

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 Petitions for Review of Final Agency Action of the
United States Environmental Protection Agency
89 Fed. Reg. 39,254 (May 8, 2024)

PETITIONER SIERRA CLUB'S OPENING BRIEF

Filed: October 9, 2024

Jonathan Kalmuss-Katz
Lakendra S. Barajas
Earthjustice
48 Wall Street Floor 15
New York, New York 10005
T: 212-823-4989
T: 212-284-8025
jkalmusskatz@earthjustice.org
lbarajas@earthjustice.org

*Attorneys for Petitioner Sierra
Club*

CERTIFICATE OF INTERESTED PARTIES

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

1. Petitioners: East Fork Enterprises, Inc.; Epic Paint Company; Sierra Club; American Chemistry Council
2. Counsel for Petitioners East Fork Enterprises, Inc. and Epic Paint Company: Keith Bradley, W. Caffey Norman, Morgan Miller, and Allen Kacenjar, Squire Patton Boggs (US) LLP
3. Council for Petitioner Sierra Club: Jonathan Kalmuss-Katz and Lakendra Barajas, Earthjustice
4. Council for Petitioner American Chemistry Council: David Chung and Amanda Shafer Berman, Crowell & Moring LLP
5. Respondents: United States Environmental Protection Agency; Michael S. Regan, in his capacity as Administrator, U.S. Environmental Protection Agency
6. Counsel for Respondents: Laura J. Brown, Senior Attorney, U.S. Department of Justice; Jeffrey Prieto, General Counsel, U.S. Environmental Protection Agency
7. Respondent-Intervenor: American Chemistry Council
8. Counsel for Intervenor: David Chung and Amanda Shafer Berman, Crowell & Moring LLP

Respectfully submitted,

/s/ Jonathan Kalmuss-Katz

Jonathan Kalmuss-Katz

Lakendra S. Barajas

Earthjustice

48 Wall Street Floor 15

New York, New York 10005

T: 212-823-4989

T: 212-284-8025

jkalmusskatz@earthjustice.org

lbarajas@earthjustice.org

*Attorneys for Petitioner Sierra
Club*

STATEMENT REGARDING ORAL ARGUMENT

Pursuant to Local Rule 28.2.3, Sierra Club respectfully requests the Court hold oral argument in this case. At issue is whether EPA violated the 2016 amendments to the Toxic Substances Control Act when it finalized a rule regulating methylene chloride despite failing to address the chemical's risks to fenceline communities, the ozone layer, and people exposed to heightened levels of ultraviolet radiation. Because this case involves issues of first impression involving a recently amended statute, as well as a voluminous and technical administrative record, Sierra Club respectfully submits that oral argument would assist the Court.

TABLE OF CONTENTS

CERTIFICATE OF INTERESTED PARTIES.....	iii
STATEMENT REGARDING ORAL ARGUMENT.....	v
TABLE OF CONTENTS	vi
TABLE OF AUTHORITIES.....	viii
INTRODUCTION	1
JURISDICTIONAL STATEMENT	3
STATEMENT OF ISSUES	4
STATEMENT OF THE CASE.....	5
I. THE 2016 TSCA AMENDMENTS EXPAND EPA’S AUTHORITY AND MANDATE TO REGULATE CHEMICALS’ UNREASONABLE RISKS	5
II. EPA’S RISK EVALUATION ACKNOWLEDGES METHYLENE CHLORIDE’S UNREASONABLE RISKS BUT DOES NOT EVALUATE RISKS TO FENCELINE COMMUNITIES OR THE OZONE LAYER...	10
A. Methylene Chloride Harms Human Health and the Environment.....	10
B. The Risk Evaluation	12
C. The Fenceline Assessment	15
D. The Revised Risk Determination	18
III. THE METHYLENE CHLORIDE RULE INCLUDES NO REQUIREMENTS TO ADDRESS THE CHEMICAL’S RISKS TO FENCELINE COMMUNITIES AND THE OZONE LAYER.....	19
SUMMARY OF ARGUMENT.....	22
ARGUMENT	24
I. STANDARD OF REVIEW.....	24
II. THE METHYLENE CHLORIDE RULE VIOLATES TSCA’S MANDATE TO DETERMINE AND ELIMINATE UNREASONABLE RISKS TO FENCELINE COMMUNITIES.....	26
A. The Methylene Chloride Rule Neither Determines Nor Eliminates the Chemical’s Unreasonable Risks to Fenceline Communities	27
B. EPA Arbitrarily and Capriciously Disregards Its Methodology for Evaluating and Addressing Fenceline Community Risks.....	32

C.	EPA’s Assessment of Methylene Chloride’s Risks to Fenceline Communities Is Contrary to TSCA and Not Supported by Substantial Evidence	36
1.	EPA fails to consider risks from combinations of methylene chloride exposures.....	36
2.	EPA understates methylene chloride’s risks to people who are more susceptible to harm because of their genetic structure.....	39
III.	EPA VIOLATED TSCA BY FAILING TO EVALUATE THE RISKS ASSOCIATED WITH METHYLENE CHLORIDE’S DEPLETION OF THE OZONE LAYER	43
A.	EPA Failed to Evaluate the Risk Methylene Chloride Poses to the Ozone Layer and Individuals with Heightened Exposure to UV Radiation, in Violation of TSCA.....	44
B.	The Regulation of Methylene Chloride Under the Clean Air Act Does Not Excuse EPA’s Violations of Its TSCA Obligations	47
IV.	SIERRA CLUB HAS STANDING TO CHALLENGE THE METHYLENE CHLORIDE RULE	53
V.	THE METHYLENE CHLORIDE RULE SHOULD BE REMANDED WITHOUT VACATUR.....	56
	CONCLUSION	58
	CERTIFICATE OF SERVICE	59
	CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT	60
	CERTIFICATIONS UNDER ECF FILING STANDARDS.....	61

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Chem. Mfrs. Ass’n v. EPA</i> , 859 F.2d 977 (D.C. Cir. 1988)	25
<i>Chem. Mfrs. Ass’n v. EPA</i> , 870 F.2d 177 (5th Cir. 1989).....	57
<i>Citizens for Clean Air & Clean Water in Brazoria Cnty. v. U.S. Dep’t of Transp.</i> , 98 F.4th 178 (5th Cir. 2024).....	55
<i>City of Waukesha v. EPA</i> , 320 F.3d 228 (D.C. Cir. 2003)	42
<i>Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.</i> , 144 S. Ct. 2440 (2024).....	56
<i>Corrosion Proof Fittings v. EPA</i> , 947 F.2d 1201 (5th Cir. 1991).....	1, 6, 8, 39
<i>El Paso Elec. Co. v. FERC</i> , 76 F.4th 352 (5th Cir. 2023).....	30
<i>Fla. Power & Light Co. v. Lorion</i> , 470 U.S. 729 (1985)	30
<i>Gulf Restoration Network, Inc. v. Salazar</i> , 683 F.3d 158 (5th Cir. 2012)	56
<i>In re Nowlin</i> , 576 F.3d 258 (5th Cir. 2009).....	27
<i>Lab. Council for Latin Am. Advancement v. EPA</i> , 12 F.4th 234 (2d Cir. 2021).....	7–8
<i>Loper Bright Enters. v. Raimondo</i> , 144 S. Ct. 2244 (2024).....	26

<i>Massachusetts v. EPA</i> , 549 U.S. 497 (2007).....	55
<i>Me. Cmty. Health Options v. United States</i> , 590 U.S. 296 (2020).....	47
<i>Motor Vehicle Mfrs. Ass’n of the U.S. v. State Farm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1983).....	25
<i>Nat. Res. Def. Council v. EPA</i> , 31 F.4th 1203 (9th Cir. 2022).....	36, 39
<i>Noranda Alumina, L.L.C. v. Perez</i> , 841 F.3d 661 (5th Cir. 2016).....	32
<i>Save Our Cmty. v. EPA</i> , 971 F.2d 1155 (5th Cir. 1992)	53
<i>Shell Chem. Co. v. EPA</i> , 826 F.2d 295 (5th Cir. 1987).....	25
<i>Sierra Club, Lone Star Chapter v. Cedar Point Oil Co. Inc.</i> , 73 F.3d 546 (5th Cir. 1996)	53
<i>Texans United for a Safe Econ. Educ. Fund v. Crown Cent. Petroleum Corp.</i> , 207 F.3d 789 (5th Cir. 2000).....	54
<i>Univ. of Tex. M.D. Anderson Cancer Ctr. v. U.S. Dep’t of Health & Hum. Servs.</i> , 985 F.3d 472 (5th Cir. 2021).....	32, 35
Statutes	
5 U.S.C. § 706(1)	25
5 U.S.C. § 706(2)	25
15 U.S.C. § 2601(b)(2).....	5, 57
15 U.S.C. § 2601(c)	5

15 U.S.C. § 2602(4)	8
15 U.S.C. § 2602(6)	46
15 U.S.C. § 2602(12)	8, 27, 40, 42
15 U.S.C. § 2605(a)	<i>passim</i>
15 U.S.C. § 2605(b)(1).....	7
15 U.S.C. § 2605(b)(2)(A).....	9
15 U.S.C. § 2605(b)(4)(A).....	<i>passim</i>
15 U.S.C. § 2605(b)(4)(F)(i).....	5, 7, 43, 44
15 U.S.C. § 2605(b)(4)(F)(iv).....	5
15 U.S.C. § 2605(c)(2)(A)	9
15 U.S.C. § 2605(c)(2)(B)	9
15 U.S.C. § 2605(c)(2)(C)	9
15 U.S.C. § 2605(i)	15
15 U.S.C. § 2605(i)(2)	3–4
15 U.S.C. § 2608(b)(1)	34, 48
15 U.S.C. § 2618(a)(1)(A).....	3
15 U.S.C. § 2618(c)(1)(B)	24
15 U.S.C. § 2618(c)(1)(B)(i)(I).....	25
15 U.S.C. § 2625(h)	4, 7, 42, 43
42 U.S.C. § 11023(b)	12
42 U.S.C. § 11023(f).....	12

42 U.S.C. § 7412(b)	52
42 U.S.C. § 7412(d)	52
42 U.S.C. §§ 7671–7671q.....	50
42 U.S.C. § 7671a.....	50
42 U.S.C. § 7671c	50
42 U.S.C. § 7671d.....	50
42 U.S.C. § 7671k.....	51
42 U.S.C. § 7671k(a)	51
42 U.S.C. § 7671k(b)	51
42 U.S.C. § 7671k(c)	51
Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016).....	7
Toxic Substances Control Act, Pub. L. No. 94-469, § 6(a), 90 Stat. 2003 (1976).....	6
Regulations	
40 C.F.R. § 23.5	3
40 C.F.R. pt. 82.....	50
40 C.F.R. § 82.170.....	51
40 C.F.R. pt. 82 subpt. A apps. A, B	50
40 C.F.R. pt. 82 subpt. G app. V.....	51
Legislative History	
161 Cong. Rec. 10257 (2015).....	8

