, burns, and cancer (called "hazard endpoints"). *See id.* at 33, JA ___.

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[3] These assessments included, but are not limited to, a 1996 assessment by U.S. National Academies, a 1997 assessment by the Occupational Safety and Health Administration, a 2000 toxicological profile conducted by the Agency for Toxic Substances Disease Registry (part of the U.S. Department of Health and Human Services) and a 2008 assessment by the California Office of Environmental Health Hazard Assessment, among others. *See* RE at 240, JA ___.

[4] EPA's risk assessment guidance describes these types of studies: statistically controlled human clinical studies involve human testing of environmental hazards; epidemiology studies involve a statistical examination of populations of humans to examine associations between "exposure to a stressor and a human health effect"; and animal studies (which can be designed and controlled to address knowledge gaps) to draw inference about the potential hazard to humans. Conducting a Human Health Risk Assessment, https://www.epa.gov/risk/conducting-human-health-risk-assessment. Information from *in vitro* and *in vivo* studies can inform biological and chemical processes related to the phenotypic changes of the human health effects. *EPA Office of Research and Development, Staff Handbook for Developing IRIS Assessments*, ("Integrated Risk System (IRIS) handbook (2022)") EPA/600/R-22/268 (2022).

The scientific literature demonstrates that methylene chloride is quickly absorbed through inhalation exposure and is rapidly distributed throughout the body, including to the liver, brain, and connective tissue. *Id.* at 243, JA ___. In humans who have died, the highest chemical concentrations have been found in the brain and liver. *Id.* Methylene chloride is primarily metabolized in the liver, as well as in the lungs and kidneys. *Id.* Methylene chloride can cross the placental barrier and into fetal blood. *Id.*at 244, JA ___. It has also been detected in human breast milk. *Id.*

Acute exposure to the chemical can cause death. For example, individuals have died after an estimated 2-or 2.5-hour exposure to between 637 and 1060 ppm of methylene chloride detected in the air. *Id.* at 251, JA ___. In other words, these values are equivalent to the amount of methylene chloride that would fill less than a quarter of a percent of a given volume of air. According to the National Institute for Occupational Safety and Health, exposure at 2300 ppm, set in 1994, is immediately dangerous to life or health for any length of time. *Id.*

After reviewing the relevant scientific literature on methylene chloride's potential human health hazards, EPA weighed the scientific evidence. *Id.* at 285–94, JA ___–___. EPA described strengths and limitations of the data to support the weight of scientific evidence along with any data gaps. *Id.* EPA considered all

results in evaluating the weight of scientific evidence supporting an adverse effect from exposure to methylene chloride. *See id.*

EPA then examined the relationship between the level of exposure (or dose) of methylene chloride and the occurrence and severity of the adverse effects, and eventually focused on neurotoxicity (for acute exposure) or liver toxicity (for chronic exposure) as key effects. This process is referred to as a "dose-response assessment" and is routinely done in hazard assessments. 2014 Framework, AR 630, at 43, JA ___. A dose-response assessment is derived from a "point of departure." *Id.* The point of departure is a point on a dose response curve, derived from experimental data, that "marks the starting point for low-dose extrapolation." *EPA Benchmark Dose Technical Guidance (2012)*, AR 624, at 73, JA ___. EPA identified acute points of departure for inhalation and dermal exposures based on acute central nervous system effects observed in humans in a 1979 study by Putz et al. RE at 33, JA ___. EPA identified the point of departure for chronic inhalation exposures based on a 1988 study observing increased liver vacuolation in rats by Nitschke et al., 1988. *Id.* This dose-response assessment is discussed in more detail in the Argument section I.A.1.a., below.

2. EPA's Human Exposure Assessment

In the exposure assessment, using reasonably available information for each condition of use, EPA estimated the level of exposure through various pathways

like inhalation, ingestion, or dermal contact, considering factors like concentration, duration, and frequency of exposure. RE at 74-226, JA ___, ___; *see also* 40 C.F.R. § 702.41(e) (2017). To that end, EPA evaluated reasonably available data on exposure scenarios (e.g., occupational and consumer), routes of exposure (e.g., dermal and inhalation) and duration of exposures (e.g., acute and chronic) for each condition of use. RE at 113, JA ___. Specifically, for inhalation exposure in occupational settings, EPA evaluated: (1) air monitoring data submitted by industry; (2) exposure data found in peer reviewed literature; and (3) peer-reviewed modeling to estimate potential exposure. *Id.* at 32, JA ___. For dermal exposure in occupational settings, EPA estimated dermal exposure levels because monitoring data was unavailable. *Id.* EPA assessed dermal and inhalation exposures in the occupational setting separately for each condition of use. *See, e.g.*, *id*. at 133–34, 139–40, JA ___–___, ___–___. Using the exposure data, EPA estimated acute and chronic exposure levels for each condition of use (assuming no reductions due to person protective equipment use) and assigned an overall confidence rating to estimates based on the quality of the data, and uncertainties. *Id.* at 187–91, JA ___–___. For each consumer condition of use, EPA derived inhalation and dermal exposure estimates based on a peer-reviewed, publicly available model designed to estimate inhalation and dermal exposures from

household products because no consumer-specific monitoring data was available. *Id.* at 193, 223, JA ___, ___.

3. EPA's Human Health Risk Characterization

In the third step of the risk assessment, risk characterization, EPA integrated the information from the hazard and exposure assessments and, taking into consideration uncertainties and the potentially exposure or susceptible subpopulations, quantified the health and environmental risks. RE at 33–35, JA ___–___; 40 C.F.R. § 702.43 (2017). To estimate the health risks posed, EPA used an accepted methodology, consistent with best available science, to calculate a "margin of exposure" for each condition of use, which it compared to the "benchmark margin of exposure" to estimate the level of risk for each condition of use. *Id.* at 34, 364, JA ___, ___. For workers, EPA estimated risks using several occupational exposure scenarios, which varied assumptions regarding the personal protective equipment. *Id.* More details on how EPA estimated health risk are described in the Argument section I.A.1.c, below.

4. EPA's Unreasonable Risk Determination

The above described three parts of the risk assessment then informed EPA's unreasonable risk determination, the final part of the risk evaluation. 40 C.F.R. § 702.41(a)(1)(v) (2017). In making that determination, EPA considered relevant risk-related factors, including, but not limited to: the effects of the chemical

substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. RE at 453, JA ___. EPA also considered the Agency's confidence in the data used in the risk estimate. *Id.* This included an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimates and the risk characterization. *Id.*

In October 2019, EPA submitted its draft Risk Evaluation for Methylene Chloride to the TSCA Science Advisory Committee on Chemicals ("SACC") [5] and published notice of its availability and requested public comments. 84 Fed. Reg. 57866 (Oct. 29, 2019), JA ___. The SACC met and reviewed the draft risk assessment portion of the risk evaluation and issued a detailed report and

[5] The TSCA SACC provides independent advice and recommendations to EPA on the scientific basis for risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. 15 U.S.C. § 2625(o). The SACC serves as a primary scientific peer review mechanism of the EPA, Office of Pollution Prevention and Toxics and is structured to provide balanced expert assessment of chemicals and chemical-related matters facing the Agency. *Id.* EPA seeks peer review on its risk evaluations from the SACC. *See* 40 C.F.R. § 702.45 (2017).

recommendations in December 2019. *SACC MeCl Meeting Minutes final Report*, AR 251, JA ___. EPA revised the risk evaluation, incorporating revisions and comments based on the peer review and public comment. *See Response to Peer Review and Public Comments on Draft Risk Evaluation*, AR 252, JA ___.

In June 2020, EPA published its final, peer-reviewed, Risk Evaluation for Methylene Chloride ("Risk Evaluation"), which concluded that the chemical substance presents unreasonable risk to human health for 47 conditions of use but does not present an unreasonable risk to human health for six conditions of use and or to the environment.[6] 85 Fed. Reg. 37942 (June 24, 2020), JA ___.

In the Risk Evaluation, EPA identified neurotoxicity effects from acute exposures that include central nervous system depression and a decrease in peripheral vision, both of which can lead to workplace accidents and are a precursor to more severe central nervous system effects like incapacitation, loss of consciousness, and death. RE at 33, JA ___. For chronic exposures, EPA identified risks of non-cancer liver effects as well as liver and lung tumors. *Id.*

At the time EPA issued the Scope and conducted the Risk Evaluation, EPA, by policy, excluded certain exposure pathways (and attendant risks) that could be regulated under other EPA-administered statutes or regulatory programs (e.g.,

[6] The six conditions of use were: (1) manufacturing (domestic), (2) processing as a reactant, (3) processing: recycling, (4) distribution in commerce, (5) industrial and commercial use as a laboratory chemical, and (6) disposal.

Clean Air Act, Clean Water Act) from the scope of risk evaluations. Accordingly, the 2020 Risk Evaluation did not assess certain pathways through which humans or the environment could be exposed to methylene chloride when that pathway was or could be regulated under another EPA-administered statute (e.g., Clean Air Act). *See, e.g.*, *Response to Peer Review and Public Comments on Draft Risk Evaluation*, at 104–105, JA ___–___.

As part of the Risk Evaluation, EPA issued an order under section 2605(i)(1) that six conditions of use did not present unreasonable risk: (1) manufacturing (domestic manufacturing), (2) processing (as a reactant), (3) processing (recycling), (4) distribution in commerce, (5) industrial and commercial use as a laboratory chemical, and (6) disposal. In July 2020, environmental, public health, and labor advocacy groups filed petitions for review challenging EPA's determination that these six conditions of use do not present unreasonable risk. *Neighbors for Env't Just. v. EPA*, No. 20-72091 (9th Cir.).

In 2021 the President signed Executive Order 13,990, entitled "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis." Exec. Order 13990 § 1.[7] The White House specifically identified the Methylene Chloride Risk Evaluation on its list of agency actions to be reviewed for

[7] *Available at* https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01765.pdf.

consistency with that Executive Order.[8] As a result, EPA filed a motion with the Ninth Circuit Court of Appeals in *Neighbors for Environmental Justice v. EPA* requesting a voluntary remand of its risk determination. The Ninth Circuit granted that motion on July 14, 2021.

In addition, as noted above, EPA did not assess exposures via surface water, drinking water, or ambient air pathways for methylene chloride in the Risk Evaluation. However, EPA decided to take a different approach in 2021 and conducted a screening level assessment for methylene chloride looking at these pathways to determine if there were risks from ambient air, surfaces water, or drinking water, that were unaccounted for in the methylene chloride risk evaluation.[9] *See, e.g.*, *Revised Unreasonable Risk Determination*, AR 837, at 4, JA ___. EPA described the findings of this screening level assessment in the methylene chloride risk management rule. EPA found no risks from water pathways but found some risks to human health from the air pathway. Methylene Chloride: Regulation Under the Toxic Substances Control Act, Proposed Rule ("Proposed Rule") 88 Fed. Reg. 28284, 28327 (May 3, 2023), AR 721, JA ___. EPA did not reopen the Risk Evaluation for further assessment because the Agency

[8] *See* Fact Sheet: List of Agency Actions for Review, *available at* https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/.
[9] The screening assessment was a result of the voluntary remand in *Neighbors for Environmental Justice v. EPA*, No. 20-72091 (9th Cir.), discussed above.

determined that it could consider the potential effects to fenceline communities under section 2605(c)(2) and concluded that the proposed regulation of the chemical substance would "largely address the risks identified in the screening analysis[.]" *Id*.

C. The Revised Risk Determination

In revising risk determination, EPA incorporated two policy changes. First, EPA made a single unreasonable risk determination for the chemical substance, rather than making individual risk determinations for each condition of use. The effect of this change was that EPA withdrew its previously issued section 2605(i)(1) orders for any conditions of use that it previously determined did not present unreasonable risk. Second, EPA no longer based its unreasonable risk determination on an assumption that workers wore personal protective equipment ("PPE"). For methylene chloride, EPA had already assessed risk with and without PPE in the Risk Evaluation. RE at 319–32, JA at ___–___. EPA made this change because it recognized that a significant subpopulation of workers (such as state and local government employees, military personnel, and self-employed workers) may not be subject to Occupational Safety and Health Administration ("OSHA") PPE requirements, some workers may use it incorrectly, and some workplaces may be out of compliance. Revised Unreasonable Risk Determination at 4, 9–10, JA ___, ___–___. Based on this assessment, EPA changed its 2020 unreasonable risk

determination for five conditions of use: (1) manufacturing (domestic manufacturing), (2) processing (as a reactant), (3) processing (recycling), (4) industrial and commercial use as a laboratory chemical, and (5) disposal. Accordingly, EPA determined in the revised risk determination that methylene chloride presents an unreasonable risk to human health, driven by 52 of 53 conditions of use assessed in the Risk Evaluation. *Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability*, AR 7, 87 Fed. Reg. 67901, 67902 (Nov. 10, 2022).

D. The Proposed Risk Management Rule.

In May 2023, EPA issued a proposed risk management rule designed to address the unreasonable risks of injury to human health presented by methylene chloride under its conditions of use, that EPA identified in the June 2020 Risk Evaluation and the November 2022 Revised Unreasonable Risk Determination. To address the unreasonable risk, EPA proposed to prohibit all consumer uses (that is, those not already banned under the 2019 Consumer Paint Rule) and prohibit most commercial and industrial uses of methylene chloride, while regulating 10 conditions of use with a Workplace Chemical Protection Program ("WCPP"). Proposed Rule, 88 Fed. Reg. at 28285/2, JA ___.

The methylene chloride WCPP is a regulatory approach centered around maximum inhalation thresholds, referred to as an existing chemical exposure limit

("ECEL") and a short-term exposure limit ("STEL"), that address the unreasonable risk from these 10 conditions of use. *Id.* at 28299, JA ___. Owners and operators of facilities in which methylene chloride is used must adopt workplace control measures that keep the concentration of methylene chloride below the prescribed ECEL and STEL levels. The WCPP provides facility owners and operators with some flexibility in determining how to prevent exceedances of the inhalation thresholds (ranging from elimination to engineering and administrative controls to PPE) and includes monitoring and recordkeeping requirements to verify that the inhalation thresholds are not exceeded. *Id.* In some circumstances the WCPP also includes other elements, such as dermal protection requirements. *Id.* EPA also proposed several general recordkeeping and downstream notification requirements for manufacturing, processing, and distribution in commerce of methylene chloride, pursuant to 15 U.S.C. § 2605(g). *Id.* at 28306, JA ___.

EPA proposed to exempt several uses of methylene chloride, including paint and coating removal in civil aviation and emergency uses by NASA, and others from the applicable prohibition or WCPP requirements for a period of 10 years. *Id.* at 28312, JA ___.

E. The Final Risk Management Rule

After considering public comments, EPA finalized the methylene chloride Risk Management Rule with a few changes. The Final Rule—challenged here—

still prohibits all consumer uses and most commercial uses of methylene chloride, but it allows three additional conditions of use[10] to manage risk through the WCPP. 89 Fed. Reg. at 39255. EPA modified some of the WCPP's requirements, including altering some of the proposed language for clarity and to respond to commenter concerns about the exposure monitoring requirements. *Id.* EPA also expanded recordkeeping and downstream notification requirements, added a *de minimis* threshold for regulation, delayed phaseout of two uses ((1) commercial use in refinishing for wooden furniture, decorative pieces, and architectural fixtures of artistic, cultural, or historic value; and (2) industrial and commercial use in adhesives and sealants), and finalized the 10-year exemption for emergency use by NASA. *Id.* at 39264–68.

SUMMARY OF ARGUMENT

I. The Court should deny the petition of Industry Petitioners.

The Rule takes a reasonable approach, well-grounded in TSCA's text, to addressing the unreasonable risk presented by methylene chloride. The health effects caused by methylene chloride exposure are undisputed. The chemical can and has caused sudden death after a short period of exposure, and liver damage and

[10] The three additional conditions of use are: (1) as a processing aid, (2) in plastics, and (3) in rubber products manufacturing. 89 Fed. Reg. at 39261–63. EPA also broadened the scope of two additional conditions of use that it proposed to regulate under the WCPP in the proposed rule. *Id.* at 39263–64.

cancer after long-term exposure. EPA reasonably concluded, based on a robust scientific record in its peer-reviewed 2020 Risk Evaluation, that methylene chloride presents an unreasonable risk of injury to health.

Unable to dispute the chemical's toxic effects, Industry Petitioners cavalierly assert that aspirin and alcohol can be toxic at high doses, yet those substances are not banned. But people are not exposed to aspirin or alcohol by simply inhaling the air in a room with an open bottle. Data demonstrates that people are primarily exposed to methylene chloride by inhaling the air around them while working with the chemical. Indoor air monitoring conducted at facilities that use methylene chloride detect the chemical at varying levels. In some of these facilities, workers are required to wear personal protective equipment to reduce exposure, but some don't wear it correctly; and in other exposure scenarios, no protection is required or used, leaving people completely exposed to the chemical's ill effects.

Congress explicitly gave EPA authority to make the technical determination what constitutes an "unreasonable risk," while providing guardrails—for instance, requiring that EPA make decisions using best available science and based on the weight of the scientific evidence. EPA acted well within those guardrails.

In EPA's 2017 risk-evaluation procedural rule, the Agency sought public comment on the appropriateness of defining "unreasonable risk" or if the Agency should instead focus its unreasonable risk determinations on the very factors EPA

considered in making its determination for methylene chloride. 82 Fed. Reg. 33726, 33734 (July 20, 2017). In that rule, the Agency noted that each risk evaluation is unique and that defining specific risk measures for use in all risk evaluations would be inappropriate to capture the full set of health and environmental risk measures that may be relevant for a given chemical. *Id.* The public overwhelmingly agreed that it was inappropriate for EPA to define unreasonable risk and that EPA's approach to instead include considerations made sense. *Id.*

EPA's decision to revise the risk determination and issue a single determination does not run afoul of TSCA. Congress authorized EPA to implement and oversee the risk evaluation process to "determine whether a chemical substance presents *an unreasonable risk* of injury to health or the environment . . . under the conditions of use." 15 U.S.C. § 2605(b)(4)(A) (emphasis added). Basic rules of English grammar dictate that the (singular) " unreasonable risk" in that sentence belongs to the (singular) "chemical substance," not the (plural) "conditions of use." Also, in the revised risk determination, EPA explained that its decision to no longer assume use of personal protective equipment was based on EPA's recognition that unreasonable risk exists for those exposed individuals who do not wear such protections because their workplaces do

not require it, or their employers are out of compliance with federal safety standards.

