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MARYLAND, MASSACHUSETTS, OREGON, VERMONT,
WISCONSIN, AND THE DISTRICT OF COLUMBIA

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Via Electronic Filing

EPA-HQ-OPPT-2020-0465

Michael Regan, Administrator
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Re: *Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)*, 88 Fed. Reg. 28,284 (May 3, 2023)

Dear Administrator Regan:

The Attorneys General of New York, Illinois, Maryland, Massachusetts, Oregon, Vermont, Wisconsin, and the District of Columbia (the “States”) submit these comments regarding the U.S. Environmental Protection Agency’s (“EPA”) proposed rule to address the unreasonable risk of injury to human health presented by methylene chloride under section 6(a) of the Toxic Substances Control Act (“TSCA”), 15 U.S.C. § 2601 *et seq.*¹

Methylene chloride, also known as dichloromethane, is acutely lethal, a neurotoxicant, a likely human carcinogen, and presents cancer and non-cancer risks following chronic exposures as well as acute risks.² Central nervous system depressant effects can result in loss of consciousness and respiratory depression, resulting in irreversible coma, hypoxia, and eventual death.³ However, methylene chloride remains available for purchase and is a widely used solvent in a variety of consumer and commercial applications, including adhesives and sealants, automotive products, and paint and coating removers.⁴

In EPA’s final revised risk determination, EPA determined that methylene chloride as a whole chemical presents an unreasonable risk of injury to human health under its conditions of use. Under section 6(a) of TSCA, EPA appropriately

¹ See *Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)*, 88 Fed. Reg. 28,284 (May 3, 2023).

² *Id.*

³ *Id.*

⁴ *Id.*

proposes banning all consumer uses and most industrial and commercial uses of methylene chloride. However, these prohibited uses would only “amount to a prohibition of an estimated 52% of annual production volume for end uses subject to TSCA.”⁵ To fulfill its obligation to address the unreasonable risk of methylene chloride, and to protect environmental justice communities, EPA must narrow the proposed rule’s exemptions and exclusions as described below.

I. 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) (discussing Congress’s purpose in enacting TSCA). TSCA reflected Congress’s concern that “we have become literally surrounded by a man-made chemical environment,” and that “certain of these chemicals present lethal health and environmental dangers.” S. Rep. No. 94-698, at 3.

In enacting TSCA, 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). While individual agencies were “authorized to regulate occupational, or environmental, or direct consumer hazards” within their limited jurisdictions, no agency “ha[d] the authority to look comprehensively at the hazards associated with the chemical.” S. Rep. No. 94-698, at 2. TSCA was designed to, among other things, give EPA “the authority to look at the hazards in total.” *Id.* To that end, TSCA granted EPA a new “information-gathering responsibility” 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.

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). EPA was authorized 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); *see also Safer Chems.*, 943 F.3d at 407 (summarizing EPA difficulties implementing TSCA). Addressing these issues, in 2016, Congress enacted the Frank R.

⁵ EPA, *Risk Management for Methylene Chloride*, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride>.

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 manufacturing, 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. 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. 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, such as persistence and bioaccumulation.⁶ *See* 15 U.S.C. § 2605(b)(1); 40 C.F.R. §§ 702.1-702.17. In December 2016, EPA published its initial list of 10 such high-priority chemical substances, which included methylene chloride.⁷

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.” 15 U.S.C. § 2605(b)(4)(A). Among other things, that analysis must consider any “unreasonable risk to a potentially exposed or susceptible 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). And a “‘potentially exposed or susceptible subpopulation’ means a group of individuals within the general population identified by [EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general

⁶ *See* EPA, TSCA Work Plan Chemicals, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals#select>.

⁷ Other priority chemicals included asbestos—a notorious carcinogen—and perchloroethylene, commonly known as PERC—a highly toxic chemical substance used frequently for dry cleaning that can cause cancer and long-term neurological impairment. *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).

population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” *Id.* § 2602(12).