162 Cong. Rec. 7984 (2016)	7
S. Rep. 94–698 (1976).....	1, 5
Federal Register Notices	
Fully Halogenated Chlorofluoroalkanes, 43 Fed. Reg. 11,318 (Mar. 17, 1978).....	46
Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7,464 (proposed Jan. 19, 2017)	10
Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 28,284 (proposed May 3, 2023)	<i>passim</i>
Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 39,254 (May 8, 2024).....	<i>passim</i>
National Air Emission Standards for Hazardous Air Pollutants; Halogenated Solvent Cleaning, 72 Fed. Reg. 25,138 (May 3, 2007).....	52
Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 89 Fed. Reg. 37,028 (May 3, 2024).....	49
Other Authorities	
EPA, <i>Benchmark Dose Technical Guidance</i> (2012)	42–43
EPA, <i>EPA Announces Path Forward for TSCA Chemical Risk Evaluations</i> (June 30, 2021).....	<i>passim</i>
EPA, <i>Guidelines for Carcinogen Risk Assessment</i> (2005).....	41, 43
GAO, <i>Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program</i> (2005).....	6
Natalie Jacewicz, <i>Risk Assessment & Cost Contamination</i> , 44 Harv. Env’t L. Rev. 417 (2020).....	7

INTRODUCTION

Congress enacted the Toxic Substances Control Act (“TSCA”) in 1976 to “protect the public and the environment” from the chemicals that “literally surround[]” us. S. Rep. 94–698, at 3 (1976).¹ For forty years, TSCA failed at that core mission. With no mandate to determine or control the risks posed by the tens of thousands of chemicals in commerce, EPA evaluated the safety of few chemicals and regulated even fewer. In the rare instances where EPA attempted to act, its efforts were thwarted by the 1976 law’s high bar for regulation, which required EPA to use the “least burdensome” means of addressing chemicals’ risks.²

TSCA was largely a dead letter by 2016, when a bipartisan majority of Congress approved sweeping amendments to the statute. Those amendments repealed provisions that had impeded chemical regulation and established new requirements to eliminate chemicals’ unreasonable risks. This case challenges a rule, issued pursuant to those new obligations, which regulates the cancer-causing and ozone-depleting chemical methylene chloride (the “Methylene Chloride Rule” or the “Rule”).

¹ Cited excerpts from TSCA’s legislative history are included in the addendum to this brief.

² See *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1216 (5th Cir. 1991) (vacating EPA ban on asbestos because EPA had not established that the rule was the “least burdensome of all those offered to it”).

The TSCA amendments impose two interrelated requirements for the evaluation and management of toxic chemicals. First, EPA must conduct risk evaluations to determine whether a chemical presents any unreasonable risk of injury to health or the environment, including unreasonable risk to groups who are more exposed to the chemical or more susceptible to harm than the general population. If EPA determines that a chemical presents unreasonable risk, it must regulate the chemical to the extent necessary to ensure it no longer presents such risk.

EPA violates these requirements in the Methylene Chloride Rule. EPA determined that methylene chloride presents unreasonable risk, triggering the Agency's obligation to eliminate those risks. But the Methylene Chloride Rule leaves communities surrounding facilities that use and release methylene chloride exposed to elevated cancer risks, and EPA has not determined whether those risks are unreasonable.³ EPA also acknowledges but fails to evaluate or regulate the risks caused by methylene chloride's depletion of the ozone layer, including increased rates of skin cancers and other serious health harms.

Those omissions defy the core mandate of the 2016 TSCA amendments—

³ Consistent with EPA's terminology, this brief refers to communities surrounding facilities that release methylene chloride as "fenceline communities." Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 39,254, 39,284 (May 8, 2024), Index No. 723, JA ____.

that EPA evaluate, determine, and eliminate chemicals' unreasonable risks. At the same time, other provisions of the Methylene Chloride Rule, unchallenged by Sierra Club, comply with TSCA and confer important protections to workers and consumers. The Methylene Chloride Rule should therefore be remanded without vacatur, leaving its protections in place while EPA completes the required analysis and regulation of methylene chloride's unaddressed risks.

JURISDICTIONAL STATEMENT

The Courts of Appeals have exclusive jurisdiction to review rules issued under TSCA. 15 U.S.C. § 2618(a)(1)(A). On May 28, 2024, Sierra Club filed a timely petition for review of the Methylene Chloride Rule in the Ninth Circuit Court of Appeals, twenty days after the rule was published in the Federal Register, 89 Fed. Reg. at 39,254, and eight days after it was “promulgat[ed]” for the purpose of judicial review. 40 C.F.R. § 23.5. The Ninth Circuit transferred that petition to this Court, where it was consolidated with other challenges to the Methylene Chloride Rule per the assignment of the Judicial Panel on Multidistrict Litigation. *See Consolidation Order, East Fork Enterprises, Inc. v. EPA*, No. 24-60256 (5th Cir. June 12, 2024), ECF No. 13.

Under TSCA, EPA's determination that “a chemical substance presents an unreasonable risk” triggers EPA's obligation to regulate the chemical and is not subject to judicial review until EPA issues such regulation. *See* 15 U.S.C. §

2605(a), (i)(2). TSCA therefore provides that the review of chemical regulations like the Methylene Chloride Rule “includ[es] the associated determination” of the chemical’s unreasonable risks. *Id.* § 2605(i)(2).

STATEMENT OF ISSUES

1. Whether the Methylene Chloride Rule violates TSCA and is unsupported by substantial evidence because, despite finding elevated cancer risks to communities where methylene chloride is released into the environment, EPA failed to determine whether these risks are unreasonable and failed to regulate methylene chloride “to the extent necessary so that [it] . . . no longer presents [unreasonable] risk.” *Id.* § 2605(a).

2. Whether the Methylene Chloride Rule violates TSCA and is unsupported by substantial evidence because EPA understated methylene chloride’s risks to fence-line communities and relied on a risk evaluation that is not supported by the “best available science.” *Id.* § 2625(h).

3. Whether the Methylene Chloride Rule violates TSCA and is unsupported by substantial evidence because, despite methylene chloride’s ability to deplete the ozone layer and the harm ozone depletion inflicts on the stratospheric environment and human health, EPA did not “take into account” and “assess” methylene chloride’s effect on the ozone layer and failed to regulate methylene chloride emissions to the extent necessary to eliminate any

unreasonable risks to health or the environment. *Id.* § 2605(a), (b)(4)(A), (b)(4)(F)(i), (b)(4)(F)(iv).

STATEMENT OF THE CASE

I. THE 2016 TSCA AMENDMENTS EXPAND EPA’S AUTHORITY AND MANDATE TO REGULATE CHEMICALS’ UNREASONABLE RISKS

Congress enacted TSCA to give EPA the “authority . . . to regulate chemical substances . . . which present an unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2601(b)(2), (c). Unlike prior environmental laws that regulated chemical exposures from a particular environmental pathway, such as the Clean Air Act (“CAA”) or Safe Drinking Water Act, TSCA directed EPA to “look comprehensively” at chemicals’ risks from manufacturing through disposal and to “protect the public and the environment from exposure to hazardous chemicals.” S. Rep. No. 94–698, at 2–3 (1976). TSCA authorized EPA to directly regulate the manufacturing and sale of toxic chemicals, which Congress found “far more effective” than relying exclusively on the downstream regulation of releases and exposures. *Id.* at 5. In explaining the need for this new authority, Congress expressed particular concern about “cancer occurring . . . [as] a result of environmental contaminants” and about chemicals’ impacts on the “deplet[ion of] the Earth’s ozone layer.” *Id.* at 4.

In practice, however, the 1976 TSCA failed to regulate even the most toxic and widespread chemicals. With only discretionary authority—not a mandate—to address the risks posed by thousands of chemicals that existed before the statute’s enactment, including methylene chloride, EPA evaluated and regulated few such chemicals. See GAO, *Chemical Regulation: Options Exist to Improve EPA’s Ability to Assess Health Risks and Manage Its Chemical Review Program* 18 (2005), <https://www.gao.gov/assets/gao-05-458.pdf> (explaining that “[o]nly five chemical substances or groups of chemical substances have been regulated under [TSCA]” between 1976 and 2005). TSCA also limited EPA’s authority to regulate chemicals that were known to present unreasonable risks, permitting EPA to address such risks only through “the least burdensome requirements.” Toxic Substances Control Act, Pub. L. No. 94-469, § 6(a), 90 Stat. 2003, 2020 (1976).

Those limitations proved fatal to EPA’s most prominent TSCA regulation: a 1989 ban on most uses of asbestos. EPA developed that rule over the course of a decade, including a scientific review that found asbestos can cause cancer “at all levels of exposure.” *Corrosion Proof Fittings*, 947 F.2d at 1207. This Court overturned EPA’s ban, holding that, because EPA had not ruled out all other regulatory options, it had “fail[ed] to meet its burden” of showing that its ban “reduce[d] the risk [from asbestos] . . . in the Congressionally mandated least burdensome fashion.” *Id.* at 1217. Following that decision, EPA did not regulate

another existing chemical under TSCA for more than two decades. *See* Natalie Jacewicz, *Risk Assessment & Cost Contamination*, 44 Harv. Env't L. Rev. 417, 437 (2020).

In 2016, a bipartisan majority of Congress amended TSCA. *Id.* at 421–22; Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016). The 2016 amendments “reject[] the regulatory approach and framework that led to the failed asbestos ban” and strengthen TSCA in several key respects. 162 Cong. Rec. 7984 (2016) (statement of Sens. Barbara Boxer, Edward Markey, Tom Udall, Jeffrey Merkley).

First, while 1976 TSCA required no safety review of chemicals that predated its enactment, the 2016 amendments require EPA to prioritize existing chemicals for evaluation and then to “conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2605(b)(1), (b)(4)(A). Such risk evaluations must “integrate and assess available information on hazards and exposures for . . . the chemical substance,” *id.* § 2605(b)(4)(F)(i), and assess the chemical’s risks “in a manner consistent with the best available science.” *Id.* § 2625(h).

Second, while “prior to 2016, [TSCA] did not prescribe procedures for conducting chemical risk evaluations,” the 2016 amendments more precisely define the objective and scope of risk evaluations. *Lab. Council for Latin Am.*

Advancement v. EPA, 12 F.4th 234, 243 (2d Cir. 2021). In addition to evaluating risks to the general public, EPA must determine whether a chemical presents unreasonable risks to any “potentially exposed or susceptible subpopulation,” 15 U.S.C. § 2605(b)(4)(A), who, “due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance.” *Id.* § 2602(12). And EPA must evaluate the chemical’s risks “under the conditions of use,” *id.* § 2605(b)(4)(A), which are “the circumstances, as determined by the Administrator, under which [the] chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” *Id.* § 2602(4).

Third, while TSCA previously “required [EPA] to consider . . . costs” when determining whether a chemical presents unreasonable risk, *Corrosion Proof Fittings*, 947 F.2d at 1222, the 2016 amendments specify that EPA must evaluate and determine whether a chemical presents unreasonable risk “without consideration of costs or other nonrisk factors.” 15 U.S.C. § 2605(b)(4)(A).

Finally, the 2016 amendments eliminate one of the statute’s “biggest flaws”: the requirement that EPA address chemicals’ unreasonable risks using the “least burdensome” means. 161 Cong. Rec. 10257 (2015) (statement of Rep. Gene Green). Under the amended law, when EPA determines that a chemical presents

unreasonable risk to health or the environment, the Agency “shall” regulate the chemical under TSCA section 6(a) “to the extent necessary so that [it] no longer presents such risk.” 15 U.S.C. § 2605(a).

