

THE ATTORNEYS GENERAL OF NEW YORK, HAWAII, ILLINOIS,
MARYLAND, MASSACHUSETTS, MINNESOTA, OREGON,
PENNSYLVANIA, VERMONT, AND WASHINGTON, AND THE
CORPORATION COUNSEL OF THE CITY OF NEW YORK

September 8, 2023

Via Electronic Filing

**EPA-HQ-OPPT-2022-0905
EPA-HQ-OPPT-2016-0723**

Michael Regan, Administrator
U.S. Environmental Protection Agency
Office of Pollution Prevention & Toxics
1200 Pennsylvania Avenue, NW
Mail Code 7401-M
Washington, D.C. 20460

Re: *1,4-Dioxane; Draft Supplement to the TSCA Risk Evaluation; Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Meeting and Request for Comment, 88 Fed. Reg. 43,562 (July 10, 2023)*

1,4-Dioxane; Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment, 88 Fed. Reg. 48,249 (July 26, 2023)

Dear Administrator Regan:

The Attorneys General of New York, Hawai'i, Illinois, Maryland, Massachusetts, Minnesota, Oregon, Pennsylvania, Vermont, and Washington, and the Corporation Counsel of the City of New York submit these comments regarding the U.S. Environmental Protection Agency's ("EPA") draft supplement to the risk evaluation for 1,4-dioxane ("Draft Supplement")¹ and draft revision to the risk determination for 1,4-dioxane ("Draft Revision")² under section 6 of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2601.

1,4-dioxane is a widely used toxic chemical and is one of the 10 chemicals

¹ EPA, *Draft Supplement to the Risk Evaluation for 1,4-Dioxane* (July 2023), <https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0905-0027>.

² EPA, *1,4-Dioxane Draft Revised Unreasonable Risk Determination* (July 2023), <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0723-0104>.

that are subject of EPA’s initial chemical risk evaluations.³ Among its many uses, 1,4-dioxane is used as a solvent in a variety of commercial and industrial applications, including in the manufacture of other chemicals; a processing aid; a laboratory chemical; and an ingredient in adhesives and sealants.⁴ 1,4-dioxane is also present as a byproduct from the breakdown of other chemicals in a variety of consumer products, including detergents, household cleaners, and personal care products.⁵ As EPA appropriately recognizes, the risks to human health and the environment from 1,4-dioxane are widespread, with the chemical being found in various environmental media such as air, water, and land.⁶ Exposure to 1,4-dioxane poses serious health risks, including the risks of liver and kidney toxicity, adverse effects in the membranes in the nose that affect the sense of smell, and cancer.⁷ Thus, careful analysis based in sound science followed by strict regulation of this dangerous chemical are of paramount importance.

In the Draft Supplement, EPA considered critical exposure pathways that it did not previously assess in its initial December 2020 risk evaluation for 1,4-dioxane (“December 2020 Risk Evaluation”), including 1,4-dioxane as a byproduct in industrial processes and commercial products and risks to the general population from releases of 1,4-dioxane to surface water, groundwater, air, and land. However, in the Draft Supplement, EPA understated or failed to consider certain other exposure pathways of 1,4-dioxane, including through drinking water contaminated by down-the-drain releases of consumer and commercial products that contain 1,4-dioxane as a byproduct, and drinking water contaminated by leaching from landfills.

In the Draft Revision, EPA appropriately considered 1,4-dioxane as a “whole chemical,” rather than on a condition of use-specific basis and justifiably determined that 1,4-dioxane as “a whole chemical” presents an unreasonable risk of injury to human health under its current conditions of use. In the December 2020 Risk Evaluation, EPA improperly made unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation. The

³ See 15 U.S.C. § 2605(b)(2)(A), requiring EPA promptly to initiate risk evaluations on ten chemical substances drawn from the agency’s *TSCA Work Plan for Chemical Assessments: 2014 Update*, https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf, and publish the list within 180 days after June 22, 2016. The initial 10 TSCA chemicals are: Asbestos, 1-Bromopropane, 1,4-Dioxane, Carbon Tetrachloride, Cyclic Aliphatic Bromide Cluster (HBCD), Methylene Chloride, N-Methylpyrrolidone (NMP), Pigment Violet 29, Perchloroethylene (PERC), and Trichloroethylene (TCE). See *Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act*, 81 Fed. Reg. 91,927 (Dec. 19, 2016).

⁴ 88 Fed. Reg. at 48,251; *id.* at 43,563.

⁵ 88 Fed. Reg. at 48,251; *id.* at 43,564.

⁶ 88 Fed. Reg. at 48,251; *id.* at 43,564.

⁷ *Id.* at 48,251; see EPA IRIS (2013), <https://iris.epa.gov/static/pdfs/0326tr.pdf>.

Draft Revision, if finalized, would appropriately supersede the condition of use-specific no unreasonable risk determinations in the December 2020 Risk Evaluation.

To meet its obligations under TSCA section 6(a), we urge EPA to finalize the Draft Supplement and Draft Revision for 1,4-dioxane and in addition, expeditiously propose an additional rule that addresses *all* the unreasonable risk presented by 1,4-dioxane, including those that the agency previously failed to acknowledge or fully address.

I. 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.”⁸ 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.”⁹

In enacting TSCA, Congress concluded that the existing regulatory framework for toxic chemicals was too “fragmented” and “inadequate” to address the health and environmental risks posed by toxic chemicals.¹⁰ 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.”¹¹ TSCA was designed to, among other things, give EPA “the authority to look at the hazards in total.”¹² 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.¹³

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.”¹⁴ EPA was authorized to impose restrictions on a chemical only “to

⁸ 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).

⁹ S. Rep. No. 94-698, at 3.

¹⁰ See H.R. Rep. No. 94-1341, at 6 (1976).

¹¹ S. Rep. No. 94-698, at 2.

¹² *Id.*

¹³ *Safer Chems.*, 943 F.3d at 406.

¹⁴ Pub L. No. 94-469, § 6(a), 90 Stat. 2003, 2020 (1976).

the extent necessary to protect adequately against such risk using the least burdensome requirements.”¹⁵

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.”¹⁶ 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 TSCA section 6. 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.”¹⁷ 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.¹⁸

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.¹⁹ 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.²⁰ In December 2016, EPA published its initial list of 10 such high-priority chemical substances, which included 1,4-dioxane.

During the second stage—the “risk evaluation” stage—EPA must determine whether a chemical “presents an unreasonable risk of injury to health or the

¹⁵ *Id.*

¹⁶ S. Rep. No. 114-67, at 2 (2015); *see also Safer Chems.*, 943 F.3d at 407 (summarizing EPA difficulties implementing TSCA).

¹⁷ 15 U.S.C. § 2605(a).

¹⁸ *See id.*; H. Rep. No. 114-176, at 23 (2015).

¹⁹ *See* 15 U.S.C. § 2605(b); H. Rep. No. 114-176, at 23-25.

²⁰ *See* EPA, TSCA Work Plan Chemicals, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals#select>; *see also* 15 U.S.C. § 2605(b)(1); 40 C.F.R. §§ 702.1-702.17.

environment, without consideration of costs or other nonrisk factors.”²¹ 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.”²² 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.”²³ 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 population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.”²⁴

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.”²⁵ EPA is not permitted to consider “costs or other nonrisk factors,”²⁶ 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.²⁷ By precluding EPA from considering “costs or other nonrisk factors,” Congress sought to address shortcomings under the original TSCA provisions, 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.”²⁸

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.²⁹

The second component requires EPA to analyze “available information” on the hazards and exposures, “including information that is relevant to specific risks

²¹ 15 U.S.C. § 2605(b)(4)(A).

²² *Id.*

²³ *Id.* § 2602(4).

²⁴ *Id.* § 2602(12).

²⁵ *Id.* § 2625(i), (h), and (k); 40 C.F.R. § 702.33.

²⁶ *See id.* § 2605(b)(4)(F).

²⁷ *See* S. Rep. 114-67, at 17.

²⁸ *Id.* at 4.

²⁹ *See* 15 U.S.C. § 2605(b)(4)(D).

of injury to health or the environment.”³⁰ 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.³¹ EPA must also identify the likely duration, intensity, frequency, and number of exposures to a chemical under the known and expected conditions of use.³² And the agency must consider chemical-specific factors, including how the chemical moves through the environment and interacts with ecological receptors.³³ EPA must then integrate and assess the reasonably available information on hazard and exposure.³⁴

In the third component of the risk evaluation, EPA must determine whether the chemical presents an unreasonable risk to health or the environment.³⁵ A determination that a chemical poses no unreasonable risk ends the TSCA process and is deemed “final agency action” subject to judicial review.³⁶ 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.³⁷

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.³⁸

When proposing or promulgating any risk management 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.³⁹

³⁰ 15 U.S.C. § 2605(b)(4)(F); *see* 40 C.F.R. § 702.41(a), (d), (e).

³¹ *See* 15 U.S.C. § 2605(b)(4)(F); 40 C.F.R. § 702.41(d).

³² *See* 15 U.S.C. § 2605(b)(4)(F); 40 C.F.R. § 702.41(e)(1).

³³ *See* 40 C.F.R. § 702.41(e).

³⁴ *See* 15 U.S.C. § 2605(b)(4)(F)(i); 40 C.F.R. § 702.43.

³⁵ *See* 15 U.S.C. § 2605(b)(4)(A); 40 C.F.R. § 702.47.

³⁶ *See* 15 U.S.C. §§ 2605(i)(1), 2618(a)(1)(A).

³⁷ *See* 15 U.S.C. § 2605(a); 40 C.F.R. § 702.49(c).

³⁸ *See* 15 U.S.C. § 2605(a).