In setting the existing-chemical exposure limit (ECEL) and short-term exposure limits (STEL), EPA considered all reasonably available information, including the epidemiological studies identified in Industry Petitioners' brief. The exposure limits are based on data in EPA's Risk Evaluation, which relied on the best available science and was peer reviewed by the independent Science Advisory Committee on Chemicals. In deriving the exposure limits, EPA relied on a standardized mathematical exercise using assumptions and approaches that follow OSHA, industry groups, and standard industrial hygiene practices.

EPA reasonably exercised its discretion in declining to refer risk management to OSHA based on its determination that significant gaps exist between OSHA's authority to set workplace standards under the Occupational Safety and Health Act ("OSH Act") and EPA's obligations under TSCA section 2605 to address unreasonable risk presented by methylene chloride under the conditions of use.

EPA prohibited certain commercial uses of methylene chloride where it determined, based on reasonably available information, that companies partaking in that use could not demonstrate that they could meet the workplace chemical protection program requirements. In prohibiting such uses, EPA adequately

considered the impacts to small businesses and identified several hundred commercially available alternative products. Finally, EPA explained that its definition of "retailer" was necessary to keep methylene chloride and products that contain it out of businesses that interact with consumers.

II. This Court likewise should deny Sierra Club's petition. Sierra Club challenges the Rule on two grounds: first, that EPA failed adequately to address the risks that methylene chloride poses to fenceline communities and people whose genetics increase their risk from methylene chloride; and second, that EPA failed adequately to consider methylene chloride's risk to the ozone layer. Neither argument is persuasive.

First, EPA properly addressed the risk that methylene chloride poses to potentially exposed or susceptible subpopulations, including fenceline communities and people with particularly vulnerable genetic makeups. The record shows that the Rule will address most methylene chloride exposures in fenceline communities. And the record backs up EPA's decision that it could adequately protect fenceline communities by considering risks to fenceline communities under section 2605(c) without revisiting the risk evaluation in a time- and resource-intensive process to formally determine whether any existing risk to fenceline communities was "unreasonable." TSCA likewise supports EPA's decision not to factor cumulative or aggregate exposure into its risk evaluation until the science on

methylene chloride's aggregate exposure risk more clearly demonstrates how best to evaluate such risk.

What's more, contrary to Sierra Club's assertion, EPA has never purported to announce an exhaustive menu of regulatory options for addressing heightened risks of chemical exposure in fenceline communities. EPA's approach here therefore is consistent with the agency's policies and past practices.

EPA also adequately addressed potential risk to people whose genetic makeup makes them more likely to develop cancer from exposure to methylene chloride. EPA extensively discussed the role of genetics in cancer risk in the Risk Evaluation, and reasonably explained its decision to adopt a conservative cancer risk estimate for methylene chloride to account for variability based on genetics.

Second, this Court should reject Sierra Club's argument that EPA failed adequately to address ostensible risk to the ozone layer. In fact, EPA has repeatedly found that methylene chloride is not ozone-depleting. Sierra Club's single contrary study does not offer any new evidence to rebut that conclusion, but instead rehashes existing evidence that EPA already considered in its previous investigation of methylene chloride's ozone-depleting properties.

Indeed, the Court should not even address this argument on the merits. Sierra Club has not shown that any of its members are likely to experience harm

due to the Rule's allegedly insufficient protection against ozone depletion, so lacks standing to challenge that aspect of the Rule.

III. Even if this Court were to identify some deficiency in the Rule, it should not vacate the Rule but instead should remand to EPA to allow the Rule to remain in place pending prompt completion of remand proceedings. Industry Petitioners' and Sierra Club's bevy of challenges strikes not at the Rule's heart, but at its periphery. EPA could correct any such procedural or record-based deficiencies on remand. Leaving the Rule in place also would ensure that the rule's important and urgent public-health benefits remain in place pursuant to Congress' instructions, while avoiding disruptive regulatory whiplash for regulated entities. And in any event, the Rule should not be vacated in its entirety, as EPA made clear that the Rule is severable.

STANDARD OF REVIEW

TSCA provides that judicial review, with one relevant exception, shall be under the standards set out in in section 706 of the Administrative Procedure Act ("APA") . *See* 15 U.S.C. § 2618(c)(1). Under the APA, a court will set aside agency action only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The APA's "arbitrary and capricious" review, 5 U.S.C. § 706(A), "is narrow." *BCCA Appeal Grp. v. EPA*, 355 F.3d 817, 824 (5th Cir. 2003). Under this standard, an action is

arbitrary and capricious "only where the agency has considered impermissible factors, failed to consider important aspects of the problem, offered an explanation for its decision that is contrary to the record evidence, or is so irrational that it could not be attributed to a difference in opinion or the result of agency expertise." *Id.* (citing *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). In reviewing an agency determination, the court may not "substitute its judgment for that of the agency." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Relevant here, the "court's review 'must be most deferential to the agency where . . . its decision is based upon its evaluation of complex scientific data within its technical expertise." *Texas v. EPA*, 91 F.4th 280, 291 (5th Cir. 2024) (internal citations omitted).

TSCA imposes a slightly more probing standard of review for EPA's factual findings that inform risk management rules and associated unreasonable risk determinations, calling for those findings to be supported by "substantial evidence in the rulemaking record taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i)(I). This Court defines "substantial evidence" as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Shell Chem. Co. v. EPA*, 826 F.2d 295, 297 (5th Cir. 1987) (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971)). But substantial evidence review is not de novo review. Although "[t]he reviewing court must take into account contradictory evidence in the record,

. . . 'the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.'" *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 523 (1981) (quoting *Consolo v. FMC*, 383 U.S. 607, 620 (1966)). Likewise, while the substantial evidence standard calls on this Court to "give careful scrutiny to agency findings," this Court must "at the same time, accord appropriate deference to administrative decisions that are based on agency experience and expertise." *Corrosion Proof Fittings*, 947 F.2d at 1214 (citation omitted). So long as the agency "cogently explain[s] why it has exercised its discretion in a given manner" and offers a "rational connection between the facts found and the choice made," its action will survive substantial evidence review. *Id.* (quotation omitted).

Finally, "[i]n administrative law, as in federal civil and criminal litigation, there is a harmless error rule." *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 659–60 (2007). The APA requires courts to take "due account" of the rule of prejudicial error (otherwise referred to as harmless error). 5 U.S.C. § 706. The rule of prejudicial error extends to TSCA because the alterations to the standard for review in TSCA section 19(c)(1)(B)(i) do not impact the relevant language in APA section 706.

ARGUMENT

I. The Industry Petition for Review Should Be Denied.

EPA's Rule is a reasonable approach to addressing the unreasonable risk presented by methylene chloride to human health and is supported by substantial evidence in the record. Acute exposure to methylene chloride can cause neurological impacts such as dizziness, incapacitation, loss of consciousness, coma, and death. Long term exposure can cause liver damage and cancer. EPA reasonably concluded, based on a robust scientific record described in its peer-reviewed 2020 Risk Evaluation, that methylene chloride "presents an unreasonable risk of injury to health." Revised Unreasonable Risk Determination, at 1, JA ___. The Rule was crafted to address that unreasonable risk.

EPA's regulatory approach reasonably applies requirements available under TSCA section 2605(a) "to the extent necessary" to ensure that methylene chloride "no longer presents" an unreasonable risk under its conditions of use. 15 U.S.C. § 2605(a). In the Rule EPA prohibited the use of methylene chloride where the record did not support that a sector could comply with WCPP. It allowed continued use where the record demonstrated compliance with WCPP was feasible and would address the unreasonable risk. In assessing this regulatory approach, EPA reasonably took into account and published a statement on the considerations required under TSCA section 2605(c)(2), including the "reasonably ascertainable

economic consequences of the final rule," and the reasonable availability of technically and economically feasible alternatives that benefit health or the environment as compared to the prohibited or restricted use. 89 Fed. Reg. at 39283/3–87/2.

A. EPA's Peer Reviewed Risk Evaluation Is Lawful, Based on the Best Available Science, and Supported by the Weight of Scientific Evidence.

In conducting the risk evaluation for methylene chloride, EPA complied with TSCA's procedural and substantive directives: it reviewed the reasonably available information, and made decisions throughout the process that are consistent with the best available science and based on the weight of the scientific evidence. 15 U.S.C. § 2625(h)–(i), (k). Industry Petitioners raise three primary arguments challenging EPA's risk evaluation. First, they contend that EPA improperly relied only on studies that showed the harmful effects presented by methylene chloride, ignored contrary studies, and then treated any risks as "unreasonable." Second, they assert that EPA's revised risk determination is unlawful because TSCA requires that EPA (a) make unreasonable risk determinations for each condition of use rather than a single determination for the chemical, and (b) assume use of personal protective equipment. Finally, they argue that the Court, not EPA, should determine what constitutes an unreasonable risk. Each of these arguments, taken in a slightly different order below, fail.

1. EPA Properly Assessed Methylene Chloride's Hazards and Exposures and Characterized its Risks.

Industry Petitioners complain that "the details" of how EPA conducted its risk evaluation are "buried in layers of technical papers, jargon, and acronyms." Industry Br. at 18. Admittedly, a risk evaluation is a complex endeavor, and the supporting documents are technical and voluminous. But in their advocacy Industry Petitioners oversimplify EPA's Risk Evaluation, and in doing so mischaracterize it. At the outset of their brief, Industry Petitioners (incorrectly) assert that EPA treated any health risks as "unreasonable." *Id.* This flawed argument is based on Industry Petitioner's misunderstanding of the "point of departure," a key concept used in health risk assessments and toxicology, that EPA used in assessing methylene chloride's hazards. Contrary to Industry Petitioner's assertion, a "point of departure" *is no*t "the highest exposure level for zero risk." *Id.* (emphasis in original). The significance of this concept (as well as others Industry Petitioners similarly misstated) is corrected below. But the correction requires an inherently technical explanation of what EPA *actually did* and the science behind it. Thus, it is necessary to walk through each step of the risk evaluation.

a. EPA's Hazard Assessment for Methylene Chloride is Based on the Best Available Science.

Industry Petitioners conflate EPA's risk assessment—the first three parts of the risk evaluation (hazard assessment, exposure assessment, and risk characterization)—with EPA's risk determination—the final part, which is a policy decision that EPA makes. Turning first to the hazard assessment for human health, as detailed above, EPA began by evaluating the reasonably available information and identified the potential adverse health effects caused by methylene chloride. RE at 239–84, JA ___–___; *see also* 40 C.F.R. § 702.41(d) (2017). Next, EPA weighed the scientific evidence to describe the evidence in more detail for each health outcome. RE at 285–94, JA ___–___. And third, EPA performed a dose-response assessment by analyzing the relationship between the dose or level of a chemical and the presence and severity of observed adverse effects, using data from scientific studies. *Id.* at 294–313, JA ___–___.

As detailed in the Procedural Background Section III.B.1. above, EPA identified neurological effects as the most observed adverse effects from short term (acute) exposure and liver effects (also called hepatic effects) as the most observed adverse effect from long-term (chronic) exposure. RE at 246, 295, JA ___, ___. In the Risk Evaluation, EPA identified each of the studies available for each health endpoint (e.g., neurotoxicity, liver toxicity, carcinogenicity) and evaluated the

strengths and limitations of the data and classified the data as either of high, medium, or low quality. [11] *Id.* at 254–94, JA ___–___.

EPA then conducted a dose-response assessment for both acute and chronic exposures. A dose response assessment examines the relationship between the dose (or exposure level) of a chemical substance and the responsive toxic effect. 2014 Framework, at 43, JA ___; 40 C.F.R. § 702.41(d)(4) (2017). It is used to predict the likelihood and severity of adverse health effects in a population based on different levels of exposure to a chemical substance. 2014 Framework, at 43, JA ___. Industry Petitioners take issue with how EPA conducted its dose-response assessments, asserting that the data EPA selected to run the assessments resulted in an overly conservative estimate of the hazards posed by methylene chloride. However, as detailed below, EPA's dose-response assessments are supported by the best available science and the weight of the scientific evidence.

To understand a dose-response assessment, some background is needed. First toxicologists measure dose-response on a dose-response curve, where the x-axis represents the dosage of the chemical, and the y-axis represents the health effects (or "response") measured. The "point of departure," discussed briefly

[11] EPA developed a set of criteria to systematically evaluate human epidemiology and animal toxicity studies for data quality. RE at 241, JA ___. EPA considered studies with acceptable ratings (high, medium, low) for hazard identification for methylene chloride, and used only high and medium quality studies for dose-response modeling. *Id.* at 242, JA ___.

above, is the point on a dose response curve, derived from experimental data (i.e., data from an appropriate study), that "marks the starting point for low-dose extrapolation." *EPA Benchmark Dose Technical Guidance (2012)*, at 73, JA ___. Depending on the data sets available, the point of departure can be derived using different approaches. It can be a dose taken directly from a toxicity study—either a no-observed-adverse effect level ("NOAEL"), or a lowest-observed-adverse effect-level ("LOAEL"). *Id.* Ideally, however, the point of departure is established by fitting the toxicity study data to a model using a benchmark dose approach, which incorporates multiple doses used in a toxicity study but can only be used when data amendable to modeling is available. *Id.*; *see also id.* at viii-iv, JA ___–___.

As Industry Petitioners correctly state, the point of departure may be based on the No Observed Adverse Effect Level from an appropriate study. The NOAEL is the highest dosage used in a particular study at which no adverse effects were observed in the subjects of the study based *solely* on the particular study's parameters. But that does not mean, as Industry Petitioners assert, that the point of departure (which may or may not be the NOAEL) is the "highest exposure for zero risk" or the "highest concentration at which there would be no adverse effects" Industry Br. at 18, 48.

A hypothetical example clarifies this concept. Assume the peer-reviewed literature concludes that exposure to Chemical X is associated with lung damage in

humans, but the toxic dose is unknown. Assume that in a hypothetical study 15 adult males, aged 18 to 25 with no underlying health conditions, are exposed to 50 ppm, 100 ppm, 150 ppm, or 200 ppm of Chemical X for four hours. Assume the study showed there was no observed adverse effects to the study participants' lung capacity at 50 ppm or 100 ppm, and that the lowest adverse effect (reduced lung capacity) was first observed at 150 ppm. The NOAEL of the study is 100 ppm and LOAEL is 150 ppm. One *cannot* reasonably conclude from that hypothetical study that individuals with different risk profiles—say, a 25-year-old man with asthma, a 40-year-old pregnant woman, or a 50-year-old man with heart disease—would also not suffer any adverse effects from Chemical X at the NOAEL, because none of those populations were part of the study. Nor could one assume that a healthy 20-year-old male exposed to 100 ppm for forty hours a week would be free from adverse effects, because that exposure length was not studied. In other words, the point of departure does not take into account the limitations of a study—including but not limited to variations in the data, the comparative sensitivity of populations excluded from the study, etc.—which contribute to the strength of the evidence and factor into benchmark "uncertainty factors." These will be elaborated on below.

Industry Petitioners object to the studies EPA selected to derive the points of departure for its acute and chronic inhalation dose-response assessments (which it also used to derive the exposure limits as part of its risk management rule,

discussed below). But as this Court has explained, "there is a presumption of regularity to the EPA's choice of analytical methodology, so challenging parties must overcome a 'considerable burden.'" *BCCA Appeal Grp.*, 355 F.3d at 832; *c.f., Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) ("[A] reviewing court must remember that the [agency] is making predictions, within its area of special expertise, at the frontiers of science. When examining this kind of scientific determination [] a reviewing court must generally be at its most deferential.").

Industry Petitioners have not carried that "considerable burden." As detailed below, EPA's selection of points of departure for its dose-response assessments are supported by substantial evidence in the record, consistent with best-available science, and based on the weight of the scientific evidence.

i. The acute inhalation point of departure is supported by substantial evidence.

To derive the point of departure for the acute inhalation hazard (neurotoxicity), EPA considered the reasonably available acute hazard studies (including those Industry Petitioners identify) and selected a 1979 study on humans by Putz et al. RE at 295, JA ___. In the Risk Evaluation, EPA explained that it selected the Putz study because it was a controlled test that minimized bias to the maximum extent by being double-blinded (both researchers and subjects were unaware whether subjects were exposed to air only or to methylene chloride). *Id.* at

247, JA ___. EPA also explained it chose the study because it objectively measured central nervous system effects rather than subjective reports of symptoms. *Id.* The Putz study exposed 12 people to methylene chloride at an air concentration of 195 ppm for four hours. *Id.* at 247, JA ___. After one and a half hours of exposure, the participants' peripheral vision decreased 7 percent. *Id.* After four hours, their hand-eye coordination decreased 36 percent, their peripheral vision decreased 17 percent, and their auditory vigilance (i.e., ability to respond to warning sounds) decreased 17 percent. *Id.* The Putz study used only one concentration (195 ppm), which resulted in an adverse effect, and EPA determined that this concentration was the LOAEL. The study did not determine a NOAEL because only one concentration was used. Thus, EPA appropriately used the LOAEL of 195 ppm to derive the point of departure specific for 15 minutes, one hour and eight hours (*i.e.,* by extrapolating for these other exposure durations).

EPA requested comment from the SACC regarding its use of the Putz study for deriving the point of departure for acute exposure, and the SACC agreed with EPA's selection. *Response to Peer Review and Public Comments on Draft Risk Evaluation* at 124–25, JA ___–___. EPA next extrapolated the value from Putz to other exposure durations, to match how people use methylene chloride, such as 8 hours to match a typical workday. EPA used a well-established and recommended

method, called the "ten Berge model,"[12] to determine that a 15-minute exposure at 478 ppm and an 8-hour exposure at 80 ppm had the same effect on the study's subjects (i.e., 7 percent decrease in peripheral vision) as the Putz study showed for a 90-minute exposure at 195 ppm. RE at 302, JA ___.