TSCA prescribes the tools that EPA can use to regulate chemicals, ranging from a prohibition on the manufacturing of the chemical to restrictions on specific uses and methods of disposal. *Id.* The amendments also specify factors that EPA “shall consider” when “selecting among prohibitions and other restrictions.” *Id.* § 2605(c)(2)(A)–(B). These considerations include “the effects of the chemical substance” on health and the environment, the “magnitude of the exposure,” “the benefits of the chemical substance,” and the “reasonably ascertainable economic consequences of the rule.” *Id.* § 2605(c)(2)(A).

EPA must factor these considerations into its regulatory decisions “to the extent practicable” and “in accordance with [TSCA section 6(a)’s]” mandate to eliminate unreasonable risks. *Id.* § 2605(c)(2)(B). But TSCA does not dictate how EPA should weigh these considerations or direct EPA to select the lowest cost or the least burdensome alternative. *See id.* Instead, the statute leaves EPA the discretion to balance the factors and to choose between alternatives that comply with TSCA’s mandate to eliminate unreasonable risk. *Id.* § 2605(c)(2)(A)–(C).

The 2016 TSCA amendments required EPA to initiate risk evaluations for ten chemicals within 180 days of the amendments’ enactment. *Id.* § 2605(b)(2)(A).

In December 2016, EPA selected methylene chloride as one of the first ten chemicals to evaluate. Memorandum from Joel Wolf, Chem. Control Div., EPA, to Maria Doa, Chem. Control Div., EPA on Docket Postings 1 (Dec. 12, 2016), Index No. 1, JA_____.

II. EPA’S RISK EVALUATION METHYLENE CHLORIDE’S UNREASONABLE RISKS BUT DOES NOT EVALUATE RISKS TO FENCELINE COMMUNITIES OR THE OZONE LAYER

A. Methylene Chloride Harms Human Health and the Environment

“[M]ethylene chloride is acutely lethal, a neurotoxicant, and a carcinogen.”

Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 39,254, 39,256 (May 8, 2024), Index No. 732, JA_____. It is

associated with multiple types of cancer and harm to the liver, brain, and reproductive system. EPA, *Risk Evaluation for Methylene Chloride*

(*Dichloromethane, DCM*) 246–269, 270–71 (2020) (“Risk Evaluation”), Index No. 839, JA____–____, ____–____. At high doses methylene chloride can kill; it “can

starve the heart of oxygen and prompt a[] [heart] attack,” and it works as an anesthetic that makes “the respiratory centers of the[] brain[] switch off.”

Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7,464, 7,482 (proposed Jan. 19, 2017), Index No. 835, JA____, ____ (citation omitted). Dozens of workers and consumers have died

from exposure to methylene chloride paint strippers, some as recently as 2023. 89 Fed. Reg. at 39,258, 39,292, JA____, ____.

Methylene chloride emissions also destroy ozone molecules in the Earth's stratosphere, damaging the planet's protective ozone layer and increasing people's exposure to ultraviolet ("UV") radiation, which can result in skin cancer, cataracts, and other health problems. Env't Investigation Agency, Comments on Methylene Chloride Risk Evaluation, at 1–2, 4 (2019) ("EIA Comments"), Index No. 704, JA____–____, ____.

People are exposed to methylene chloride in many ways. According to EPA, more than 900,000 people are exposed to methylene chloride at work and more than 15,000,000 are exposed from consumer products containing methylene chloride, including paint strippers, automotive products, sealants, and adhesives. 89 Fed. Reg. at 39,256, 39,284, JA____, ____.

Commercial and industrial facilities also release methylene chloride to air and water, exposing people who live or work nearby. *Id.* at 39,284, JA____; EPA, *Problem Formulation of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)* 54 (2018), Index No. 33, JA____; Memorandum from Kevin Vuilleumier & Franklyn Hall, Existing Chem. Risk Assessment Div., EPA, to, Joel Wolf, Existing Chem. Risk Mgmt. Div., EPA, on Methylene Chloride: TRI Release Data Sensitivity Analysis 3, 6 (Sept. 1, 2022) ("Sensitivity Analysis"),

Index No. 778, JA____, _____. These exposures are significant; industrial facilities in the United States manufacture and import more than 200 million pounds of methylene chloride each year, and they release more than one million pounds to the environment. Earthjustice, Comments on Proposed Methylene Chloride Rule, at 1 (2023) (“Earthjustice Comments on Proposed Rule”), Index. No. 1040, JA____.⁴

B. The Risk Evaluation

To assess methylene chloride’s risks—or the likelihood that the chemical will cause harm to human health or the environment—EPA undertook a multi-step risk evaluation process. First, EPA estimated the levels of methylene chloride that people and wildlife are exposed to under the chemical’s conditions of use. *See, e.g.*, Risk Evaluation at 92–98, 113–29, 191–203, JA____–____, ____–____, ____–____ (describing methodology for calculating environmental, occupational, and consumer exposures). EPA then analyzed the hazards associated with methylene chloride and the exposure levels at which those hazards occur. *Id.* at 285–313, JA____–____. EPA combined that exposure and hazard information to calculate methylene chloride’s health risks. To measure cancer risks, EPA calculated the increased likelihood of developing cancer from long-term methylene

⁴ These figures understate actual releases, since they are based solely on data reported to the Toxics Release Inventory (“TRI”). Not all facilities fall within the Standard Industrial Classification codes that report to the TRI, and facilities that fall within the covered codes are only required to report if they use at least 10,000 pounds of the chemical per year. *See* 42 U.S.C. § 11023(b), (f).

chloride exposure. *Id.* at 454–55, JA ____–____.⁵ Finally, EPA compared those calculated risks to established risk thresholds, referred to as “benchmark” levels, to determine if they are unreasonable. *Id.*⁶

In June 2020, EPA issued its final risk evaluation for methylene chloride. The Risk Evaluation evaluated the risks associated with fifty-three “conditions of use” of methylene chloride, from the manufacturing of the chemical to its commercial use as a degreaser and its consumer use in spot cleaners and adhesives. *Id.* at 47–55, JA ____–____. EPA determined that forty-seven of those conditions of use present unreasonable risk to human health and that six conditions of use present no unreasonable risk. *Id.* at 39–42, JA ____–____.

However, as acknowledged by EPA’s expert peer review panel, the Science Advisory Committee on Chemicals (“SACC”), the Risk Evaluation provides an “incomplete picture” of methylene chloride’s real-world risks and leaves key

⁵ To measure non-cancer risks, such as liver disease and neurological harm, EPA divided the exposure levels associated with the adverse health effect by estimated human exposure levels (also known as the “margin of exposure” or “MOE”). Risk Evaluation at 364, JA ____.

⁶ While these benchmarks are “not a bright line,” and the Agency may consider other factors in its unreasonable risk determinations, Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 28,284, 28,327 (proposed May 3, 2023), Index No. 721, JA ____, ____, EPA states that “a calculated cancer risk estimate that is greater than the cancer benchmark supports a determination of unreasonable risk.” Risk Evaluation at 455, JA _____. In the Risk Evaluation, every time that EPA calculated risk in excess of an applicable benchmark it found that the condition of use contributes to methylene chloride’s unreasonable risks. *Id.* at 462–514, JA ____–____.

sources of methylene chloride exposure “unaccounted for.” Sci. Advisory Comm. on Chems., Report on Draft Methylene Chloride Risk Evaluation, at 15 (2020) (“SACC Report on Risk Evaluation”), Index No. 251, JA____; *see also id.* at 16–17, JA____–____ (warning that flaws in the Risk Evaluation “are likely to underestimate actual exposures” and to “underestimate[] the risk” associated with methylene chloride exposures). Several of the deficiencies identified by the SACC are relevant to Sierra Club’s claims.

First, EPA ignored the risks from releases of methylene chloride into air, water, and soil. *See id.* at 15, JA____. As a result, the Risk Evaluation failed to account for the risks to fence-line communities living and working near industrial and commercial sites that release methylene chloride.

Second, EPA failed to adequately consider risks to people who are more susceptible to harm due to genetic factors that predispose them to develop cancer from methylene chloride exposure. *Id.* at 42, JA____ (explaining that genetics “play[] an important role in individual response to methylene chloride exposures” and recommending EPA evaluate risks to people whose genes leave them more susceptible to harm from methylene chloride). This shortcoming resulted in calculations of methylene chloride’s cancer risks that are “less protective than previous . . . assessments” conducted by EPA and other federal agencies. *Id.* at 18, JA____.

Finally, EPA did not evaluate methylene chloride’s depletion of the ozone layer, and consequently did not account for the resulting risks to the environment and to human health from increased UV radiation. *Id.* at 77, JA____ (recommending that the “impact of methylene chloride emissions to the atmosphere on ozone depletion . . . be considered in the Evaluation”).

In July 2020, Sierra Club and other environmental, community, and labor organizations challenged EPA’s determinations that six of methylene chloride’s conditions of use present no unreasonable risk.⁷ At EPA’s request, the U.S. Court of Appeals for the Ninth Circuit voluntarily remanded those determinations to allow EPA to reconsider its methylene chloride analyses and associated risk determinations. Earthjustice Comments on Proposed Rule, at 6, JA____.

C. The Fenceline Assessment

In June 2021, EPA announced “important policy changes surrounding risk evaluations issued under [TSCA],” including the methylene chloride risk evaluation. EPA, *EPA Announces Path Forward for TSCA Chemical Risk Evaluations* (June 30, 2021) (“Path Forward”), Index No. 43, JA____. EPA acknowledged that its initial ten risk evaluations “fail[ed] to consistently and comprehensively address potential exposures to potentially exposed or susceptible

⁷ Under TSCA section 6(i), findings of no unreasonable risk are memorialized in an order that is subject to immediate judicial review, whereas findings of unreasonable risk are not. 15 U.S.C. § 2605(i).

subpopulations, *including fenceline communities.*” *Id.* (emphasis added). To fill that gap, EPA proposed to conduct new, “screening-level” assessments to determine if methylene chloride and other previously evaluated chemicals “present unreasonable risks to these communities.” Path Forward, JA ____.

Shortly thereafter, EPA released its *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0* (2022) (“Fenceline Assessment Methodology”), Index No. 1164, JA ____.⁸ The Fenceline Assessment Methodology “uses reasonably available data, information, and models to quantify environmental releases, evaluate exposures to fenceline communities and characterize risks associated with such releases and exposures.” Fenceline Assessment Methodology at 11, JA ____ . EPA compared those risk calculations to benchmark levels—including a 1-in-1,000,000 cancer risk benchmark for fenceline communities, *id.* at 54, JA ____⁹—to determine “the potential for unreasonable risk.” Path Forward, JA ____ . The stated purpose of the

⁸ While the Fenceline Assessment Methodology bears the heading “Public Comment Draft – Do Not Cite or Quote,” Fenceline Assessment Methodology at 1, JA ____, EPA itself cited that document, *see* EPA, Response to Public Comments on Methylene Chloride Risk Management Rule, at 30 n.8 (2024) (“Response to Comments on Risk Mgmt. Rule”), Index No. 944, JA ____, and incorporated it by reference in the Methylene Chloride Rule. 89 Fed. Reg. at 39,284, JA ____ .

⁹ EPA often expresses cancer risks in exponential form, with a 1-in-1,000,000 risk written as “ 1×10^{-6} ,” *see* Risk Evaluation at 734, JA ____, or “1E-06.” Accordingly, a cancer risk of 9.4-in-1,000,000—as EPA calculated from the release of methylene chloride from plastic production facilities—can also be expressed as 9.4×10^{-6} or 9.4E-06. *See* Fenceline Assessment Methodology at 129, JA ____ .