When conducting the risk evaluation, EPA is required to make a determination based on the “weight of scientific evidence,” using the “best available science” and all “reasonably available information.” *Id.* § 2625(i), (h), and (k); 40 C.F.R. § 702.33. EPA is not permitted to consider “costs or other nonrisk factors,” *see id.* § 2605(b)(4)(F), meaning EPA must assess the risk to human health and the environment without considering “the costs or benefits of the substance or possible restrictions on the substance” under other statutory schemes. *See* S. Rep. 114-67, at 17. By precluding EPA from considering “costs or other nonrisk factors,” Congress sought to address shortcomings under the original TSCA scheme, which hindered EPA’s ability to take regulatory action by suggesting “that cost and benefit considerations must be applied to the Agency’s decisions on the health and environmental risks posed by a chemical substance.” *Id.* at 4.

The risk evaluation itself 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* 15 U.S.C. § 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.” 15 U.S.C. § 2605(b)(4)(F); *see* 40 C.F.R. § 702.41(a), (d), (e). Among other things, this compels EPA to consider the types of human and environmental hazards, the relationship between the dose of the chemical substance and the health and environmental effects, and all relevant potentially exposed and susceptible subpopulations. *See* 15 U.S.C. § 2605(b)(4)(F); 40 C.F.R. § 702.41(d). EPA must also identify the likely duration, intensity, frequency, and number of exposures to a chemical under the known and expected conditions of use. *See* 15 U.S.C. § 2605(b)(4)(F); 40 C.F.R. § 702.41(e)(1). And the agency must consider chemical-specific factors, including how the chemical moves through the environment and interacts with ecological receptors. *See* 40 C.F.R. § 702.41(e). EPA must then integrate and assess the reasonably available information on hazard and exposure. *See* 15 U.S.C. § 2605(b)(4)(F)(i); 40 C.F.R. § 702.43.

In the third component of the risk evaluation, EPA must determine whether the chemical presents an unreasonable risk to health or the environment. *See* 15 U.S.C. § 2605(b)(4)(A); 40 C.F.R. § 702.47. A determination that a chemical poses no unreasonable risk ends the TSCA process and is deemed “final agency action” subject to judicial review. *See* 15 U.S.C. §§ 2605(i)(1), 2618(a)(1)(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* 15 U.S.C. § 2605(a); 40 C.F.R. § 702.49(c).

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* 15 U.S.C. § 2605(a).

When proposing or promulgating any rule under section 6(a), EPA must consider and publish a statement on: the effects of the substance or mixture on health and the magnitude of the exposure of people; the effects of the substance or mixture on the environment and the magnitude of the environmental exposure; the benefits of using the substance or mixture; the likely economic consequences of a restriction, taking into account the effect on the economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed ban or restriction and the primary alternatives considered by the EPA; and the cost-effectiveness of the proposed ban or restriction and the primary alternatives considered by the EPA. 15 U.S.C. § 2605(c)(2).

EPA must select the means for banning or restricting the substance based on the factors listed above. If a ban or restriction substantially prevents a condition of use, EPA must consider a phase-in of the restriction and whether a technically and economically feasible alternative will be available when the ban or restriction is in place. 15 U.S.C. §§ 2605(c)(2)(B) and 2605(c)(2)(C). EPA may exempt critical or essential uses from bans and restrictions. To grant this exemption, EPA must find that there is no technically and economically feasible safer alternative available, or compliance with the ban or restriction would significantly disrupt the national economy, national security or critical infrastructure, or the condition of use provides a substantial benefit to health, the environment or public safety. 15 U.S.C. § 2605(d).

EPA must propose a rule banning or restricting the substance within one year of publication of the risk evaluation, and must promulgate a final rule within two years of publication of the risk evaluation. With certain exceptions, these deadlines can be extended for a total of two years. 15 U.S.C. § 2605(c)(1)(C). The risk management measures adopted by EPA, along with the unreasonable risk determination, are subject to judicial review. *See id.* §§ 2605(i)(2), 2618(a)(1)(A).