In challenging EPA's data selection, Industry Petitioners assert that another controlled human study (Winneke 1974) found no effect on multiple measures up to the highest concentration for 24 hours. Industry Br. at 50, n.16. Industry Petitioners are incorrect. First, the Winneke study exposed participants for 3.8 hours—not 24 hours, as Petitioners claim. RE at 252, JA ___. Second, the study *did* identify multiple effects, which the authors classified as a "lowered degree of C[entral] N[ervous] S[ystem]-activation" among four experiments. Winneke (1974), AR 673, at 141, JA ___. These effects included decreased visual vigilance in volunteers in one of four experiments (at both 300 and 800 ppm), decreased auditory vigilance (from 300 to 800 ppm) in all four experiments, and decreased ability in 10 of 14 psychomotor tasks (such as speed of reaction, control of hand precision) at 800 ppm in one experiment. RE Table 3-3, 252–53, JA ___. As a

[12] The ten Berge model is recommended for extrapolating exposure durations by EPA's Risk Assessment Forum, *A Review of the Reference Dose and Reference Concentration Processes (2002)*, AR 614, at 2-2. JA ___. It is also used by the National Research Council of the National Academies of Sciences, Engineering, and Medicine in setting Acute Exposure Guideline Levels. Acute Exposure Guideline Levels for Selected Airborne Chemicals (2004), https://www.epa.gov/sites/default/files/2014-11/documents/tsd56.pdf.

result, the study authors concluded that "[t]he present [Threshold Limit Value] for methylene chloride of 500 ppm *must be checked*, since behavioral impairment *obviously occurs* at lower concentrations." Winneke (1974) at 143, JA ___ (emphasis added). And in a follow up study (Winneke Fodor 1976), the authors concluded that exposure to methylene chloride at 500 ppm between two and three hours depressed the participants central nervous system, including lapses of attention (characterized as "short microsleeps"). Winneke Fodor (1976), AR 674, at 49, JA ___.

As EPA explained in the Risk Evaluation, the Winneke studies reported similar effects to the Putz study. RE at 254, JA ___. But EPA also noted that the Winneke studies were only single-blinded (contrasted to the double-blinded Putz study), which could introduce bias into the results rendering them less reliable.[13] *Id.* Thus, as the record shows, EPA did not "disregard" the Winneke studies. Industry Br. at 50 n.16. Rather, EPA reasonably explained its decision to derive the point of departure from the Putz study, which was supported by the SACC. RE at 301, JA ___. Accordingly, EPA's decision to rely on Putz study was reasonable and supported by the record, and should be upheld.

[13] In a single-blinded study, only participants are blinded to their treatment group.

ii. The chronic inhalation point of departure is supported by substantial evidence.

For similar reasons, Industry Petitioners' objections to the chronic inhalation point of departure also fail. To derive the point of departure for chronic inhalation hazard, EPA considered all reasonably available chronic inhalation hazard studies (including those Industry Petitioners claim EPA ignored) and selected a 1988 animal study by Nitschke et al. RE at 295, JA ___. EPA explained that it selected the Nitschke study because it was a chronic study (i.e., conducted over two years) with the lowest exposure concentrations, identified a sensitive health effect, and was rated high for data quality. *Id.* In that study rats were exposed to methylene chloride at either 0 ppm, 50 ppm, 200 ppm or 500 ppm for six consecutive hours a day, five days a week for two years. *Id.* at 297, JA ___. The rats exposed to 500 ppm showed "hepatic lipid vacuolation and multinucleated hepatocytes." *Id.* at 257, JA ___. Lipid vacuolation is a buildup of fat in the liver and is called fatty liver disease in humans.

To determine the point of departure for chronic inhalation, EPA used a benchmark dose, rather than a NOAEL or LOAEL, because the Nitschke study used multiple doses that could be modeled (unlike the Putz study, which used only one dose, and thus was not appropriate for dose-response modeling). *Id.* at 304, JA ___. The benchmark dose is the chemical concentration that produces a predetermined effect, in this case, appearance of liver vacuolation (fatty liver). *Id.*

at 242, n.12. JA ___. In using the benchmark dose approach, the experimental data (i.e., air concentrations and liver effects) are modeled using a low-level response of 10 percent increase in incidence (number of animals) with fatty liver compared with controls as the benchmark response to determine the benchmark dose lower confidence limit (or $BMDL_{10}$ - using a subscript of 10 signifies use of a benchmark response of 10 percent).

To calculate the benchmark dose for rodents for methylene chloride, EPA used a biological model for dose-response modeling, as recommended by EPA's peer-reviewed *Benchmark Dose Technical Guidance* (2012) and *Review of the Reference Dose and Reference Concentration Processes* (2002) at 3-28. EPA first input all four doses used in the Nistchke study into its peer-reviewed rat physiologically based pharmacokinetic ("PBPK") model built with specific data for methylene chloride metabolism in rodents. RE at 304, JA ___. That model calculated the daily internal liver doses (i.e., the amount of methylene chloride metabolized in the rats' liver via a particular metabolic pathway) based on the external methylene chloride doses used in the Nitchske study. *Id.* at 685, JA ___. Next, as recommended by EPA's peer-reviewed *Benchmark Dose Technical Guidance* (2012), EPA input the PBPK model's internal dose data into available benchmark dose models and identified the model that had the "best fit" (i.e., the model that most accurately represented the data in the Nitschke study) to identify

the *internal* benchmark does for rodents (the internal dose that causes fatty liver disease). *Id.* at 305, JA ___.

Additionally, because the Nitschke study is a rodent study and rodents, which have evolved to live in dirtier environments, metabolize chemical substances differently than humans,[14] RE at 244, JA ___, EPA had to determine the human equivalent point of departure. *Id.* at 304–06. To scale the internal benchmark dose from rodents to humans, EPA used a standardized well accepted scaling ratio: BW3/4.[15] *Id.* Then EPA identified the external air concentration level associated with the internal benchmark dose and identified a human equivalent concentration ("HEC"). *Id.* The HEC is "[t]he human concentration (for inhalation exposure) of an agent that is believed to induce the same magnitude of toxic effect as the experimental animal species concentration."[16] *Review of the Reference Dose*

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[14] Metabolism is how a chemical or other substance is broken down and then is eventually excreted by the body. For instance, generally, the higher a subject's the metabolism, the higher dose is needed to produce the same effect on a subject with a lower metabolism. *See* Their, et al. (1988), AR 598, at 1.

[15] Using BW3/4 scaling is a default approach of converting animal data to human equivalence based on simple allometric scaling of physiological rates or quantities to relative growth and size (mass or volume) of one animal species relative to another animal species. This ratio was used because the dose-metric is a rate of metabolism and the clearance of these metabolites is expected to be slower per volume tissue in the human compared with the rat. RE at 685, JA ___.

[16] The HEC is the terminology used for the inhalation route because the methylene chloride measurements are expressed as concentrations in air. For the dermal route, EPA used the term human equivalent dose (HED), RE at 243, JA ___ or human equivalent dermal dose (HEDD), RE at 313, tbl.3-22, JA ___, to appropriately

and Reference Concentration Processes (2002) ("Reference Dose Review"), AR 614, at G-4, JA ___. EPA calculated the HEC based on the first percentile to account for susceptibility from the toxicokinetic variability among humans related to differences in metabolism. RE at 305, JA ___.

Industry Petitioners insinuate that basing the HEC on the first percentile was inappropriate. Industry Br. at 44. But if EPA had used a higher percentile, EPA would have had to address the susceptibility later in its uncertainty analysis, such as by adding another uncertainty factor when it conducted the risk characterization, *see* Section I.A.1.c., below. Industry Petitioners also (incorrectly) assert that EPA failed to properly consider three human epidemiological[17] studies that they assert showed no liver toxicity: (1) a 1983 study by Ott et al., (2) a 1990 Study by Kolodner et al., and (3) a 1993 study by Soden et al. Industry Br. at 41 & n.12. Contrary to the Industry Petitioners' claims, EPA considered all three of these studies in the Risk Evaluation, and also contrary to Industry Petitioner's claims, the

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describe the *dose* from the dermal route of exposure as also defined within EPA's 2002 guidance.

[17] An epidemiological study examines disease patterns within a population, observing associations between exposures and outcomes without actively manipulating variables, while a human controlled study (such as the Putz study described above), actively intervenes by assigning participants to different treatment groups to directly test the effects of a specific factor on a health outcome, allowing for a more controlled analysis of causation. Reference Dose Review, G-3, JA ___.

studies identify the potential for adverse liver effects in humans, as discussed below. *See* RE at 255, 568, JA ___, ___.

In the Risk Evaluation, EPA noted that two of the three studies (Ott and Kolodner) showed increases of bilirubin in blood, which was a biological concern and could signify the potential for liver disease. RE at 255, JA ___. Even so, EPA determined the studies were not appropriate measures by which to quantify hazard in a dose response assessment because the increase of bilirubin did not provide clear evidence of adverse liver effects, *id.*, and because of limitations of the studies' methodologies (including lack of information on participant selection, length of exposure, etc.) Response to Public Comments ("RTC") at 57, AR 944, JA ___.

The Ott study identified a consistent relationship between increased bilirubin and increased methylene chloride among some population subgroups (non-white women, white men, white women) across multiple levels of methylene chloride exposure (60, 140, 280, and 475 ppm).[18] Ott et al. (1983), AR 538, at 23, JA ___. The study's authors noted that this finding, "could point to either liver injury or

[18] This also shows that methylene chloride levels associated with the statistically significant increases in a measure suggestive of liver toxicity are lower than 475 ppm, yet the Industry Petitioners cite only this high level. Industry Br. at 41. A non-statistically significant increase was also seen at the highest exposure level in GE (1990), which was estimated to be 49 ppm (approximately ten times lower than 475 ppm).

hemolysis" but that other indicators of liver toxicity were not identified. *Id.* The study's authors explained that "[u]nfortunately, additional tests which could have clarified the situation further (e.g., direct bilirubin and reticulocyte counts [immature red blood cells]) were not performed." *Id.* at 23–24, JA ___–___.

The Kolodner study (called the General Electric study in the Risk Evaluation) assessed methylene chloride's effect on worker health using health data collected for 896 General Electric employees over one year. Kolodner et al. (1990), AR 457, at iv, JA ___. The study divided the employees into four exposure categories, high, medium, low, and no exposure, with mean exposures for the four groups of 49 ppm, 10.9 ppm, 3.3 ppm and <1.0 ppm, respectively, based on personal air monitoring conducted over a six-year period. *Id.* The study showed dizziness/vertigo was significant among the exposure groups, and "showed a significant dose-response relationship." *Id.* at 37, JA ___. Although the study did not show statistically significant changes in serum total bilirubin, it identified higher bilirubin in the high versus the minimal exposure group. *Id.* at 59, Table 5, JA ___. Further, the portion of subjects with abnormalities in total bilirubin (as diagnosed by a physician) was ten percent at the highest exposure level versus three percent at the lowest level. *Id.* at 60, Table 6, JA ___. The study did not show any trends with other liver function tests. *Id.* at 39–40, JA ___–___. The study authors noted its limitations, including, but not limited to, its "cross-sectional

design," which "limited [the authors'] ability to assess cumulative exposure and the time of occurrence of a health condition in relation to the exposure." *Id.* at 44, JA ___.

The Soden study was undertaken after OSHA proposed to reduce the occupation exposure limit to methylene chloride from 500 ppm to 25 ppm over an 8-hour time weighted average based on concern that chronic exposure adversely affected cardiac, neurologic, and hepatic function. Soden (1993), AR 585, at 282, JA ___. The study compared two sets of workers: one set was exposed to 475 ppm of methylene chloride on average, and the other set that was unexposed. *Id.* at 283, JA ___. The study used blood tests to screen for liver injury. The Soden study concluded that there was no statistically significant difference between the liver function results between the exposed and non-exposed workers. *Id.* at 285, JA ___. The authors also noted that not all workers in the study underwent every blood test. *Id.* at 284, JA ___

In the Risk Evaluation and the Response to Comments, EPA identified limitations to the above-described epidemiological studies. RE at 255, JA ___; RTC at 57, JA at ___. None of the studies identified actual years worked; Ott and Soden identified only whether the workers were exposed more than 5 or 10 years, respectively, and Kolodner did not indicate number of years employed. *Id.* In the Risk Evaluation, EPA assumed 31-and 40-year exposures. *Id.* Thus, the observed

increases in bilirubin would likely progress to more severe effects with longer exposure for 31 to 40 years, at least in a portion of the working population. Other limitations across studies include limited to no information on participant selection or attrition, which can affect results. *Id.* For instance, if individuals have left the workplace due to illness (such as liver disease), that illness and associated symptoms would not have been identified in the study. And EPA noted that the indicators of liver injury may not be detectable in the blood serum levels measured in the studies. *Id.* This was supported by the Soden study, in which the author stated:"[s]ome functional tests have limited use as early indicators of liver damage because they are fairly insensitive, registering only significant damage capable of impairing liver function in grossly measurable ways." Soden (1993) at 284, JA ___. EPA explained that by contrast, the multiple animal inhalation studies in several species[19] identify liver toxicity using more sensitive or definitive indicators such as hepatic vacuolization, necrosis, hemosiderosis, and hepatocellular degeneration that are observed after long-term exposure in post-mortem analysis, which is simply not feasible with human studies. RTC at 57, JA ___. EPA reasonably concluded that because at least two of the epidemiological studies suggest liver injury in humans, the liver effects are an important outcome

[19] The Nitschke study is supported by multiple animal studies showing similar effects. RE at 255-256, JA ___.

associated with methylene chloride exposure. *Id.* Therefore, EPA determined the rat chronic inhalation study by Nitschke et al. to be the best study available and most robust and scientifically sounds to quantify liver toxicity caused by methylene chloride, and the foundation for the chronic inhalation assessment.

The Industry Petitioners correctly noted that epidemiological studies received medium data quality ratings and point out that the Putz study (described above) was also considered medium quality. Industry Br. at 41–42. Even still, the Nitchske study received a high data quality rating. Contrary to Industry Petitioners' assertion, EPA's selection of the Putz study (rated medium quality) from which to derive the acute inhalation hazard does not amount to an internal inconsistency (*id.* at 42) because no acute studies were rated high-quality. And given the limitations in the epidemiological studies for quantitative assessment for chronic exposure, EPA appropriately relied on animal toxicity data—the Nitschke study.

As noted above, Industry Petitioners fault EPA for not relying on studies that purportedly showed no adverse liver effects, but to identify a hazardous dose in a dose-response assessment, EPA *must rely* on studies that have data on concentrations that cause adverse effects. Industry Petitioners paint EPA's point of departure and HEC determinations as overly conservative extrapolations that reduce potential risk to zero. *Id.* at 42–44. This is a gross mischaracterization. In calculating the point of departure as part of its dose-response assessment, EPA

used the best available science, including peer-reviewed and widely accepted modeling methods. And in identifying the human equivalent concentration and points of departure, EPA is not determining risk, but rather, the hazard level. In other words, EPA is identifying the point (or dosage) on a response curve that, based on the available data, is shown to either produce or not produce an adverse effect based on the parameters of the underlying study.

The record demonstrates that EPA considered all reasonably available studies, including those identified by Industry Petitioners, RE at 246–54, JA ___–___ and conducted a weight of the scientific evidence evaluation by considering other information, including animal studies that identified adverse effects, RE at 285–87, JA ___–___. EPA explained its rationale using the Putz and Nitschke studies to derive the different points of departure for acute and chronic inhalation hazards. Because EPA has considered the relevant factors and articulated a rational connection between the facts found and the choices made, its decision must be upheld. *State Farm*, 463 U.S at 43.

b. Substantial Evidence Supports EPA's Exposure Assessment.

The second step of the risk assessment is an exposure assessment, which describes how humans encounter a particular chemical. 2014 Framework at 39, JA ___. Industry Petitioners do not object to EPA's exposure assessment, but brief discussion is necessary to understand the third step of the risk assessment: risk

characterization. As described in the Procedural Background Section III.B.2 above, for inhalation exposure in occupational settings, EPA evaluated (1) air monitoring data submitted by industry; (2) exposure data found in peer reviewed literature; and (3) peer-reviewed modeling to estimate potential exposure. RE at 32, JA ___. Using the exposure data, EPA estimated acute and chronic exposure levels for each condition of use (assuming no reductions due to personal protective equipment use) and assigned an overall confidence rating to estimates based on the quality of the data, and uncertainties. Id. at 187–91, JA ___–___.

c. EPA Properly Characterized Methylene Chloride's Risk to Human Health.

After assessing methylene chloride's hazards and exposures, EPA integrated those assessments to estimate the risk methylene chloride poses to human health. RE at 33–36, JA ___–___. To be clear, the risk characterization is distinct from the risk determination, described in Section I.A.2, below. As part of the risk characterization, EPA used an accepted methodology, consistent with best available science, to calculate a "margin of exposure" for each condition of use, which it compared to the "benchmark margin of exposure" to estimate the level of risk for each condition of use. *Id.* at 34, 364, JA ___, ___. For workers, EPA estimated risks using several occupational exposure scenarios, which varied assumptions regarding the personal protective equipment. *Id.*

EPA calculated the margin of exposure for each condition of use by dividing the points of departure or human equivalent concentrations identified in the hazard assessment by the exposure levels in the same units, estimated for each condition of use in the exposure assessment. RE at 364, JA ___. Industry Petitioners incorrectly assert that the "margin of exposure is that highest exposure for zero risk." Industry Br. at 18. This is a mischaracterization. The margin of exposure is the point of departure divided by the exposure level. Recall the hypothetical study described above where 15 adult males, ages 18-25 exposed to a chemical known to cause lung damage for four hours. The point of departure of that study was 100 ppm. Yet as discussed above, it cannot be concluded that 100 ppm would not produce adverse effects in others, particularly more sensitive populations, because of uncertainty associated with the study and limitations of the data.

The benchmark margins of exposure for both acute and chronic exposures account for uncertainty by incorporating uncertainty factors. In risk assessments, an uncertainty factor is a number used to account for gaps in scientific knowledge and variability in data.[20] RE at 361–62, JA ___. For example, EPA based the

[20] EPA's use of the margin of exposure (MOE) approach includes uncertainty factors that have been standard practice for many years when conduction risk assessments. In contrast to setting reference concentrations or reference doses, the MOE approach considers the uncertainty factors as a *separate step* in the risk evaluation. *See, e.g.*, EPA's Risk Assessment Forum, A Review of the Reference Dose and Reference Concentration Processes (2002), AR 614, JA ___.

acute inhalation point of departure on the Putz study, which included only 12 males and females (non-smoking, non-pregnant) ages 18 to 40 years old. As part of a TSCA risk evaluation, EPA must consider potentially exposed or susceptible subpopulations, such as infants, children, pregnant women, workers, and the elderly. 15 U.S.C. § 2605(b)(4)(A), (b)(4)(F)(i). The Putz participants did not include such subpopulations.[21] EPA also determined that it is unlikely that cardiac patients— a significant susceptible subpopulation for methylene chloride, RE at 249, 286, 303, JA ___, ___, ___—were included in this study because the Putz participants underwent medical examinations that included an electrocardiogram (ECG) and were seen by a physician who then recommended the individuals for inclusion in the Putz study. Putz (1979) at 99, JA ___. The participants in the Putz study also did not include smokers, *id.*, another susceptible subpopulation specifically identified for methylene chloride, *see* RE at 303, JA ___.

