No. 24-60227

United States Court of Appeals for the Fifth Circuit

EAST FORK ENTERPRISES, INCORPORATED; EPIC PAINT COMPANY,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; MICHAEL S. REGAN, Administrator, United States Environmental Protection Agency,
Respondents,

consolidated with

No. 24-60256

EAST FORK ENTERPRISES, INCORPORATED; EPIC PAINT COMPANY; SIERRA CLUB; AMERICAN CHEMISTRY COUNCIL,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; MICHAEL S. REGAN, Administrator, United States Environmental Protection Agency,
Respondents.

On Petition for Review of Final Agency Action by the U.S. Environmental Protection Agency

BRIEF FOR THE STATES OF NEW YORK, CONNECTICUT, HAWAI'I, ILLINOIS, MARYLAND, MASSACHUSETTS, MINNESOTA, NEW JERSEY, OREGON, RHODE ISLAND, AND VERMONT; THE DISTRICT OF COLUMBIA; AND THE CITY OF NEW YORK, AS AMICI CURIAE IN SUPPORT OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY AND IN OPPOSITION TO THE INDUSTRY PETITION

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CERTIFICATE OF INTERESTED PERSONS
Supplemental Statement Pursuant to Local Rule 29.2

East Fork Enterprises, Incorporated, et al. v. EPA et al.
Nos. 24-60227, 24-60256

Under the fourth sentence of Fifth Circuit Rule 28.2.1, all the signatories listed below are governmental entities and need not furnish a certificate of interested persons.

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FEDERAL RULE OF APPELLATE PROCEDURE 29
Brief of an Amicus Curiae

East Fork Enterprises, Incorporated, et al. v. EPA et al.
Nos. 24-60227, 24-60256

Under the first sentence of Rule 29(a)(2), the signatory States below may file a brief without the consent of the parties or leave of the Court.

Under the second sentence of Rule 29(a)(2), the signatory City of New York states that all petitioners and respondents have consented to amici's filing this amicus brief.

Under Rule 29(a)(4), signatory the City of New York, New York, state: (i) no party's counsel authored the accompanying brief in whole or in part; (ii) neither a party nor a party's counsel contributed money that was intended to fund preparing or submitting the brief; and (iii) no person – other than the signatories of this brief – contributed money that was intended to fund preparing or submitting the brief.

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INTRODUCTION AND INTERESTS OF AMICI CURIAE

Congress enacted the Toxic Substances Control Act, 15 U.S.C. § 2601 et seq. (TSCA), in 1976, to protect human health and the environment from the dangerous chemical substances that surround us. In 2016, Congress amended TSCA, directing the United States Environmental Protection Agency (EPA) to prioritize review of the most dangerous chemicals and comprehensively evaluate the risks those substances pose to human health and the environment. Methylene chloride is one of the highly toxic chemical substances that EPA prioritized for initial review. Inhalation of methylene chloride fumes can cause death within minutes, and long-term exposure can cause cancer, liver and kidney failure, and a variety of other long-term health effects.

EPA determined that methylene chloride, as a whole chemical substance, presents an unreasonable risk of injury to health under the conditions of use. EPA then took final action, as TSCA requires, to address the unreasonable risk of methylene chloride exposure by phasing out the most dangerous uses while providing additional protection to workers exposed to methylene chloride, but affording limited exemptions for critical uses of the chemical. East Fork Enterprises, Epic Paint

Company, and the American Chemistry Council ("Industry Petitioners") now challenge EPA's final action.

Pursuant to Federal Rule of Appellate Procedure 29(a)(2), the States of New York, Connecticut, Hawai'i, Illinois, Maryland, Massachusetts, Minnesota, New Jersey, Oregon, Rhode Island, and Vermont; the District of Columbia; and the City of New York submit this brief in support of EPA and in opposition to the petition filed by Industry Petitioners. The experience of Amici confirms that methylene chloride exposure poses significant public health and environmental risks. Amici also have a substantial interest in implementation of EPA's final rule because the federal government plays a complementary role in regulating methylene chloride that supports Amici's own efforts. And if EPA's rule is set aside, Amici will incur higher costs to address the severe public health and environmental harms caused by methylene chloride.

Amici also have an interest in the proper construction of TSCA. Contrary to Industry Petitioners' assertion, TSCA requires EPA to evaluate the risks posed by a chemical's "conditions of use" comprehensively and collectively. Congress enacted TSCA to give EPA the power to

address the risks of a chemical substance as a whole, and Industry Petitioners' use-by-use approach contravenes that mandate.