II. The Severe and Imminent Health Risks Posed by Methylene Chloride

A. Methylene Chloride is Lethal in High Doses, Causes Severe, Long-Term Illness, and Harms the Environment

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 the borders of the States.⁸ Over 260 million pounds of methylene chloride are produced each year in the United States.⁹ The chemical is used in a wide range of industrial, commercial, and consumer applications, including paint stripping and removal (30%), adhesives (22%), pharmaceuticals (11%), metal cleaning (8%), aerosols (8%), chemical processing (8%), and flexible polyurethane foam (5%). See EPA, *Problem Formulation of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)*, at 11 (May 2018) (“MC Problem Formulation”).

Methylene chloride can cause severe adverse health risks from both short- and long-term exposures. 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 down, leading to hypoxia, coma, and death.¹¹ See EPA, *Risk Evaluation for Methylene Chloride (Dichloro-methane, DCM)* (June 2020) (“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 who used methylene chloride on the job. *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

⁸ See EPA, *Nontechnical Summary of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)*, at 3 (June 2020).

⁹ See *Methylene Chloride (MC); Final Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability*, 85 Fed. Reg. 37,942, 37,944 (June 24, 2020).

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); see also U.S. Dep’t of Health & Human Servs., Agency for Toxic Substances & Disease Registry, *Toxicological Profile for Methylene Chloride* (“Toxicological Profile”), at 15-28 (Sept. 2000).

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*, <https://saferchemicals.org/us-deaths-from-methylene-chloride/> (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.

Massachusetts who died while cleaning a 250-gallon reactor vessel 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. 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 venting 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 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.

In addition to health risks, methylene chloride presents significant risks to the environment. The air in many parts of the United States is polluted with methylene chloride.¹⁶ And methylene chloride is also known to cause ozone depletion, which causes higher exposures to ultraviolet radiation at the Earth's surface, damaging plants and marine ecosystems, among other things.¹⁷

B. States' Residents Are Exposed to Methylene Chloride Through Diverse Pathways

The States' 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

¹⁴ *U.S. Deaths from Methylene Chloride*, <https://saferchemicals.org/us-deaths-from-methylene-chloride/>.

¹⁵ *See* TSCA Work Plan, at 88-89.

¹⁶ Toxicological Profile, at 3.

¹⁷ *See* EPA, *Health and Environmental Effects of Ozone Layer Depletion*, <https://www.epa.gov/ozone-layer-protection/health-and-environmental-effects-ozone-layer-depletion>.

products, footwear, and toys.¹⁸ See MC Problem Formulation, at 40-41; MC Risk Evaluation, at 74-226 (assessing human and environmental exposure pathways).

Residents of the States 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.¹⁹ In New York alone, there are 57 environmental remediation sites where methylene chloride is listed as a chemical of concern.²⁰ Five of these sites are located in Nassau and Suffolk Counties, where groundwater is the sole source of drinking water for almost 3 million residents.²¹ 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.

In light of the significant public health and environmental risks of methylene chloride, the States have enacted 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. 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. See N.Y. Evtl. Conserv. Law §§ 39-0103, 39-0105(1)-(2). The State has also set a health-based guideline to limit methylene chloride in indoor air.²²

Maryland's protective measures have included banning the sale, supply, offer for sale, or manufacture of a variety of products containing methylene chloride, including adhesive removers, electric cleaners, construction panel and floor covering adhesives, and graffiti removers. See Md. Code Regs. §§ 26.11.32.08–26.11.32.09. Maryland has also restricted the concentration of methylene chloride allowed in any flammable multi-purpose solvent or paint thinner. See *id.* § 26.11.32.05-1. And Maryland has introduced monitoring measures that require the manufacturers of consumer products containing methylene chloride to report the name of the product and the total volume of in-State sales. See *id.* § 26.11.32.14(c).