Fenceline Assessment Methodology is to “ensure potential risks to fenceline communities will not go . . . unaddressed” by identifying risks that warrant mitigation or supplemental evaluation. Fenceline Assessment Methodology at 17, JA____.

Using that methodology, EPA identified at least fourteen facilities where the risks from methylene chloride releases to air exceed EPA’s cancer risk benchmark. Fenceline Assessment Methodology at 141, JA____; 89 Fed. Reg. at 39,284, JA____. Those calculations, however, understate many communities’ exposures and risks. While EPA repeatedly described its Fenceline Assessment Methodology as “conservative,” *see, e.g.*, Fenceline Assessment Methodology at 30, 33, 58, JA____, _____, _____, the SACC warned that EPA’s calculations “may not be protective overall because potential key exposure pathways are excluded and because cumulative exposures, multiple source exposures, [and] aggregate exposures . . . were not considered.” Sci. Advisory Comm. on Chems, Report on Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0, at 15 (2022) (“SACC Report on Fenceline Assessment Methodology”), Index No. 841, JA____. The SACC urged EPA to revise the Fenceline Assessment Methodology to “include aggregate . . . exposures from populations exposed at work who live in the community, or who

may also be exposed to multiple facility emissions,” among other changes. *Id.* at 18, JA ____.

The SACC also advised EPA to “analyze more than one year of [Toxics Release Inventory] data” when calculating fenceline community risks, because “[e]mission data may vary or fluctuate dramatically over the years.” *Id.* at 23, 50, JA ____, _____. In response, EPA prepared a “sensitivity analysis” that recalculated methylene chloride’s risks using six years’ worth of air release data. Sensitivity Analysis at 2, JA _____. When multiple years of data were considered, EPA found that methylene chloride’s risks to fenceline communities were “up to three . . . times greater” than EPA’s original calculations. *Id.* at 4, JA _____.

D. The Revised Risk Determination

In November 2022, EPA revised its unreasonable risk determinations for methylene chloride and formally withdrew its finding that six conditions of use present no unreasonable risk. EPA, Revised Risk Determination for Methylene Chloride, at 25 (2022) (“Revised Risk Determination”), Index No. 46, JA _____.¹⁰

The revised risk determination incorporates two key changes. First, EPA made “an unreasonable risk determination for methylene chloride as a whole chemical substance,” replacing the separate unreasonable risk determinations it

¹⁰ The lawsuit challenging EPA’s determinations of no unreasonable risk, *see supra* p. 15, was voluntarily dismissed following EPA’s withdrawal of those determinations.

made for individual conditions of use in the 2020 Risk Evaluation. *Id.* at 3, JA ____.

Second, EPA determined it would no longer assume that workers who use methylene chloride “are always provided and appropriately wear [personal protective equipment],” such as respirators and chemical-resistant gloves. 89 Fed. Reg. at 39,257, JA ____; Revised Risk Determination at 4, JA ____.

Based on those changes, EPA determined that methylene chloride presents an unreasonable risk of injury to health, “superseding the prior ‘no unreasonable risk’ determinations for specific conditions use.” 89 Fed. Reg. at 39,257, JA ____.

However, EPA did not address the other flaws that the SACC and public commenters identified in the Risk Evaluation, and it did not determine whether methylene chloride’s harm to fence-line communities or depletion of the ozone layer contribute to the chemical’s unreasonable risks.

III. THE METHYLENE CHLORIDE RULE INCLUDES NO REQUIREMENTS TO ADDRESS THE CHEMICAL’S RISKS TO FENCELINE COMMUNITIES AND THE OZONE LAYER

On May 3, 2023, EPA proposed the Methylene Chloride Rule. 88 Fed. Reg. at 28,284, JA ____.

After consideration of public comment, including comments from Petitioner Sierra Club and other public interest organizations, EPA finalized that rule on May 8, 2024. 89 Fed. Reg. at 39,254, JA ____.

The Methylene Chloride Rule adopts different regulatory approaches for different conditions of use. *Id.* at 39,255, JA _____. To address methylene chloride’s unreasonable risks to consumers, EPA prohibited consumer uses of products containing the chemical. *Id.* at 39,282, JA _____. EPA found that such prohibitions were “necessary to eliminate the unreasonable risk” to consumers, 88 Fed. Reg. at 28,321, JA _____, and that safer alternatives were available. *Id.* at 28,325, JA _____. However, EPA excluded from that ban products containing up to 0.1 percent methylene chloride by weight. 89 Fed. Reg. at 39,268, JA _____.

To address methylene chloride’s unreasonable risks to workers, EPA relied on a combination of bans and other occupational controls. EPA allowed several industries to continue using methylene chloride—including the “high-volume” use of methylene chloride as a reactant in the production of refrigerants and other chemicals, *id.* at 39,256, 39,273 JA _____, _____, while reducing workers’ exposures from those uses by limiting the maximum concentration of methylene chloride permitted in the air in workplaces. *Id.* at 39,275, JA _____. EPA set that limit, also known as an Existing Chemical Exposure Limit, at the highest exposure level that would avoid the unreasonable risks to workers identified in the methylene chloride risk evaluation. *Id.* at 39,275, JA _____; EPA, *Existing Chemical Exposure Limit (ECEL) for Occupational Use of Methylene Chloride 1* (2020), Index No. 743, JA _____. The Methylene Chloride Rule permits employers to comply with that limit

by releasing more methylene chloride from a facility into the outdoor air, increasing exposures and risks to people outside the facility. *Id.* at 39,284, JA ____.

Overall, approximately two-thirds of total methylene chloride production, and half of TSCA-regulated production, may continue under the Methylene Chloride Rule. Earthjustice Comments on Proposed Rule at 7, JA ____; 88 Fed. Reg. at 28,286, JA ____.¹¹ Facilities will therefore continue to release methylene chloride to the air, exposing surrounding communities. *See* 89 Fed. Reg. at 39,284, JA ____ . EPA found that fenceline communities will experience risks exceeding EPA’s cancer risk benchmark, even after the Methylene Chloride Rule is fully implemented. *Id.*; Sensitivity Analysis at 6; JA ____ . But EPA claimed that it was “unable to . . . determine” whether those risks to fenceline communities “contribute to the unreasonable risk” from methylene chloride, 89 Fed. Reg. at 39,284, JA ____, and it did not limit methylene chloride releases from the facilities where ongoing use of methylene chloride presents elevated fenceline community risks.

The Methylene Chloride Rule also ignores the risks associated with methylene chloride’s depletion of the ozone layer, including increased cancer risks from UV radiation. Rather, while commenters emphasized that “[m]ethylene

¹¹ EPA determined that certain uses of methylene chloride, such as its use in the manufacturing of pharmaceuticals, fall outside TSCA’s definition of “chemical substances” and are not subject to regulation under TSCA. 89 Fed. Reg. at 39,256, JA ____ .

chloride . . . poses an increasing threat to . . . ozone recovery” and urged EPA to evaluate and address the associated risks, EIA Comments at 9, JA____, EPA did not mention ozone depletion once in the Methylene Chloride Rule.

Sierra Club petitioned for review of the Methylene Chloride Rule on May 28, 2024.

SUMMARY OF ARGUMENT

The 2016 TSCA amendments require EPA to “evaluat[e]” whether methylene chloride presents a “risk of injury to health or the environment,” to “determine” whether those risks are unreasonable, and to regulate methylene chloride “to the extent necessary so that [it] no longer presents [unreasonable] risk.” 15 U.S.C. § 2605(a), (b)(4)(A). These requirements are connected; without fully evaluating methylene chloride’s risks—including risks to potentially exposed or susceptible subpopulations—and determining whether they are unreasonable, EPA cannot determine the extent of regulation needed to eliminate unreasonable risks.

Such is the case here. First, despite calculating elevated cancer risks to communities surrounding facilities that use and release methylene chloride, EPA admits that it never determined whether those risks are unreasonable. Second, despite EPA’s recognition that these elevated cancer risks to fence-line communities may be unreasonable, the Methylene Chloride Rule fails to address those risks. Instead, the Rule leaves communities exposed to cancer risks that exceed EPA’s

own threshold for further action, violating TSCA's mandate to ensure the elimination of all of methylene chloride's unreasonable risks.

EPA's failure to protect fenceline communities also arbitrarily and capriciously disregards EPA's own Fenceline Assessment Methodology. The stated purpose of that methodology is to determine whether a chemical's risks to fenceline communities exceed EPA's threshold for either regulation or supplemental analysis. Here, EPA calculated risks that exceed EPA's threshold but it neither mitigated those risks through the Methylene Chloride Rule nor supplemented its Risk Evaluation, departing from its guidance without any explanation.

EPA also understates methylene chloride's risks to fenceline communities by failing to consider people who are exposed from multiple sources or who are more susceptible to harm from methylene chloride because of their genetic makeup. Therefore, even if EPA had eliminated the elevated risks it identified to fenceline communities, the flaws in EPA's underlying risk calculations would still render the Methylene Chloride Rule contrary to TSCA and unsupported by substantial evidence.

Finally, EPA fails to consider or address the risks associated with methylene chloride's depletion of the ozone layer. EPA does not contest that methylene chloride damages the ozone layer, resulting in increased exposure to UV radiation that causes skin cancer and eye damage. EPA ignored those risks in the Risk Evaluation and

Methylene Chloride Rule because it claimed they would be addressed by the Clean Air Act. But TSCA requires EPA to determine and eliminate methylene chloride's unreasonable risks regardless of whether the chemical has been regulated in some way under another environmental law. And EPA has not identified a single Clean Air Act provision or regulation that comprehensively addresses, much less eliminates, the risks from methylene chloride's depletion of the ozone layer.

The deficiencies in the Methylene Chloride Rule place the Sierra Club and its members at risk. Sierra Club members live in fenceline communities that EPA overlooked in the Rule and will remain exposed to a highly toxic chemical because of EPA's TSCA violations. Other Sierra Club members live at the nation's highest altitudes and spend much of their time outdoors, making them particularly susceptible to harm from methylene chloride's depletion of the ozone layer. EPA's failure to determine and eliminate methylene chloride's unreasonable risks to fenceline communities and the ozone layer harms those members, and their injuries would be redressed by an order directing EPA to fill those gaps. The Sierra Club thus has standing.

ARGUMENT

I. STANDARD OF REVIEW

TSCA's judicial review provision incorporates most of the Administrative Procedure Act's ("APA's") standard of review. 15 U.S.C. § 2618(c)(1)(B).

Therefore, when reviewing TSCA section 6(a) risk management rules courts must hold as unlawful EPA action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(1)–(2). Agency action is arbitrary and capricious when “the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

TSCA contains one exception to the APA’s standard of review, however, stating that “the standard for review prescribed by paragraph (2)(E) of [5 U.S.C.] section 706 shall not apply and the court shall hold unlawful . . . [a TSCA section 6(a)] rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole.” 15 U.S.C. § 2618(c)(1)(B)(i)(I). This TSCA-specific substantial evidence standard is “less deferential” than arbitrary and capricious review, *Shell Chem. Co. v. EPA*, 826 F.2d 295, 297 (5th Cir. 1987), and is a “fairly rigorous standard of record review,” *Chem. Mfrs. Ass’n v. EPA*, 859 F.2d 977, 992 (D.C. Cir. 1988) (describing substantial evidence review under TSCA as “particularly ‘demanding’” (citation omitted)).