BACKGROUND

A. The Toxic Substances Control Act (TSCA)

Congress enacted TSCA in 1976 to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S. Rep. No. 94-698, at 1 (1976); *see Safer Chems. v. EPA*, 943 F.3d 397, 406-07 (9th Cir. 2019). Congress concluded that the existing regulatory framework for toxic chemicals was too "fragmented," and that it was "inadequate" to address the health and environmental risks posed by toxic chemicals. *See* H.R. Rep. No. 94-1341, at 6 (1976). To address those deficiencies, TSCA granted EPA "the authority to look at the hazards in total," S. Rep. No. 94-698, at 2, and authorized the agency to regulate "chemicals themselves"—as opposed to products containing chemicals, or chemical discharges and emissions, *Safer Chems.*, 943 F.3d at 406.

As relevant here, section 6(a) of TSCA required EPA to restrict the manufacture, processing, or distribution of a chemical if the agency found

"a reasonable basis to conclude" that those processes posed "an unreasonable risk of injury to health or the environment." Pub. L. No. 94-469, § 6(a), 90 Stat. 2003, 2020 (1976). When first enacted, TSCA authorized EPA to impose restrictions on a chemical only "to the extent necessary to protect adequately against such risk using the least burdensome requirements[.]" *Id.*

Despite Congress's goals, EPA's implementation of TSCA was hindered "by shortcomings in the statute itself, and by several key decisions of Federal Courts and the Agency's interpretation of those decisions." S. Rep. No. 114-67, at 2 (2015). Addressing these issues, in 2016, Congress enacted the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified at 15 U.S.C. § 2601 et seq.), to amend TSCA and "provide broad protection of human health and the environment" and "improve availability of information about chemicals," S. Rep. No. 114-67, at 6.

The 2016 amendments strengthened section 6 of TSCA. Section 6 now provides that if EPA determines "that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance . . . presents an unreasonable risk of injury to health or the environment,"

EPA must take regulatory measures—up to and including a complete prohibition on use and distribution—"to the extent necessary so that the chemical substance . . . no longer presents such risk." 15 U.S.C. § 2605(a). Under the amendments, EPA is no longer required to use the least burdensome means to address a chemical's risk to health or the environment. *See id.*; H.R. Rep. No. 114-176, at 23 (2015).

The 2016 amendments also enacted a new section 6(b), which creates a comprehensive risk evaluation process for determining whether a chemical substance presents an unreasonable risk to human health or the environment. *See* 15 U.S.C. § 2605(b); H.R. Rep. No. 114-176, at 23-25. During the first stage of the process, EPA must identify "high-priority" chemicals, i.e., chemicals posing the greatest potential risk to human health or the environment based on the potential for hazard and exposure, among other considerations. *See* 15 U.S.C. § 2605(b)(1).

During the second stage—the "risk evaluation" stage—EPA must determine whether a chemical "presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors[.]" *Id.* § 2605(b)(4)(A). Among other things, that analysis must consider any "unreasonable risk to a potentially exposed or suscep-

tible subpopulation identified as relevant to the risk evaluation by [EPA], under the conditions of use." *Id.* The term "'conditions of use' means the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* § 2602(4).

The risk evaluation has three linked components. The first component requires EPA to prepare an initial scope document that identifies the focus of the risk evaluation, including the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that EPA expects to consider. *See id.* § 2605(b)(4)(D). The second component requires EPA to analyze "available information" on the hazards and exposures, "including information that is relevant to specific risks of injury to health or the environment[.]" *Id.* § 2605(b)(4)(F). The third component requires EPA to determine whether the chemical presents an unreasonable risk to health or the environment. *See id.* § 2605(b)(4)(A).