Under the Massachusetts Toxics Use Reduction Act, Mass. Gen. Laws ch. 21I (the "Massachusetts Act"), Massachusetts requires certain chemical users in the Commonwealth to report annually on their use of toxic chemicals and complete

¹⁸ See also EPA, *Draft Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)* (Oct. 2019) ("Draft MC Risk Evaluation"), at 35-36; Toxicological Profile, at 3.

¹⁹ Toxicological Profile, at 3.

²⁰ See New York State Department of Environmental Conservation, *Environmental Remediation Sites*, <https://data.ny.gov/Energy-Environment/Environmental-Remediation-Sites/c6ci-rzpg>.

²¹ See *id.*

²² See New York State Department of Health, *Tenant Notification Fact Sheet for Dichloromethane*, <https://www.health.ny.gov/environmental/indoors/air/contaminants/dichloromethane.htm>.

toxics-use reduction planning every two years. *See* Mass. Gen. Laws ch. 21I, §§ 10 and 11. Methylene chloride is on the hazardous chemicals list developed in accordance with the Massachusetts Act and is subject to the statute's requirements. *See id.* §§ 9 and 9A. Moreover, the Massachusetts Toxics Use Reduction Institute and the Massachusetts Office of Technical Assistance and Technology, its partner agency, work with Massachusetts businesses and communities to reduce their use of toxic solvents, including methylene chloride. *See id.* §§ 6 and 7. And methylene chloride emissions are subject to regulation and enforcement under the Massachusetts Clean Air Act, Mass. Gen. Laws ch. 111, §§ 142A-142N.

New Jersey prohibits the in-state sale, distribution, supply, and manufacture of a variety of products that contain methylene chloride. *See* N.J. Admin. Code § 7:27-24.4(n). Methylene chloride is also listed in the "Special Health Hazard Substance List" for purposes of the New Jersey Worker and Community Right to Know Act, which means that employers must periodically report to the State about their use and storage of methylene chloride. *See id.* § 8:59-9.1 & app. A.

Vermont regulates methylene chloride in several ways. First, Vermont treats methylene chloride as a hazardous air contaminant subject to emission limits. *See* Vt. Code R. § 16.3-100:5-261(1)(a) & Apps. B & C. Second, the State has established a water quality standard in all Vermont waters for both human health and aquatic biota protection. *See* Vt. Code R. § 16.5-100:3-01(B)(10) & App. C. Third, the State requires manufacturers of children's products containing methylene chloride to report certain information about the products to the State. *See* Vt. Stat. Ann. tit. 18, §§ 1773, 1775; Vt. Code R. § 12.5-54:5.0-6.0. Fourth, the State has designated methylene chloride as a "hazardous waste" for purposes of waste disposal and management. *See* Vt. Code R. § 16.3-202:7-213 & App. II.

Although the States and have taken a variety of steps to protect their residents and the environment from the harmful consequences of methylene chloride exposure, EPA's authority under TSCA is an important complement to those efforts. States have many tools to regulate the use of toxic substances, but federal law may in some circumstances constrain what States 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(a)(1)(B)(ii). In some instances, final EPA action determining that a chemical poses no unreasonable risk will preempt state and local efforts to address the same chemicals addressed by EPA. *See* 15 U.S.C. § 2617(a)(1)(B), (b), (c), (d) & (e).

III. EPA’s Risk Evaluation and Proposed Risk Management Rule for Methylene Chloride

A. EPA’s Risk Determinations

On June 24, 2020, EPA published the final MC Risk Evaluation for methylene chloride.²³ 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* MC Risk Evaluation, at 517-20. 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 concluded that six significant uses of methylene chloride do not pose unreasonable risk to the health of workers, occupational non-users, consumers, or bystanders. MC Risk Evaluation, 517-18. Those uses are: (1) the domestic manufacture of methylene chloride, (2) the processing of methylene chloride as a reactant, (3) the processing of methylene chloride in recycling, (4) the distribution of methylene chloride in commerce, (5) industrial and commercial uses of methylene chloride as a laboratory chemical, and (6) the disposal of methylene chloride. MC Risk Evaluation, 517-18. EPA also 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.