³⁹ 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 ban or restriction and whether a technically and economically feasible alternative will be available when the ban or restriction is in place.⁴⁰ 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.⁴¹

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.⁴² The risk management measures adopted by EPA, along with the unreasonable risk determination, are subject to judicial review.⁴³

II. The Severe Health Risks Posed by 1,4-Dioxane and Actions Taken by the States

Exposure to 1,4-dioxane poses serious health risks, including the risks of liver and kidney toxicity, adverse effects in the membranes in the nose that affect the sense of smell, and cancer.⁴⁴

Despite its toxicity, 1,4-dioxane—a clear liquid that easily dissolves in water—is widely used as a solvent in the manufacture of chemicals and as a laboratory reagent.⁴⁵ 1,4-dioxane is also formed as a byproduct during the production of certain types of surfactants used in personal care and cleaning products.⁴⁶ 1,4-dioxane is also a trace contaminant of some chemicals used in cosmetics, detergents, and shampoos.⁴⁷ Historically, 90% of all 1,4-dioxane was

⁴⁰ 15 U.S.C. §§ 2605(c)(2)(B) and 2605(c)(2)(C).

⁴¹ 15 U.S.C. § 2605(d).

⁴² 15 U.S.C. § 2605(c)(1)(C).

⁴³ *See id.* §§ 2605(i)(2), 2618(a)(1)(A).

⁴⁴ 88 Fed. Reg. at 48,251; *see* EPA IRIS (2013), <https://iris.epa.gov/static/pdfs/0326tr.pdf>.

⁴⁵ Agency for Toxic Substances and Disease Registry, *Toxicological Profile for 1,4-Dioxane*, at 1 (Apr. 2012), <https://www.atsdr.cdc.gov/toxprofiles/tp187.pdf>; Agency for Toxic Substances and Disease Registry, *1,4-Dioxane ToxFAQs*, CAS # 123-91-1, at 1 (Apr. 2012), <https://www.atsdr.cdc.gov/toxfaqs/tfacts187.pdf>.

⁴⁶ *See* EPA, *Draft Risk Evaluation for 1,4-Dioxane*, at 6 (June 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0011>.

⁴⁷ Problem Formulation at 22.

used as a stabilizer for chlorinated solvents, especially 1,1,1-trichloroethane (TCA).⁴⁸

1,4-dioxane can be released into the air, water, and soil in locations where it is produced or used as a solvent.⁴⁹ The physical and chemical properties and behavior of 1,4-dioxane create challenges for its characterization and treatment.⁵⁰ In air, 1,4-dioxane rapidly breaks down into different compounds.⁵¹ In water, 1,4-dioxane is stable and does not break down.⁵² In soil, 1,4-dioxane does not stick to soil particles and can rapidly move from soil into groundwater.⁵³

1,4-dioxane is likely present at many sites contaminated with certain chlorinated solvents.⁵⁴ As of 2016, 1,4-dioxane had been identified at more than 34 hazardous waste sites on the EPA National Priorities List and may also be present at many other sites.⁵⁵ Moreover, 1,4-dioxane has been found in groundwater at sites throughout the United States.⁵⁶ EPA lists 1,4-dioxane on EPA's Contaminant Candidate List under the Safe Drinking Water Act ("SDWA"),⁵⁷ meaning that 1,4-dioxane is of potential concern in public water systems.⁵⁸

Currently, there is no National Primary Drinking Water Regulation for 1,4-dioxane under the SDWA.⁵⁹ 1,4-dioxane is currently listed on EPA's Fifth Contaminant Candidate List and was subject to occurrence monitoring in public water systems under the third Unregulated Contaminants Monitoring Rule

⁴⁸ Agency for Toxic Substances and Disease Registry, *Toxicological Profile for 1,4-Dioxane*, at 159 (Apr. 2012), <https://www.atsdr.cdc.gov/toxprofiles/tp187.pdf>.

⁴⁹ Agency for Toxic Substances and Disease Registry, *1,4-Dioxane ToxFAQs*, CAS # 123-91-1, at 1 (Apr. 2012), <https://www.atsdr.cdc.gov/toxfaqs/tfacts187.pdf>.

⁵⁰ EPA, *Technical Fact Sheet-1,4-Dioxane*, at 1 (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffrro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

⁵¹ Agency for Toxic Substances and Disease Registry, *1,4-Dioxane ToxFAQs*, CAS # 123-91-1, at 1 (Apr. 2012), <https://www.atsdr.cdc.gov/toxfaqs/tfacts187.pdf>.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ EPA, *Technical Fact Sheet-1,4-Dioxane*, at 1 (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffrro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

⁵⁵ *Id.* at 2.

⁵⁶ *Id.* at 1.

⁵⁷ 42 U.S.C. §§ 300f *et seq.*

⁵⁸ Problem Formulation, at 43; EPA, *Contaminant Candidate List (CCL) and Regulatory Determination*, <https://www.epa.gov/ccl/ccl-5-chemical-contaminants>.

⁵⁹ Problem Formulation at 43.

(“UCMR3”).⁶⁰ EPA uses the Unregulated Contaminant Monitoring Rule program to collect data for contaminants suspected to be present in drinking water, but that do not have health-based standards set under the SDWA.⁶¹ Under UCMR 3, water systems were monitored for 1,4-dioxane during 2013-2015.⁶² Of the 4,915 water systems monitored, 1,077 systems had detections of 1,4-dioxane in at least one sample.⁶³ To aid in evaluation of UCMR 3 data, EPA provides a health reference range of 0.35 to 35 µg/L for 1,4-dioxane based on a lifetime cancer risk range of 1 in one million (10-6) to 1 in ten thousand (10-4).⁶⁴ In UCMR 3, 341 systems (6.9%) had results at or above 0.35 µg/L (which corresponds to a one-in-a-million-lifetime cancer risk).⁶⁵

As but one example of the scope of exposure risks from drinking water, according to a recent report by the New York Public Interest Research Group, at least 12 million New Yorkers drink water with some level of 1,4-dioxane contamination.⁶⁶ In particular, 1,4-dioxane has been detected in Long Island’s groundwater, which is the sole source of drinking water for almost three million Long Island residents.⁶⁷ Testing data gathered from 2013–2015 in compliance with UCMR 3 indicated the presence of 1,4-dioxane in many water systems on Long Island in exceedance of 0.35 µg/L.⁶⁸ EPA data from 2013 and 2014 showed that 40 public water supplies in New York contained 1,4-dioxane and that 31 of these water supplies are located on Long Island.⁶⁹ Suffolk County Water Authority data

⁶⁰ *Id.*

⁶¹ See EPA, *The Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary, January 2017* (Jan. 2017), <https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf>.

⁶² Problem Formulation at 43.

⁶³ *Id.*

⁶⁴ EPA, *Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary* (Jan. 2017), <https://www.epa.gov/sites/default/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf>.

⁶⁵ *Id.*

⁶⁶ New York Public Interest Research Group, *Emerging Contaminants in New York’s Drinking Water Systems: What’s In My Water?* (May 2019), https://www.nypirg.org/pubs/201905/Whats_in_my_water_2019.pdf; *Where 1, 4-Dioxane has Turned Up in Drinking Water*, *Newsday* (Feb 9, 2019), <https://projects.newsday.com/databases/long-island/dioxane-in-drinking-water/>.

⁶⁷ See EPA, *The Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary, January 2017* (Jan. 2017), <https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf>; EPA, *Sole Source Aquifers for Drinking Water*, <https://www.epa.gov/dwssa>.

⁶⁸ *Id.*

⁶⁹ Suffolk County Department of Health Services, *1,4-Dioxane in our Water Resources – Fact Sheet* (June 2015), [https://www.suffolkcountyny.gov/Portals/0/FormsDocs/Health/WWM/Dioxane%20fact%20sheet%206-19-15%20\(4\).pdf](https://www.suffolkcountyny.gov/Portals/0/FormsDocs/Health/WWM/Dioxane%20fact%20sheet%206-19-15%20(4).pdf).

indicate that 1,4-dioxane was detected in approximately 272 public water supply wells in the county, or roughly 40% of their wells sampled from January 2013 through October 2014.⁷⁰ 1,4-dioxane has also been found in 16 of the 28 public water supply wells in Nassau County's Town of Hempstead.⁷¹

In New Jersey, in data from UCMR 3, 1,4-dioxane was detected above the reporting level of 0.07 µg/L in 80 (46%) of the 174 public water systems that were tested, and it was detected above the health reference concentration for a one in a million lifetime cancer risk level of 0.35 µg/L in 30 (17%) of the 174 water systems.⁷²

The states have taken various actions to protect against the dangers of 1,4-dioxane.⁷³ For example, in December 2019, New York limited the permissible amount of 1,4-dioxane in household cleaning, cosmetics, and personal care products.⁷⁴ As a byproduct of the manufacturing process, 1,4-dioxane is not listed on product labels as an ingredient, making it difficult for consumers to know whether a product is contaminated with 1,4-dioxane.⁷⁵ According to independent testing conducted by Citizens Campaign for the Environment, 1,4-dioxane was found in 65 out of 80 products, including shampoos, body washes, baby products, laundry detergents, and hand and dish soaps.⁷⁶ As a result, the chemical could in turn end up in household wastewater, which may ultimately pollute groundwater.⁷⁷

⁷⁰ *Id.*

⁷¹ See EPA, *The Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary, January 2017* (Jan. 2017), <https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf>; Citizens Campaign for the Environment, *Lawsuits Over 1,4 Dioxane in Long Island Drinking Water Pile Up* (Oct. 16, 2019), <https://www.citizenscampaign.org/whats-new-at-cce/lawsuits-over-1-4-dioxane-in-long-island-drinking-water-pile-up>.

⁷² See New Jersey Drinking Water Quality Institute Health Effects Subcommittee, *Health-Based Maximum Contaminant Level Support Document 1,4-Dioxane*, at 20 (Sept. 24, 2021), <https://www.state.nj.us/dep/watersupply/pdf/14dioxane-rec-sum-appendixa.pdf>.

⁷³ See, e.g., *Draft Risk Evaluation for 1,4-Dioxane*, at 195 (June 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0011>.

⁷⁴ See N.Y. Env'tl. Conserv. L. §§ 35-0105, 37-0115, 71-3703; see also N.Y. State Dep't of Env'tl Conserv., *1,4-Dioxane Limits for Household Cleansing, Personal Care, and Cosmetic Products*, <https://www.dec.ny.gov/chemical/121658.html>.