If EPA determines that a chemical presents an unreasonable risk to health or the environment, the agency must immediately move to the final stage, risk management. *See id.* § 2605(a). Congress specified that,

during the risk management stage, EPA must implement rules to eliminate the unreasonable risk, including use restrictions, limitations on production, warning labels, recordkeeping, or product or disposal bans. *See id.*

B. Regulation of Methylene Chloride Under TSCA

Methylene chloride, also known as dichloromethane and DCM, is a highly toxic and volatile solvent that is currently manufactured, processed, distributed, and disposed of within Amici's borders. *See* Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 39,254, 39,256 (May 8, 2024). Over 260 million pounds of methylene chloride are produced each year in the United States. *See* Methylene Chloride (MC); Final Toxic Substances Control Act (TSCA) Risk Evaluation, 85 Fed. Reg. 37,942, 37,944 (June 24, 2020). The chemical is used in a wide range of industrial, commercial, and consumer applications.[1] In 2016, EPA identified methylene chloride as one of the

[1] *See* EPA, *Problem Formulation of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)*, at 11 (May 2018) ("MC Problem Formulation"), EPA-HQ-OPPT-2016-0742-0083.

high-priority chemicals posing the greatest potential risk to human health or the environment under TSCA's newly enacted section 6(b).[2]

In June 2020, EPA published the final Risk Evaluation concerning methylene chloride. 85 Fed. Reg. 37,942. The risk evaluation identified 53 different "conditions of use" for methylene chloride, each of which corresponds to an occupational setting where the chemical is present (e.g., "domestic manufacturing"), or a consumer, commercial, or industrial application of the chemical (e.g., "consumer uses in adhesives"). *See* EPA, *Risk Evaluation for Methylene Chloride (Dichloro-methane, DCM)*, at 517-20 (June 2020) ("MC Risk Evaluation"), EPA-HQ-OPPT-2016-0742-0121. Although TSCA was enacted to ensure that EPA considers the risks posed by each chemical "in total," S. Rep. No. 94-698, at 2, EPA chose to base its evaluation on the risks posed by methylene chloride to health and the environment on a use-by-use basis. Ultimately, EPA concluded that methylene chloride poses an unreasonable health risk under 47 out of 53 conditions of use. *See* MC Risk Evaluation, at 518-20. EPA also

[2] *See* Designations of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act, 81 Fed. Reg. 91,927, 91,928 (Dec. 19, 2016).

found no unreasonable risk to the environment from any use of methylene chloride. *See* MC Risk Evaluation, at 517-20; 85 Fed. Reg. at 37,943.

In August 2020, certain Amici timely filed a petition for review of EPA's "no unreasonable risk" determination. That petition was consolidated with another petition for review of the same EPA action in the United States Court of Appeals for the Ninth Circuit. *See Neighbors for Environmental Justice v. EPA*, No. 20-72091 (9th Cir. 2020), ECF No. 30. In July 2021, the Ninth Circuit granted EPA's motion for voluntary remand for the limited purpose of permitting the agency to reconsider the challenged no unreasonable risk determinations. *Id.*, ECF No. 80.

In November 2022, EPA issued a final revision to the risk determination, finding that methylene chloride, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under the conditions of its use.[3]

In May 2024, EPA issued its final risk management rule to address the unreasonable risk of injury to human health presented by methylene

[3] Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability, 87 Fed. Reg. 67,901 (Nov. 10, 2022).

chloride under its conditions of use as documented in EPA's June 2020 MC Risk Evaluation and EPA's November 2022 revision.[4] The rule, which is the subject of this challenge, prohibits all consumer uses and most commercial uses of methylene chloride.[5]

ARGUMENT

POINT I

METHYLENE CHLORIDE POSES SEVERE AND IMMINENT HEALTH RISKS AND COSTS TO AMICI AND THEIR RESIDENTS

The experience of Amici confirms that methylene chloride exposure poses significant public health and environmental risks. And Amici have a strong interest in ensuring that the federal government plays a robust and complementary role in regulating methylene chloride. If EPA's rule were set aside, Amici's residents would continue to be exposed to methylene chloride and its severe and imminent health risks, and Amici would be forced to incur higher costs to address the severe public health and environmental harms caused by methylene chloride.

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[4] *See* 89 Fed. Reg. 39,254.

[5] *Id.*

Amici's residents are exposed to methylene chloride through both commercial and consumer activities. EPA estimates that over 6.8 million workers and 1.4 million occupational non-users nationwide face exposure to methylene chloride each year. MC Risk Evaluation, at 130-31, Table 2-27. Individuals may be exposed to methylene chloride through consumer or commercial uses of products that contain the chemical—such as paints, adhesives, lubricants, automotive products, footwear, and toys.[6] *See* MC Problem Formulation, at 40-41; MC Risk Evaluation, at 74-226 (assessing human and environmental exposure pathways).