EPA stated that it was in the process of developing risk management rules to address the unreasonable risks posed by the 47 conditions of use for which it found an unreasonable risk, and it had up to one year—i.e., until June 2021—to propose and take public comments on any such action.²⁴ 15 U.S.C. § 2605(c)(1)(A). With respect to the six conditions of use for which EPA found no unreasonable risk, EPA stated that it did not plan to propose any risk management measures.

EPA’s “no unreasonable risk” determination was a final agency action subject to judicial review in the United States Court of Appeals for the District of Columbia or the circuit in which the petitioner resides. *See* 15 U.S.C. §§ 2605(i)(1), 2618(a).

²³ In October 2019, EPA published the Draft MC Risk Evaluation. Several of the States and the municipality submitted timely comments to EPA identifying deficiencies in the agency’s draft.

²⁴ EPA, *Risk Management for Methylene Chloride*, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride>.

B. Legal Challenges to EPA’s No Unreasonable Risk Determinations

On August 17, 2020, pursuant to Federal Rule of Appellate Procedure 15, TSCA sections 6(i)(1) and 19(a), *see* 15 U.S.C. §§ 2605(i)(1), 2618(a), and section 10 of the Administrative Procedure Act (“APA”), *see* 5 U.S.C. §§ 701-706, certain States and a municipality (“State and Municipal Petitioners”) timely filed a petition for review of EPA’s “no unreasonable risk” determination in the United States Court of Appeals for the Second Circuit. *See State of New York v. EPA*, No. 20-2729 (2d Cir. 2020), ECF No. 1. On November 4, 2020, the petition for review was transferred to Ninth Circuit pursuant to 28 U.S.C. § 2112(a)(5). *See* ECF No. 63. On November 24, 2020, the petition was consolidated with another petition for review of the same EPA action. *See Neighbors for Environmental Justice v. EPA*, No. 20-72091 (9th Cir.), ECF No. 30.

In January 2021, State and Municipal Petitioners filed their opening brief in the “no unreasonable risk” litigation in the Ninth Circuit.²⁵ State and Municipal Petitioners argued that EPA’s final risk evaluation for methylene chloride should be set aside because EPA’s analysis is arbitrary and capricious, without substantial evidence, and violated TSCA’s requirements in several respects. By analyzing the risks of methylene chloride only on a use-by-use basis, EPA violated the statute’s clear mandate to evaluate the risks of a chemical substance comprehensively and holistically. EPA also failed to analyze significant exposure pathways from environmental pollution, improperly considered regulatory protections under other statutes that TSCA forbids EPA from considering, and failed to comply with TSCA’s mandate to consider the unique risks posed by methylene chloride to especially susceptible and vulnerable populations.

Independently, State and Municipal Petitioners argued that EPA’s analysis must be set aside because the risk evaluation fails to satisfy TSCA’s evidentiary requirements. TSCA requires EPA’s findings to be supported by substantial evidence and directs EPA to use reliable and representative data. Despite these clear statutory requirements, EPA relied on unfounded assumptions lacking record support or explanation when concluding that six uses of methylene chloride pose no unreasonable risk to human health or the environment.

State and Municipal Petitioners argued that to cure these manifest deficiencies, the Court should set aside EPA’s final order and require EPA to revise its risk evaluation to comprehensively address the risks presented by methylene chloride.

²⁵ *State of New York v. EPA*, No. 20-2729, ECF No. 24.