When reviewing EPA’s interpretations of TSCA, this Court must pay “careful attention to the judgment of the Executive Branch [which] may help inform that inquiry,” while exercising its “independent judgment” in deciding whether an agency has acted within its statutory authority. *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2273 (2024).

II. THE METHYLENE CHLORIDE RULE VIOLATES TSCA’S MANDATE TO DETERMINE AND ELIMINATE UNREASONABLE RISKS TO FENCELINE COMMUNITIES

EPA found that facilities’ emissions of methylene chloride cause elevated cancer risks in fence-line communities. TSCA requires EPA to protect those communities from unreasonable risk. The Methylene Chloride Rule fails to do so.

The Rule leaves fence-line communities exposed to high cancer risks from methylene chloride releases without any determination of whether those risks are unreasonable, violating TSCA’s mandates to determine and eliminate methylene chloride’s unreasonable risks. *See infra* Point II.A. EPA also arbitrarily disregards its own policies that call for the mitigation or supplemental analysis of the very risks that EPA failed to address. *See infra* Point II.B. Finally, EPA ignored the recommendations of its own science advisory panel and understates the risks methylene chloride poses to fence-line communities. As a result, even if EPA had eliminated the elevated risks that it identified, the Methylene Chloride Rule would

still violate TSCA and be unsupported by substantial evidence. *See infra* Point III.C.

A. The Methylene Chloride Rule Neither Determines Nor Eliminates the Chemical’s Unreasonable Risks to Fenceline Communities

“When interpreting a statute, we begin by examining its language.” *In re Nowlin*, 576 F.3d 258, 261 (5th Cir. 2009). TSCA requires EPA to “conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation.” 15 U.S.C. § 2605(b)(4)(A). “If the Administrator determines” that a chemical “presents an unreasonable risk of injury to health or the environment,” EPA “shall” regulate the chemical “to the extent necessary so that [it] . . . no longer presents such risk.” *Id.* § 2605(a).

EPA found that facilities’ emissions of methylene chloride to the air cause elevated cancer risks in nearby communities. Sensitivity Analysis at 6, JA____. Residents of those communities are a potentially exposed or susceptible subpopulation under TSCA, as they experience “greater risk than the general population” due to their “greater exposure” to methylene chloride. 15 U.S.C. § 2602(12) (defining “potentially exposed or susceptible subpopulation”); *see also* Path Forward, JA____ (describing “fenceline . . . near industrial facilities” as a potentially exposed or susceptible subpopulation). But EPA failed to identify

fenceline communities as a potentially exposed or susceptible subpopulation in its Risk Evaluation, which neither evaluated methylene chloride’s risks to those communities nor determined whether such risks were unreasonable. *See* Path Forward, JA ____.

In recognition of that error, which “resulted in a failure to consistently and comprehensively address potential exposures to potentially exposed or susceptible subpopulations,” EPA conducted a separate assessment of methylene chloride’s fenceline community risks. *Id.* Despite relying on a methodology that EPA was informed “may underestimate risk,” SACC Report on Fenceline Assessment Methodology at 34, JA ____, and “may not be protective overall,” *id.* at 15, JA ____, EPA still calculated elevated risks to several fenceline communities, including cancer risks exceeding the Agency’s unreasonable risk benchmark of 1-in-1,000,000. 89 Fed. Reg. at 39,284, JA ____; *see also* Fenceline Assessment Methodology at 126–31, JA ____–____.¹² Yet, even after conducting that analysis, EPA claimed that it was “unable to . . . determine” whether methylene chloride presents unreasonable risks to fenceline communities. 89 Fed. Reg. at 39,284, JA ____; 88 Fed. Reg. at 28,326–27, JA ____–____.

¹² Some of those communities also experience increased non-cancer risks of liver damage from methylene chloride emissions. Fenceline Assessment Methodology at 90–91, 127, 129, JA ____–____, ____, ____.

In addition to violating TSCA's mandate to determine whether methylene chloride presents unreasonable risks to fence-line communities, EPA fails to eliminate the elevated risks it identified in its fence-line assessment. The Methylene Chloride Rule requires no emissions reductions from any facility that will continue to use and release methylene chloride, despite their acknowledged risks to surrounding residents. *See* 89 Fed. Reg. at 39,284–85, JA ____–____; Sensitivity Analysis at 6, JA _____. To the contrary, under that rule, methylene chloride releases from facilities that present risks to fence-line communities are permitted *to increase*. 89 Fed. Reg. at 39,284, JA ____ (acknowledging that facilities could comply with the Methylene Chloride Rule's workplace exposure limits by "ventilat[ing] more methylene chloride outside," thereby reducing exposure to workers inside the facility while increasing exposure to residents outside). By leaving fence-line communities exposed to cancer risks that exceed the Agency's risk benchmark without a determination of whether those unaddressed risks are reasonable or unreasonable, EPA violates TSCA's requirement to "ensure that methylene chloride no longer presents an unreasonable risk." Response to Comments on Risk Mgmt. Rule at 7, JA ____; 15 U.S.C. § 2605(a).

EPA offers two excuses for its failure to determine and address methylene chloride's risks to fence-line communities. First, EPA claims that it could not determine whether the unaddressed risks are unreasonable because its Fence-line

Assessment Methodology “was not developed for that purpose.” Response to Comments on Risk Mgmt. Rule at 28–29, JA ____ – ____; 89 Fed. Reg. at 39,284, JA ____ . But it was EPA who developed that methodology and chose to use it to assess methylene chloride’s risks. Path Forward, JA ____; *see also* Fenceline Assessment Methodology at 17, JA ____ (“The Agency believes the [Fenceline Assessment Methodology] . . . can be used to ensure potential risks to fenceline communities will not go unidentified and unaddressed.”). Moreover, there is nothing in the record that provides a more detailed analysis or characterization of methylene chloride’s risks to fenceline communities, because EPA declined to conduct such an analysis. *See* 89 Fed. Reg. at 39,285, JA ____ . If EPA’s chosen methodology is inadequate to satisfy TSCA’s mandate to determine the risks that methylene chloride presents to fenceline communities, 15 U.S.C. § 2605(b)(4)(A), EPA is “not free simply to disregard [that] statutory responsibilit[y].” *El Paso Elec. Co. v. FERC*, 76 F.4th 352, 362 (5th Cir. 2023) (citation omitted). Rather, “the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation.” *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985).

Second, referring to the uses of methylene chloride that it banned to protect workers and consumers, EPA claims the Methylene Chloride Rule would “largely” address risks to fenceline communities. 89 Fed. Reg. at 39,284–85, JA ____ – ____ . In particular, EPA calculated fenceline risks exceeding its cancer benchmark from a

total of fourteen facilities, eight of which are associated with conditions of use that EPA is banning to address the unreasonable risks EPA identified to consumers and workers. *Id.* at 39,284, JA____; Sensitivity Analysis at 6, JA____. But the Methylene Chloride Rule does not regulate releases from facilities that will continue to use methylene chloride, even though releases from those facilities present risks that exceed the risks from many of the facilities where methylene chloride use is prohibited. *See id.*¹³ EPA’s claim to have addressed methylene chloride’s risks to only some fenceline communities is a concession, not a defense. TSCA requires EPA to regulate methylene chloride until it “no longer presents” unreasonable risk. 15 U.S.C. § 2605(a). The Methylene Chloride Rule, by EPA’s own account, does not do so.

The core purpose of the 2016 TSCA amendments is to require EPA to determine and eliminate chemicals’ unreasonable risks. *Id.* § 2605(a), (b)(4)(A); *see also supra* pp. 7–9. If EPA could skirt its obligation to eliminate acknowledged risks by simply declining to determine whether they are unreasonable, even when the risks exceed the benchmark identified in EPA’s Fenceline Assessment Methodology,

¹³ For instance, EPA calculated cancer risks exceeding 4-in-1,000,000 from the ongoing incorporation of methylene chloride into products, formulations, and reaction products and exceeding 2-in-1,000,000 from the ongoing use of methylene chloride in plastic product manufacturing, both of which are greater than the maximum calculated risk to fenceline communities from the prohibited use of methylene chloride in cellulose triacetate film production. Sensitivity Analysis at 6, JA____.

these requirements would be toothless and the amended TSCA would be no stronger than the failed law it replaced. Because EPA neither determined whether methylene chloride presents unreasonable risk to fenceline communities nor protected those communities from the serious risks it identified, the Methylene Chloride Rule is unlawful.

B. EPA Arbitrarily and Capriciously Disregards Its Methodology for Evaluating and Addressing Fenceline Community Risks

In addition to violating TSCA's mandates to determine and eliminate methylene chloride's unreasonable risks, the Methylene Chloride Rule arbitrarily and capriciously reverses EPA's past positions and current guidance concerning the evaluation and management of fenceline communities' risks. When deviating from past positions, an agency "must 'offer[] a reasoned explanation' for such departure." *Noranda Alumina, L.L.C. v. Perez*, 841 F.3d 661, 665 (5th Cir. 2016) (alteration in original) (citation omitted); *Univ. of Tex. M.D. Anderson Cancer Ctr. v. U.S. Dep't of Health & Hum. Servs.*, 985 F.3d 472, 479–80 (5th Cir. 2021). Here, EPA departed from its stated policies, including those set forth in the Fenceline Assessment Methodology, without any acknowledgement, much less a reasoned explanation.

In June 2021, EPA announced "important policy changes surrounding . . . the first 10 chemicals to undergo risk evaluation," including methylene chloride. Path Forward, JA____. Those changes included a "screening level approach" to evaluate risks to fenceline communities that EPA had unlawfully excluded from its prior risk

evaluations and to determine whether previously evaluated chemicals present “the potential for unreasonable risk[s]” that require further action or analysis. *Id.* To inform that determination, the Fenceline Assessment Methodology compares the risks from a facility’s methylene chloride releases to EPA’s “benchmark” cancer risk value of 1-in-1,000,000. Fenceline Assessment Methodology at 30, 191, JA____, ____.¹⁴ The SACC endorsed EPA’s use of that benchmark level. SACC Report on Fenceline Assessment Methodology at 27–28, JA____ - ____.

The Fenceline Assessment Methodology outlines five hypothetical situations to illustrate how the results of EPA’s fenceline assessments “may be used to further inform or support . . . risk management.” Fenceline Assessment Methodology at 18, JA____. If EPA calculates fenceline risks below its benchmark levels, those risks are deemed reasonable and do not require further action under EPA’s methodology. *Id.* at 19, JA____ (Outcome 1). In contrast, if EPA calculates risks above its benchmark level, the Fenceline Assessment Methodology describes different actions that EPA may take to address those risks. According to EPA, those options include:

- Issuing a risk management rule that prohibits the use causing fenceline community risks above EPA’s benchmark, *id.* (Outcome 2), or “reduce[s] .

¹⁴ As described above, EPA used different benchmark levels to evaluate non-cancer risks. *See supra* p. 13.

. . releases to levels below which an unreasonable risk is expected.” *Id.*
(Outcome 3).