Amici's residents also face exposure from environmental pollution. Methylene chloride has been found in urban air and at hazardous waste sites, which release methylene chloride into the air, groundwater, surface water, and soil.[7] In New York alone, there are 137 environmental remediation sites where methylene chloride is listed as a chemical of

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[6] *See also* EPA, *Draft Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)*, at 35-36 (Oct. 2019) ("Draft MC Risk Evaluation"), EPA-HQ-OPPT-2019-0437-0023; U.S. Dep't of Health & Human Servs., Agency for Toxic Substances & Disease Registry, *Toxicological Profile for Methylene Chloride*, at 3 (Sept. 2000) ("Toxicological Profile") (internet). (For sources available on the internet, full URLs appear in the Table of Authorities.).

[7] Toxicological Profile, at 3.

concern.[8] Twelve of these sites are located in Nassau and Suffolk Counties, where groundwater is the sole source of drinking water for almost 3 million residents.[9] Methylene chloride is also released in surface waters, which can cause exposures to amphibians and fish. *See* MC Risk Evaluation, at 102-08; *see also* Draft MC Risk Evaluation, at 290, 389, 569-91.

The severe adverse health risks of both short- and long-term exposures to methylene chloride are undisputed. Significantly, methylene chloride turns into carbon monoxide in the body and can stop the oxygen supply to the heart.[10] *See* MC Problem Formulation, at 45. At high doses, methylene chloride can thus be immediately lethal: it can result in death by heart attack or asphyxiation within minutes. Acute exposures can also cause the breathing center of the victim's brain to shut

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[8] *See* N.Y. State Dep't of Env't Conservation, *Environmental Remediation Sites* (internet).

[9] *See id.*

[10] *See also* EPA, Office of Chemical Safety & Pollution Prevention, TSCA Work Plan Chemical Risk Assessment: Methylene Chloride: Paint Stripping Use ("TSCA Work Plan"), at 79 (Aug. 2014) (internet); *see also* Toxicological Profile, at 15-28.

down, leading to hypoxia, coma, and death.[11] *See* MC Risk Evaluation, at 33, & App. J. Other acute nervous system effects include sensory impairment and loss of consciousness. *See* MC Risk Evaluation, at 33, App. J.

Although many deaths attributable to methylene chloride are misidentified or unreported, EPA identified at least 85 fatalities in the United States between 1980 and 2018 that were caused by acute methylene chloride exposure.[12] *See* MC Risk Evaluation, App. J. Of these fatalities, over 80% were occupational users. *Id.* Examples of such occupational fatalities include a worker in New York who died from acute methylene chloride exposure while helping his father refinish a bathtub in a hotel bathroom,[13] and a worker in Massachusetts who died after

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[11] *See also* Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7,464, 7,482-85 (Jan. 19, 2017) (discussing adverse health effects of methylene chloride studied in earlier EPA assessments).

[12] *See also* Safer Chemicals, Healthy Families, *U.S. Deaths from Methylene Chloride* (Mar. 2018) (internet) (reporting a similar fatality figure and noting that many fatalities "may not have been reported or the death may have been mistakenly attributed to a cause other than methylene chloride exposure").

[13] *See* 82 Fed. Reg. at 7,482.

scraping varnish off the inside of a 500-gallon tank that had been coated with methylene chloride.[14]

Long-term exposure to methylene chloride can also result in serious adverse health effects. Prolonged exposure to methylene chloride can result in severe nervous system effects, including cognitive impairment and attention deficits. *See* MC Risk Evaluation, at 288-89; 82 Fed. Reg. at 7,483. In addition, methylene chloride has been linked to cancers of the liver, brain, and lung, non-Hodgkin's lymphoma, multiple myeloma, and toxicity of the liver, kidneys, and reproductive systems. *See MC Problem Formulation*, at 45-46; MC Risk Evaluation, at 33, App. L.4; 82 Fed. Reg. at 7,471.

These adverse health effects are not limited to direct users of products containing methylene chloride. Because methylene chloride is highly volatile and can be transported by air and through heating and ventilation systems, individuals in the vicinity of someone using methylene chloride may also suffer from the acute and long-term health effects of methylene chloride exposure.[15] For example, in one incident in South

[14] Safer Chemicals, Healthy Families, *supra*.

[15] *See* TSCA Work Plan, at 88-89.

Carolina, two workers went to check on a third colleague who had been using a paint remover containing methylene chloride. All three workers died from acute methylene chloride exposure, and three emergency responders required hospitalization following their exposure to the toxic chemical. *See* 82 Fed. Reg. at 7,482-83.