In May 2021, EPA filed a motion for voluntary remand to allow EPA to reconsider its no unreasonable risk determinations and requested remand without vacatur of the challenged determinations.²⁶

In June 2021, EPA “announced important policy changes surrounding risk evaluations issued under the Toxic Substances Control Act,” explaining that the Trump administration’s exclusion of several pathways of exposure failed to address risks to potentially exposed or susceptible subpopulations, including fenceline communities.²⁷ EPA decided to conduct a screening-level approach to determine if there is the potential for unreasonable risk to fenceline communities associated with air and water exposures.²⁸

However, EPA’s fenceline screening approach failed to provide the comprehensive evaluation of risk that TSCA requires and resulted in the understatement of risk, especially the risk faced by environmental justice communities.²⁹ Indeed, EPA’s Science Advisory Committee on Chemicals stated that EPA’s “screening methodology was not protective because of the lack of consideration for cumulative exposures, multiple source exposures, or additional risk factors such as stress, poverty, and/or diet that may interact to affect exposures.”³⁰

In July 2021, the Ninth Circuit granted EPA’s motion and remanded the matter to EPA for the limited purpose of permitting the agency to reconsider the challenged no unreasonable risk determinations.³¹ The Court held the proceedings in the consolidated petitions in abeyance pending EPA’s reconsideration and ordered EPA to file regular status reports on its progress.³²

C. EPA’s Revised Risk Determination

In July 2022, pursuant to section 6(b) of TSCA, EPA issued a draft revision to the risk determination for the MC Risk Evaluation.³³ In November 2022, EPA issued a final revision to the risk determination for the MC Risk Evaluation, determining that methylene chloride, as a whole chemical substance, presents an

²⁶ *State of New York v. EPA*, No. 20-2729, ECF No. 51.

²⁷ EPA, *EPA Announces Path Forward for TSCA Chemical Risk Evaluations* (June 30, 2021), <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>.

²⁸ *Id.*

²⁹ See Comment Submitted by the New York State Office of the Attorney General, et al. (Mar. 22, 2022), <https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0415-0080>.

³⁰ Science Advisory Committee on Chemicals, *Meeting Minutes and Final Report: A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0* at 38 (May 16, 2022).

³¹ *State of New York v. EPA*, No. 20-2729, ECF No. 62.

³² *Id.*

³³ *Methylene Chloride; Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment*, 87 Fed. Reg. 39,824 (July 5, 2022).

unreasonable risk of injury to health when evaluated under the conditions of its use.³⁴ In addition, the revised risk determination does not reflect an assumption that all workers always appropriately wear personal protective equipment (PPE). Not assuming the use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed.³⁵ Such risk exists because workers may not be covered by the Occupational Safety and Health Administration (OSHA) standards, their employers are out of compliance with OSHA standards, many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are "outdated and inadequate for ensuring protection of worker health," the OSHA permissible exposure limit (PEL) alone may be inadequate for ensuring protection of worker health, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.³⁶ EPA's November 2022 revision superseded the condition of use-specific no unreasonable risk determinations in the June 2020 MC Risk Evaluation and EPA withdrew the associated final order included in the June 2020 MC Risk Evaluation.

Accordingly, in June 2023, the parties in the consolidated petitions filed a joint stipulation of dismissal without prejudice.³⁷ On June 16, 2023, the Ninth Circuit entered an order dismissing the petitions.³⁸

D. EPA's Proposed Risk Management Rule

In May 2023, pursuant to section 6(a) of TSCA, EPA issued its proposed rule to address the unreasonable risk of injury to human health presented by methylene chloride under its conditions of use as documented in EPA's June 2020 MC Risk Evaluation and November 2022 revised risk determination for methylene chloride.³⁹

To address the identified unreasonable risk, EPA is proposing to prohibit the manufacture, processing, and distribution in commerce of methylene chloride for consumer use; prohibit most industrial and commercial uses of methylene chloride; require a workplace chemical protection program, which would include a requirement to meet inhalation exposure concentration limits and exposure monitoring for certain continued conditions of use of methylene chloride; require recordkeeping and downstream notification requirements for several conditions of use of methylene chloride; and provide certain time-limited exemptions from

³⁴ *Methylene Chloride; Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability*, 87 Fed. Reg. 67,901 (Nov. 10, 2022).