- “[R]eferring such risk findings to be managed under another EPA administered Federal law,” *id.* at 20, JA ____ (Outcome 4), if EPA determines the risk to fence-line communities “could be eliminated or reduced to a sufficient extent by actions taken under” that other law. 15 U.S.C. § 2608(b)(1).
- “Undertak[ing] additional analysis” and “supplement[ing] the published risk evaluation” to more specifically characterize those risks and determine whether additional risk management measures are needed. Fence-line Assessment Methodology at 20, JA ____ (Option 5).

None of these options permit EPA to leave fence-line communities exposed to risks exceeding EPA’s benchmark level without regulatory action or more refined analysis that supports a finding of no unreasonable risk. Yet that is precisely what the Methylene Chloride Rule does. EPA calculated elevated risks to fence-line communities, exceeding its cancer risk benchmark, from facilities that may continue to use and release methylene chloride under EPA’s rule. Sensitivity Analysis at 3, 6, JA ____, ____.¹⁵ But the Methylene Chloride Rule does not require any reduction in

¹⁵ As described below, this assessment understated methylene chloride’s risks and thus failed to identify all the communities exposed to potentially unreasonable risks. *See infra* Point II.C.

those facilities' emissions or any other measure to reduce the surrounding communities' risks. *See supra* pp. 30–31. Nor did EPA identify any other law that would reduce those facilities' current methylene chloride releases, let alone require the use of such a law to eliminate the elevated risks identified in its fenceline assessment.¹⁶ And EPA declined to conduct a “supplemental risk evaluation” to “revisit” its calculations of fenceline communities' risks from exposure to methylene chloride in air. 89 Fed. Reg. at 39,285, JA _____. Instead, EPA cast aside its own policies and left multiple communities exposed to cancer risks that exceed EPA's trigger for further action.

The Fenceline Assessment Methodology establishes a process for identifying risks that requires further action or evaluation, to “ensure [that] potential risks to fenceline communities will not go unidentified and unaddressed.” Fenceline Assessment Methodology at 17, JA _____. Because EPA departed from that process without any acknowledgement of the change, let alone a “reasoned explanation,” the Methylene Chloride Rule is arbitrary and capricious. *Univ. of Tex. M.D. Anderson Cancer Ctr.*, 985 F.3d at 479–80.

¹⁶ EPA claims that it “does not have reason to believe . . . there will be [a] significant increase in fenceline exposures” from facilities that will continue to use methylene chloride because they are “heavily regulated by the [Clean Air Act].” 89 Fed. Reg. at 39,284, JA _____. But the relevant question is not whether risks from those facilities will increase under the Methylene Chloride Rule, but rather whether they will decrease below the levels associated with potentially unreasonable risk.

C. EPA’s Assessment of Methylene Chloride’s Risks to Fenceline Communities Is Contrary to TSCA and Not Supported by Substantial Evidence

EPA’s failure to address the serious cancer risks it identified to fenceline communities is sufficient to require remand. Here, EPA compounded that error by understating the risks methylene chloride presents to those communities and others. Therefore, even if EPA had eliminated the risks to fenceline communities that it acknowledged in the Methylene Chloride Rule, the Rule would still be unlawful because EPA’s underlying risk estimates are contrary to TSCA and unsupported by substantial evidence. *See Nat. Res. Def. Council v. EPA*, 31 F.4th 1203, 1209 (9th Cir. 2022) (holding that EPA decision based on flawed risk estimates was unsupported by substantial evidence).

1. EPA fails to consider risks from combinations of methylene chloride exposures

TSCA requires EPA to eliminate the unreasonable risks associated with the “manufacture, processing, distribution in commerce, use, or disposal of [methylene chloride], or . . . any combination of such activities.” 15 U.S.C. § 2605(a) (emphasis added). To comply with that mandate, EPA must evaluate the risks to people who are exposed to methylene chloride from combinations of conditions of use. *See id.* § 2605(a), (b)(4)(A).

As EPA has acknowledged, people are exposed to methylene chloride in a variety of ways. Those exposures occur at home and at work, Risk Evaluation at

33–34, 220, JA____–____, _____, from consumer products and industrial processes. *Id.* at 31, JA____, and through the air and drinking water, Fenceline Assessment Methodology at 99–118, JA____–____. Fenceline communities are also exposed to methylene chloride releases from multiple facilities spanning different conditions of use. Env’t Def. Fund, Comments on Proposed Risk Management Rule for Methylene Chloride, at 24, 64 (2023), Index No. 1048, JA____, _____ (identifying three facilities within one mile of each other in Midland, Michigan that collectively release more than 15,000 pounds of methylene chloride).

In its Risk Evaluation and its calculations of fenceline community risks, however, EPA calculated the risks from each individual exposure route and condition of use in isolation, without adding together known and foreseen combinations of exposures. This piecemeal analysis understates the risks to residents who are exposed to methylene chloride from multiple facilities, or from a combination of environmental and occupational exposures, even though “[i]n many fenceline communities, members of the community also work at the polluting facility and so may have occupational exposures that also contribute to . . . toxicological risk[.]” SACC Report on Fenceline Assessment Methodology at 48–49, JA____–____.

EPA also ignored the risks to people who are exposed to methylene chloride from environmental releases and products in their homes, which, under the Methylene Chloride Rule, may contain up to 0.1 percent of methylene chloride by weight. 89 Fed. Reg. at 39,268, JA____. EPA claims these “de minimis” exposures do not present unreasonable risk, *id.*, but it only modeled such risks for a single type of product (aerosol degreasers) without modeling any additional methylene chloride exposures. Memorandum from Yvette Selby-Mohamadu, Existing Chems. Risk Assessment Div., EPA, to Joel Wolf, Existing Chems. Risk Mgmt. Div., EPA, at 1 (Aug. 14, 2023) (“De Minimis Memo”), Index No. 909, JA____. There is no evidence that EPA ever considered whether people who live near facilities that release methylene chloride and who also use products that contain up to 0.1 percent of the chemical would experience unreasonable risk, and it made no attempt to address such risks in the Methylene Chloride Rule. *Id.*

The SACC advised EPA that it is “important to include aggregate . . . exposures,” including exposures from “multiple facilities,” in its fenceline assessments. SACC Report on Fenceline Assessment Methodology at 58, JA____; *see also id.* at 15, JA____ (warning that EPA Fenceline Assessment Methodology “may not be protective” because “aggregate exposures . . . were not considered.”). EPA agreed, explaining that it would seek to evaluate such exposures “in future risk evaluations.” Response to Comments on Risk Mgmt. Rule at 30, JA____. The

promise of TSCA-compliant risk evaluations for future chemicals is cold comfort to those who are exposed to methylene chloride today. Because EPA's findings of unreasonable risk are "no better than the methodology used to reach [them]," the flaws in EPA's underlying risk calculations render the Methylene Chloride Rule unsupported by substantial evidence. *Corrosion Proof Fittings*, 947 F.2d at 1227; *See also Nat. Res. Def. Council*, 31 F.4th at 1208–09 (overturning EPA rule based on flaws in underlying risk assessment).

2. EPA understates methylene chloride's risks to people who are more susceptible to harm because of their genetic structure

EPA also understated risks to fenceline community residents and other individuals whose genetics place them at greater risk of cancer from methylene chloride exposures.

According to EPA, thirty-two percent of the population has a specific combination of genes activated—known as GSTT1 +/+—that metabolize methylene chloride to form other toxic chemicals. Risk Evaluation at 450–51, JA ____–____. People with those genes receive a higher "internal dose" from exposure to methylene chloride, meaning exposure to the same amount of the chemical will result in greater methylene chloride levels in the organs of people with GSTT1 +/+ genes than in people without that gene combination. *See EPA, Toxicological Review of Dichloromethane (Methylene Chloride)* 233 tbl.5-19

(2011) (“IRIS Assessment”), Index No. 623, JA_____ (comparing internal doses for GSTT1 +/+ and mixed populations following exposure to one microgram per cubic meter of methylene chloride). As a result, this subpopulation is “more susceptible to getting cancer from methylene chloride.” Risk Evaluation at 450–51, JA_____–_____.

EPA has long recognized the increased susceptibility of this subpopulation. In two prior assessments of methylene chloride, EPA calculated a cancer risk value—also known as the Inhalation Unit Risk or “IUR”¹⁷—“specifically for the [GSTT1 +/+] population,” thereby “protect[ing] . . . the population” that is considered “most sensitive to the carcinogenic effect.” IRIS Assessment at 233–34, 238, JA_____; see also EPA, *TSCA Work Plan Chemical Risk Assessment: Methylene Chloride – Paint Stripping Use* 273 (2014), Index No. 632, JA_____ (relying on an IUR “from the most sensitive (GSTT1+/+) genotype”).

However, despite TSCA’s mandate to evaluate and protect those with “greater susceptibility,” 15 U.S.C. § 2602(12), the Methylene Chloride Rule departs from EPA’s longstanding approach and relies on a lower IUR based on the U.S. population as a whole, which is dominated by people who do not have this heightened genetic susceptibility. Risk Evaluation at 683, JA_____ (“Sampling of

¹⁷ The IUR reflects the cancer risk associated with long-term inhalation of one microgram per cubic meter of methylene chloride. *Id.* at 683, 724, JA_____, _____.

the full distribution of GSTT1 genotypes in the human population (GSTT1+/, GSTT1+/- and GSTT1 -/-) was done to derive the IUR for liver and lung tumors.”). According to EPA, this change in EPA’s risk calculation methodology reduced methylene chloride’s calculated cancer risks by approximately seventy-five percent. EPA, Response to Public Comments on Methylene Chloride Risk Evaluation, at 141 (2020) (“Response to Comments on Risk Eval.”), Index No. 252, JA_____.

EPA’s failure to calculate risks to this potentially exposed or susceptible subpopulation is contrary to EPA’s own cancer risk guidelines, the recommendations of the SACC, and the plain text of TSCA. *See* Risk Evaluation at 451, JA_____ (identifying “GSTT1 +/+ individuals” as a potentially exposed or susceptible subpopulation). EPA’s *Guidelines for Carcinogen Risk Assessment* calls on EPA to “derive separate [risk] estimates for susceptible populations,” including “those bearing a particular genetic susceptibility,” so “these risks can be explicitly characterized.” EPA, *Guidelines for Carcinogen Risk Assessment* 3-27 (2005) (“Cancer Risk Guidelines”), Index No. 617, JA_____; *see also id.* at 3-28, JA_____ (calling on EPA to analyze cancer risk data “with an eye toward adjusting the general population estimate for susceptible individuals”). The SACC also acknowledged the “important role” of GSTT1 genes in determining how people respond to methylene chloride, and SACC members called on EPA to more

specifically evaluate risks to that genetically susceptible subpopulation. SACC Report on Risk Evaluation at 42, 60, JA____, _____. And, in addition to requiring EPA to evaluate methylene chloride's risks to those with "greater susceptibility," 15 U.S.C. §§ 2602(12), 2605(b)(4)(A), TSCA directs EPA to conduct its risk evaluations "in a manner consistent with the best available science." *Id.* § 2625(h). EPA's rejection of its own risk assessment guidelines and the SACC's recommendations violates that "best available science" mandate. *Id.*; *see also City of Waukesha v. EPA*, 320 F.3d 228, 250 (D.C. Cir. 2003) (relying on recommendations of EPA scientific advisory board to determine the "best available science").