Because the point of departure did not account for possible increased risk to these susceptible populations, EPA included an "intraspecies uncertainty factor" of 10 to account for the differences in susceptibility among humans exposed. RE 302–03, 313, JA ___–___, ___. Use of this uncertainty factor is well-established across

[21] For methylene chloride EPA identified the following potentially exposed or susceptible subpopulations: workers, occupational non-users, consumers, bystanders, individuals with genetic polymorphisms; smokers; individuals with cardiac disease, newborn infants, and babies. RE 450–51, JA ___.

EPA offices and other institutions such as the National Academies and the Agency for Toxic Substances and Disease Registry. Reference Dose Review at 4-42, JA ___ (recommending that 10 should be the default uncertainty factor for intraspecies variation).

EPA also used a second uncertainty factor to account for the fact the Putz study only identified a LOAEL (and not a NOAEL), which EPA used in determining the point of departure. RE at 304, JA ___. Use of such an uncertainty factor is also a well-established practice used by multiple EPA offices and agencies when assessing risk. Reference Dose Review at 4-44, JA ___. To account for a LOAEL, EPA used an uncertainty factor of 3 rather than a more typical value of 10 because EPA considered the decrease of 7 percent peripheral vision to be of small magnitude, and therefore not supportive of the full factor of 10. RE at 304, JA ___; Reference Dose Review at 4-44, JA ___ (noting that an uncertainty factor of 10 is routinely applied when only a LOAEL is available). After identifying those two uncertainties, EPA calculated the benchmark margin of exposure for acute effects, to be 30 (by multiplying the uncertainty factors). which constitutes the benchmark MOE for acute inhalation exposure. RE at 361, JA ___.

To identify the benchmark margin of exposure for the chronic inhalation risk, EPA had to quantify the two uncertainties associated with the modeled HEC value derived from the Nitschke study. For the chronic value, EPA first had to

account for species differences in animal to human extrapolation for potential interspecies uncertainty/variability. *Id.* at 306, JA ___. This interspecies uncertainty factor consists of two separate areas of uncertainty to account for differences in the toxicokinetics and toxicodynamics of animals and humans. *Id.* at 307, JA ___. The models and assumptions EPA used in deriving the HEC from the Nitschke study already accounted for some of the expected variation in susceptibility between rodents and humans (interspecies). RE at 363, JA ___. The modeled value incorporated differences between rodents and humans in toxicokinetics (i.e., how the body absorbs, distributes, metabolizes, and excretes a chemical or toxicant over time). *Id.* Because the toxicokinetic variability was accounted for in the PBPK modeling to derive the HEC, only the toxicodynamic uncertainties in extrapolating from animals to humans remained, EPA used an uncertainty factor of 3 to account for this uncertainty. RE at 363, JA ___.

Likewise, the model accounted for some differences among the human population (intraspecies uncertainty). Recall EPA used the 1st percentile to account for susceptibility from the toxicokinetic variability among humans related to differences in metabolism. *Id.* at 305, JA ___. Because EPA used a human model and used the 1st percentile of toxicokinetic distributions among humans, EPA reduced the second uncertainty factor for intraspecies variability from 10 to 3. The remaining value of 3 adjusts for any differences in toxicodynamics (i.e., how a

toxic agent interacts with a biological target, causing molecular, biochemical, and physiological effects). *Id.* Combining the toxicodynamic intraspecies and interspecies factors, the total uncertainty factor for chronic inhalation was calculated to be 10, which constitutes the benchmark margin of exposure for chronic exposure.

For workers, EPA estimated risks using several occupational exposure scenarios, which varied assumptions regarding the use of personal protective equipment for respiratory and dermal exposures for workers directly handling methylene chloride. RE at 34, JA ___. In other words, EPA calculated margins of exposures for each condition of use changing the exposure estimate in the denominator of the equation based on non-PPE use and PPE use. *Id.*

As noted above, EPA compared the margin of exposure for each condition of use to the benchmark margin of exposure (i.e, the total uncertainties). When the margin of exposure for acute and chronic non-cancer hazards (neurotoxicity and liver effects) was less than the respective benchmark margin of exposure (30 or 10), EPA concluded that risk existed for that condition of use. To be clear, this characterization of the risk was not the unreasonable risk determination for the chemical, but rather the information that informed the unreasonable risk determination.

Additionally, contrary to Industry Petitioners' claims, *see* Industry Brief, at 14, applying the benchmark margin of exposure to the above-mentioned points of departure and comparing the hazard values with human exposure estimates for the conditions of use does not result in zero risk. The methods EPA uses to determine the methylene chloride points of departure and then divide by the benchmark margin of exposure are consistent with well-established methods for establishing reference doses and concentrations. *See, e.g.*, Integrated Risk System (IRIS) handbook (2022), JA ___. When deriving a reference dose used for chronic exposure duration as part of the Integrated Risk System (IRIS), EPA's "objective is to determine an exposure level 'likely to be without an appreciable risk of deleterious effects during a lifetime.'" *Id.* at 8-2. The reference dose process used by IRIS is like EPA's process under TSCA of dividing the point of departure by exposure and comparing with the benchmark margin of exposure, except that the IRIS process incorporates the uncertainty factors *as part of* the reference dose rather than using them in a separate step as part of the benchmark MOE. Thus, similar to how the reference dose is defined, the combination of the benchmark MOE plus the POD/HED process under TSCA is 'without appreciable risk.' Without appreciable risk does not mean no risk.

Another source of residual risk comes when estimating human exposure. EPA did not aggregate exposure across inhalation and dermal exposure routes

within a particular condition of use because of difficulties in doing so within the PBPK model that was specific for the inhalation route. However, EPA believes that inhalation and dermal exposure could occur simultaneously for workers and for household exposures. RE at 452, JA ___. Thus, EPA is aware that not adding inhalation and dermal exposures for a given task and individual could have led to an underestimate of exposure in some situations, even though inhalation is expected to be the dominant route of exposure. Thus, using the points of departure and benchmark margin of error compared with human exposure estimates is not expected to result in *zero* risk. EPA also quantified uncertainties associated with the data. *Id.* at 302, 306, JA ___, ___. Using a model, EPA extrapolated the inhalation points of departure to identify the dermal points of departure because none of the dermal toxicity studies were appropriate for a dose-response assessment. *Id.* at 311, JA ___.

2. EPA's Unreasonable Risk Determination Is Supported by Substantial Evidence.

After comprehensively assessing methylene chlorides's hazards and exposures and characterizing its risks, EPA determined that methylene chloride presents an unreasonable risk to human health, under its conditions of use. That determination should be upheld. Indeed, Industry Petitioners do not dispute that exposure to methylene chloride presents a real, non-speculative, risk to human health, including possible death. As this Court recently articulated in *Texas v.*

United States Environmental Protection Agency, 91 F.4th 280, 291 (5th Cir. 2024), the court's review "'must be 'most deferential' to the agency where, as here, its decision is based upon its evaluation of complex scientific data within its technical expertise."

Industry Petitioners cloak their policy disagreement with EPA's unreasonable risk determination (drawn from the scientific record as detailed above) as an issue of "statutory interpretation" and assert that EPA has "interpreted" the meaning of "unreasonable risk" too broadly. They baselessly assert it is "up to this Court, not EPA, to determine" what constitutes an "unreasonable risk of injury to health." Industry Br. at 34. Industry Petitioners argue that the Court must tailor the meaning of phrase "unreasonable risk" to avoid constitutional concerns under the major-questions doctrine and the nondelegation doctrine.

None of these arguments are valid and none give the Court license to disregard Congress' express direction assigning to EPA the ultimately *technical* task of determining whether a chemical substance presents unreasonable risk. EPA's judgment about the degree of risk that is "unreasonable"—guided by the factors Congress set out in Section 2605(b)(1)(a) and (b)(4)(F)—is readily supported by substantial evidence in the record and warrant this Court's respect. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2261 (2024) (noting that the

Administrative Procedure Act "mandate[s] that judicial review of agency policymaking and factfinding be deferential").

a. EPA Used its Scientific and Technical Expertise to Determine Unreasonable Risk as Congress Directed.

Congress unequivocally assigned EPA the authority "to determine" whether a chemical presents an "unreasonable" risk for purposes of implementing TSCA. 15 U.S.C. § 2605(b)(4)(A) ("The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment[.]"). Indeed, Congress recognized that determining whether a chemical substance presents an unreasonable risk is a technical determination that depends on the substance under evaluation and the circumstances under which it is being assessed. *See, e.g.,* 162 Cong. Rec. S3511-01, S3522 (Senator Vitter's statement that "'[u]nreasonable risk does not mean no risk; it means that *EPA must determine*, on a case-by-case basis, whether the risks posed by a specific high priority substance are reasonable in the circumstances of exposure and use.") (emphasis added). In addition, Congress rejected the notion that, in determining reasonableness, EPA must conduct a "balancing test like that familiar in tort law," 162 Cong. Rec. S3511-01, S3516, instead instructing EPA not to consider costs or other nonrisk factors in determining whether a risk is unreasonable, 15 U.S.C. 2605(b)(4)(A), (F)(iii).

As discussed in detail above, in identifying unreasonable risk, EPA did not determine that *any* risk was unreasonable, as Industry Petitioners assert. Instead, as required by Congress, EPA performed a risk evaluation subject to statutory requirements and limitations. *See, e.g.*, 15 U.S.C. § 2605(b)(4), 2625(h)–(i), (k). In making its unreasonable risk determination, EPA considered all the risk-related factors, articulated by Congress, including, but not limited to: information on adverse health effects (including information on the nature and severity) and human exposure to methylene chloride under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations); and the duration, intensity, frequency, and number of exposures under the conditions of use. RE at 453, JA ___; *see* 15 U.S.C. § 2605(b)(4)(F)(i)–(v). EPA also complied with the scientific standards Congress required in carrying out a risk evaluation and, including considering uncertainties associated with the information described above, and made its risk determination consistent with the best available science and based on the weight of the scientific evidence. *See, e.g.*, 15 U.S.C. § 2625(h)–(i).

Faced with EPA's robust record and application of its scientific and technical expertise, Industry Petitioners invent a statutory interpretation argument. Industry Petitioners latch on to the term "unreasonable" and attempt to pour meaning into that word from various dictionary definitions. But that approach

ignores the meaning that *Congress* gave to that term through the detailed enumeration of factors EPA is required to consider in arriving at a determination that a chemical substance's risks are unreasonable.[22] *See id.* § 2605(b)(4)(A), (F).

The plain meaning of the word "reasonable" is "appropriate *in a particular situation*," Oxford English Dictionary (emphasis added), or "fair, proper, or moderate *under the circumstances*," Black's Law Dictionary (emphasis added)—with unreasonable meaning "not reasonable." But neither these definitions nor those that Industry Petitioners proffer can readily answer the question: "When is a risk posed by methylene chloride unreasonable?" That is, Industry Petitioners cannot provide a definition of the term "unreasonable" that can (or should) definitively resolve the question of what amount of harm methylene chloride poses to public health is unreasonable (or reasonable, for that matter), because the question, and answer, is ultimately one of health *policy* and is based on the circumstances of the particular chemical at issue. Congress understood that the idea of "unreasonable risk" was relative and would require EPA to consider multiple factors like the severity of harm, the nature of exposure, and the weight of the scientific evidence (including uncertainties). 15 U.S.C. § 2605(b)(4)(F).

[22] EPA has also not defined unreasonable risk in its risk evaluation procedural rules, in part because of public comments that a definition was inappropriate, as each risk evaluation will be unique. *See Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act*, 82 Fed. Reg. at 33735, JA ___.

Congress also explicitly directed EPA *not to consider* costs and other nonrisk factors, such as the potential industrial benefits of the methylene chloride in determining whether the risk is presents is unreasonable. *Id.* § 2605(b)(4)(a). EPA followed Congress' direction: After assessing the hazards and exposures of methylene chloride, EPA characterized its risk, using an accepted methodology consistent with best available science, to calculate the "margin of exposure" for each condition of use, which it compared to "benchmark margin of exposure" to determine the level of risk for non-cancer endpoints and, using those objective scientifically-based measures, made its unreasonable risk determination.

Congress assigned the courts the role of evaluating whether EPA's decisions flowing from those considerations were supported by substantial evidence. In short, no parsing of the term "unreasonable" will establish whether the risk posed by methylene chloride is, in fact, "unreasonable." Congress assigned to EPA the task of determining what risks are "unreasonable" for a given chemical substance based on EPA's scientific and technical expertise. Applications of that expertise are entitled to the Court's respect. *See Loper Bright Enters.,* 144 S. Ct. at 2261 (noting that the Administrative Procedure Act "mandate[s] that judicial review of agency policymaking and factfinding be deferential").

Here, substantial evidence in the record demonstrates that EPA reasonably determined, based on its robust and highly technical analysis described in its peer-

reviewed 2020 Risk Evaluation, that methylene chloride presents an unreasonable risk of injury to health. Based on the weight of the scientific evidence, EPA found that effects from acute exposure during use of methylene chloride include neurological impacts such as dizziness, incapacitation, loss of consciousness, coma, and death. Effects from chronic exposure include liver damage and cancer.

To convince the Court that it must construe "unreasonable risk" narrowly, Industry Petitioners argue that the Court must tailor the meaning of phrase "unreasonable risk" to avoid constitutional concerns under the major-questions doctrine and the nondelegation doctrine. Both of these constitutional concerns, however, are unfounded.

b. The Major-Question Doctrine Is Inapplicable.

The major-question doctrine applies when an agency asserts authority over issues of vast economic and political significance without clear authorization from Congress. *See West Virginia v. EPA*, 597 U.S. 697, 732 (2022). It applies only in "certain extraordinary cases" involving transformative claims of statutory authority where the "history and the breadth" of a newly asserted authority has such profound economic and political significance that there is "reason to hesitate" before concluding that Congress meant to confer that authority. *Id*. at 723–24.

This is not one of those cases. For one, EPA is clearly authorized to evaluate a chemical substance's risks and determine whether any such risks are

"unreasonable." *See* 15 U.S.C. § 2605(a). That is not a "rarely used," "ancillary" statutory provision, *West Virginia*, 597 U.S. at 724; it is the central mandate of the 2016 Amendments. There is "clear congressional authorization," *id*. at 723, for EPA to engage in the task Congress gave it: evaluating a chemical substance's risks, based on the many factors elaborated in Section 2605(b)(1)(A), Section 2605(b)(4), and beyond. The major-question doctrine simply does not apply.

Moreover, this is not an "extraordinary case" where the history and breadth of the authority asserted and the economic and political consequences of that assertion provide reason to hesitate before concluding that Congress intended to confer such authority. Congress recently amended TSCA in 2016, and EPA's risk evaluation follows the statutory language to a tee. The Rule's economic effects are minimal: the estimated costs imposed of the Rule are just under $40 million, 89 Fed. Reg. at 39285/3, which pales in comparison to the hundreds of billions of dollars at issue in the Supreme Court's major-question cases. The Rule regulates a small portion of the American economy (equal to less than 0.1 percent of the Gross Domestic Product when calculated conservatively). *Id.* In any event, Congress clearly anticipated that certain TSCA regulations could have a large economic impact and created a statutory exemption for EPA to apply in those scenarios as appropriate. *See* 15 U.S.C. § 2605(g)(1)(B) (authorizing EPA to exempt specific

conditions of use from the requirements of a rule if the rule would "significantly disrupt the national economy").

In short, Industry Petitioners ask this Court to set aside the Supreme Court's reminder that "the major questions doctrine is a tool for discerning—not departing from—the text's most natural interpretation." *Biden v. Nebraska*, 600 U.S. 477, 508 (2023) (Barrett, J., concurring). The Court should reject that invitation. Congress knew what it was empowering EPA to do when it amended TSCA in 2016, it did so after careful deliberation, and EPA has not departed from Congress's directions here.

c. Congress Constitutionally Authorized EPA to Implement TSCA Section 2605.

Nor is Section 2605(b) an unconstitutional delegation of legislative authority. Congress may delegate authority and discretion to the Executive through its administrative agencies so long as Congress has set out an "intelligible principle" to guide the agency's exercise of authority. *Jarkesy v. Sec. & Exch. Comm'n*, 34 F.4th 446, 461 (5th Cir. 2022), *cert. granted* 143 S. Ct. 2688 (2023), and *cert. denied*, 143 S. Ct. 2690 (2023), and *aff'd and remanded* 144 S. Ct. 2117 (2024). "Applying this 'intelligible principle' test to congressional delegations . . . has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more *technical problems*, Congress simply

cannot do its job absent an ability to delegate power under broad general directives." *Mistretta v. United States*, 488 U.S. 361, 372 (1989) (emphasis added).

In amending TSCA, Congress promulgated intelligible principles to which EPA must conform. First, EPA must conduct a risk evaluation to determine whether the substance presents an unreasonable risk of injury to health or the environment, under the chemical's conditions of use. 15 U.S.C. § 2605(b)(3)–(4). If, through the risk evaluation, EPA determines that the chemical presents an unreasonable risk, EPA must then engage in risk management and regulate to address any unreasonable risks. *Id.* § 2605(a), (c). Congress prescribed standards by which EPA must undertake these responsibilities. For instance, TSCA section 2605(b)(4)(F) describes what EPA must consider (and not consider) in its Risk Evaluation. *Id.* § 2605(b)(4)(F). And in section 2605(c)(2), Congress set forth detailed requirements for any regulation restricting or prohibiting a chemical substance. *Id.* § 2605(c). Additionally, Congress required that EPA make scientific decisions using best available science and based on the weight of the scientific evidence. *Id.* § 2625(h), (i). Moreover, the statute's use of the "flexible" term *unreasonable* is evidence enough "that the agency is authorized to exercise a degree of discretion." *Loper Bright*, 144 S. Ct. at 2263. Here, the question is whether EPA "has engaged in 'reasoned decisionmaking,'" *id*., in its determination of what risk is unreasonable. "By doing so, a court upholds the traditional

conception of the judicial function that the APA adopts." *Id.* Thus, the statute's text is sufficiently clear on the interpretive question presented.