³⁵ *Id.* at 67,905.

³⁶ *Id.*

³⁷ *See Neighbors for Environmental Justice v. EPA*, No. 20-72091, ECF No. 100.

³⁸ *See id.* at ECF No. 101.

³⁹ *Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA)*, 88 Fed. Reg. 28,284 (May 3, 2023).

requirements for uses of methylene chloride that EPA says would otherwise significantly disrupt national security and critical infrastructure.⁴⁰

IV. EPA’s Proposed Risk Management Rule for Methylene Chloride Must Satisfy TSCA Section 6(a)

A. The States Strongly Support Phasing Out the Most Dangerous Uses of Methylene Chloride

The States strongly support EPA proposal to ban all consumer uses and most industrial and commercial uses of methylene chloride in accordance with section 6(a) of TSCA.⁴¹ Under TSCA section 6(a), since EPA found that methylene chloride presents an unreasonable risk of injury to health, EPA must “apply one or more of the [section 6(a)] requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk.”

As required, among other things, EPA developed a proposed regulatory action and one primary alternative regulatory action.⁴² EPA also appropriately considered several factors as required by section 6(c)(2) of TSCA in selecting the appropriate section 6(a) requirements, including (i) the effects of methylene chloride on health and the environment, (ii) the magnitude of exposure to methylene chloride of human beings and the environment, (iii) the benefits of methylene chloride for various uses, and (iv) the reasonably ascertainable economic consequences of the rule.⁴³

EPA also appropriately considered regulatory authorities under statutes administered by other agencies as well as other EPA-administered statutes in connection with section 9 of TSCA.⁴⁴ EPA also correctly found that, under section 6(c)(2)(C) of TSCA, for most of the uses of methylene chloride that EPA is proposing to prohibit, alternative products with similar costs and efficacy to methylene chloride products are generally available.⁴⁵ EPA further set proposed compliance dates in accordance with the requirements in section 6(d)(1)(B) of TSCA.⁴⁶

In sum, based on EPA’s consideration of alternatives, the broad range of work environments and activities, and the severity of the hazards of methylene chloride, EPA correctly determined that prohibition is the best way to address the

⁴⁰ 88 Fed. Reg. at 28,284.

⁴¹ *See id.* 28,298.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*; EPA, *EPA Proposes Ban on All Consumer, Most Industrial and Commercial Uses of Methylene Chloride to Protect Public Health* (Apr. 20, 2023), <https://www.epa.gov/newsreleases/epa-proposes-ban-all-consumer-most-industrial-and-commercial-uses-methylene-chloride>.

⁴⁶ *Id.*

unreasonable risk from methylene chloride driven by all consumer uses and most industrial and commercial uses.⁴⁷

B. EPA Appropriately Proposed Additional Requirements under TSCA to Address the Unreasonable Risk to Workers

EPA appropriately proposes additional requirements under TSCA to address the unreasonable occupational risks of methylene chloride to workers, including exposure limits and action levels.⁴⁸ As EPA recognizes, “Congress intended for EPA to consider occupational risks from chemicals it evaluates under TSCA[.]”⁴⁹ In turn, the risk-based requirement under section 6(a) of TSCA is “distinguishable from approaches mandated by other laws, including the Occupational Safety and Health Act (OSH Act), which includes both significant risk and feasibility (technical and economic) assessments in its rulemaking.”⁵⁰ In addition, “the great majority of OSHA’s chemical standards are outdated or do not sufficiently reduce significant risk to workers” and would be “unlikely to address unreasonable risk to workers within the meaning of TSCA[.]”⁵¹ The States agree that “it is necessary for EPA to conduct risk evaluations and, where it finds unreasonable risk to workers, develop risk management requirements for chemical substances that OSHA also regulates[.]”⁵²

C. To Comply with its TSCA Mandate, EPA’s Proposed Exemptions and Exclusions Should be Narrowly Tailored

Despite finding that methylene chloride presents an unreasonable risk of injury to health, the prohibited uses of methylene chloride would only “amount to a prohibition of an estimated 52% of annual production volume for end uses subject to TSCA.”⁵³ As a result, EPA has not eliminated the unreasonable risk of methylene chloride, including the risk faced by communities at the fenceline of facilities that use methylene chloride.