These public health effects also impose substantial costs on Amici. Work-related illnesses can generate substantial healthcare costs in the form of emergency room visits, long-term care expenses, and medications, among other things.[16] Studies show that many of these costs will not be covered by workers' compensation or other forms of private insurance, and will instead be borne by Amici States through Medicaid and other programs.[17] Moreover, many of the chronic illnesses caused by methylene chloride—such as cancer, liver disease, and kidney disease—may not manifest until long after workers would be able to claim private,

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[16] *See, e.g.*, J. Paul Leigh, *Economic Burden of Injury and Illness in the United States*, 89 Milbank Q. 728, 731 (2011); Paul A. Schulte, *Characterizing the Burden of Occupational Injury and Disease*, 47 J. Occupational & Env't Med. 607, 616 (2005); The Pew Charitable Trusts, *States Collectively Spend 17 Percent of their Revenue on Medicaid* (Jan. 9, 2020) (internet).

[17] *See* Leigh, *supra* at 749; Schulte, *supra* at 615.

employer-provided benefits.[18] Occupational illnesses caused by methylene chloride exposure also harm Amici by decreasing worker productivity. Extended work absences due to illness result in lost wages and diminished economic output by private employers, lowering tax revenue for Amici.[19]

Independently, Amici have borne and will continue to bear the costs of cleaning up methylene chloride pollution within their borders.[20] As explained above, air, water, and soil across the United States is polluted with methylene chloride. *See supra* at 11-12. In New York alone, there are scores of environmental remediation sites where methylene chloride is listed as a chemical of concern.[21] In the past, Amici have expended substantial funds to remediate hazardous pollution caused by methylene

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[18] *See* J. Paul Leigh, Shagufta Yasmeen, & Ted R. Miller, *Medical Costs of Fourteen Occupational Illnesses in the United States in 1999*, 29 Scandinavian J. Work, Env't & Health 304, 306 (2003).

[19] *See* Leigh, *supra* at 731; Schulte, *supra* at 616.

[20] *See, e.g.,* Richard Maxwell and Toby Miller, *The Environmental Ruin of Eastman Kodak*, Psychology Today (Apr. 12, 2018) (internet); U.S. Att'y's Office, S. Dist. of N.Y., *Manhattan U.S. Attorney and EPA Announce Agreement with Eastman Kodak Company for Clean Up of Rochester, New York, Business Park and the Genesee River* (Mar. 12, 2014) (internet).

[21] *See* N.Y. State Dep't of Env't Conservation, *supra*.

chloride. For example, New York was required to spend between $49 to $99 million to clean up hazardous wastes, including methylene chloride, that were dumped into Genesee River by Eastman Kodak Company for over a century.[22]

Amici have enacted their own measures to address the harmful effects of methylene chloride exposure. For example, New York has prohibited in-state sales of a variety of products that contain methylene chloride, including certain adhesives, adhesive removers, electrical cleaners, footwear or leather care products, and graffiti removers.[23] *See* 6 N.Y.C.R.R. § 235-3.1(g)(3), (l)(1), (m)(1). New York has also restricted the use of methylene chloride in plumbing and sewage cleaners, thereby reducing the presence of the chemical in New York's waters.[24] *See* N.Y. Envtl. Conserv. Law §§ 39-0103, 39-0105(1)-(2). New York has also set a

[22] *See, e.g.,* Maxwell & Miller, *supra*; U.S. Att'y's Office, *supra*.

[23] Maryland and New Jersey have enacted similar restrictions on sales of products containing methylene chloride. Md. Code Regs. §§ 26.11.32.08–26.11.32.09; N.J. Admin. Code § 7:27-24.4(n).

[24] Maryland has restricted the concentration of methylene chloride allowed in flammable multi-purpose solvent or paint thinner. Md. Code Regs. § 26.11.32.05-1.

health-based guideline to limit methylene chloride in indoor air.[25] Finally, several States impose a variety of reporting requirements on the use of methylene chloride.[26]

EPA's authority under TSCA is an important complement to those efforts. While States and local governments have many tools to regulate the use of toxic substances, federal law may in some circumstances constrain what they can do to address the public health costs of methylene chloride exposure, including as to the known risks of toxic chemical exposure once EPA has acted under TSCA. *See* 15 U.S.C. § 2617. In some instances, final EPA action determining that a chemical poses no unreasonable risk, or final EPA action restricting a chemical that poses unreasonable risk, will preempt state and local efforts to address the

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[25] *See* N.Y. State Dep't of Health, *Tenant Notification Fact Sheet for Dichloromethane* (internet). Vermont imposes emission limits on methylene chloride. *See* Vt. Code R. § 16.3-100:5-261(1)(a) & Apps. B & C.