EPA claims that it did not need to evaluate cancer risks for the GSTT1 +/- population because of a separate, allegedly conservative calculation in another part of its cancer risk estimates. EPA calculated methylene chloride's carcinogenicity based on a study of liver and lung tumors in mice following methylene chloride exposure. Risk Evaluation at 682, JA____. When determining the methylene chloride level that causes those tumors (also known as the benchmark dose level), EPA used "the lower 95% confidence limit," meaning EPA is 95% confident that the selected level would result in a significant increase in tumors in mice. *Id.* at 308, JA____. But that approach is not conservative; it is a standard, and recommended, part of the EPA risk evaluation process. *See, e.g., EPA, Benchmark*

Dose Technical Guidance 5–6 (2012) (“Benchmark Dose Tech. Guidance”), Index No. 624, JA _____. And that confidence limit is not related to the increased susceptibility of the GSTT1 +/+ subpopulation, which is why, in addition to recommending the use of the lower ninety-five percent confidence limit as a general practice, EPA’s Cancer Risk Guidelines also call for “*separate estimates for susceptible populations.*” Cancer Risk Guidelines at 1-14, 3-27, JA _____, _____ (emphasis added); *see also* Benchmark Dose Tech. Guidance at 37, JA _____ (“Confidence limits . . . do not account for or assume any correspondence between the modeled animal data and the human population of concern.”). Here, EPA ignored that policy, violating TSCA’s mandate to use the “best available science” and to specifically evaluate risks to “potentially exposed or susceptible subpopulations.” 15 U.S.C. §§ 2605(b)(4)(A), 2625(h).

III. EPA VIOLATED TSCA BY FAILING TO EVALUATE THE RISKS ASSOCIATED WITH METHYLENE CHLORIDE’S DEPLETION OF THE OZONE LAYER

EPA violated TSCA by failing to evaluate the risks associated with methylene chloride’s depletion of the ozone layer when conducting the Risk Evaluation. First, EPA failed to “integrate and assess available information” about the effect of methylene chloride on the ozone layer when conducting the Risk Evaluation, 15 U.S.C. § 2605(b)(4)(F)(i), which in turn meant EPA was unable to determine what regulations are needed to prevent unreasonable risks to human

health and the environment from ozone depletion caused by methylene chloride.

See infra Point III.A.

Second, EPA unlawfully relies on the Clean Air Act to relieve EPA of its obligation to evaluate the risks methylene chloride poses to the ozone layer, violating TSCA and EPA's own policy regarding how to conduct risk evaluations.

See infra Point III.B. Third, even if EPA was permitted to rely on the Clean Air Act to manage risks that EPA never evaluated under TSCA, the Clean Air Act provisions upon which EPA relied do not regulate the effects of methylene chloride on the ozone layer.

A. EPA Failed to Evaluate the Risk Methylene Chloride Poses to the Ozone Layer and Individuals with Heightened Exposure to UV Radiation, in Violation of TSCA

By failing to evaluate the effects of methylene chloride's depletion of the ozone layer, EPA violated its obligation under TSCA to evaluate methylene chloride's risks to health and the environment, 15 U.S.C. § 2605(b)(4)(A), and to "integrate and assess available information on hazards and exposures" when conducting a risk evaluation. *Id.* § 2605(b)(4)(F)(i).

Methylene chloride can deplete the ozone layer, harming our atmospheric environment. *See* R. Hossaini et al, *Growth in Stratospheric Chlorine from Short-lived Chemicals Not Controlled by the Montreal Protocol*, 42 *Geophysical Res. Letters* 4573, 4575–76 (2015), Index No. 425, JA _____. Methylene chloride has a

life span of six months or less in the lowest layer of our atmosphere. Hossaini et al. at 4573, JA _____. When it degrades it releases chlorine, a chemical that destroys ozone molecules. *See id.* The danger methylene chloride presents to the ozone layer was historically misunderstood by scientists who incorrectly believed methylene chloride was unable to harm stratospheric ozone before breaking down due to its short life span. *See* EIA Comments at 3, JA _____. However, recent studies have rejected this view, and scientists now caution that methylene chloride can and does reach the stratospheric ozone layer where it destroys ozone molecules. *Id.* Indeed, scientists warn that “continued growth in methylene chloride emissions at current rates could delay full recovery of the ozone layer by 30 years.” *Id.* at 4, JA _____.

In addition to damaging the atmospheric environment, ozone layer depletion caused by methylene chloride emissions also harms public health. The ozone layer functions as a protective shield, absorbing UV radiation and preventing it from reaching the Earth’s surface in harmful amounts. *Id.* at 1–2, JA _____–_____. When the ozone layer degrades, it allows more harmful radiation to reach the Earth’s surface than would be possible with an intact ozone layer. This increase in exposure to UV radiation then increases the incidences of all three types of skin cancer, cataracts, and growths on the eyes. *Id.*

EPA failed to assess the serious risks associated with methylene chloride's depletion of the ozone layer when completing the Risk Evaluation, despite multiple members of the public and EPA's own science advisory committee pressing it to evaluate these risks. *See generally id.*, JA____; Earthjustice, Comments on Draft Risk Evaluations for Methylene Chloride and N-methylpyrrolidone, at 5–6 (Nov. 26, 2019), Index No. 691, JA____; SACC Report on Risk Evaluation at 77, JA_____.

This lack of evaluation is unlawful. EPA has previously acknowledged that ozone depletion presents both “health and environmental risk,” as defined under TSCA. Fully Halogenated Chlorofluoroalkanes, 43 Fed. Reg. 11,318, 11,319 (Mar. 17, 1978), JA ____ (banning other ozone-depleting chemicals under TSCA to address the “unreasonable risk of injury to health and the environment” associated with their depletion of the ozone layer).

TSCA defines the environment to include the “air . . . and the interrelationship which exists among and between water, air, and land and all living things.” 15 U.S.C. § 2602(6). Located in the atmosphere above the Earth's surface, the ozone layer constitutes a layer of “air.” And EPA does not contest that cancer and other harms associated with increased exposure to UV radiation constitute a risk to “health.” 43 Fed. Reg. at 11,318, JA____ (“[I]ncreased UV radiation leads to a statistically significant increase in skin cancer.”).

Because ozone depletion presents risks to both health and the environment, the plain text of TSCA requires EPA to evaluate methylene chloride's effect on the ozone layer. TSCA states that EPA “*shall* conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2605(b)(4)(A); *see Me. Cmty. Health Options v. United States*, 590 U.S. 296, 310 (2020) (“The first sign that the statute imposed an obligation is its mandatory language: ‘shall.’”). This mandatory language requires EPA to evaluate *all* the risks posed by methylene chloride. Despite this requirement, EPA failed to evaluate the effect of methylene chloride on the ozone layer in the Risk Evaluation. This is unlawful.

B. The Regulation of Methylene Chloride Under the Clean Air Act Does Not Excuse EPA's Violations of Its TSCA Obligations

EPA attempts to justify its failure to evaluate the risk methylene chloride poses to the ozone layer by asserting that “ozone depletion risks are adequately assessed and effectively managed under the Clean Air Act (CAA).” EPA, Response to Public Comments on Scope Documents for the First Ten Chemicals for Risk Evaluation Under TSCA, at 6 (2018) (“Response to Comments on Scopes”), Index No. 36, JA____; Response to Comments on Risk Eval. at 219, JA____. EPA's reliance on the CAA to excuse its violation of TSCA is unlawful for two reasons.

First, as EPA has repeatedly acknowledged, TSCA does not permit EPA to forego evaluating a chemical's risks to health or the environment because another statute regulates the same chemical in some way. TSCA and other environmental laws, such as the CAA, have different scopes and statutory mandates, and only TSCA requires EPA to comprehensively evaluate a chemical's risks and then to regulate the chemical to the extent necessary so that it no longer presents unreasonable risk. 15 U.S.C. § 2605(a), (b)(4)(A). While, in certain circumstances not applicable here, *see infra* pp. 50–52, TSCA section 9 permits EPA to rely on other laws to *manage* the risks that EPA has already evaluated and found to be unreasonable, before doing so EPA must identify an unreasonable risk and “determine[] that [the] risk to health or the environment . . . could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in . . . other [EPA-administered] laws.” *Id.* § 2608(b)(1). EPA did not, and could not, make that determination with respect to methylene chloride's depletion of the ozone layer, since EPA admits that it never evaluated the risks methylene chloride poses to the ozone layer under TSCA and therefore cannot say how much regulation would be needed to “eliminate” or “sufficient[ly]” reduce those risks, *id.*, to the point that they are “no longer” unreasonable. *Id.* § 2605(a).

Indeed, EPA expressly endorsed this interpretation of TSCA's requirements, agreeing to evaluate the risks from chemical releases to the air and water under

TSCA, including from exposures that “were or could be regulated under another EPA-administered statute.” Revised Risk Determination at 4, JA _____. *See also* Response to Comments on Scopes at 6, JA _____; Response to Comments on Risk Eval. at 219, JA _____. EPA has “firmly rejected the[] argument[] . . . that EPA should exclude conditions of use and exposure pathways from TSCA risk evaluations when those uses/exposures could be managed under the purview of another environmental statute.” Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act, 89 Fed. Reg. 37,028, 37,032 (May 3, 2024). EPA further stated that “such an interpretation contradicts the plain language of the 2016 TSCA amendments directing EPA to, without caveat, evaluate risks from chemical substances under the conditions of use.” *Id.*

EPA evaluated other methylene chloride exposures in line with this position. For instance, EPA independently evaluated the risks from methylene chloride exposures in ambient air and drinking water, even though those exposure pathways are also regulated by the CAA and Safe Drinking Water Act, respectively. *See* Revised Risk Determination at 4, JA _____; *see also* EPA, Response to Public Comments on Revised Risk Determination, at 42 (2022), Index No. 47, JA _____. EPA provides no rationale for why its approach to evaluating the effect of methylene chloride emissions on the ozone layer should be any different.

Second, even if EPA had evaluated the risks associated with methylene chloride's depletion of the ozone layer, as TSCA requires, EPA has not identified a single provision of the CAA that satisfies TSCA's obligation to determine and eliminate any unreasonable risks. The CAA regulates ozone depletion primarily through its Stratospheric Ozone Protection statutory provisions ("Title VI"), and corresponding regulations. *See generally* 42 U.S.C. §§ 7671–7671q; 40 C.F.R. pt. 82. Title VI phases out the production and use of certain chemicals that are designated as "ozone depleting substances." 42 U.S.C. §§ 7671a, 7671c, 7671d. Despite methylene chloride's ozone depleting properties, however, it is not classified as an ozone depleting substance under Title VI. *Id.* § 7671a (listing ozone depleting chemicals subject to regulation under Title VI); 40 C.F.R. pt. 82 subpt. A apps. A, B. As such, the CAA provisions in place to manage chemicals that deplete the ozone layer do not address the risks posed by methylene chloride.

EPA instead relies on two different provisions of the CAA to justify its failure to evaluate and regulate the risk methylene chloride poses to the ozone layer. Neither provision satisfies EPA's obligations under TSCA.

First, EPA asserts it has "evaluated . . . specific uses" of methylene chloride under the CAA's Significant New Alternatives Policy ("SNAP") program. Response to Comments on Scopes at 6, JA _____. However, the purpose of SNAP is not to determine whether methylene chloride's depletion of the ozone layer

presents unreasonable risks or to eliminate any such risk. Instead, SNAP requires EPA to identify acceptable and unacceptable alternatives for certain uses of ozone depleting substances. 42 U.S.C. § 7671k. If a chemical is listed as an acceptable substitute, that does not mean that it presents no unreasonable risk, merely that the risks associated with a given use of the chemical are deemed lower than those of the chemical being replaced. *See* 40 C.F.R. § 82.170. And if a chemical is listed as an unacceptable substitute for a given use, that does not restrict the use or release of the chemical for any other use. *See* 42 U.S.C. § 7671k(a)–(c).