⁷⁵ Quint Nigro, *Yale Researchers Seek Participants for Study of 1,4-Dioxane in Long Island Drinking Water* (Aug. 11, 2023), <https://riverheadlocal.com/2023/08/11/yale-researchers-seek-participants-for-study-of-14-dioxane-in-long-island-drinking-water>.

⁷⁶ Citizens Campaign for the Environment, *Shopping Safe: The 2019 Consumer Shopping Guide, Protecting your Household from 1,4-Dioxane Exposure* (2019), <https://static1.squarespace.com/static/5b72eb5b8ab7222baffc8dbb/t/5c9a8745ee6eb01dd7c77d5e/1553631051532/FINAL319+The+2019+Consumer+Shopping+Guide+.pdf>.

⁷⁷ Quint Nigro, *Yale Researchers Seek Participants for Study of 1,4-Dioxane in Long Island Drinking*

As of Dec. 31, 2022, New York established a maximum allowable concentration of 2 parts per million of 1,4-dioxane for household cleansing and personal care products.⁷⁸ On December 31, 2023, the maximum allowable concentration will be reduced to one part per million.⁷⁹ New York also established a maximum concentration level of 10 parts per million for cosmetics as of Dec. 31, 2022.⁸⁰ The New York Department of Environmental Conservation granted temporary waivers to 1,471 consumer products with concentrations of 1,4-dioxane higher than the 2 parts per million currently allowed by state law, revealing the widespread presence of the chemical.⁸¹

In July 2020, New York also adopted a maximum contaminant level for 1,4-dioxane in drinking water.⁸² Since enactment of the maximum contaminant level, numerous water purveyors on Long Island have installed and are piloting water treatment technologies to reduce 1,4-dioxane concentrations in the water they provide to their customers.⁸³ And in Massachusetts, the Department of Environmental Protection's Office of Research and Standards has set a 1,4-dioxane drinking water guideline at of 0.3 µg/L.⁸⁴

Furthermore, the New York Department of Environmental Conservation is undertaking a rulemaking to require manufacturers of domestic and commercial

Water (Aug. 11, 2023), <https://riverheadlocal.com/2023/08/11/yale-researchers-seek-participants-for-study-of-14-dioxane-in-long-island-drinking-water>.

⁷⁸ See N.Y. State Dep't of Env'tl Conserv., *1,4-Dioxane Limits for Household Cleansing, Personal Care, and Cosmetic Products*, <https://www.dec.ny.gov/chemical/121658.html>.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ Quint Nigro, *Yale Researchers Seek Participants for Study of 1,4-Dioxane in Long Island Drinking Water* (Aug. 11, 2023), <https://riverheadlocal.com/2023/08/11/yale-researchers-seek-participants-for-study-of-14-dioxane-in-long-island-drinking-water>; See also Lisa L. Colangelo, *Products with Likely Carcinogens in Homes; Despite New Limits, State Grants More than 1,400 Waivers* (Apr. 24, 2023), <https://www.newsday.com/news/health/waiver-1-4-dioxane-household-products-xik22eop>.

⁸² 10 N.Y.C.R.R. § 5-1.52; see also New York State Department of Health, *Public Water Systems and NYS Drinking Water Standards for PFAS and Other Emerging Contaminants*, https://www.health.ny.gov/environmental/water/drinking/emerging_pfas_publicwater.htm#:~:text=N ew%20York's%20drinking%20water%20standards.for%201%2C4%2Ddioxane.

⁸³ See, e.g., David M. Schwartz, *Bethpage Gets LI's Second 1,4-Dioxane Treatment System at a Cost of \$4M* (Oct. 24, 2019), <https://www.newsday.com/long-island/environment/1-4-dioxane-online-bethpage-water-district-y86844>.

⁸⁴ Massachusetts Department of Environmental Protection Office of Research and Standards, *Standards and Guidelines for Contaminants in Massachusetts Drinking Water* (2020), <https://www.mass.gov/guides/drinking-water-standards-and-guidelines#-standards>.

cleaning products to make available information regarding the ingredients in these products, including 1,4-dioxane.⁸⁵

In addition, in 2020, New York enacted the New York's Child Safe Products Act (S.501-B),⁸⁶ requiring New York's Department of Environmental Conservation to consider 1,4-dioxane and a host of other chemicals in promulgating a list of "chemicals of concern." Then, the law requires a manufacturer who offers a children's product for sale or distribution in New York to file a report with the department identifying any chemical of concern or high-priority chemical present at or above practical quantification limits.⁸⁷ The reports are due twelve months after a chemical of concern or high-priority chemical appears on the department's list.⁸⁸ The department is in the process of developing regulations to implement the law.⁸⁹

III. EPA's Risk Evaluation for 1,4-Dioxane

A. EPA's Risk Evaluation and Risk Determinations

In May 2018, EPA published the problem formulation for 1,4-dioxane ("Problem Formulation"), which excluded consumer uses from the scope of the risk evaluation.⁹⁰ On August 3, 2018, the Attorneys General of 10 states and the District of Columbia submitted comments to EPA identifying deficiencies in the Problem Formulation.⁹¹ In those comments, the Attorneys General identified, among other deficiencies, that EPA's 1,4-dioxane formulation ignored significant exposure pathways for the chemical, an approach contradicting TSCA's plain language and Congress' intent that EPA's risk evaluations assess the human health and environmental risk posed by each chemical comprehensively.

In June 2019, EPA published the draft risk evaluation for 1,4-dioxane, which did not rectify the deficiencies pointed out by the Attorneys General and other

⁸⁵ New York State Department of Environmental Conservation, *Household Cleansing Product Information Disclosure Program*, <https://www.dec.ny.gov/chemical/109021.html>.

⁸⁶ <https://legislation.nysenate.gov/pdf/bills/2019/S501B>.

⁸⁷ N.Y. Env't'l Conserv. L. § 37-0907.

⁸⁸ *Id.*

⁸⁹ New York State Department of Environmental Conservation, *DEC: Several New Requirements Taking Effect for 2023 to Protect Consumers from Harmful Chemicals* (Dec. 30, 2022), <https://www.dec.ny.gov/press/126880.html>.

⁹⁰ *Problem Formulation of the Risk Evaluation for 1,4-Dioxane*, at 18 (May 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0064>.

⁹¹ Comments of the Attorneys General of Massachusetts, California, Hawaii, Maine, Maryland, New Jersey, New York, Oregon, Vermont, Washington, and the District of Columbia (Aug. 3, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0090>. By electronic filing in the EPA docket HQ-OPPT-2016-0732, the Attorney General of Rhode Island joined the comments (Aug. 15, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0096>.

commentators, leading to a serious understatement of the risk posed by 1,4-dioxane (“Draft Risk Evaluation”).⁹² Numerous commenters reiterated those deficiencies in comments submitted to EPA on the Draft Risk Evaluation.⁹³

In July 2019, the American Cleaning Institute and the Grocery Manufacturers Association, reversing their previous position, urged that EPA expand the scope of the risk evaluation to include 1,4-dioxane’s presence as a byproduct as a condition of use to block “likely inconsistent” state-level regulations on the chemical’s presence as a byproduct in consumer products.⁹⁴

On November 20, 2020, EPA published, on short notice, a supplemental analysis to the Draft Risk Evaluation. EPA did not revise its analysis to rectify the numerous deficiencies previously identified by the Attorneys General and others. Rather, the supplemental analysis expanded the scope of the Draft Risk Evaluation in line with the urgings of the American Cleaning Institute and the Grocery Manufacturers Association, adding to the evaluation eight consumer uses where 1,4-dioxane is present as a byproduct, including surface cleaners, laundry/dishwashing detergents, and paint/floor lacquer. The supplemental analysis also assessed exposure to the general population from 1,4-dioxane in surface water. EPA preliminarily found no unreasonable risk to consumers from the eight conditions of use assessed. EPA also preliminarily found no unreasonable risks to the general population from exposure to 1,4-dioxane under any of the conditions of use.

On December 10, 2020, the Attorneys General of 15 states and the District of Columbia and the Corporation Counsel of the City of New York submitted comments to EPA identifying problems with the supplemental analysis and Draft Risk Evaluation (the “AG Supplemental Analysis Comments”).⁹⁵ The AG Supplemental Analysis Comments noted, among other deficiencies, that EPA failed to evaluate general population exposures and other exposure pathways purportedly addressed under other statutes administered by EPA, EPA failed to evaluate the

⁹² See EPA, *Draft Risk Evaluation for 1,4-Dioxane* (June 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0011>.

⁹³ See, e.g., Comments of Earthjustice and the Occupational Safety & Health Law Project (Aug. 30, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0046>; Comments of Environmental Defense Fund (Aug. 30, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0058>.

⁹⁴ Comments of the American Cleaning Institute and Grocery Manufacturers Association (July 29, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0030>.

⁹⁵ Comments of the Attorneys General of New York, Hawai‘i, Illinois, Maine, Maryland, Massachusetts, Minnesota, Oregon, New Jersey, North Carolina, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, and the District of Columbia, and the Corporation Counsel of the City of New York (Dec. 10, 2020), <https://www.regulations.gov/comment/EPA-HQ-OPPT-2019-0238-0085>. The AG Supplemental Comments are attached hereto as Exhibit A and incorporated by reference.

risk of 1,4-dioxane on relevant subpopulations, EPA understated the risk of 1,4-dioxane in other ways, including by failing to aggregate exposures under the conditions of use for consumers and the general population and by discounting the risk to workers on the assumptions that workers will use personal protective equipment (“PPE”) and that the PPE will protect against 1,4-dioxane exposure, and EPA failed to subject the supplemental analysis to peer review and adequate notice and comment.