[26] **Maryland**: Md. Code Regs. § 26.11.32.14(c) (manufacturers of consumer products containing methylene chloride must report name of product and total volume of in-State sales). **Massachusetts**: Mass. Gen. Laws ch. 21I, §§ 10, 11 (certain chemical users must report annually on use of toxic chemicals). **New Jersey**: N.J. Admin. Code § 8:59-9.1 & app. A (employers must periodically report use and storage of methylene chloride). **Vermont**: Vt. Stat. Ann. tit. 18, §§ 1773, 1775; Vt. Code R. § 12.5-54:5.0-6.0 (manufacturers of children's products containing methylene chloride must report certain information about products).

same chemicals addressed by EPA. *See* 15 U.S.C. § 2617(a)(1)(B), (b), (c), (d) & (e). Accordingly, Amici have a strong interest in robust federal regulation of methylene chloride to support their efforts to protect public health and the environment.

POINT II

THE RULE PROPERLY CONSIDERS THE RISKS OF METHYLENE CHLORIDE AS A WHOLE

Contrary to the arguments of Industry Petitioners (at 22-29), EPA properly considered the risks posed by methylene chloride exposure as a whole rather than on a use-by-use basis. Congress enacted TSCA to address a specific problem: the piecemeal regulation of toxic chemicals and the absence of a single agency with "authority to look comprehensively at the hazards associated with the chemical." S. Rep. No. 94-698, at 2. Pre-TSCA laws authorized different agencies to address the hazards associated with discrete uses of particular chemicals in consumer products or occupational settings, and agencies could "only look at the hazards within their jurisdiction in isolation from other hazards associated with the same chemical." *Id.* In enacting TSCA section 6, Congress sought to give EPA "the authority to look at the hazards *in total*." *Id.* (emphasis

added). And when Congress strengthened the provisions of section 6 in 2016, that fundamental purpose remained intact. *See* S. Rep. No. 114-67, at 7.

The text of section 6 reflects Congress's aim to ensure that EPA comprehensively evaluate the hazards of each chemical substance. TSCA section 6(b) requires EPA to determine "whether a *chemical substance*," as opposed to the substance's separate uses, "presents an unreasonable risk of injury to health or the environment[.]" 15 U.S.C. § 2605(b)(4)(A) (emphasis added). Section 6(a) provides that EPA must promulgate risk management rules if it determines that "the manufacture, processing, distribution in commerce, use, or disposal of *a chemical substance* or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment[.]" *Id.* § 2605(a) (emphasis added). TSCA's directive to assess the risk of each *substance*—separate and apart from the risk of any activity or combination of activities involving the chemical—precludes EPA from dissecting a substance's risk on a use-by-use basis, as Industry Petitioners mistakenly contend (at 22-29).

Other provisions of TSCA confirm that EPA must make a single risk determination for the chemical substance as a whole. TSCA section

19(a) authorizes judicial review of any "order" under section 6(i). *See* 15 U.S.C. § 2618(a). And section 6(i), in turn, provides that "*a* determination" by EPA "that *a chemical substance*" does or does not present an unreasonable risk is an order constituting final agency action for judicial review purposes. *See id.* § 2605(i) (emphases added). This provision makes clear that EPA must make a single, binary determination "whether *a substance meets or does not meet* the safety standard." S. Rep. No. 114-67, at 17 (emphasis added).

To be sure, TSCA also requires EPA to identify and evaluate the risks of each chemical's conditions of use as part of its risk evaluation.[27] *See* 15 U.S.C. § 2605(b)(4)(F). Congress imposed that requirement to help the agency identify relevant exposure pathways and activities that should be targeted for risk management, if EPA finds an unreasonable risk. *See* S. Rep. No. 114-67, at 17. But the instruction to consider a substance's

[27] Section 6(b)(4)(F) lays out the specific requirements for EPA's risk evaluation. The provision mentions "conditions of use" twice, requiring EPA to (1) "integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance," and (2) to "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered[.]" 15 U.S.C. § 2605(b)(4)(F)(i)-(ii). Nowhere does this provision suggest that EPA's analysis may proceed only on a use-by-use basis.

conditions of use does not supplant TSCA's clear requirement that EPA evaluate the overall risk posed by a chemical substance.