Congress's direction that EPA use its technical and scientific judgment to determine when a risk is "unreasonable" was not open-ended. Indeed, Industry Petitioners rightly describe the constraints Congress imposed on EPA, "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 [EPA] must not consider." Industry Br. at 37. In other words, in assigning to EPA the authority to make unreasonable risk determinations, Congress also provided guardrails. And in promulgating the Rule, EPA acted well within those bounds.

3. EPA Properly Revised its Unreasonable Risk Determination.

EPA acted well within its authority when it revised its risk determination. As described in Part C of the Procedural Background above, EPA's 2020 Risk Evaluation concluded that 47 of the 53 conditions of use of methylene chloride present unreasonable risk and made individual determinations of unreasonable risk for each of those 47 uses. In 2022, EPA revised its determination in two ways. First, it reevaluated the record to assume that occupational users were *not* necessarily using personal protective equipment when using methylene chloride. That changed assumption led EPA to conclude that an additional five conditions of use would present unreasonable risk, or 52 of the 53 conditions of use. Second,

EPA concluded that the methylene chloride risk determination should be based on whether the chemical substance as a whole presents an unreasonable risk of injury to human health under its conditions of use, resulting in a single section 2605(b) determination as to methylene chloride, rather than 53 separate determinations for each of methylene chloride's conditions of use.

EPA reviewed the 2020 Risk Evaluation in accordance with Executive Order 13990. *See* 87 Fed. Reg. at 67901, JA ___. And EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also State Farm*, 463 U.S. at 42.

a. EPA's Considerations Regarding PPE Were Reasonable.

EPA's 2020 Risk Evaluation characterized methylene chloride's risk under each condition of use applying two occupational use scenarios: one assessing exposures if a worker was using personal protective equipment, and one assessing exposures if a worker was not. RE at 319–32 (tbl. 4-2), JA ___–___.When EPA revised its risk determination, it did not change any of the scientific analyses done in the hazard assessment, exposure assessment, or risk characterization sections of the Risk Evaluation. The only substantive change was that, in making its risk determination, EPA relied on the exposure scenario in which workers would *not* be

using personal protective equipment. EPA's decision to move away from assuming, absent reasonably available information, that occupational users are always and effectively using personal protective equipment when using methylene chloride is consistent with the statute, and supported by the record.

First, the statute: TSCA requires EPA to consider information on exposures. 15 U.S.C. §§ 2605(b)(4)(F), 2625(k). This includes information on the intensity of the exposure. *Id.* § 2605(b)(4)(F)(iv). The intensity of exposures is affected by the use and reliability of personal protective equipment. If such equipment is not used, then people are exposed to the chemical substance at higher concentrations. Congress mandated that EPA base its risk determinations on reasonably available information about exposures, *id.* § 2625(k)—not on assumptions about use patterns. EPA's approach to personal protective equipment in the Revised Risk Evaluation is consistent with that mandate.

Industry Petitioners contend that it is necessary to assume that users are using personal protective equipment because doing so in inherent to the "condition of use." Industry Br. at 30-31. Not so. Conditions of use are the "circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). Whether people exposed to the chemical substance in those circumstances are using personal protective

equipment—and what kind, what efficacy, and with what reliability that equipment is used—affects the exposure intensity in those circumstances, but it is not itself the "condition of use." *See* RE at 187, JA ___.

Second, the record: in the Revised Risk Determination, EPA explained that reasonably available information shows that there are many scenarios in which workers exposed to methylene chloride in a particular condition of use are not using personal protective equipment. Response to Comments on Revised Risk Determination, AR 47, at 23–25, JA ___–___. That may be because their workplaces are not covered by OSHA standards that may otherwise call for personal protective equipment, which is the case for many self-employed workers who died due to acute methylene chloride poisoning. *Id.* at 25. Or that may be because their employers are out of compliance with OSHA standards. Revised Risk Determination at 4. In short, the information available to EPA indicated that workers exposed to methylene chloride under various conditions of use are *not* universally or reliably protected by personal protective equipment.

Indeed, EPA is obligated to consider worker exposures under TSCA's requirement that EPA consider unreasonable risks "a potentially exposes or susceptible subpopulation." 15 U.S.C. § 2605(b)(4)(A). Workers are specifically called out in the Risk Evaluation as a potentially exposed or susceptible subpopulation. RE at 450, JA ___. And workers that are not covered by OSHA

standards—such as self-employed workers—are part of that group of potentially exposed or susceptible subpopulation, and are more exposed to methylene chloride than those who are following the OSHA standards.

Indeed, because some workplaces may not be covered by OSHA, EPA's decision not to assume that all exposed workers are (properly) using personal protective equipment is not equivalent to regulating "intentional misuse," as Industry Petitioners assert. Industry Br. at 33. The record is clear that non-compliance with OSHA standards does occur, including information EPA received *after* it completed its 2020 risk determination that assumed PPE use. For example, EPA subsequently considered a 2021 investigation that found that between 1980 and 2018, at least 85 methylene chloride-related fatalities occurred, most often in the workplace. Response to Comments on the Revised Risk Determination at 18, JA ___. Given that new information, EPA's decision to move away from assuming, absent reasonably available information, that PPE use is always and effectively used, is supported by reasoned explanation. *FCC*, 556 U.S. at 515.

b. EPA's Single Risk Determination Is Consistent with the Statute.

EPA's decision to make a single risk determination for the chemical substance was appropriate and consistent with TSCA. First, EPA reasonably explained its decision to revise its unreasonable risk determinations and make a single risk determination for methylene chloride, rather than making unreasonable

risk determinations separately on each individual condition of use evaluated in the risk evaluation. EPA explained that TSCA section 2605(a) repeatedly refers to determining whether *a chemical substance* presents unreasonable risk under its conditions of use. 87 Fed. Reg. at 67903/2, JA ___ (emphasis added). EPA further explained a single risk determination was appropriate because the margin of exposure had exceeded the benchmarks in a substantial number of the conditions of use, and because the adverse health effects caused by methylene chloride can be severe and irreversible. *Id.* at 67904/1.

Second, EPA's decision to make a single unreasonable risk determination was consistent with the operative risk evaluation procedural rule in effect at the time of the revision. Industry Petitioners contend otherwise, arguing that the operative procedural regulations required unreasonable risk determinations for each condition of use. *See* Industry Br. at 22. That is incorrect. The operative procedural regulations, known as the Framework Rule, gave EPA discretion to decide whether to complete a use-by-use or a single risk determination, as the Ninth Circuit noted in *Safer Chemicals v. EPA*, 943 F.3d 397 (9th Cir. 2019). Either approach—a single determination or multiple—was therefore consistent with those regulations.

EPA's decision to make a single determination of unreasonable risk for methylene chloride reflects the best reading of the statute. Congress directed EPA

to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use." 15 U.S.C. § 2605(b)(4)(A). The statutory text requiring EPA to determine whether "a chemical substance" presents an unreasonable risk of injury to health or the environment, "under the conditions of use" The object of EPA's "determination" is *the chemical substance*, not "conditions of use of a chemical substance" and requires a determination on the chemical substance—not individual conditions of use. In addition, the plain language instructs EPA determine whether the chemical substance presents an unreasonable risk "under the conditions of use" (plural), not under each individual condition of use. As such, EPA's determination is based on analysis of the chemical's conditions of use as a whole—rather than on each condition of use independently.

This alone is sufficient to show that Congress intended a singular risk determination on the chemical substance. *Conn. Nat. Bank v. Germain*, 503 U.S. 249, 253–54 (1992). But to reaffirm its intention, the statute also refers to a singular determination on the "chemical substance" in a number of other provisions—meaning this reading of the statute is also supported by the structure of TSCA. *See* 15 U.S.C. § 2605(b)(4)(D), (b)(4)(F), (i). For example, TSCA section 2605(a) requires EPA to manage risks "to the extent necessary so that *the chemical substance* no longer presents such risk." *Id*. § 2605(a) (emphasis added).

The phrasing suggests that the chemical substance presents unreasonable risk and not the conditions of use. TSCA section 2605(i)(1) and (2), relating to final Agency actions resulting from TSCA risk evaluations, also similarly refer to a chemical substance presenting unreasonable risk, not individual conditions of use. Moreover, TSCA's preemption provisions under section 18 of the Act also refer to a singular risk determination on the chemical substance. It is well-established that "[a] word or phrase is presumed to bear the same meaning throughout a text." *Genus Lifesciences, Inc. v. Azar*, 486 F. Supp. 3d 450, 460 (D.C. Cir. 2020) (citing Antonin Scalia & Bryan A. Garner, Reading Law 144, 170 (2012)).

Moreover, even if EPA had issued unreasonable risk determinations based on condition of use, rather than a single unreasonable risk determination for methylene chloride, EPA would have regulated the conditions of use in the same manner in its 2024 methylene chloride risk management rule. In other words, Industry Petitioners were not in any way impacted by EPA's decision to issue a single unreasonable risk determination. The substance of EPA's unreasonable risk determination changed only because EPA no longer assumed PPE use (discussed below). Thus, even if the Court were to find EPA's decision to make a single determination of unreasonable risk inconsistent with the language of the statute, it would only amount to harmless error. *See Nat'l Ass'n of Home Builders*, 551 U.S. at 659–60.

Regardless of this Court's position on the appropriateness of EPA's decision to issue a single risk determination for methylene chloride, EPA's alleged error is not prejudicial if it "'is one that clearly had no bearing on the procedure used or the substance of decision reached.'" *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 215 (5th Cir. 1979) (quoting *Braniff Airways v. CAB*, 378 F.2d 453 (D.C. Cir. 1967)); *see also United States v. Johnson*, 632 F.3d 912, 930 (5th Cir. 2011). And that is the case here. In the original no unreasonable risk order, EPA found no unreasonable risk from six conditions of use. In its revised risk determination, when EPA no longer assumed PPE use, the Agency determined that 52 of the 53 conditions of use "drove" the unreasonable risk. In other words, it was the PPE assumptions—not the single risk determination—that impacted what conditions of use were subject to risk management under section 2605(a). Even assuming that EPA should have made an individual risk determination and issued an order pursuant to 2605(i) for the remaining condition of use that presented no unreasonable risk, such an order would not have altered the Rule in any way.

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In sum, Industry Petitioners cannot legitimately dispute the evidence on methylene chloride's hazardous health effects. Nor can they dispute individuals are primarily exposed through inhalation, that is by simply breathing air near where the chemical is being used. Instead, Industry Petitioners create red herrings,

arguing EPA should have relied on lesser quality studies, and downplay the severity of health effects and the potential for unprotected exposure. Industry Petitioner's dismiss the details of EPA's risk evaluation by claiming they are "buried in layers of technical papers." Industry Br. at 18. But Industry Petitioners cannot simply write off the substantial evidence that supports EPA's unreasonable risk determination because the record is admittedly technically complex and lengthy. EPA's well supported risk evaluation and revised unreasonable risk determination should be upheld.

B. The Risk Management Rule Is Lawful and Supported by the Record.

After conducting the risk assessment, EPA determined that methylene chloride presents an unreasonable risk to human health. When EPA determines that a chemical substance presents and unreasonable risk to human health, TSCA requires that EPA "shall by rule" apply one or more of possible "requirements" listed in the statute "to the extent necessary so that the chemical substance or mixture no longer presents such risk. 15 U.S.C. § 2605(a). Those statutory options include "prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement." *Id.* § 2605(a)(2)(A).

The Rule here generally uses one of two requirements to manage methylene chloride's risks (in addition to overarching recordkeeping and monitoring requirements): For most conditions of use, the Rule prohibits the use of methylene chloride after a specified compliance period. For others, the Rule requires workplaces to implement measures called a "Workplace Control Protection Plan" that will be sufficient to keep methylene chloride exposures below dangerous levels, known as the existing chemical exposure limit (ECEL) and the short-term exposure limit (STEL).

Industry Petitioners object to these requirements on six grounds. First, they contend that the exposure limits are too conservative and contrary to the scientific evidence. Second, they argue that the Rule prohibits uses of methylene chloride based on a lack of information that industry sectors could comply with those, rather than substantial evidence. Third, they argue that EPA should have referred regulation to Occupational Safety and Health Administration. Fourth, they argue that EPA failed to consider that alternatives to methylene chloride are inadequate. Fifth, they argue that EPA failed to consider the impact prohibition will have on small businesses. And, finally, they argue that EPA's prohibition on retailer sales will eliminate distributors for the uses that remain allowed. As detailed below, each of these arguments fail.

EPA's regulatory approach reasonably applies requirements available under section 2605(a) "to the extent necessary" to ensure that methylene chloride "no longer presents" an unreasonable risk under its conditions of use. 15 U.S.C. § 2605(a). In the Rule EPA prohibited the use of methylene chloride where it did not have information that a sector could comply with WCPP. It allowed continued use where the record demonstrated compliance with WCPP was feasible and would address the unreasonable risk. In deriving the exposure limits, EPA relied on a standardized mathematical exercise using assumptions and approaches that follow OSHA, industry groups, and standard industrial hygiene practices. In assessing this regulatory approach, EPA reasonably took into account and published a statement on the considerations required under TSCA section 2605(c)(2), including the "reasonably ascertainable economic consequences of the rule," and the reasonable availability of technically and economically feasible alternatives that benefit health or the environment as compared to the prohibited or restricted use. 89 Fed. Reg. at 39283/3–87/2.

1. The Exposure Limits Are Reasonable and Supported by the Substantial Evidence in the Record.

Industry Petitioners assert that EPA set unreasonably low exposure limits and then improperly prohibited many uses of methylene chloride based on an assumption that those limits could not be met. Industry Br. at 34–40. This is simply untrue. EPA considered the various options prescribed by Congress "to apply" to

methylene chloride "to the extent necessary so that [methylene chloride] no longer presents such risk." 15 U.S.C. § 2605(a). Industry Petitioners assert that in selecting requirements to address the unreasonable risk methylene chloride presents to human health, EPA "may *only* regulate to 'the extent necessary' for a substance to no longer present the unreasonable risk." Industry Br. at 39 (emphasis added). But Industry Petitioners insert the word "only," into their reading of the statute, where it does not exist. Under section 2605(a), "to the extent necessary" is a minimum requirement: EPA must "apply one or more of the following requirements . . . to the extent necessary so that the chemical substance or mixture no longer presents such risk." 15 U.S.C. § 2605(a). Thus, section 2605(a) imposes an obligation on EPA—it must ensure that its regulation has addressed the risk—rather than, as Industry Petitioners assert, a limitation on EPA's ability to regulate.

EPA prohibited the use of methylene chloride where the reasonably available evidence demonstrated that under the condition of use, compliance with WCPP was infeasible to reduce exposure to the limits (ECEL/STEL) identified to address the unreasonable risk. Those exposure limits are the scientific levels of exposure below which the chemical no longer presents an unreasonable risk.

In setting the exposure limits, EPA considered all reasonably available information, including all the studies Industry Petitioners claim EPA ignored. The exposure limits are based on data in the Risk Evaluation that was peer reviewed by

the independent Science Advisory Committee on Chemicals, are consistent with the best available science, and are based on the weight of the scientific evidence. *Id.* § 2625(h), (i). In deriving the exposure limits, EPA relied on a standardized mathematical exercise using relevant hazard inputs and exposure assumptions that are consistent with other occupational exposure limits such as those codified by OSHA and NIOSH as well as standard industrial hygiene practices. *See* RTC at 60, JA ___.

a. The 2 ppm Existing Chemical Exposure Limit Is Supported by the Record.

EPA has reasonably determined that a 2 ppm (8 mg/m^3) 8-hour Time Weighted Average (TWA) existing chemical exposure limit or ECEL represents the concentration at or below which an adult, including those in a potentially exposed or susceptible subpopulation, would be *unlikely* to suffer adverse health effects if exposed to methylene chloride for a working lifetime. *EPA Dec. 2020 memorandum re: Existing Chemical Exposure Limit (ECEL) for Occupational Use of Methylene Chloride* ("Exposure Limit Memo"), AR 743 at 1, JA ___. Contrary to Industry Petitioners' assertions, EPA has not determined that exposure at this level will address all health risks, but rather will address any *unreasonable* health risks. *Id.*, JA ___; Proposed Rule, 88 Fed. Reg. at 28300/1, JA at ___; RTC at 58, JA ___. Risk always exists when using hazardous chemical substances.

Industry Petitioners assert that the 2 ppm ECEL contradicts the best evidence on human health risks because the record fails to support EPA's conclusion that exposures above 2 ppm cause liver toxicity. Industry Br. at 40. Industry Petitioners assert that the Ott, Soden, and Kolodner epidemiological studies found no adverse effects on the liver at higher exposure levels. *Id.* at 41. But as detailed in Section A.1.a.ii, EPA considered those studies, and determined they *did show* indications of liver toxicity. All the same, based on those studies' limitations, EPA explained its basis for relying on the Nitschke study to derive the chronic non-cancer point of departure. *See* RTC at 57, JA ___. As also described above, EPA ran the Nitschke data through the methylene chloride specific physiological-based pharmacokinetic model to more accurately account for both inter-species differences and intra-specifies differenced or human variability. Proposed Rule, 88 Fed. Reg. at 28290/3, JA ___. Internal PBPK-modeled doses were also benchmark-dose modeled to better refine the point of departure estimate, resulting in a human equivalent concentration of 4.8 ppm based on continuous exposure with a benchmark margin of exposure (equal to the product of all uncertainty factors) of 10. *Id.* To arrive at the ECEL, EPA divided the HEC by the benchmark MOE and adjusted for differences between the animal toxicity study and typical worker assumptions about exposure and frequency. Exposure Limit Memo at 3, JA ___. The resulting ECEL is 2 ppm.

b. The 16 ppm STEL is Supported by the Record.

As detailed above, the well-established and severe acute health effects identified for methylene chloride—ranging from blurred vision to death—can be experienced in very short timeframes. RTC at 69, JA ___. Therefore, EPA reasonably determined a short-term exposure limit, or STEL, of 16 ppm (57 mg/m3) as a 15-minute TWA was necessary to ensure the unreasonable risk was fully addressed in occupational settings.