In December 2020, EPA published the December 2020 Risk Evaluation.⁹⁶ In the December 2020 Risk Evaluation, EPA found unreasonable risks to workers and occupational non-users from 13 conditions of use.⁹⁷ EPA found no unreasonable risks to the environment, consumers, bystanders, or the general population.⁹⁸

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

On March 22, 2021, a group of States and one municipality timely filed a petition for review of EPA’s “no unreasonable risk” determinations in the United States Court of Appeals for the Ninth Circuit.⁹⁹ On April 29, 2021, the petition was consolidated with four other petitions for review of the same EPA action.¹⁰⁰

On June 8, 2021, EPA filed a motion for voluntary remand in these consolidated proceedings to allow EPA to reconsider its no-unreasonable-risk determinations and to request remand without vacatur of the challenged determinations.¹⁰¹

On June 30, 2021, EPA “announced important policy changes surrounding risk evaluations issued under the Toxic Substances Control Act,” acknowledging that during the prior Presidential administration the agency erred in excluding several pathways of exposure, leading to a failure to address risks to potentially exposed or susceptible subpopulations, including fenceline communities.¹⁰² 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

⁹⁶ See *1,4-Dioxane; Final Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability*, 86 Fed. Reg. 1,495 (Jan. 8, 2021).

⁹⁷ EPA, *Final Risk Evaluation for 1,4 Dioxane* at 35-36 (Dec. 2020), <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0092>.

⁹⁸ *Id.* at 30.

⁹⁹ See *State of New York v. EPA*, No. 21-70684 (9th Cir. 2021), ECF No. 1.

¹⁰⁰ See *Environmental Defense Fund, et al. v. EPA*, No. 21-70162 (9th Cir. 2021), ECF No. 13 (consolidated with Case Nos. 21-70194, 21-70684, 21-70727, 21-70930).

¹⁰¹ *State of New York v. EPA*, No. 21-70684, ECF No. 19.

¹⁰² 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>.

exposures.¹⁰³

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.¹⁰⁴ 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."¹⁰⁵

On August 10, 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.¹⁰⁶ 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.¹⁰⁷

C. EPA's Draft Supplement to the Risk Evaluation and Revised Risk Determination

In July 2023, EPA published the Draft Supplement to consider critical exposure pathways not previously assessed.¹⁰⁸ EPA stated that it conducted this supplemental analysis because, contrary to the law's requirement for TSCA risk evaluations to be carried out on the "chemical substance" under the conditions of use, the December 2020 Risk Evaluation excluded certain known human exposure pathways that are important to understanding the health implications of exposure to 1,4-dioxane.¹⁰⁹

Specifically, the Draft Supplement includes evaluation of additional conditions of use in which 1,4-dioxane is present as a byproduct in industrial processes and commercial products and evaluates risks from general population exposures to 1,4-dioxane released to ambient surface water and groundwater,

¹⁰³ *Id.*

¹⁰⁴ See Comment of 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>.

¹⁰⁵ 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).

¹⁰⁶ *State of New York v. EPA*, No. 21-70684, ECF No. 30.

¹⁰⁷ *Id.*

¹⁰⁸ 88 Fed. Reg. at 43,564.

¹⁰⁹ Draft Supplement at 19.

ambient air, and land.¹¹⁰ The Draft Supplement will be subject to peer review during the Science Advisory Committee on Chemicals' meeting scheduled for September 2023.¹¹¹

Also in July 2023, EPA also published the Draft Revision, determining that 1,4-dioxane, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use.¹¹² In the December 2020 Risk Evaluation, EPA made condition of use-specific no unreasonable risk determinations and failed to determine whether the whole chemical presents an unreasonable risk.¹¹³

According to EPA, the Draft Revision considers the occupational and consumer exposures from the December 2020 Risk Evaluation, as well as the occupational, general population, and fence-line community exposures addressed in the Draft Supplement. These include exposures that result from conditions of use where 1,4-dioxane is present due to production as a byproduct, and the risks from general population and fence-line communities' exposures to 1,4-dioxane released under the conditions of use to drinking water sourced from surface and ground water and ambient air.¹¹⁴

In addition, the Draft Revision appropriately does not reflect an assumption previously relied on by EPA that all workers always properly wear PPE.¹¹⁵ EPA recognizes that unreasonable risk may exist for subpopulations of workers that may be highly exposed because (a) they are not covered by Occupational Safety and Health Administration ("OSHA") standards, (b) their employers are out of compliance with OSHA standards, (c) 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," or (d) EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.¹¹⁶

EPA states that the Draft Revision, when finalized, would supersede the condition of use-specific no unreasonable risk determinations in the December 2020 Risk Evaluation (resulting in withdrawal of the associated order) and that the

¹¹⁰ 88 Fed. Reg. at 43,564.

¹¹¹ Draft Supplement at 20.

¹¹² 88 Fed. Reg. at 48,249.

¹¹³ *Id.* at 48,250.

¹¹⁴ *Id.*

¹¹⁵ *Id.*

¹¹⁶ *Id.*

agency would make a revised determination of unreasonable risk for 1,4-dioxane as a whole chemical substance.¹¹⁷

IV. EPA is Reasonably is Proposing to Determine that 1,4-Dioxane Presents Unreasonable Risk

A. EPA Appropriately Proposed a “Whole Chemical” Determination

In the Draft Revision, EPA correctly proposes determining that 1,4-dioxane, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use.¹¹⁸ The Attorneys General strongly support EPA’s whole chemical approach and risk determination for 1,4-dioxane for the reasons set forth in, among other things, the AG Supplemental Analysis Comments and the Opening Brief for Petitioners State of New York et al., *Neighbors for Environmental Justice, et al. v. EPA*, Case No. 20-72091, ECF No. 42 (9th Cir. Jan. 25, 2021).¹¹⁹

B. EPA Appropriately Eliminated its Assumption of PPE Use

In the Draft Revision, EPA correctly eliminated the assumption that all workers always appropriately wear PPE. EPA states that it now recognizes that unreasonable risk may exist for subpopulations of workers that may be highly exposed because (a) they are not covered by OSHA standards, (b) their employers are out of compliance with OSHA standards, (c) 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,” or (d) EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.¹²⁰ The Attorneys General strongly support EPA’s elimination of the assumption of PPE use for the reasons set forth in, among other things, the AG Supplemental Analysis Comments and the Opening Brief for Petitioners State of New York et al., *Neighbors for Environmental Justice, et al. v. EPA*, Case No. 20-72091, ECF No. 42 (9th Cir. Jan. 25, 2021).¹²¹

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 48,249.

¹¹⁹ See AG Supplemental Comments at 10-14; Opening Brief for Petitioners State of New York et al. at 30-42. The Opening Brief for Petitioners State of New York et al. is attached hereto as Exhibit B and incorporated by reference.

¹²⁰ *Id.* at 48,250.

¹²¹ See AG Supplemental Comments at 14; Opening Brief for Petitioners State of New York et al. at 43-49.

C. EPA Should Address Understated or Omitted Risks of 1,4-Dioxane During the Risk Management Process

In the Draft Revision, “EPA proposes that exposure to drinking water sourced from water that is contaminated by 1,4-dioxane released from industrial facilities contributes to the unreasonable risk from 1,4-dioxane.”¹²² However, EPA proposes that other exposures to drinking water contaminated with 1,4-dioxane, including surface water or groundwater contaminated with down-the-drain releases of consumer and commercial products that contain 1,4-dioxane as a byproduct, hydraulic fracturing releases, and leaching from landfills, do not contribute to the unreasonable risk from 1,4-dioxane.¹²³ EPA also did not consider other potential sources of drinking water contamination, including down-the-drain releases to septic fields of consumer and commercial products containing 1,4-dioxane as well as historical disposals of 1,4-dioxane.¹²⁴

The Attorneys General agree that exposure to drinking water sourced from water that is contaminated by 1,4-dioxane released from industrial facilities contributes to the unreasonable risk from 1,4-dioxane. However, the Attorneys General believe that other exposures to drinking water contaminated with 1,4-dioxane may also contribute to the unreasonable risk of 1,4-dioxane. For example, unintended spills, historic disposal practices, and industrial wastewater have been recognized as major sources of 1,4-dioxane contamination in surface water and ground water that may serve as a source of drinking water.¹²⁵ In addition, “[w]astewater can serve as a source of 1,4-dioxane contamination to both surface and groundwater used for drinking water and is also increasingly being directly or indirectly used as drinking water itself.”¹²⁶

In particular, 1,4-dioxane containing personal care and cleaning products can contaminate drinking water.¹²⁷ The use of these products generates at least two 1,4-dioxane-containing waste streams. First, solid waste (bottles with product residues) are generally sent to landfills.¹²⁸ 1,4-dioxane-containing products sent to municipal landfills can release 1,4-dioxane into landfill leachate.¹²⁹ This leachate can contaminate groundwater, especially in older landfills that lack adequate

¹²² Draft Revision at 16-19.

¹²³ *Id.*

¹²⁴ Draft Supplement at 23.

¹²⁵ Anne-Cooper Doherty, et al., *Contribution of Household and Personal Care Products to 1,4-Dioxane Contamination of Drinking Water*, Environmental Science & Health at 1 (Feb. 2023), <https://doi.org/10.1016/j.coesh.2022.100414>.

¹²⁶ *Id.*

¹²⁷ *Id.* at 2.

¹²⁸ *Id.* at 3.

¹²⁹ *Id.* at 5.

lining to prevent release of leachate to underlying groundwater.¹³⁰ Leachate may also be sent to wastewater treatment plants.¹³¹ However, standard treatment at most wastewater treatment plants do not remove 1,4-dioxane.¹³² In turn, wastewater effluent may be “released to surface water or groundwater that may then be used as a source of drinking water.”¹³³

Second, wastewater containing 1,4-dioxane may be sent down the drain and enter treatment plants.¹³⁴ Although consumer products “may not always be the dominant source of 1,4-dioxane to wastewater, they represent a constant and significant source that is difficult to address given the chemical’s persistence and ubiquity of consumer product use.”¹³⁵ This is particularly concerning because most wastewater treatment plants do not remove 1,4-dioxane, as mentioned above.¹³⁶ 1,4-dioxane from personal care and cleaning products can also enter the drinking water supply through onsite wastewater systems such as septic tanks.¹³⁷ Approximately 20% of household wastewater nationwide “is processed by septic systems and these systems are not designed to remove trace organic contaminants.”¹³⁸

Although other exposures to drinking water contaminated with 1,4-dioxane may also contribute to the unreasonable risk of 1,4-dioxane, the Attorneys General agree with EPA that “[u]nder TSCA section 6(a), EPA is not limited to regulating the specific activities found to contribute to the unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities contributing to the unreasonable risk.”¹³⁹ Since TSCA requires whole chemical risk determinations, if a chemical is determined to present unreasonable risk, then the entire chemical must be placed in risk management and EPA has broad discretion in how the agency applies TSCA’s risk management tools to eliminate that risk. 15 U.S.C. § 2605(a).