To the extent that specific conditions of use of a chemical pose a less severe hazard, Congress granted EPA authority to address that differential risk, but only during the risk *management* stage, *after* EPA has completed its risk evaluation. In the 2016 amendments, Congress intentionally disaggregated the risk evaluation process from risk management to ensure that EPA considers the risks of a substance in total, and to address shortcomings under the original TSCA scheme that hindered EPA's ability to take regulatory action. Under the prior regime, EPA was required to apply cost-benefit considerations when assessing risk, which typically caused EPA to understate the hazards of a particular chemical and diminish the basis for regulatory action. *See supra* at 4.

Under the 2016 amendments, however, Congress directed EPA to evaluate the health and environmental risks of a substance in total, without consideration of costs and benefits. *See* 15 U.S.C. § 2605(b)(4). It is only *after* EPA has concluded that a substance presents an unreasonable risk that TSCA section 6(g) authorizes EPA to "grant an exemption" from a risk management rule—such as a complete ban on manufacturing. *See*

15 U.S.C. § 2605(g). Such an exemption may be granted only "for *a specific* condition of use of a chemical substance," and only if EPA determines that one of several additional requirements is satisfied.[28] *See id.* That Congress expressly granted EPA authority to carve out specific conditions of use during the risk management stage, but provided no similar authority during the risk evaluation stage, further confirms that EPA's risk evaluation must address each substance in total. *See, e.g.*, *Egebjerg v. Anderson (In re Egebjerg)*, 574 F.3d 1045, 1050 (9th Cir. 2009) (Congress's express provision of exemption in one part of statute but not another reflects intentional omission).

Industry Petitioners mistakenly rely (at 24) on TSCA section 6(b)(4)(D)—an inapposite provision governing EPA's preparation of the

[28] To grant an exemption, EPA must determine that (1) the condition of use "is a critical or essential use for which no technically and economically feasible safer alternative is available"; (2) a "compliance requirement . . . would significantly disrupt the national economy, national security, or critical infrastructure"; or (3) "the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety." 15 U.S.C. § 2605(g)(1)(A)-(C).

initial scope document for the risk evaluation.[29] A separate provision of TSCA—section 6(b)(4)(F)—governs the substance of the risk evaluation, and nothing in the latter provision authorizes EPA to disaggregate its risk analysis on a use-by-use basis. *See* 15 U.S.C. § 2605(b)(4)(F). To the contrary, section 6(b)(4)(F) recognizes the common-sense proposition that multiple exposures to the same chemical from different activities will increase the risks to health and the environment. Accordingly, that provision requires EPA to "*integrate and assess*" all of the relevant information on "hazards and exposures for the conditions of use." 15 U.S.C. § 2605(b)(4)(F)(i) (emphasis added).

Even if section 6(b)(4)(D) of TSCA were relevant—and it is not—that provision still would not support Industry Petitioners' use-by-use approach. Section 6(b)(4)(D) requires EPA to publish an initial scope document identifying the "conditions of use" to be studied during the risk evaluation. *See* 15 U.S.C. § 2605(b)(4)(D). But the mere fact that EPA is

[29] In relevant part, section 6(b)(4)(D) provides that EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider." 15 U.S.C. § 2605(b)(4)(D).

required to identify the relevant conditions of use does not support use-by-use evaluation. Rather, the requirement serves to clarify that EPA must identify all of the relevant activities in which a substance is used, distributed, or sold so that all of the known and reasonably foreseeable risks can be evaluated. *See Safer Chems.*, 943 F.3d at 419.

CONCLUSION

This Court should deny the petition for review filed by Industry Petitioners.

Dated: New York, New York
January 3, 2025

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This brief complies with the type-volume limitations of Fed. R. App. P. 29(a)(5) and 32(a)(7)(B) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this brief contains 4,769 words.

2. This brief complies with the type-face 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 brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook, and is double-spaced, except for headings, quotes of two lines or more, and footnotes.

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January 3, 2025

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CERTIFICATE OF SERVICE

I hereby certify that on January 3, 2025, the foregoing brief for amici curiae was filed electronically using the Court's CM/ECF system. Notice of this filing will be sent to all parties for whom counsel has entered an appearance by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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January 3, 2025

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