EPA derived the STEL from the Putz study, described in Section A.1.a *supra*. Recall, in that controlled experiment, 12 people were exposed to methylene chloride at a concentration 195 ppm. RE at 247, JA ___. After one and a half hours of exposure, the participants' peripheral vision decreased seven percent. *Id.* Therefore, the Putz study demonstrates that significant progression of neurological effects is likely among a non-sensitive population in less than a single day's exposure. EPA explained that it selected the Putz to derive the STEL because it used an objective test to measure central nervous system effects rather than subjective reports of symptoms and was double-blinded. *Id.* at 295, JA ___. While EPA agrees with the Industry Petitioners' assertion that such an effect is of relatively lesser severity, Industry Petitioners description of the effect in the Putz study as temporary and small, Industry Brief at 49–50, is misleading. The Putz study demonstrated continued (and worsening) effects that included a further 17

percent decrease in peripheral vision, a 36 percent decline in eye-hand coordination, and 17 percent declined in auditory processing when exposure continued for just another 2.5 hours. RE at 247, JA ___.

Along with this progression of severity effects observed in the Putz study, EPA determined that using the less severe effect for acute neurotoxicity to assess risk and as the basis of the STEL was important because of the nature of the hazard and the very real concern for severe effects that can occur rapidly, including death. Information on air concentrations and the timing at which deaths can occur from methylene chloride exposure is imprecise because the levels of methylene chloride in air were measured after exposure or were re-created to understand the potential for exposure after fatalities occurred. RE at 686–90, JA ___–___. This uncertainty regarding methylene chloride air concentrations and the timing at which death may occur demands a level of caution and regulating using effects that are less severe to avoid rapid progression to much more severe outcomes. For example, for two fatalities (21- and 27-year-old males), breathing zone air concentrations that were sampled or re-created were between 64 and 109 ppm. RE at 687, JA ___. These levels are only 4 to 7 times higher than the STEL of 16 ppm. Although the workers could have been breathing higher concentrations than 109 ppm if they were bending over the methylene chloride containers, there is significant uncertainty related to actual exposure levels (and timing) that lead to death.

In sum, EPA reasonably determined that a requirement that exposures are kept at or below ECEL and STEL will address the unreasonable risk of injury to health driven by inhalation of methylene chloride in occupational settings, which is exactly what Congress directed and intended EPA do. 162 Cong. Rec. S3511-01, S3515 (Senator Merkley explaining that amended TSCA "will tremendously improve how we regulate toxic chemicals in the United States . . . the Environmental Protection Agency will have the tools and resources needed to evaluate the dangerous chemicals and to eliminate any unsafe uses").

2. The Rule Prohibits Uses of Methylene Chloride Based on Reasonably Available Information.

Congress authorized EPA to prohibit manufacturing, processing, or distribution in commerce chemical substances it determined present an unreasonable risk of injury to human health. 15 U.S.C. § 2605(a)(1). TSCA also requires EPA to use reasonably available information when proposing and finalizing regulations to address the risks from methylene chloride such that they are no longer unreasonable. *Id.* § 2605(c)(2)(A). Industry Petitioners incorrectly argue that EPA did not have evidence that businesses cannot comply with the exposure limits discussed above and that EPA did not allow time for commenters to establish that compliance was feasible. Industry Br. at 53.

EPA prohibited certain commercial uses where it determined, based on reasonably available information, that companies partaking in the given condition

of use did not demonstrate that they could meet the WCPP requirements. EPA also explained that the nature of some work activities inhibit compliance with an ECEL. Proposed Rule, 88 Fed. Reg. at 28318/2, JA ___. For example, EPA identified work activities that occur in the field, such as on-site paint removal or the use of adhesives in construction or renovation, make it challenging to establish a regulated area and conduct monitoring. *Id.* In other contexts, EPA determined that the donning of air-supplied respirators would create challenges for movement and feasibility of work activities that may take place in small, enclosed spaces. *Id.* Additionally, EPA explained that work activities that require a high range of motion or require other PPE, such as use of an anti-spatter welding aerosol where use of a welding mask would impede the donning of an air-supplied respirator, make it difficult for those workplaces to comply with the WCPP. *Id.*

EPA's determination was supported by comments on the proposed rule submitted on behalf of workers. For example, the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO) submitted comments "commend[ing] EPA for its proposal to protect all workers from the unreasonable risks methylene chloride poses, even below the current OSHA permissible exposure limit." AFL-CIO Comments, AR 997, at 1, JA ___. AFL-CIO commented that it "fully support[s] a ban on most commercial uses of methylene chloride, namely for the conditions of use EPA identifies in its proposal . . . [t]his

includes [its] full support of a ban on all uses of methylene chloride in construction" *Id.* at 1, JA ___. The AFL-CIO explained that air supplied respirators to control methylene chloride exposures can be problematic "because they can limit vision, movement, and communication and, therefore, create new safety hazards." *Id.* at 9, JA ___.

EPA also explained that reasonably available information demonstrates that there remain occupational deaths and nonfatal incidents related to methylene chloride exposure, as well as ongoing noncompliance with current OSHA Standards. *Final Regulatory Flexibility Analysis for Methylene Chloride,*("Reg. Flex. Analysis"), AR 942, at 4-5, JA ___–___. For example, from October 2022 through September 2023, OSHA issued 44 citations and conducted 14 inspections on their methylene chloride standard, spanning 11 industries including 93 furniture manufacturing and automotive repair workplaces. *Id.* at 5, JA ___. In addition, OSHA has documented a fatality from methylene chloride as recently as July 2023. *Id.* Thus, EPA explained that compliance with workplace protections cannot be assumed. Industry Petitioners would have EPA ignore the available information that some workplaces will be unable to successfully implement the WCCP for methylene chloride.

And even if EPA were to regulate all workplaces via implementation of the WCPP, EPA determined, based on the full record, that it would present significant

and widespread implementation difficulties across multiple industry sectors, leading to high non-compliance rates that would undermine the health-protectiveness of the rule. *Id.* Given this background, EPA determined it was not reasonable to assume that entities with ongoing difficulty implementing the WCPP will cease use of methylene chloride because they cannot comply with the WCPP. Rather, EPA concluded that those entities would instead continue attempting (and failing) to implement such protections, leaving the unreasonable risk unmitigated. Thus, a rule requiring only WCPP would fail to ensure that methylene chloride no longer presents an unreasonable risk to health, as required by TSCA section 2605(a).

Notwithstanding, where EPA has information demonstrating that companies can meet the WCPP reliably, there is a record basis upon which EPA can determine that the condition of use can continue under the WCPP without contributing to the unreasonable risk posed by methylene chloride. And since 2017 and throughout the rulemaking process, all industry sectors have had numerous opportunities to provide EPA with information for consideration regarding compliance with exposure limits. For example, in the proposed rule, EPA "request[ed] comment . . . on degree to which users of methylene chloride in these sectors could successfully implement the WCPP, including requirements to meet an ECEL and EPA STEL." Proposed Rule, 88 Fed. Reg. at 28322, JA ___. As a

result, EPA received information that three additional sectors could comply with the exposure limits, and in the final Rule EPA allowed those three additional uses to continue under the WCPP along with the 10 original conditions of use identified in the proposed rule.[23] Final Rule, 89 Fed. Reg. at 39262–63, JA ___–___.

In sum, all industry sectors had many opportunities to provide the Agency with monitoring or other data during the risk evaluation phase to inform EPA on exposures to methylene chloride, and again during the proposed rule phase to indicate the ability for effective exposure reduction for their uses. But in some cases, and for some conditions of use, none were provided, and so it was reasonable for EPA to determine in those instances that WCPP alone would be insufficient to mitigate unreasonable risk.

3. EPA Reasonably Exercised its Discretion in Deciding Not to Defer Regulation of Workplace Safety to OSHA.

Industry Petitioners assert that the Rule is unlawful because EPA should have referred risk management to OSHA pursuant to TSCA Section 9(a), 15 U.S.C. § 2608(a). Industry Br. at 57. That argument misreads the statute.

TSCA section 2608(a) expressly provides EPA with *discretion* to determine whether the unreasonable risk presented by a chemical substance may be prevented

[23] These three uses are (1) as processing agent, (2) in plastic and rubber products manufacturing, including in interfacial polymerization for polycarbonate plastic manufacturing, and (3) in paint and coating removal from safety critical, corrosion sensitive components of aircraft and spacecraft.

or eliminated by action taken under another federal statute. TSCA only requires referral to another agency "*if*" EPA makes that discretionary determination. Here, as discussed below, EPA considered whether the OSH Act, administered by OSHA, would address the unreasonable risk of injury to human health, and in its discretion, concluded it would not. EPA's decision not to refer the matter to OSHA is committed to its discretion and is not subject to judicial review.[24]

First, TSCA's judicial review provision does not provide for review of determinations made under Section 9(a). *See* 15 U.S.C. § 2618 (providing judicial review for rules or orders issued pursuant to TSCA, with no mention of referral decision pursuant to section 2608). Indeed, Senate drafters of the 2016 TSCA Amendments explained that none of the revisions to Section 9 are "intended to alter the clear intent of Congress, reflected in the original legislative history of TSCA, that these decisions would be completely discretionary with the Administrator and not subject to judicial review in any manner." 162 Cong. Rec. S3511-01, S3517. Furthermore, Section 701(a)(2) of the Administrative Procedure Act, Title 5 § 701(a)(2) "preclude[s] judicial review of certain categories of administrative decisions that courts traditionally have regarded as 'committed to

[24] To the extent that Industry Petitioners believe that referral of risk management is mandatory under TSCA section 9(c), which it is not, they should have brought an action in district court under TSCA section 20(a)(2) seeking to force EPA to take such action. 15 U.S.C. § 2619(a)(2). They did not.

agency discretion.'" *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993) (internal quotations omitted); *Cf. Pub. Citizen, Inc. v. E.P.A.*, 343 F.3d 449, 463–65 (5th Cir. 2003) (holding that EPA's alleged failure to issue a notice of deficiency pursuant to the Clean Air Act was unreviewable because the statute did not obligate EPA to determine that the permitting authority was not adequately administering a program).

In *Environmental Defense Fund v. EPA*, the petitioners challenged EPA's use of the Clean Water Act, instead of TSCA, to regulate a substance. 598 F.2d 62, 76 (D.C. Cir. 1978). The D.C. Circuit rejected the petitioners' argument that EPA should have used TSCA, stating that TSCA section 2608 "leaves EPA the choice of regulating toxic substances under TSCA, other statutes [ ], or both." *Id.* at 77. The court further explained that "Congress determined that a choice among regulatory authorities was necessary so that EPA could use the most effective means available to combat unknown and potentially extreme risks from toxic substances, and that judicial review of EPA's choice was inappropriate." *Id.* The court also noted that the legislative history of TSCA specifically provides that "it is clear that the Administrator's determination that it is in the public interest to use this Act, is a completely discretionary decision not subject to judicial review in any manner." *Id.* at 77 n.57 (quoting H. R. Rep. No. 94-1679, at 85 (1976)).

However, even if EPA's determination not to refer risk management to OSHA were reviewable, the record supports it. EPA addressed its consideration regarding referral to OSHA extensively in the proposed rule. Proposed Rule, 88 Fed. Reg. at 28287–91, 28330–31, JA ___, ___. TSCA requires that EPA select regulatory requirements "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk." 15 U.S.C. § 2605(a). EPA explained that TSCA's risk-based requirement is distinguishable from approaches mandated by the OSH Act, which includes both significant risk and feasibility (technical and economic) assessments in its rulemaking. Proposed Rule, 88 Fed. Reg. at 28287/3, JA ___. When OSHA set its permissible exposure limit (PEL) for methylene chloride in 1997, it concluded that "at the 25 ppm PEL the residual risk still greatly *exceeds any significant* risk threshold," but set the PEL at that level because it was the lowest level for which OSHA could document technological and economic feasibility across the affected industries at that time. *Id.* at 28330, JA ___ (citing 62 Fed. Reg. 1494, 1575 (Jan. 10, 1997) (emphasis added)). Meanwhile, in its Rule, EPA explained that it determined the risk-based level of 2 ppm is achievable, and indeed, is already being achieved in some industrial conditions of use based on advances in technology since OSHA set the PEL based on monitoring data received during the risk evaluation and feedback during Small Business Advisory Review. *Id.* at 28330/2, JA ___. In addition, EPA emphasized that the

WCPP approach under TSCA is essential for addressing the unreasonable risk presented by methylene chloride, including to individuals who may not be covered by OSHA requirements, such as students, volunteers, self-employed persons, and state and local government workers. *Id.*

In *Corrosion Proof Fittings*, this Court endorsed EPA's decision not to refer unreasonable risk from asbestos to other agencies, including OSHA, because EPA explained "no one other authority could address all the risks posed 'throughout the life cycle' by asbestos, and any action by one or more of the other agencies still would leave an unacceptable residual risk." 947 F.2d 1201, 1216 (5th Cir. 1991) (vacating the rule on other grounds). This Court expressly validated EPA's decision "to use TSCA as a comprehensive statute designed to fight a multi-industry problem." *Id.* The opinion in *Corrosion Proof Fittings* recognized that EPA was best positioned to make the determination about whether referral to other agencies was appropriate. Importantly, the decision to refer a risk to other agencies was not treated as mandatory simply based on the mere possibility that other agencies *may* be able to regulate that risk. While TSCA was amended after the decision in *Corrosion Proof Fittings*, the amendments to section 9(a) did not limit EPA's discretion to issue or decline to issue a determination.

In sum, EPA reasonably exercised its discretion in declining to refer risk management to OSHA based on its determination that significant gaps exist

between OSHA's authority to set workplace standards under the OSH Act and EPA's obligations under TSCA section 2605 to address unreasonable risk presented by chemical substances under the conditions of use.

4. EPA Considered Technically and Economically Feasible Alternatives to Methylene Chloride.

Section 2605(c)(2)(C) directs EPA to "consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health . . . compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute." 15 U.S.C. § 2605(c)(2)(C). Contrary to Industry Petitioners' assertions, Industry Br. at 61, EPA complied with that duty.

For products currently containing methylene chloride, EPA identified several hundred commercially available alternative products that do not contain the chemical substance and listed their ingredients in an Alternatives Assessment. *See generally*, *Alternatives Assessment for Use of Methylene Chloride* ("Alternatives Assessment"), AR 803, JA ___. For each of the ingredients, EPA identified whether it functionally replaced methylene chloride for the product use and screened product ingredients for human health and environmental hazard. *Id.* EPA also conducted a use and alternatives analysis as part of the economic analysis of the proposed rule. *See generally*, *Economic Analysis of the Proposed Regulation of Methylene Chloride* ("Economic Analysis"), AR 892, JA ___.

Industry Petitioners assert that EPA did not consider substitutes for use by the automotive industry in stripping wheels. Industry Br. at 63. First, section 2605(c)(2)(C) requires EPA consider "to the extent practicable," whether substitutes will be reasonably available when the proposed prohibition or other restriction takes effect, which EPA did, as described above. Contrary to Industry Petitioner's assertions, TSCA only requires that EPA consider if the available substitute is "technically or economically feasible" and not whether the substitute is technically or economically identical to methylene chloride. EPA is also not required to recommend specific substitutes for specific sub-uses. Second, EPA *did consider* alternatives for paint and other coating removers and aerosol cleaners/degreasers used by the automotive industry. *See* Economic Analysis at 3-31–3-32, JA ___–___(identifying use categories for the automotive repair/maintenance industry). In the Alternatives Assessment EPA identified 65 alternative products that exist for coating removal, as well as mechanical and/or thermal methods. Alternatives Assessment at 41–42, JA ___–___. And for use in aerosol cleaners and degreasers, including for automotive uses, EPA identified 69 alternative products (after removing alternative products that contain chemical substances also under risk evaluation by EPA). *Id.* at 34–35, JA ___–___.

Industry Petitioners also assert that EPA failed to consider in its Alternatives Analysis that paint-stripper formulators recycle methylene chloride from

pharmaceutical manufacturing. First, EPA did consider alternatives to methylene chloride for paint stripping and identified suitable alternatives. *Id.* at 41–42, JA ___–___. As for recycling, EPA explained that pharmaceutical companies that sell spent methylene chloride can keep pursuing recycling methods through sales intended for uses identified for the WCPP in the Rule. RTC at 55, JA ___. EPA also investigated the comments on additional disposal costs of methylene chloride from the pharmaceutical industry and determined that 5 million pounds of methylene chloride are sold by pharmaceutical manufacturers to other processors or users following use of the methylene chloride in pharmaceutical production. RTC at 167, JA ___. EPA explained that it did not believe these sales would be disrupted, because several industrial and commercial uses of methylene chloride, in addition to processing methylene chloride, will continue for at least five years with some uses continuing for much longer (or indefinitely) under the WCPP. *Id.* In addition, EPA explained that recyclers can export methylene chloride and have other viable options instead of incinerating the reclaimed chemical. *Id.* Finally, it is noteworthy that EPA did not receive comments on this issue from the pharmaceutical industry, but only received this comment from firms in the furniture refinishing industry. *Id.*

Industry Petitioners assert that EPA's Economic Analysis is insufficient because EPA did not estimate all costs of alternatives, such as increased labor time

and wait times. Industry Br. at 65. EPA acknowledged in its Economic Analysis that uncertainties and unquantifiable costs exist in switching to alternative products, including that "there may be some applications where methylene chloride is more effective, reducing labor time and wait time, and this analysis was unable to quantify these costs." Economic Analysis at 7-50, JA ___. As noted above, the statute requires EPA to consider whether "economically feasible" alternatives exist "to the extent practicable." The statute does not require EPA to quantify costs that are unquantifiable.

Industry Petitioners also complain that EPA's alternatives analysis for brake cleaning products is insufficient because one of the alternatives EPA identified is extremely flammable. As EPA explained in the alternatives analysis section of the Economic Analysis, and again in response to public comments, brake cleaners containing methylene chloride have been banned by multiple states because they contain high levels of volatile organic compounds. Economic Analysis at 5-16, JA ___; RTC at 158, JA ___. Accordingly, methylene chloride products only account for a small percentage of brake cleaning products. Economic Analysis at 5-15–5-17, JA ___–___; RTC at 158, JA ___. Thus, chemical alternative brake cleaners are available that are technologically and economically feasible because brake cleaners that do not contain methylene chloride are the most used brake cleaners.