Fenceline communities are a “potentially exposed or susceptible subpopulation” under TSCA and EPA must eliminate the unreasonable risk that this subpopulation faces. 15 U.S.C. § 2602(4). In addition, as fenceline communities are often environmental justice communities, EPA’s failure to protect

⁴⁷ See 88 Fed. Reg. at 28,307.

⁴⁸ *Id.* at 28,290.

⁴⁹ *Id.* at 28,287.

⁵⁰ *Id.* (quoting 15 U.S.C. § 2605(a)).

⁵¹ *Id.* at 28,288.

⁵² *Id.* at 28,289.

⁵³ EPA, *Risk Management for Methylene Chloride*, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride>.

this subpopulation also undermines the Biden administration commitment to environmental justice.⁵⁴

To manage the unreasonable risks of methylene chloride, EPA should phase out as many uses of the chemical as possible. Only if these uses cannot be phased out, may EPA grant time-limited exemptions in accordance with TSCA section 6(g). In the proposed rule, however, EPA proposes exemptions and exclusions that do not comport with TSCA section 6(g).

For example, EPA proposes an exemption under section 6(g)(1)(B) of TSCA for the civil aviation sector's use for paint and coating removal for 10 years to alleviate concerns of disrupting national security and critical infrastructure.⁵⁵ However, EPA's proposed exemption appears to be based on unsupported assertions of the Aerospace Industries Association and Boeing.⁵⁶

EPA also proposes an exemption under section 6(g)(1)(A) of TSCA for the National Aeronautics and Space Administration (NASA) to continue to use methylene chloride in emergencies.⁵⁷ However, NASA has not identified a "specific condition of use ... for which no technically or economically safer alternative is available." 15 U.S.C. § 2605(g)(1)(A).

EPA further proposes generally allowing the continued use of methylene chloride for the production of hydrofluorocarbon-32 (HFC-32), without satisfying the requirements of TSCA section 6(g).⁵⁸ According to EPA, this continued use would support its work to reduce hydrofluorocarbons under the American Innovation and Manufacturing Act of 2020.⁵⁹

Although EPA would require the civil aviation sector, NASA, and manufacturers of HFC-32 to follow a workplace chemical protection program for the continued use of methylene chloride,⁶⁰ EPA's proposal will allow many uses of methylene chloride to continue for at least another 10 years. Furthermore, the WCPP would not protect fence-line communities.

Given the documented extreme and unreasonable risk associated with methylene chloride exposures, EPA should exercise its authority to further limit the

⁵⁴ See Executive Order on Revitalizing Our Commitment to Environmental Justice for All (Apr. 21, 2023), <https://www.whitehouse.gov/briefing-room/presidential-actions/2023/04/21/executive-order-on-revitalizing-our-nations-commitment-to-environmental-justice-for-all/>.

⁵⁵ 88 Fed. Reg. at 28,309.

⁵⁶ *Id.* at 28,312-13.

⁵⁷ *Id.* at 28,311.

⁵⁸ *Id.* at 28,286.

⁵⁹ *Id.*

⁶⁰ *Id.* at 28,298.

proposed rule's exemptions and exclusions to meet its statutory mandate to address the risks presented by exposures to methylene chloride.

VI. Conclusion

For the foregoing reasons, we urge EPA to finalize a risk management rule under section 6(a) of TSCA that bans all consumer uses and most industrial and commercial uses of methylene chloride. We further urge EPA to narrow the proposed rule's exemptions and exclusions as much as possible consistent with the position set forth above.

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