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.* at 3.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.* at 5.

¹³⁸ *Id.*

¹³⁹ Draft Revision at 6.

V. Conclusion

For the reasons set forth above, the Attorneys General urge EPA to expeditiously finalize the Draft Supplement and Draft Revision. The Attorneys General further urge EPA to promptly fulfill its obligations under TSCA by proposing and finalizing an additional risk management rule that eliminates all of 1,4-dioxane's unreasonable risks, including risks that were understated or omitted from EPA's Draft Supplement and December 2020 Risk Evaluation, as described in Section IV.C above.

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EXHIBIT A

AG Supplemental Analysis Comments

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NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND,
VERMONT, VIRGINIA, WASHINGTON, DISTRICT OF COLUMBIA, AND THE
CORPORATION COUNSEL OF THE CITY OF NEW YORK**

December 10, 2020

Via Electronic Filing

EPA–HQ–OPPT–2019–0238

Andrew Wheeler, Administrator
U.S. Environmental Protection Agency
Document Control Office (7407M)
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: *1,4-Dioxane; Supplemental Analysis to the Draft Toxic Substances Control Act (TSCA) Risk Evaluation; Notice of Availability and Public Comment, 85 Fed. Reg. 74,341 (Nov. 20, 2020)*

Dear Administrator Wheeler:

The Attorneys General of New York, Hawai‘i, Illinois, Maine, Maryland, Massachusetts, Minnesota, Oregon, New Jersey, North Carolina, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, District of Columbia, and the Corporation Counsel of the City of New York submit these comments regarding the U.S. Environmental Protection Agency’s (“EPA”) supplemental analysis to the draft risk evaluation for 1,4-dioxane, for which notice was published on November 20, 2020.¹ The chemical substance 1,4-dioxane is one of the 10 chemicals² that are the subject of EPA’s initial chemical risk evaluations required under the

¹ *Draft Risk Evaluation for 1,4-Dioxane* (June 2019) (“1,4-Dioxane Draft Risk Evaluation”), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0011>; *Draft Supplemental Analysis to the Risk Evaluation for 1,4-Dioxane* (Nov. 2020) (“1,4-Dioxane Draft Supplemental Analysis”), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0067>.

² See 15 U.S.C. § 2605(b)(2)(A), requiring EPA promptly to initiate risk evaluations on ten chemical substances drawn from the agency’s *TSCA Work Plan for Chemical Assessments: 2014 Update*, https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf, and publish the list within 180 days after June 22, 2016. The initial 10 TSCA chemicals are: Asbestos, 1-Bromopropane, 1,4-Dioxane, Carbon Tetrachloride, Cyclic Aliphatic Bromide Cluster (HBCD), Methylene Chloride, N-Methylpyrrolidone (NMP), Pigment Violet 29, Perchloroethylene (PERC), and Trichloroethylene (TCE). See *Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act*, 81 Fed. Reg. 91,927 (Dec. 19, 2016).

Frank R. Lautenberg Chemical Safety for the 21st Century Act (the “Lautenberg Act”),³ amending the Toxic Substances Control Act (“TSCA”).⁴

Our states have a significant interest in ensuring that the risk evaluation is prepared in accordance with TSCA and the EPA implementing regulations at 40 C.F.R. Part 702, Subpart B. EPA selected 1,4-dioxane as one of the initial 10 chemical substances because of its potential for substantial harm to human health and the environment.⁵ 1,4-dioxane is widely used, among other things, as a solvent in a variety of commercial and industrial applications, including in the manufacture of other chemicals, as a processing aid, a laboratory chemical, and in adhesives and sealants. 1,4-dioxane is also present as a byproduct from the breakdown of other chemicals in a variety of consumer products, including detergents, household cleaners, and personal care products. EPA recognizes that 1,4-dioxane is present in various environmental media such as air, water, and land. According to EPA, 1,4-dioxane is likely to be carcinogenic to humans.⁶ If EPA fails to fully identify the risks posed by exposures from the many uses of this chemical—as it fails to do here—the agency cannot then effectively manage the chemical substance to protect against unreasonable risk of injury to human health and the environment as TSCA requires.

In the supplemental analysis to the draft risk evaluation for 1,4-dioxane, EPA failed to correct the deficiencies that a number of state Attorneys General and other commenters identified in the 1,4-dioxane problem formulation⁷ and draft risk evaluation. Instead, EPA expanded the scope of the defective draft risk evaluation to cover eight major consumer uses, including surface cleaners, laundry/dishwashing detergents, and paint/floor lacquer. The agency found no unreasonable risk to consumers from these uses. EPA also found no unreasonable risks under any of the conditions of use to the general population from exposure to 1,4-dioxane even though EPA only examined exposure to the general population from recreational swimming in surface water. Among other deficiencies, the draft risk evaluation excludes numerous significant exposure pathways in which the general population and environment are exposed to 1,4-dioxane—such as the well-documented risks to those exposed to contaminated drinking water—thereby understating the overall risk of 1,4-dioxane exposure. Residents of low-income and communities of color may face greater exposure to 1,4-dioxane, making EPA’s failure to comply with TSCA and EPA implementing regulations particularly egregious from the perspective of environmental justice.

Accordingly, we urge that EPA withdraw the draft risk evaluation and supplemental analysis for 1,4-dioxane and re-evaluate the risks posed by this extremely toxic chemical in a manner that fully complies with the agency’s obligations under TSCA to conduct the thorough and comprehensive evaluation of all the chemical’s risks before issuing its final risk evaluation.

³ Pub. L. No. 114-182, 130 Stat. 448 (Jun. 22, 2016).

⁴ 15 U.S.C. § 2601 *et seq.*

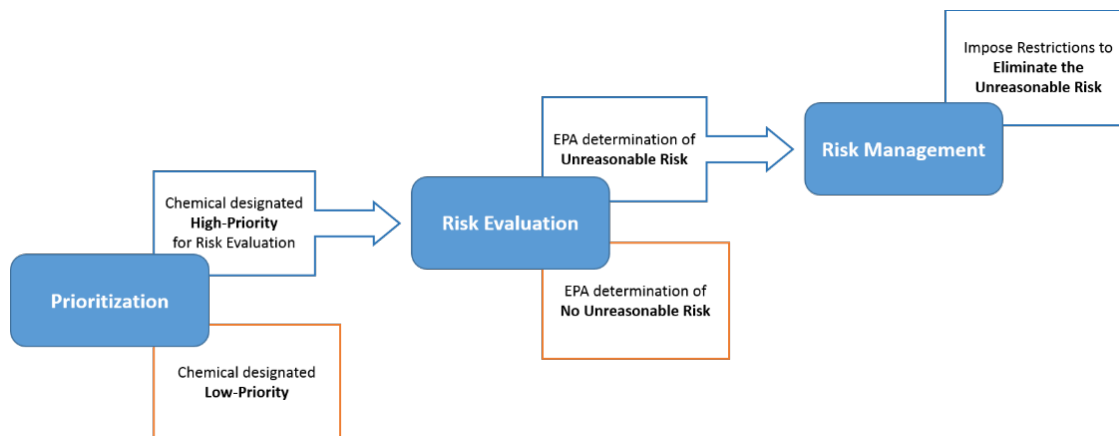
⁵ 81 Fed. Reg. 91,927.

⁶ 1,4-Dioxane Draft Risk Evaluation, at 107.

⁷ *Problem Formulation of the Risk Evaluation for 1,4-Dioxane* (May 2018) (“1,4-Dioxane Problem Formulation”), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0064>.

A. Overview of EPA’s Evaluation of the Safety of Chemicals Under TSCA

The Lautenberg Act requires EPA to evaluate the safety of existing chemicals under TSCA via three interrelated stages: (1) prioritization, (2) risk evaluation, and (3) risk management:⁸



Source: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals>.

The first stage, prioritization, consists of a process to focus EPA’s limited resources on “high-priority” chemicals, that is, chemicals with the greatest potential for risk to human health or the environment. *See* 15 U.S.C. § 2605(b)(1); 40 C.F.R. §§ 702.1-702.17.

The second stage is risk evaluation. *See* 15 U.S.C. § 2605(b)(2)-(4); 40 C.F.R. §§ 702.31-702.51. The overall purpose of a risk evaluation is to determine whether a chemical presents an unreasonable risk to human health or the environment, under the conditions of the chemical’s use, including to a potentially exposed or susceptible subpopulation. 15 U.S.C. § 2605(b)(4)(A). EPA is required to make a determination about such risk using the “best available science,” “weight of scientific evidence,” and “reasonably available information.” 15 U.S.C. § 2625(h), (i) (k); 40 C.F.R. § 702.33. EPA must not consider “costs or other nonrisk factors” in making its determination. 15 U.S.C. § 2605(b)(4)(F); 40 C.F.R. § 702.43(a)(3).

The risk evaluation stage has three linked components: (1) an initial scope document that provides the focus of the risk evaluation, including the hazards, exposures, conditions of use,⁹ and the potentially exposed or susceptible subpopulations; (2) hazard and exposure assessments, along with a risk characterization to inform the risk determination; and (3) finally, a risk determination stating whether or not a chemical presents an unreasonable risk to health or the

⁸ EPA explains how it evaluates the safety of existing chemicals at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals>.

⁹ 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.” 15 U.S.C. § 2602(4).

environment under the conditions of use. *See* 15 U.S.C. §§ 2605(b)(4)(D), 2605(b)(4)(F); 40 C.F.R. § 702.41(a)(1).