For methylene chloride, SNAP simply identifies the chemical as an unacceptable substitute for other ozone depleting chemicals used as blowing agents in the production of flexible polyurethane foam. 40 C.F.R. pt. 82 subpt. G app. V. Since emissions from the production of flexible polyurethane foam represent only one of many uses of methylene chloride that create air emissions, Risk Evaluation at 47–55, JA____–____, and SNAP does not limit total methylene chloride emissions, it does not come close to “adequately assess[ing] and effectively manag[ing]” the risks of ozone depletion associated with methylene chloride. Response to Comments on Scopes at 6, JA_____.

Next, EPA invokes section 112 of the CAA to justify its failure to evaluate the risk methylene chloride poses to the ozone layer and human health. Through section 112, EPA sets emissions standards for hazardous air pollutants, including

methylene chloride, for certain “source categories.” 42 U.S.C. § 7412(b), (d). EPA summarily asserts that because section 112 regulates certain methylene chloride releases, an independent evaluation of the risks associated with methylene chloride’s ozone depletion is unnecessary. *See* Response to Comments on Risk Eval. at 219, JA _____. But EPA has not identified a single regulation under section 112 that evaluates methylene chloride’s depletion of the ozone layer, much less eliminates all unreasonable risks associated with those ozone-depleting effects. Section 112 rules that do regulate methylene chloride do not mention or purport to address methylene chloride’s depletion of the ozone layer. *See, e.g.*, National Air Emission Standards for Hazardous Air Pollutants; Halogenated Solvent Cleaning, 72 Fed. Reg. 25,138 (May 3, 2007). Indeed, more than one million pounds of methylene chloride are released per year despite the chemical’s regulation under section 112, contributing to the ozone depletion that EPA failed to consider in the Risk Evaluation. Earthjustice Comments on Proposed Rule at 1, JA _____. Neither section 112 nor any other provision of the CAA justifies EPA’s violation of its TSCA obligation to evaluate the risks from methylene chloride’s depletion of the ozone layer and to eliminate any unreasonable risks.

IV. SIERRA CLUB HAS STANDING TO CHALLENGE THE METHYLENE CHLORIDE RULE

The Sierra Club has standing to challenge the deficiencies in the Methylene Chloride Rule.

An organization such as Sierra Club has standing to bring an action on behalf of its members where: (1) the organization's members would have standing to sue individually; (2) the organization is seeking to protect interests that are germane to its purpose; and (3) neither the claim asserted nor the relief requested requires the organization's members to participate in the lawsuit.

Sierra Club, Lone Star Chapter v. Cedar Point Oil Co. Inc., 73 F.3d 546, 555 (5th Cir. 1996).

Sierra Club's members have standing to sue on their own behalf because they have (1) suffered an actual or threatened "injury in fact"; (2) that is fairly traceable to the challenged action; and (3) is likely to be redressed by a favorable decision. *Id.* at 555–56; *see also Save Our Cmty. v. EPA*, 971 F.2d 1155, 1160 (5th Cir. 1992).

EPA's failure to evaluate and regulate methylene chloride emissions to the extent TSCA requires injures Sierra Club members in two ways. First, Sierra Club members like Sarah Harju live near facilities emitting methylene chloride.

Declaration of Sarah Harju ("Harju Decl.") ¶¶ 6–8. These members are exposed to methylene chloride emissions, which are associated with an increased risk of cancer and other serious diseases. *See Risk Evaluation* at 453; JA _____. Concern

about the negative effects methylene chloride emissions will have on their health also affects Sierra Club members' ability to safely recreate near their homes and workplaces. For example, Ms. Harju lives less than two miles from a pair of chemical plants in Midland, Michigan that collectively release thousands of pounds of methylene chloride each year. Harju Decl. ¶¶ 6–8. Due to concern about these emissions, she is less likely to hike and recreate in the parks around these facilities, despite a history of recreating in the area and a desire to continue those activities. Harju Decl. ¶ 12. These injuries confer standing. *Texans United for a Safe Econ. Educ. Fund v. Crown Cent. Petroleum Corp.*, 207 F.3d 789, 792 (5th Cir. 2000) (“[B]reathing and smelling polluted air is sufficient to demonstrate injury-in-fact . . .”).

Second, Sierra Club has members who live at high elevations and as a result are exposed to greater UV radiation than individuals living closer to sea level, exposures that are more significant due to methylene chloride's depletion of the ozone layer. For example, Sierra Club member Frank Lilly lives in Silverthorne, Colorado at an elevation of 8,700 feet above sea level. Declaration of Frank Lilly (“Lilly Decl.”) ¶ 7. A retiree, Mr. Lilly participates in outdoor activities on an almost daily basis, year-round, at elevations above 8,000 feet, exposing him to high levels of dangerous UV radiation that are exacerbated by EPA's failure to evaluate and regulate methylene chloride emissions as TSCA requires. *Id.* ¶ 7–16.

Mr. Lilly’s increased risk of health problems stemming from heightened exposure to UV radiation injures him and other Sierra Club members living at high elevations who recreate outside near their homes. Additionally, the damage methylene chloride does to the ozone layer itself harms our stratospheric environment, by thinning the ozone layer.

Sierra Club’s members’ injuries are all “fairly traceable” to EPA’s failure to manage the risks methylene chloride poses to fenceline communities and the ozone layer, itself a consequence of EPA’s failure to properly evaluate these risks when completing the Risk Evaluation. Sierra Club members are currently exposed to methylene chloride emissions and heightened levels of UV radiation, and will continue to experience these exposures, until EPA manages these risks.

These harms are also redressable by a decision remanding the Methylene Chloride Rule back to EPA, which would create at least “some possibility” that after EPA evaluated the risks methylene chloride poses to fenceline communities and the ozone layer it would publish a risk management rule that reduces Sierra Club’s members’ injuries. *Citizens for Clean Air & Clean Water in Brazoria Cnty. v. U.S. Dep’t of Transp.*, 98 F.4th 178, 187 (5th Cir. 2024) (quoting *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007)).

Sierra Club also meets the two remaining prongs of the associational standing test. Sierra Club’s interest in protecting its members from methylene

chloride exposure is germane to Sierra Club’s mission to protect public health and the environment. Declaration of Aaron Isherwood ¶¶ 7, 11. Sierra Club’s interests in this case also align with its mission to address the widespread toxic chemical pollution that threatens communities across the country, particularly communities on the fenceline. *Id.*

Finally, because Sierra Club seeks injunctive relief, and its claims are broadly applicable to people living around facilities emitting methylene chloride and individuals at higher risk of exposure to UV radiation, “the claims asserted and the relief sought by [Sierra Club] are not particular to any individual” and “are thus properly resolved in a group context.” *Gulf Restoration Network, Inc. v. Salazar*, 683 F.3d 158, 168 (5th Cir. 2012) (citation omitted).

V. THE METHYLENE CHLORIDE RULE SHOULD BE REMANDED WITHOUT VACATUR

“[W]hen a court rules that an agency must provide additional explanation for the challenged agency action or must regulate some entity or activity more extensively . . . courts have remanded to the agency without vacatur.” *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 144 S. Ct. 2440, 2466 n.6 (2024) (Kavanaugh, J., concurring). Sierra Club challenges EPA’s failure to adequately regulate methylene chloride, and it seeks remand so EPA can further evaluate methylene chloride’s risks to fenceline communities, evaluate the risks methylene chloride poses to the stratospheric environment and people exposed to high levels

of UV radiation, and strengthen the Methylene Chloride Rule as needed to eliminate any unreasonable risks. Sierra Club does not challenge any of the Methylene Chloride Rule’s protections for workers or consumers—indeed, Sierra Club supports those protections—and it does not seek to vacate any portion of the Methylene Chloride Rule. Rather, vacatur would be disruptive and contrary to TSCA’s core purpose and mandate to protect public health and the environment.

Sierra Club thus seeks remand without vacatur. In *Chemical Manufacturers Association v. EPA*, this Court granted the Natural Resource Defense Council’s petition for review of Clean Water Act pollutant discharge standards for chemical and plastic manufacturing plants but left the standards in place pending remand, explaining that “Congress’ concern for limiting the discharge of toxic pollutants” would be best served by remand without vacatur and “the industrial petitioners are not prejudiced by being subjected to [best available technology] limitations which, if anything, may be too lenient.” 870 F.2d 177, 236 (5th Cir. 1989). Here, too, TSCA’s purpose of “regulat[ing] chemical substances and mixtures which present an unreasonable risk of injury to health or the environment” is best met by leaving the Methylene Chloride Rule in place during remand, 15 U.S.C. § 2601(b)(2), and there would be no prejudice in maintaining methylene chloride restrictions that suffer only from being overly lenient. To protect consumers, workers, and other exposed populations from methylene chloride’s unreasonable risks, the Court

should remand the Methylene Chloride Rule without vacatur while EPA determines how to revise it to satisfy this Court's decision.

CONCLUSION

Congress amended TSCA to require EPA to evaluate the risks from chemicals like methylene chloride, to determine whether those risks are unreasonable, and, if so, to ensure that such risks are eliminated. EPA's failure to determine and address methylene chloride's risks to fence-line communities, as well as the risks from the chemical's depletion of the ozone layer, violates those mandates. The Court should grant Sierra Club's petition and remand the Methylene Chloride Rule, without vacatur, so EPA can conduct the required analyses of those unaddressed risks and revise the rule to eliminate all unreasonable risks to health and the environment as TSCA requires.

Respectfully submitted,

/s/ Jonathan Kalmuss-Katz

Jonathan Kalmuss-Katz

Lakendra S. Barajas

Earthjustice

48 Wall Street Floor 15

New York, New York 10005

T: 212-823-4989

T: 212-284-8025

jkalmusskatz@earthjustice.org

lbarajas@earthjustice.org

*Attorneys for Petitioner Sierra
Club*

CERTIFICATE OF SERVICE

I hereby certify that on October 9, 2024, I electronically filed the foregoing Brief in Support of Sierra Club's Petition for Review using the appellate CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

/s/ Jonathan Kalmuss-Katz
Jonathan Kalmuss-Katz

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT

This document complies with the type-volume limit of Fed. R. App. P. 32(a)(7)(B) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f) and Fifth Circuit Rule 32.1: this document contains 12,996 words.

This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5), and Fifth Circuit Rule 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 for Microsoft 365 using size 14 Times New Roman font.

/s/ Jonathan Kalmuss-Katz
Jonathan Kalmuss-Katz

CERTIFICATIONS UNDER ECF FILING STANDARDS

Pursuant to paragraph A(6) of this Court's ECF Filing Standards, I hereby certify that (1) required privacy redactions have been made, 5th Cir. R. 25.2.13; (2) the electronic submission is an exact copy of the paper document, 5th Cir. R.25.2.1; and (3) the document has been scanned for viruses with the most recent version of a commercial virus scanning program and is free of viruses.

/s/ Jonathan Kalmuss-Katz
Jonathan Kalmuss-Katz