See Economic Analysis at 5-16, Table 5-9, JA ___ (showing that acetone-containing products have the largest market share).

In sum, substantial evidence in the record demonstrates, that EPA considered the economic and technological feasibility of alternatives. Indeed, in some conditions of use where alternatives did not seem to be readily available, EPA modified the final rule. For instance, EPA extended the prohibition time frame to five years for certain wood refinishing uses to allow time for the sector to demonstrate that can meet the ECEL and operate under the WCPP or identify and transition to an alternative. 89 Fed. Reg, at 39254, JA ___.

5. EPA Adequately Considered Impacts to Small Businesses.

Contrary to Industry Petitioners' assertions, EPA did not ignore potential impacts to small businesses. First, EPA convened a Small Business Advocacy Review Panel, solicited input from small entity representatives that informed the regulatory approaches where possible and Panel recommendations which were included in the proposed rule. *See* Proposed Rule, 88 Fed. Reg. at 28293/3, JA ___. Additionally, EPA published an initial regulatory flexibility analysis and final regulatory flexibility analysis. Reg. Flex. Analysis, JA ___. In the Rule, EPA identified the impacts of the Rule on small businesses and sought to identify flexibilities that could be provided. 89 Fed. Reg. at 39285/3, JA ___. EPA determined that of the small businesses potentially impacted by the Rule, 99

percent are expected to have impacts of less than one percent to their revenues, one percent are expected to have impacts between one and three percent to their revenues and half a percent are expected to have impacts greater than three percent to their revenues. *Id.*

Contrary to Industry Petitioners' assertion, EPA did not ignore comments by small entity representatives. Petitioners cite to comments by W.M. Barr & Company that currently available alternatives to methylene chloride are not as effective at stripping paint and comments by Benco Sales that costs would not be saved by using an alternative to methylene chloride. Industry Br. at 67, n.22. The referenced W.M. Barr & Company's and Benco Sales' comments were submitted in the Halogenated Solvent Industry Alliance's comments to the 2017 proposed rule to prohibit consumer use of methylene chloride containing paint and coating removers. *Final Report of the Small Business Advocacy Review Panel*, Sept. 26, 2016, AR 154, JA ___. In its Response to Comments on this Rule, EPA acknowledged that for some uses, such as paint stripping, methylene chloride is the preferred chemical and that the Rule may have significant cost implications. RTC at 181, JA ___. However, EPA cannot overlook unreasonable risk posed by a chemical simply because replacements are not equally effective or are more costly. As discussed above, EPA identified 65 alternative products for paint-stripping. *See* Alternatives Assessment, at 41, JA ___.

TSCA requires that EPA address the unreasonable risk presented by methylene chloride irrespective of the size of the business that uses it. Entities of any size that engage in the conditions of use for which EPA is finalizing the WCPP, phaseouts, or time-limited exemptions may continue to process or use methylene chloride under the restrictions and requirements of the rule; EPA is not prohibiting or limiting participation due to firm size. In sum, EPA reasonably determined no special accommodations could be made specific to small businesses while still meeting the regulatory requirement of mitigating the unreasonable risk.

6. EPA Reasonably Defined "Retailer" to Remove the Identified Unreasonable Risk to Consumers.

The Rule prohibits retailers from distributing methylene chloride in commerce and all products containing methylene chloride. 89 Fed. Reg. at 39282/3. In defining "retailers," EPA used the same definition as in its 2019 Consumer Paint Rule. *Id.* (citing 84 Fed. Reg. 11420). A retailer is any person or business entity that distributes or makes products available to at least one consumer, including through e-commerce internet sales or distribution. *Id.* Retailers are distinguished from distributers, which make products available solely to commercial or industrial end-users. *Id.*

Industry Petitioners argue that EPA's definition of retailer is overbroad and overly stringent because it extends to companies that sell any product, not just methylene chloride, to a consumer and makes no exception for good faith errors.

Industry Br. at 70. Petitioners East Fork and Epic Paint further argue that they will be unable to find any distributors for their products that is not also considered a retailer under the broad regulatory definition. *Id.* at 70–71.

During litigation on the 2019 Consumer Paint Rule, industry petitioners made an almost identical argument—that the definition of "retailer" was overly broad and would create supply chain issues for commercial users—and failed. *See Lab. Council for Latin Am. Advancement*, 12 F.4th at 250–51. The court rejected that argument, finding that "far from ignoring these potential [supply chain] consequences of the Rule, EPA considered them, described them, and concluded that potential for new markets to replace the losses initially caused by the Rule supported the rule's implementation." The court concluded that "[r]easonable minds might have reached a different conclusion from the evidence available to the EPA, but 'the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.'" *Id.* (quoting *Corrosion Proof*, 947 F.2d at 1213).

The same reasoning applies here. In the proposed rule, EPA explained that it did not find that supply chain issues arose as a result of the 2019 Consumer Paint Rule, which used the same definition. Proposed Rule, 88 Fed. Reg. at 28308/2, JA ___. EPA further noted that "small businesses that are non-retail distributors exist and even participated as small entity representatives consulted as part of the SBAR

process for this rulemaking." *Id.* Nonetheless, in the proposed rule EPA solicited comment on whether similar supply chain issues for uses that are permitted under the WCPP were anticipated. *Id.*

While Petitioner East Fork and Epic Paint did not submit comments raising their concerns, a trade association asserted that the two existing bulk distributors would be unable to serve all existing small businesses. *See* RTC at 128, JA ___. In response to that comment, EPA acknowledged that some small businesses may need to find new suppliers, and explained its expectation that distributors who are not retailers will evolve to meet the needs of both small and large businesses who use methylene chloride-containing products. *Id.* EPA explained that this expectation was supported by small businesses' ability to adapt to the 2019 Consumer Paint Rule. *Id.* Regardless, the mere fact that the retailer ban may have an incidental effect on the availability of methylene chloride for some businesses does not render it irrational.

And EPA considered the alternative restrictions identified by Industry Petitioners, Industry Br. at 72, such as allowing retailer sale but requiring verification. RTC. at 127, JA ___. However, EPA explained that the retailer definition and associated prohibitions on distribution in commerce was necessary to keep methylene chloride and methylene chloride-containing products out of businesses that interact with consumers, and thus result in methylene chloride

products being unavailable to consumers. *Id.* at 128, JA ___. Industry Petitioners may be unsatisfied by EPA's response, but the requirement to produce a rule that is "supported by substantial evidence in the [rulemaking] record taken as a whole," 15 U.S.C. § 2618(c)(1)(B), "does not impose an obligation to reconcile the rule with every comment submitted, much less to accept the validity of every such comment." *Lab. Council for Latin Am. Advancement*, 12 F.4th at 249–50.

Besides, when EPA determines that a chemical substance presents unreasonable risk, it must address that risk through Section 2605(a) risk management regulation. Congress made this obligation clear in the 2016 TSCA amendments by replacing the prior Section 2605(a)'s standard that rules must "protect adequately against [the unreasonable risk] *using the least burdensome requirement*" with the requirement to apply restrictions "to the extent necessary" so that "the chemical substance or mixture no longer presents such risk." *See* Pub. L. No. 114-182, 130 Stat. 460 (2016) (emphasis added). The fact that there may be some burden associated with the retailer definition does not undermine the substantial evidence supporting EPA's decision.

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In sum, the Rule reasonably limits methylene chloride's use "to the extent necessary" to ensure that methylene chloride "no longer presents" an unreasonable risk under its conditions of use. 15 U.S.C. § 2605(a). EPA prohibited the use of

methylene chloride where it did not have information that a sector could comply with WCPP. It allowed continued use where the record demonstrated compliance with WCPP was feasible and would address the unreasonable risk. EPA reasonably took into account and published a statement on the considerations required under section 2605(c)(2), including the "reasonably ascertainable economic consequences of the rule," and the reasonable availability of technically and economically feasible alternatives that benefit health or the environment as compared to the prohibited or restricted use. Substantial evidence in the record supports the Rule. It is lawful and should be upheld.

II. Sierra Club's Petition for Review Should Be Denied.

Attacking the rule from an opposing perspective, Sierra Club argues that the Rule is insufficiently stringent to comply with TSCA. To be sure, methylene chloride is a dangerous chemical substance that poses substantial risks to human health, and TSCA therefore required EPA to impose stringent regulations to address those unreasonable risks. But contrary to Sierra Club's arguments, EPA did precisely that. EPA thoroughly considered all the component risks that TSCA instructs the agency to address, and issued a Rule that effectively controls that risk. This Court should deny Sierra Club's petition for review.

A. The Rule adequately protects vulnerable subpopulations.

Sierra Club principally challenges the Rule's allegedly insufficient protections for fenceline communities—that is, people living near facilities that use methylene chloride—and people with heightened genetic susceptibility to developing cancer from methylene chloride. *See* Sierra Club Br. 26, 40. TSCA instructs EPA to evaluate "whether a chemical substance presents an unreasonable risk of injury to health . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator." 15 U.S.C. § 2605(b)(4)(A). And EPA identified both fenceline communities and people with heightened genetic vulnerability to methylene chloride-induced cancer as "potentially exposed or susceptible subpopulation[s]" for methylene chloride because they are "at greater risk than the general population of adverse health effects from exposure to a chemical substance." 15 U.S.C. §§ 2602(12), 2605(b)(4)(A). *See* RE at 450–51, JA ___–___ (identifying people with heightened genetic susceptibility to developing cancer from methylene chloride as a potentially exposed or susceptible subpopulation); Proposed Rule, 88 Fed. Reg. at 28298, JA ___ (noting that fenceline communities "may also be considered potentially exposed or susceptible subpopulations"). But contrary to Sierra Club's argument, the record makes clear that EPA adequately addressed the risks to both groups.

1. EPA's consideration of exposures to fenceline communities was thorough, consistent with TSCA, and supported by substantial evidence.

EPA adequately addressed risks to fenceline communities in the Rule. EPA extensively considered existing methylene chloride exposures in those communities as well as the expected reduction in exposures brought about by the Rule. Though EPA identified some existing risk to fenceline communities, it ultimately determined that the Rule would adequately address that risk. See 89 Fed. Reg. at 39284. That determination was reasonable, consistent with TSCA, and supported by substantial evidence in the record

First, EPA thoroughly considered the risk of exposures to fenceline communities. *Contra* Sierra Club Br. 28. EPA did not initially identify fenceline communities as a potentially exposed or susceptible subpopulation in the Risk Evaluation for methylene chloride, *see* RE at 450–51, JA ___–___, so had no occasion to specifically determine in the Risk Evaluation whether methylene chloride presented an unreasonable risk to fenceline communities, *see* 89 Fed. Reg. at 39284. But EPA subsequently reconsidered that position, and did identify fenceline communities as a potentially exposed or susceptible subpopulation. *See, e.g.*, Proposed Rule, 88 Fed. Reg. at 28298, JA ___. Rather than reopen the time- and resource-intensive Risk Evaluation on this basis—and thereby frustrate Congress' desire for EPA to address risks from toxic chemicals on an expedited

basis—EPA reasonably decided to conduct a screening level analysis to evaluate exposure pathways and populations that were not addressed in the Risk Evaluation. *See EPA Announces Path Forward for TSCA Chemical Risk Evaluations* (June 30, 2021) ("Path Forward"), AR 43, JA ___; *see also* Sierra Club Br. 27–28 (acknowledging EPA's screening assessment).

EPA designed its Screening Level Approach to allow the Agency to consider whether there are risks to fenceline communities from methylene chloride that were not adequately evaluated in the Risk Evaluation. *See Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0* (2022) ("Screening Level Approach"), AR 1164, at 16, JA ___. As part of the Screening Level Approach, EPA evaluated ambient air exposures and surface water exposures to fenceline communities to determine whether the communities were exposed, and if so at what level of exposure. *See* Path Forward. EPA presented its Screening Level Approach to the Science Advisory Committee on Chemicals and tailored the approach in response to the Committee's comments. *See* 89 Fed. Reg. at 39284. EPA's analysis was thorough, and science based.

Second, EPA properly factored its findings from the Screening Level Approach into the Rule's restrictions rather than revisiting its 2020 Risk Evaluation. TSCA instructs EPA to consider a variety of human health,

environmental, and economic factors when proposing and finalizing a risk management rule. 15 U.S.C. § 2605(c)(2)(A)–(B). Here, EPA evaluated its screening level findings through the prism of those factors and determined that the Rule would address the unreasonable risk from methylene chloride, including risks to fenceline communities. *See* 89 Fed. Reg. at 39283–85. And based on that evaluation, EPA determined that the Rule would "largely address the risks identified . . . to any general population or fenceline communities close to facilities engaging in methylene chloride use." *Id.* at 39285. EPA therefore concluded that it did not need to reopen the Risk Evaluation. *See id.*

Sierra Club objects to EPA's failure to formally determine whether methylene chloride's risk to fenceline communities was "unreasonable." Sierra Club Br. 28. But TSCA did not compel EPA to make such a determination here. TSCA instructs EPA to make unreasonable risk determinations for susceptible subpopulation during a risk evaluation. *See* 15 U.S.C. § 2605(b). But here, EPA identified fenceline communities as a potentially exposed or susceptible subpopulation only after completing the Risk Evaluation. Proposed Rule, 88 Fed. Reg. at 28298, JA ___. Rather than reopen the prior stage of TSCA's regulatory framework, EPA opted to factor in the potential risk to fenceline communities as a human health effect that informed the Rule's choice of restrictions, pursuant to its

authority under section 2605(c)(2) of TSCA. *Id.* at 39283–85 (citing 15 U.S.C. § 2605(c)(2)). That decision was proper, and consistent with TSCA.

Third, the record supports EPA's conclusion that there is limited existing risk to fenceline communities from surface water exposure. EPA's analysis showed no increased risk relative to benchmarks for ambient water exposure. *See* Methylene Chloride: Fenceline Technical Support – Water Pathway 5, (Oct. 19, 2022), AR 816, JA ___. EPA did identify the potential for acute noncancer risk if the effluent discharges from one facility were to reach drinking water. *See id.* But on further review, EPA noted that there are no drinking water sources near that facility, making the exposure risk through drinking water exceedingly small. *Id*; *see also* 89 Fed. Reg. at 39284.

Fourth, the record supports EPA's determination that the Rule will "address the majority of exposures to . . . fenceline communities" from ambient air exposures. 89 Fed. Reg. at 39284. Unlike ground water exposure, EPA's fenceline screening assessment did indicate some existing risk from ambient air exposure to fenceline communities. *Id.* Of the fourteen facilities indicating some risk, only six will continue using methylene chloride under the Rule. *Id.* For those six facilities, EPA analyzed exposure concentrations and associated risks 100 meters from the facilities, pursuant to its peer-reviewed methodology. *See id.* That analysis indicated potentially risky concentrations at 100 meters "for only three facilities

representing two conditions of use." *Id.* EPA expects that one of those conditions of use—processing into a formulation, mixture, or reaction product—will decline under the new Rule because the Rule prohibits most downstream uses of such formulations, mixtures, or reaction products. *Id.* As a result, the facilities representing that condition of use will release less methylene chloride under the Rule. *Id.* And EPA expects that the other condition of use—plastic and rubber product manufacturing—will remain consistent under the Rule, resulting in no increase in methylene chloride releases. *Id*. Based on those findings, EPA found that the Rule will greatly reduce methylene chloride concentrations in fenceline communities and so effectively address any risk to those communities. *Id.* Because the Rule's risk management measures are sufficient to address risks to those communities from ambient air exposure, EPA so saw no need to conduct a supplemental risk evaluation on that issue. *See* 89 Fed. Reg. at 39285.

Sierra Club argues that the three facilities posing risks to fenceline communities will likely ventilate more methylene chloride *outside* the facility to reduce workplace exposure *within* the facility. *See* Sierra Club Br. 29. But the record shows otherwise. Those facilities already have low in-workplace exposure levels and will not need to take such measures to comply with the Rule. 89 Fed. Reg. at 39284. What's more, existing Clean Air Act regulations for methylene

chloride apply to those facilities and thus limit their leeway to vent methylene chloride into the air in the way Sierra Club fears. *See id.*

Finally, Sierra Club does not, and cannot, contend that EPA would have adopted any more stringent requirements had it formally determined whether methylene chloride's risk to fenceline communities is "unreasonable." Therefore, even if EPA's failure were error, it "clearly had no bearing" the final rule, so was harmless. *Johnson*, 632 F.3d at 930.

EPA analyzed the potential risks to fenceline communities, Proposed Rule, 88 Fed. Reg. at 28292, JA ___. EPA thoroughly explained the results of this analysis in both the proposed, *id.* at 28326–27, JA ___–___, and final rule, 89 Fed. Reg. at 39283–85. Based on those findings, EPA reasonably determined that the Rule provides adequate protection for fenceline communities. *Id.* at 39285.

2. TSCA does not require EPA to consider aggregate risk from cumulative exposure pathways.

Sierra Club also argues that EPA erred in its screening-level assessment because TSCA required EPA to evaluate the risk from the cumulative or aggregate exposure to methylene chloride that may occur in fenceline communities. *See* Sierra Club Br. 36 (citing 15 U.S.C. § 2605(a), (b)(4)(A)). To be sure, EPA has the authority to consider cumulative or aggregate exposures where appropriate. *See* 40 C.F.R. § 702.39(d)(8); 89 Fed. Reg. at 37038–39; 82 Fed. Reg. at 33731. But in drafting TSCA, Congress specifically declined to require EPA to consider risk

from cumulative or aggregate exposures in risk evaluations. 15 U.S.C. § 2605(b)(4)(F)(ii) (instructing EPA to "describe *whether* aggregate . . . exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration" (emphasis added)).

The provision Sierra Club cites as a basis for EPA's ostensible duty to evaluate these risks—15 U.S.C § 2605(a)—states only that "if" EPA determines that a "combination" of activities presents an unreasonable risk, then EPA shall adopt appropriate regulations to address any such risk. *Id.* § 2605(a). At no point does section 2605(a) require EPA to consider risk from aggregate exposure in the first instance. *See generally id.* Nor does section 2605(b)—which forms the basis of EPA's mandate to conduct risk evaluations—contain any reference to "combinations" of activities. *See generally id.* § 2605(b). TSCA's risk evaluation requirements make it quite clear that EPA has the *authority*, but not the *obligation*, to consider aggregate exposures (where appropriate). *Id.* § 2605(b)(4)(F)(ii). *See also* 40 C.F.R. § 702.39(d)(8) (subsequent version of the TSCA risk evaluation rule, laying out when EPA will consider aggregate exposures).