In the hazard assessment, EPA must identify hazards the chemical may cause to human health or the environment. 15 U.S.C. §§ 2605(b)(4)(F); 40 C.F.R. § 702.41(d)(2). The hazard information must be reviewed in a manner consistent with best available science and the weight of scientific evidence. 40 C.F.R. § 702.41(d)(2). Human and environmental hazards must be evaluated. 15 U.S.C. §§ 2605(b)(4)(F); 40 C.F.R. § 702.41(d)(3). The relationship between the dose of the chemical substance and the health and environmental effects must also be evaluated. 15 U.S.C. §§ 2605(b)(4)(F); 40 C.F.R. § 702.41(d)(4). The human health hazard assessment must also consider all relevant potentially exposed and susceptible subpopulations. 15 U.S.C. §§ 2605(b)(4)(F); 40 C.F.R. § 702.41(d)(7).

In the exposure assessment, EPA must identify the likely duration, intensity, frequency, and number of exposures to a chemical under the conditions of use. 15 U.S.C. §§ 2605(b)(4)(F); 40 C.F.R. § 702.41(e)(1). EPA must examine chemical-specific factors, including physical-chemical properties of the chemical at issue and how the chemical moves through the environment. 40 C.F.R. § 702.41(e)(2). Exposure information must also be reviewed in a manner consistent with best available science and weight of scientific evidence. 40 C.F.R. § 702.41(e)(3). EPA must also include a human health exposure assessment that considers potentially exposed and susceptible subpopulations. 15 U.S.C. §§ 2605(b)(4)(F); 40 C.F.R. § 702.41(e)(4). EPA must further include an environmental health exposure assessment that evaluates the interaction of the chemical with the ecological receptors and considers animal and plant populations and communities. 15 U.S.C. §§ 2605(b)(4)(F); 40 C.F.R. § 702.41(e)(5).

EPA must then formulate a risk characterization by integrating and assessing the reasonably available information on hazard and exposure. 15 U.S.C. § 2605(b)(4)(F)(i); 40 C.F.R. § 702.43. EPA must ultimately make a determination as to whether the chemical presents an unreasonable risk to health or the environment. 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 process and is subject to judicial review. 15 U.S.C. §§ 2605(i)(1), 2618(a)(1)(A).

If, at the end of the risk evaluation process, EPA determines that a chemical presents an unreasonable risk to health or the environment, the agency must immediately move to the third stage—risk management under TSCA. 15 U.S.C. § 2605(a); 40 C.F.R. § 702.49(c). EPA is required to implement, via regulation, restrictions on the manufacture, processing, distribution, use or disposal of the chemical to eliminate the unreasonable risk. 15 U.S.C. § 2605(a). EPA must provide the opportunity for public comment at each stage. *See, e.g.*, 40 C.F.R. §§ 702.7, 702.41(c)(7)(iii), 702.49(a).

B. The State and Municipal Interests in Evaluating the Risk of 1,4-Dioxane

TSCA required that EPA choose the first 10 chemicals for evaluation from the list of 90 chemical substances on the 2014 update of the TSCA Work Plan for Chemical Assessments.¹⁰ TSCA Work Plan chemicals were selected based on their hazard and potential for exposure, as

¹⁰ 81 Fed. Reg. at 91,928.

well as other considerations such as persistence and bioaccumulation. In selecting the first 10 chemical substances, EPA took into account scientific information documented in the 2014 Work Plan, and recommendations from stakeholders and the public.¹¹

1,4-dioxane—a clear liquid that easily dissolves in water—is often used as a solvent in the manufacture of chemicals and as a laboratory reagent.¹² 1,4-dioxane can also be formed as a byproduct during the production of certain types of surfactants used in personal care and cleaning products.¹³ 1,4-dioxane is a trace contaminant of some chemicals used in cosmetics, detergents, and shampoos.¹⁴ 1,4-dioxane was also released into the environment with its use as a stabilizer for 1,1,1-trichloroethane (TCA).¹⁵

1,4-dioxane can be released into the air, water, and soil at places where it is produced or used as a solvent.¹⁶ The physical and chemical properties and behavior of 1,4-dioxane create challenges for its characterization and treatment.¹⁷ In air, 1,4-dioxane rapidly breaks down into different compounds.¹⁸ In water, 1,4-dioxane is stable and does not break down.¹⁹ In soil, 1,4-dioxane does not stick to soil particles, so it can rapidly move from soil into groundwater.²⁰

1,4-dioxane is a likely contaminant at many sites contaminated with certain chlorinated solvents.²¹ As of 2016, 1,4-dioxane had been identified at more than 34 hazardous waste sites on the EPA National Priorities List and may also be present at many other sites.²² 1,4-dioxane has been found in groundwater at sites throughout the United States.²³ EPA lists 1,4-dioxane on the chemical contaminant list, meaning that 1,4-dioxane is a potential concern in public water

¹¹ *Id.* at 91,928-29.

¹² Agency for Toxic Substances and Disease Registry, *Toxicological Profile for 1,4-Dioxane*, at 1 (Apr. 2012), <https://www.atsdr.cdc.gov/toxprofiles/tp187.pdf>; Agency for Toxic Substances and Disease Registry, *1,4-Dioxane ToxFAQs*, CAS # 123-91-1, at 1 (Apr. 2012), <https://www.atsdr.cdc.gov/toxfaqs/tfacts187.pdf>.

¹³ 1,4-Dioxane Draft Risk Evaluation, at 6.

¹⁴ Agency for Toxic Substances and Disease Registry, *Toxicological Profile for 1,4-Dioxane*, at 1 (Apr. 2012), <https://www.atsdr.cdc.gov/toxprofiles/tp187.pdf>.

¹⁵ *Id.* at 159.

¹⁶ Agency for Toxic Substances and Disease Registry, *1,4-Dioxane ToxFAQs*, CAS # 123-91-1, at 1 (Apr. 2012), <https://www.atsdr.cdc.gov/toxfaqs/tfacts187.pdf>.

¹⁷ EPA, *Technical Fact Sheet-1,4-Dioxane*, at 1 (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffrro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

¹⁸ Agency for Toxic Substances and Disease Registry, *1,4-Dioxane ToxFAQs*, CAS # 123-91-1, at 1 (Apr. 2012), <https://www.atsdr.cdc.gov/toxfaqs/tfacts187.pdf>.

¹⁹ *Id.*

²⁰ *Id.*

²¹ EPA, *Technical Fact Sheet-1,4-Dioxane*, at 1 (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffrro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

²² *Id.* at 2.

²³ *Id.* at 1.

systems.²⁴ Currently, there is no National Primary Drinking Water regulation for 1,4-dioxane under the Safe Drinking Water Act (“SDWA”).²⁵ EPA established a health advisory level of 35 µg/L (which corresponds to a 1 in ten thousand lifetime cancer risk) for 1,4-dioxane.²⁶ 1,4-dioxane is also currently listed on EPA’s Fourth Contaminant Candidate List (CCL 4) and was subject to occurrence monitoring in public water systems under the third Unregulated Contaminants Monitoring Rule (UMCR 3).²⁷ EPA uses the Unregulated Contaminant Monitoring Rule (UCMR) program to collect data for contaminants suspected to be present in drinking water, but that do not have health-based standards set under the SDWA.²⁸ Under UCMR 3, water systems were monitored for 1,4-dioxane during 2013-2015.²⁹ Of the 4,915 water systems monitored, 1,077 systems had detections of 1,4-dioxane in at least one sample.³⁰ None of the systems measured levels greater than the health advisory level, however, 341 systems (6.9%) had results at or above 0.35 µg/L (which corresponds to a 1 in a million-lifetime cancer risk).³¹

As but one example of the scope of exposure risks from drinking water, according to a recent report by the New York Public Interest Research Group (NYPIRG), at least 12 million New Yorkers drink water with some level of 1,4-dioxane contamination.³² In particular, 1,4-dioxane has been detected in Long Island’s groundwater, which is the sole source of drinking water for the almost three million Long Island residents.³³ Testing data gathered from 2013-2015 in compliance with UCMR 3 indicated the presence of 1,4-dioxane in many water systems on Long Island in exceedance of 0.35 µg/L.³⁴ EPA data from 2013 and 2014 showed that 40 public water supplies in New York contained 1,4-dioxane and that 31 of these water supplies are located on Long Island.³⁵ Suffolk County Water Authority data indicate that 1,4-dioxane was

²⁴ 1,4-Dioxane Problem Formulation, at 43; EPA, *Contaminant Candidate List (CCL) and Regulatory Determination*, <https://www.epa.gov/ccl/chemical-contaminants-ccl-4>.

²⁵ 1,4-Dioxane Problem Formulation, at 43.

²⁶ *Id.*

²⁷ *Id.*

²⁸ See EPA, *The Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary, January 2017* (Jan. 2017), <https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf>.

²⁹ 1,4-Dioxane Problem Formulation, at 43.

³⁰ *Id.*

³¹ *Id.*

³² New York Public Interest Research Group, *Emerging Contaminants in New York’s Drinking Water Systems: What’s In My Water?* (May 2019), https://www.nypirg.org/pubs/201905/Whats_in_my_water_2019.pdf; *Where 1, 4-Dioxane has Turned Up in Drinking Water*, Newsday (Feb 9, 2019), <https://projects.newsday.com/databases/long-island/dioxane-in-drinking-water/>.

³³ See EPA, *The Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary, January 2017* (Jan. 2017), <https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf>; EPA, *Sole Source Aquifers for Drinking Water*, <https://www.epa.gov/dwssa>.

³⁴ *Id.*

³⁵ Suffolk County Department of Health Services, *1,4-Dioxane in our Water Resources – Fact Sheet* (June 2015), <https://www.suffolkcountyny.gov/Portals/0/FormsDocs/Health/WWM/Dioxane%20fact%20sheet%206-19->

detected in approximately 272 public water supply wells, or roughly 40% of their wells sampled from January 2013 through October 2014.³⁶ 1,4-dioxane has also been found in 16 of the 28 public water supply wells in the Town of Hempstead.³⁷

Exposure to 1,4-dioxane poses serious harms to human health. Short-term exposure to 1,4-dioxane has been shown to cause eye and nasal irritation, clinical signs of central nervous system depression, including staggered gait, narcosis, paralysis and coma, liver and kidney degeneration and necrosis, and death.³⁸ Long-term exposure to 1,4-dioxane has been shown to cause centrilobular necrosis in the liver, and degeneration of the kidney and respiratory epithelium.³⁹ EPA also classifies 1,4-dioxane as “likely to be carcinogenic to humans.”⁴⁰ Due to its many uses, workers face high levels of exposure to 1,4-dioxane.⁴¹ In fact, the National Institute for Occupational Safety and Health considers 1,4-dioxane a potential occupational carcinogen.⁴²

The states have taken various actions to protect against the dangers of 1,4-dioxane.⁴³ For example, in December 2019, over the opposition of the Household Commercial Products Association and the American Cleaning Institute,⁴⁴ New York limited the permissible amount of 1,4-dioxane in household cleaning, cosmetics, and personal care products.⁴⁵ In July 2020, New York adopted a maximum contaminant level for 1,4-dioxane in drinking water.⁴⁶ Numerous water purveyors on Long Island have installed and are piloting water treatment technologies,

[15%20\(4\).pdf](#).

³⁶ *Id.*

³⁷ See EPA, *The Third Unregulated Contaminant Monitoring Rule (UCMR 3): Data Summary, January 2017* (Jan. 2017), <https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf>; Citizens Campaign for the Environment, *Lawsuits Over 1,4 Dioxane in Long Island Drinking Water Pile Up* (Oct. 16, 2019), <https://www.citizenscampaign.org/whats-new-at-cce/lawsuits-over-1-4-dioxane-in-long-island-drinking-water-pile-up>.

³⁸ 1,4-Dioxane Draft Supplemental Analysis, at 86.

³⁹ 1,4-Dioxane Draft Risk Evaluation, at 106.

⁴⁰ *Id.* at 107.

⁴¹ *Id.* at 21.

⁴² EPA, *Technical Fact Sheet-1,4-Dioxane*, at 3 (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffrro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

⁴³ See, e.g., 1,4-Dioxane Draft Risk Evaluation, at 195.

⁴⁴ American Cleaning Institute and Household & Commercial Products Association, *Manufacturing Groups: Dioxane Bill Could Take Familiar and Trusted Products Off Store Shelves* (July 8, 2019), <https://www.cleaninginstitute.org/newsroom/releases/2019/manufacturing-groups-dioxane-bill-could-take-familiar-and-trusted-products>; American Cleaning Institute, *American Cleaning Institute Reaction—NY Gov. Cuomo Signs Dioxane Bill into Law* (Dec. 9, 2019), <https://www.cleaninginstitute.org/newsroom/releases/2019/american-cleaning-institute-reaction-ny-gov-cuomo-signs-dioxane-bill-law>.

⁴⁵ See N.Y. Envtl. Conserv. L. §§ 35-0105, 37-0115, 71-3703.

⁴⁶ 10 N.Y.C.R.R. § 5-1.52; see also https://regs.health.ny.gov/sites/default/files/pdf/recently_adopted_regulations/Maximum%20Contaminant%20Levels%20%28MCLs%29.pdf.

incurring huge expenses in doing so, in order to reduce 1,4-dioxane concentrations in the water they provide to their customers.⁴⁷ Furthermore, New York’s Department of Environmental Conservation is undertaking a rulemaking to require manufacturers of domestic and commercial cleaning products to make available information regarding the ingredients in these products.⁴⁸

C. EPA’s Deficient TSCA Safety Review of 1,4-Dioxane

In May 2018, EPA published the problem formulation for 1,4-dioxane, which excluded consumer uses from the scope of the risk evaluation.⁴⁹ On August 3, 2018, the Attorneys General of 10 states and the District of Columbia submitted comments to EPA identifying deficiencies in the agency’s problem formulation for 1,4-dioxane (“AG Problem Formulation Comments”).⁵⁰ In the AG Problem Formulation Comments, the Attorneys General identified, among other deficiencies, that EPA’s 1,4-dioxane formulation ignored significant exposure pathways for the chemical, an approach contradicting TSCA’s plain language and Congress’ intent that EPA’s risk evaluations assess the human health and environmental risk posed by each chemical comprehensively. In June 2019, EPA published the draft risk evaluation for 1,4-dioxane, which did not rectify the deficiencies pointed out by the Attorneys General and other commentators, leading to a serious understatement of the risk posed by 1,4-dioxane. Numerous commenters reiterated those deficiencies in comments submitted to EPA on the agency’s draft risk evaluation.⁵¹

In July 2019, the American Cleaning Institute and the Grocery Manufacturers Association, reversing their previous position, urged that EPA expand the scope of the risk evaluation to include 1,4-dioxane’s presence as a byproduct as a condition of use to block “likely inconsistent” state-level regulations on the chemical’s presence as a byproduct in consumer products.⁵² For several years, industry groups had urged EPA to exclude 1,4-dioxane’s presence as a byproduct in various consumer products within the scope of its risk evaluation.⁵³ But

⁴⁷ See, e.g., David M. Schwartz, *Second Treatment System in Bethpage; Water District Works to Remove 1,4-Dioxane* (Oct. 25, 2019), <https://www.newsday.com/long-island/environment/1-4-dioxane-online-bethpage-water-district-1.37859603#:~:text=After%20%244%20million%20and%20almost,sending%20water%20through%20residents'%20taps.>

⁴⁸ New York State Department of Environmental Conservation, *Household Cleansing Product Information Disclosure Program*, <https://www.dec.ny.gov/chemical/109021.html>.

⁴⁹ 1,4-Dioxane Problem Formulation, at 18.

⁵⁰ Comments of the Attorneys General of Massachusetts, California, Hawaii, Maine, Maryland, New Jersey, New York, Oregon, Vermont, Washington, and the District of Columbia (Aug. 3, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0090>. By electronic filing in the EPA docket HQ-OPPT-2016-0732, the Attorney General of Rhode Island joined the comments (Aug. 15, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0096>.

⁵¹ See, e.g., Comments of Earthjustice and the Occupational Safety & Health Law Project (Aug. 30, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0046>; Comments of Environmental Defense Fund (Aug. 30, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0058>.

⁵² Comments of the American Cleaning Institute and Grocery Manufacturers Association (July 29, 2019), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0030>.

⁵³ See, e.g., Comments of the American Cleaning Institute (Mar. 6, 2017),

according to the American Cleaning Institute and the Grocery Manufacturers Association, recent state-level actions “have elevated the need for EPA to consider ethoxylation in the draft risk evaluation for 1,4 dioxane.” They pointed to a number of recent policies at the state level, including the bill that had recently cleared the New York legislature to limit 1,4-dioxane as a byproduct in household cleansing products, and California’s holding of a “public dialogue” about taking action on the substance under its Safer Consumer Products program. These industry groups stated that both New York and California recently established ingredient transparency policies for cleaning products that include disclosure mandates for the chemical. They stated that “[w]ithout consideration of byproducts in the final evaluation, the consumer products industry will be subject to additional and likely inconsistent state policies that are without justification under a durable, uniform process of scientific review.” These industry groups urged the EPA to “exercise its discretion” and consider 1,4-dioxane as an unintentionally present ingredient in its final evaluation.⁵⁴

On November 20, 2020, EPA published, on short notice, a supplemental analysis to the 1,4-dioxane draft risk evaluation. EPA did not revise its analysis to rectify the numerous deficiencies previously identified by the Attorneys General and others. Rather, the supplemental analysis expanded the scope of the draft risk evaluation in line with the urgings of the American Cleaning Institute and the Grocery Manufacturers Association, adding to the evaluation eight consumer uses, including surface cleaners, laundry/dishwashing detergents, and paint/floor lacquer, where 1,4-dioxane is present as a byproduct. The supplemental analysis also assessed exposure to the general population from 1,4-dioxane in surface water. EPA preliminarily found no unreasonable risk to consumers from the eight conditions of use assessed. EPA also preliminarily found no unreasonable risks under any of the conditions of use to the general population from exposure to 1,4-dioxane.

The hastened and woefully deficient supplemental analysis is both arbitrary and capricious and violates TSCA in a variety of ways. Numerous deficiencies with respect to the draft risk evaluation remain uncorrected.

<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0005>; Comments of The Procter & Gamble Company (Mar. 10, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0008>; Comments of the Household & Commercial Products Association (Aug. 16, 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0101>; *see also* Comments of the American Chemistry Council (Mar. 15, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0022>; Comments of the Consumer Specialty Products Association (Mar. 15, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0723-0013>.

⁵⁴ *Cleaning Products Groups Push for Expanded 1,4-Dioxane TSCA Risk Evaluation* (Aug. 2, 2019), <https://chemicalwatch.com/80665/cleaning-products-groups-push-for-expanded-14-dioxane-tsca-risk-evaluation>. Other industry groups have also begun to take a similar approach. For example, in June 2019, the American Coatings Association commented that with respect to the next batch of 20 substances likely to enter the risk evaluation process, “a situation could arise where EPA excludes a condition of use in a manner that prevents EPA’s risk evaluation from being comprehensive while limiting federal preemption.” Excluding relevant uses, it added, could open the door “for a patchwork of state-level requirements.” *See id.*; *see also* *ACA to Comment on EPA’s Priority Chemicals for TSCA Risk Evaluation* (June 17, 2019), <https://www.paint.org/tsca-comments/>.