Here, EPA explained that the science on cumulative and aggregate exposures to methylene chloride is still "evolving." RTC at 30, JA ___. Reflecting TSCA's instruction that EPA must rely on the "best available science" and "take into consideration information . . . that is reasonably available" when conducting

risk evaluations, 15 U.S.C. § 2625(h), (k), EPA opted to address known unreasonable risks now rather than wait to see how the science on aggregate exposure risk might develop. That determination was reasonable, consistent with TSCA, and supported by substantial evidence. It should be upheld.

3. The Rule is consistent with EPA's Screening Level Approach.

Sierra Club additionally argues that EPA "disregard[ed]" its Screening Level Approach (which Sierra Club refers to as EPA's "Fenceline Assessment Methodology") by allegedly "revers[ing] EPA's past positions and current guidance concerning the evaluation and management of fenceline communities' risks" without reasoned explanation. Sierra Club Br. 32–34. Specifically, Sierra Cub argues that EPA announced in the Screening Level Approach that it would pursue one of five specified outcomes whenever EPA calculates risks to fenceline communities above benchmark levels. *Id.* at 33. Sierra Club alleges that EPA failed to pursue any of those specified outcomes here, *id.* at 34–35, and argues that this alleged failure amounts to an impermissible departure from EPA's past position, *id.* at 32. But Sierra Club's argument rests on a fundamental misunderstanding of the Screening Level Approach.

EPA's Screening Level Approach does not enumerate the full range of possible responses that EPA may take in response to an unreasonable risk determination. EPA took care to explain that it was offering only "simplified

hypothetical examples" of possible outcomes and "only to provide insight into the next steps following completion of a screening level analysis." Screening Level Approach at 18, JA ___. In other words, EPA's examples were illustrative, not prescriptive. And though the Screening Level Approach suggests five possible "outcomes" of EPA responses to the illustrative hypothetical scenarios, *id.* at 19–20, JA ___–___, EPA expressly disclaimed reliance on these hypotheticals and stated that the possible outcomes were not final agency actions, *id.* at 18, JA ___. Indeed, the "outcomes" themselves refer repeatedly to EPA's example scenarios and are themselves plainly intended as hypotheticals. *See id.* at 19–20, JA ___–___.

As it happens, EPA's chosen approach—considering the potential risks to fenceline communities under section 2605(c)(2) of TSCA for the many methylene chloride conditions of use for which EPA had found unreasonable risk—*did* end up resembling Outcomes Two and Three. *See id.* Thus, even if Sierra Club were correct in its assertion that EPA was bound to apply one or more of its "simplified hypothetical examples," its argument still would fail. And regardless, Sierra Club's characterization of EPA's hypothetical "outcomes" as a binding menu of regulatory options is off-base and warrants no further consideration.

4. EPA appropriately addressed risks to people whose genetics make them particularly susceptible to harm from methylene chloride.

EPA also adequately considered variability within the population when evaluating cancer risk from methylene chloride. As Sierra Club rightly notes, nearly a third of the population has a particular genetic makeup known as GSTT1 +/+, which causes their bodies to process methylene chloride in a manner that increases its carcinogenicity. *See* RE at 243, JA ___. For that reason, EPA identified people with heightened genetic susceptibility to developing cancer from methylene chloride as a potentially exposed or susceptible subpopulation. *See* RE at 450, JA ___.

EPA adequately considered that risk here, consistent with "the best available science." 15 U.S.C. § 2625(h). Throughout the Risk Evaluation, EPA extensively analyzed the role of GSTT1 genotype in determining an individual's cancer risk, *see, e.g.*, RE at 244, JA ___, as well as the science behind why the GSTT1 +/+ genotype is associated with increased risk from methylene chloride, *see, e.g.*, RE at 243, JA ___. Based on that science, EPA reiterated that "GSTT1 +/+ individuals are more susceptible to getting cancer from methylene chloride." *Id.* at 451, JA ___. What's more, after peer reviewers of EPA's draft risk evaluation suggested that genetics "should be further discussed" in the final evaluation, SACC Report on Risk Evaluation at 42, JA ___, EPA heeded that expert advice and engaged in a

more detailed analysis of the role GSTT1 +/+ in cancer risk in the final Risk Evaluation, *Response to Peer Review and Public Comments on Draft Risk Evaluation* at 140–41, JA ___–___.

EPA took these findings into consideration when modeling risk as part of the risk evaluation. Specifically, EPA chose to set the inhalation unit risk value for methylene chloride—an estimate of the increased cancer risk from inhalation exposure that EPA uses to model risk—based on the lower 95% confidence limit. *See* RE at 308, JA ___; *see also id.* at 304, JA ___ (explaining process for modelling risk). EPA determined that this conservative estimate "adequately include[s] risk for the GSTT1 +/+ population," and so obviated the need to develop a separate inhalation unit risk for susceptible subpopulations. *Id.* at 308, JA ___.

Nor was EPA required to calculate risks for the GST11 +/+ population separately as a part of the Risk Evaluation. *Contra* Sierra Club Br. 41. TSCA requires EPA to "includ[e]" unreasonable risks to potentially susceptible subpopulations in its risk evaluations—not to conduct separate a risk evaluation for each subpopulation the agency identifies as relevant. 15 U.S.C. § 2605(b)(4)(A); *see also Include*, Merriam–Webster's Collegiate Dictionary 629 (11th ed. 2005) (defining "include" to mean "to take in or comprise as a part of a whole or group"). And while EPA has previously stated that it "*strives* to derive separate estimates for susceptible populations" when determining cancer risk, it has never announced

a firm policy of doing so. *Guidelines for Carcinogen Risk Assessment*, at 3-27 (2005), AR 617, JA ___.

Moreover, EPA's decision to rely on a conservative estimate for the general population rather than calculating a new estimate for the GSTT1 +/+ subpopulation was reasonable based on the data. The available science suggests that fully one-third of humans possess the GSTT1 +/+ genotype. *See* RE at 243, JA ___. Thus, unlike statistically small subpopulations whose risk profiles might be lost within a model of the general population, it is reasonable to expect that risk to the GSTT1 +/+ subpopulation is reflected within the risks to the general population.

Sierra Club may disagree that EPA's approach was sufficiently conservative. *See* Sierra Club Br. 42. But Sierra Club cannot show that EPA's methodology or scientific findings were unreasonable. As EPA's extensive evaluation of scientific studies makes clear, topics such as cancer risk modeling, metabolic pathways for chemical substances, and population genetics involve highly technical judgments. EPA's determinations on these topics are not "simple findings of fact," but fall "within its area of special expertise, at the frontiers of science." *Balt. Gas & Elec. Co.*, 462 U.S. at 103. And "[t]his court's review must be most deferential to the agency where, as here, its decision is based upon its evaluation of complex scientific data within its technical expertise." *Texas v. EPA*, 91 F.4th at 291. Here, EPA reasonably determined that it could effectively address risk the GSTT1 +/+

subpopulation by basing its risk evaluation on a conservative inhalation unit risk value, and that decision should be upheld.

B. Sierra Club's challenge to EPA's alleged failure to address ozone depletion risk fails.

1. EPA's decision not to consider Sierra Club's proffered ozone study does not undermine the Rule.

Sierra Club also argues that the Rule fails to address the risk that methylene chloride emissions pose to atmospheric ozone. Not so. Although EPA initially deemed threats to atmospheric ozone out of scope and so declined to consider that issue in the Risk Evaluation, *see Response to Peer Review and Public Comments on Draft Risk Evaluation* at 219, AR 252, JA ___, Sierra Club is wrong to argue that EPA has entirely ignored the issue of whether methylene chloride poses a risk to atmospheric ozone. *See* Sierra Club Br. 44. Instead, EPA continued to hold its long-standing position that methylene chloride is not an ozone depleting substance. *See, e.g.*, *Alternatives Assessment*, JA ___; *Appendices: An Alternatives Assessment for Use of Methylene Chloride; Proposed Regulation of Methylene Chloride under TSCA Section 6(a)* (Nov. 2022), AR 895, at Appendix A, JA ___ (comparing methylene chloride's ozone depleting potential with that of potential alternatives).

EPA consistently and repeatedly has expressed the view that methylene chloride is not an ozone depleting substance. EPA first made this finding in 1994,

when it listed methylene chloride as an acceptable alternative to commercially used ozone depleting substances. *See Protection of Stratospheric Ozone,* 59 Fed. Reg. 13044, 13082 (Mar. 18, 1994). EPA reached this conclusion as part of an extensive evaluation of the ozone-depleting properties of various commercial foam blowing agents and cleaning solvents, during which it found methylene chloride not to have ozone depleting potential. *See id.* at 13082–94. And EPA has reiterated that finding in subsequent rulemakings, including recent rulemakings under TSCA. *See, e.g.*, *Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a*), 82 Fed. Reg. 7464, 7469, 7499 (Jan. 19, 2017).

Sierra Club proffers a single study to rebut EPA's position that methylene chloride does not deplete ozone, but that study does not alter EPA's scientifically grounded conclusion. *See* Sierra Club Br. 44 (citing R. Hossaini et al., *Growth in Stratospheric Chlorine from Short-lived Chemicals Not Controlled by the Montreal Protocol*, 42 Geophysical Rsch. Letters 4573, 4575–76 (2015), AR 425, JA ___ ("Hossaini Study")). Sierra Club does not point to any new data that the Hossaini Study offers about methylene chloride's impact on ozone levels. *See id.* at 45. Instead, the Hossaini Study employs updated scientific models based on alternative assumptions about methylene chloride's stability in the atmosphere. *See id.* The Hossaini Study therefore offered "no new information" for EPA's consideration and so does not undermine EPA's decision based on the best available science.

Midwater Trawlers Co-op. v. Dep't of Commerce, 393 F.3d 994, 1004 (9th Cir. 2004).

For that reason, if EPA were to have specifically addressed the Hossaini Study in the Risk Evaluation, EPA would have reached the same position that it has reached before and continues to hold: that methylene chloride is not an ozone-depleting substance. And even if EPA's decision not to address the Hossaini Study based on its 2020 policy *was* in error, it "clearly had no bearing on the procedure used or the substance of decision reached," so was harmless. *Johnson*, 632 F.3d at 930.

2. In any event, Sierra Club has not established standing to challenge EPA's alleged failure to consider the Rule's impact on ozone levels.

As the party seeking to establish federal jurisdiction, Sierra Club bears the burden of establishing each element of Article III standing. *See Ctr. for Biological Diversity v. EPA*, 937 F.3d 533, 536 (5th Cir. 2019) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)). Sierra Club has not met that burden here, as its assertion of standing relies on a series of unlikely contingencies. *See Ctr. for Biological Diversity*, 937 F.3d at 537–38.

Specifically, Sierra Club has not demonstrated that its members are likely to be harmed by EPA's alleged failure to adequately consider impacts to atmospheric ozone. Citing a cascading chain of potentialities, Sierra Club asserts that the Rule

harms its members insofar as it increases their risk of developing cancer. But "[i]ncreased-risk claims . . . often cannot satisfy the 'actual or imminent' requirement" of Article III standing. *Shrimpers & Fishermen of RGV v. Texas Comm'n on Env't Quality*, 968 F.3d 419, 424 (5th Cir. 2020). Just so here: Sierra Club argues that the Rule *might* lead to an increase (or insufficient decrease) in emissions of methylene chloride, which *might* survive long enough in the atmosphere to break down atmospheric ozone, which reduction *might* increase the amount of ultraviolet radiation to which its members are exposed over their lifetimes, which in turn *could* increase its members' risk of developing cancer.

Each step in that causal chain is conjectural. And some are downright unlikely. For example, the record suggests that very little methylene chloride is emitted into the atmosphere by affected facilities, and that EPA already regulates methylene chloride emissions as a hazardous air pollutant. *See* 89 Fed. Reg. at 39284. Sierra Club does not identify any evidence in the record to rebut that finding. Nor does anything in Sierra Club's brief or its members' declarations suggest that any Sierra Club member faces an actual or imminent risk of developing cancer due to ultraviolet exposure. *See* Sierra Club Br. 54–55. And in any event, the prevailing science suggests that methylene chloride is not an ozone-depleting substance. *See supra* Section II.B.1. Instead of an imminent injury, then, Sierra Club alleges only a "highly attenuated chain of possibilities" that do not

suffice to establish standing. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013).

III. Even if Remand Is Warranted, Vacatur Is Not.

The Rule is lawful and should be upheld. But if the Court were to identify some flaw in the Rule, it should not vacate the Rule but instead should remand to EPA to allow the Rule to remain in place pending prompt completion of remand proceedings.

Though this Court has at times characterized vacatur as the "default" remedy for APA review, *Data Mktg. P'ship, LP v. U.S. Dep't of Labor*, 45 F.4th 846, 859 (5th Cir. 2022), it likewise has held that remand without vacatur "is generally appropriate when there is at least a serious possibility that the [agency] will be able to substantiate its decision given an opportunity to do so, and when vacating would be disruptive," *Cent. & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (cleaned up); *see also Allied-Signal, Inc. v. Nuclear Regul. Comm'n*, 988 F.2d 146, 150 (D.C. Cir. 1993) (explaining that "[a]n inadequately supported rule ... need not necessarily be vacated"). In deciding whether to vacate unlawful agency action, this Court considers: (1) the likelihood that the agency's action could be sustained on remand; and (2) the disruptive consequences that might flow from vacatur of the action. *Cent. & S. W. Servs.*, 220 F.3d at 692. Here, both prongs show that remand without vacatur is proper.

First, the record demonstrates that EPA likely would reach a similar result on remand. Many of Industry Petitioners' and Sierra Club's arguments are alleged record-based deficiencies that EPA could address and correct on remand. For example, Industry Petitioner's challenge to the Rule's exposure limits, *see supra* Section I.B.1, and Sierra Club's challenge to EPA's consideration of risks to fenceline communities, *see supra* Section II.A.1, turn on the substantiality of the evidence supporting EPA's factual findings, which EPA could bolster on remand. Similarly, Sierra Club's challenge to EPA's failure to address risks to atmospheric ozone levels is premised on an alternative analysis of data that EPA already considered, so would be unlikely to alter EPA's findings on remand. *See supra* Section II.B.1. What's more, to the extent Industry Petitioners or Sierra Club argue that the Rule is procedurally deficient, any such procedural deficiencies likewise could be rectified on remand. *See Tex. Ass'n of Mfrs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 389–90 (5th Cir. 2021) (remanding without vacatur agency rule that failed to complete proper notice-and-comment rulemaking).

Second, and more critically, any vacatur of the Rule would disrupt and impede EPA's compliance with the Act. In particular, vacatur would delay EPA's ongoing efforts to implement Congress's instruction that it "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S.

Rep. No. 94-698, at 1 (1976), as reprinted in 1976 U.S.C.C.A.N. 4491. Congress made clear in the 2016 Amendments that it saw the health risks posed by chemicals as a problem in need of an urgent solution, so imposed ambitious deadlines by which EPA was required to take certain regulatory actions. *See, e.g.*, 15 U.S.C. § 2605(b)(2)(A)–(B). EPA has worked diligently to comply with that mandate. Any vacatur of the Rule would not only unwind nearly a decade of EPA's progress toward protecting public health, the environment, and vulnerable subpopulations—thereby frustrating the will of Congress—but also clog the pipeline of risk evaluations and rules for other chemical substances that TSCA instructs EPA to maintain. Vacatur also would be disruptive to the regulated community. *See Cent. & S. W. Servs., Inc.*, 220 F.3d at 692 (determining that vacatur was inappropriate where rule applied to other members of a regulated community and therefore would be disruptive). By contrast, remanding the Rule without vacatur would enable EPA to make any necessary adjustments to the Rule while maintaining the Rule's protections, ensuring stability for regulated parties and the general public, and respecting Congress' desire for prompt regulation of toxic substances.

Finally, no matter what remedy this Court orders, it should limit that remedy to address only those provisions of the Rule that it deems unlawful. *See VanDerStok v. Garland*, 86 F.4th 179, 196–97 (5th Cir. 2023) (concluding that

vacatur of an entire rule was improper where court only two provisions of the rule were unlawful). Regulations are presumptively severable, *see Barr v. Am. Ass'n of Pol. Consultants, Inc.*, 591 U.S. 610, 625–26 (2020), and federal courts will sever an unlawful regulation so long as severance would "not impair the function of the statute as a whole, and there is no indication that the regulation would not have been passed but for its inclusion," *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988). Here, EPA explained that it "intends that each provision of this rulemaking be severable," and it therefore "crafted [the Rule] so that different risk management approaches are reflected in different provisions or elements of the rule that are capable of operating independently." 89 Fed. Reg. at 39271. And EPA further noted that it separately "evaluated the risk management . . . for each condition of use" and that the "regulation of one condition of use . . . functions independently from EPA's regulation of other conditions of use." *Id.* So, "if any provision or element of this rule is determined by judicial review or operation of law to be invalid, that partial invalidation will not render the remainder of this rule invalid." *Id.* Consequently, if this Court were to deem one or more sections of the Rule unlawful, it should remand only the offending provisions to EPA and leave the rest of the Rule undisturbed.

CONCLUSION

This Court should deny all the petitions for review.

Respectfully submitted,

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December 13, 2024

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing Response Brief electronically via the Court's CM/ECF system, which will electronically serve copies on all parties registered for electronic service.

Dated: December 13, 2024

s/Laura J. Brown
Laura J. Brown

CERTIFICATE OF COMPLIANCE

I hereby certify that this document complies with the type-volume limit of Fed. R. App. P. 32(a)(7)(B) and this Court's September 24, 2024, Order, because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), and 5th Cir. R. 32.1, this document contains 30,512 words according to the count of Microsoft Word and is therefore within this Court's September 24, 2024, Order setting Respondents' word limit at 31,000 words.

I further certify that this document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and 5th Cir. R. 32.1 and the type-style requirements of Fed R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman, and is double-spaced, except for headings, quotes of two lines or more, and footnotes.

Dated: December 13, 2024

/s/ Laura J. Brown
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