1. EPA Fails to Evaluate General Population Exposures and Other Exposure Pathways That Purportedly Are Addressed Under Other Statutes Administered by EPA

EPA recognizes in its draft risk evaluation that “exposures to the general population [to 1,4-dioxane] may occur from the conditions of use due to releases to air, water or land.”⁵⁵ In turn, these exposures can lead to serious health risks, as discussed above. However, in contravention of TSCA and its implementing regulations, EPA excluded numerous exposure pathways in its risk evaluation. EPA stated that it “did not evaluate unreasonable risk to the general population from ambient air, drinking water, and sediment pathways for any conditions of use in this risk evaluation, and the draft unreasonable risk determinations do not account for exposures to the general population from ambient air, drinking water, and sediment pathways.”⁵⁶

EPA wrongfully asserts that it need not evaluate general population and other exposures because such exposures might be covered under other environmental statutes administered by EPA.⁵⁷ EPA asserted:

During the course of the risk evaluation process for 1,4-dioxane, EPA worked closely with the offices within EPA that administer and implement regulatory programs under the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), the Resource Conservation and Recovery Act (RCRA), and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with the statutory text and legislative history, particularly as they pertain to TSCA’s function as a “gap-filling” statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadlines for completing risk evaluations. EPA has therefore tailored the scope of the risk evaluation for 1,4-dioxane using authorities in TSCA Sections 6(b) and 9(b)(1).⁵⁸

Although protections under other regulatory schemes may reduce exposure potential from that particular pathway, under TSCA, EPA must eliminate unreasonable risk to human health and the environment posed by the chemical through all exposure pathways combined. EPA can only satisfy this duty by including in its risk evaluations all known exposure pathways assessed

⁵⁵ 1,4-Dioxane Draft Supplemental Analysis, at 5.

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

cumulatively. Nothing in TSCA justifies EPA’s dispensing with evaluation of risks to the general population and environment because EPA arbitrarily, and without any supporting data, asserts its other regulatory programs sufficiently address those exposures.

Indeed, the lack of regulatory authority under existing schemes of other environmental laws comprehensively to address the risks of toxics exposure was one of the key drivers for the toxics legislation that resulted in TSCA’s passage in 1976,⁵⁹ with the statute authorizing EPA to evaluate all the hazards posed by the chemical. As the Commerce Committee report noted: “there is no agency which has the authority to look comprehensively at the hazards associated with the chemical. Existing authority allows the agencies to only look at the hazards within their jurisdiction in isolation from other hazards associated with the same chemical. The bill would grant [EPA] the authority to look at the hazards in total.”⁶⁰ Thus, a foundational TSCA principle is to provide a mechanism for a *comprehensive* review of a chemical’s hazards—an “all hazards” approach providing a mechanism to account for and address all routes of exposure to a chemical—rather than through the lenses of compartmentalized air, water and solid waste regulatory programs.

Furthermore, TSCA section 9(b)(1) specifically prescribes how EPA must coordinate actions taken under TSCA with action taken under other EPA-administered statutes. 15 U.S.C. § 2608(b)(1). EPA must fully complete the risk evaluation and determine whether a chemical substance presents an unreasonable risk of injury to health or the environment before coordinating action under other EPA-administered statutes. 15 U.S.C. § 2608(b)(1). EPA cannot, as it has done here, defer to other EPA-administered statutes without first completing the risk evaluation and making a risk finding as TSCA requires. This makes perfect sense: if there were no risk, there would be no need to make a determination as to whether other federal laws administered by EPA “protect against such risk.” *See* H.R. Rep. No. 94-1679, at 85 (1976) (Conf. Rep.) (“Of course, the requirement to examine other EPA laws and to make determinations applies only when [EPA] takes regulatory action to protect against unreasonable risk under this Act.”).⁶¹ TSCA section 9(b)(1) affirms “the fundamental expectation that, where EPA concludes that a chemical presents an unreasonable risk, [EPA] should act in a timely manner to ensure that the chemical substance no longer presents such risk.” 162 Cong. Rec. S3517 (June 7, 2016).

In addition to this error regarding consideration of other environmental statutes, there is also no indication that existing environmental laws such as the SWDA have adequately addressed the risks of 1,4-dioxane.⁶² 1,4-dioxane has been found in groundwater at sites

⁵⁹ *See Report to Senate from the Committee on Commerce*, S. Rep. No. 94-698 (Mar. 16, 1976).

⁶⁰ *Id.*

⁶¹ *See also* S. Rep. No. 94-1302, at 85 (1976) (stating that the requirement of deference to other EPA authorities is limited to “regulatory action to protect against an unreasonable risk”); 162 Cong. Rec. S3517 (June 7, 2016) (stating that TSCA section 9(b)(2) “only applies where the Administrator has already determined that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by additional actions taken under other EPA authorities”).

⁶² *See, e.g.,* Cheryl Hogue, *1,4-Dioxane: Another Forever Chemical Plagues Drinking-Water Utilities*, Chemical and Engineering News (Nov. 8, 2020), <https://cen.acs.org/environment/pollution/14-Dioxane-Another-forever->

throughout the United States.⁶³ EPA lists 1,4-dioxane on the chemical contaminant list, meaning that 1,4-dioxane is a potential concern in public water systems.⁶⁴ However, because EPA has not established a National Primary Drinking Water regulation for 1,4-dioxane under the SDWA, many Americans may have a likely carcinogen in their water supply.⁶⁵

Accordingly, the draft risk evaluation must be revised, and EPA's subsequent risk evaluation must consider exposures that occur despite the fact that other environmental statutes may address certain releases of 1,4-dioxane to the environment.

2. EPA Does Not Evaluate the Risk of 1,4-Dioxane on Relevant Subpopulations

TSCA and the EPA implementing regulations require that EPA evaluate risk to relevant potentially exposed or susceptible subpopulations. *See* 15 U.S.C. § 2605(b)(4)(A); 40 C.F.R. §§ 702.41(d), (e). The term “potentially exposed or susceptible subpopulation” means “a group of individuals within the general population identified by the Administrator 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 or mixture, such as infants, children, pregnant women, workers, or the elderly.” 15 U.S.C. § 2602(12). However, EPA fails to evaluate the risk of exposure to 1,4-dioxane on relevant potentially exposed or susceptible subpopulations.⁶⁶

For example, it is well-documented that 1,4-dioxane is present in groundwater throughout the United States.⁶⁷ Subpopulations exposed to 1,4-dioxane from contaminated groundwater may be exposed to higher levels of 1,4-dioxane than the general population.⁶⁸ Environmental justice communities, which are already subject to socioeconomic and health stressors and other types of pollution, may be particularly impacted by the additional exposure to 1,4-dioxane.⁶⁹

[chemical/98/i43](#).

⁶³ EPA, *Technical Fact Sheet-1,4-Dioxane* (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

⁶⁴ EPA, *Contaminant Candidate List (CCL) and Regulatory Determination*, <https://www.epa.gov/ccl/chemical-contaminants-ccl-4>.

⁶⁵ EPA, *Technical Fact Sheet-1,4-Dioxane* (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

⁶⁶ According to EPA, there is no evidence of increased susceptibility for any single group relative to the general population. 1,4-Dioxane Draft Supplemental Analysis, at 5. However, EPA's conclusion is unfounded.

⁶⁷ *See, e.g.*, EPA, *Technical Fact Sheet-1,4-Dioxane*, at 1 (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

⁶⁸ Sophia Sidhu, *1,4-Dioxane, Bioremediation, and Women's Health*, UCLA Center for the Study of Women (Apr. 23, 2018), <https://csw.ucla.edu/2018/04/23/14-dioxane-bioremediation-and-womens-health/>.

⁶⁹ California Environmental Protection Agency, *1,4-Dioxane in Personal Care and Cleaning Products*, at 3-4 (May 23, 2019), https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/05/Background-Document_14-dioxane.pdf; Sophia Sidhu, *1,4-Dioxane, Bioremediation, and Women's Health*, UCLA Center for the Study of Women (Apr. 23, 2018),

This issue may be further exacerbated by the fact that “safer,” “greener” consumer products are often more expensive and, therefore, out of reach for these economically disadvantaged populations.⁷⁰ EPA’s failure to address the risk to this subpopulation results in an understatement of the overall risk of exposure to 1,4-dioxane and contravenes TSCA’s express requirements that EPA consider the risks to such subpopulations.

3. EPA Understates the Risk in Other Ways

EPA understates the risks posed by 1,4-dioxane in several additional ways. First, EPA fails to consider aggregate exposures under the conditions of use for consumers. EPA must, as a part of the risk evaluation, describe whether aggregate exposures under the conditions of use were considered and the basis for their consideration. 15 U.S.C. § 2605(b)(4)(F)(ii). The term “aggregate exposure” is defined as “the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways.” 40 C.F.R. § 702.33. EPA admits that “[b]ackground levels of 1,4-dioxane in indoor and outdoor air are not considered or aggregated in this analysis; therefore, there is a potential for underestimating consumer inhalation exposures, particularly for populations living near a facility emitting 1,4-dioxane or living in a home with other sources of 1,4-dioxane, such as other 1,4-dioxane-containing products stored and/or used in the home such as personal care products that are not covered under TSCA.”⁷¹ EPA further admits that “inhalation and dermal exposures were evaluated on a product-specific basis and are based on use of a single product type within a day, not multiple products. There was no aggregation of dermal and inhalation exposure to single products either.”⁷² EPA’s failure to combine exposure across these routes results in an understatement of risk for consumers.

Second, EPA fails to consider aggregate exposures under the conditions of use for the general population. Exposure to 1,4-dioxane can come from numerous sources, including ambient air, indoor air, drinking water, and sediment pathways. These sources of exposure are additive and, therefore, must be aggregated to evaluate overall risk. EPA’s failure to consider exposure through multiple environmental pathways violates TSCA and leads to a severe understatement of 1,4-dioxane’s human health impacts. As no other environmental law enables EPA to evaluate exposure across all environmental media, TSCA analyses must address the additive and cross-media risks of 1,4-dioxane. EPA offers no justification for its failure to consider these exposures except to state, “EPA did not assess exposures from ambient air, drinking water, and sediment pathways because they fall under the jurisdiction of other environmental statutes administered by EPA, *i.e.*, CAA, SDWA, RCRA, and CERCLA.”⁷³ As explained above, EPA’s entirely conclusory justification based on purported protections under other statutes has no foundation in law or common sense.

<https://csw.ucla.edu/2018/04/23/14-dioxane-bioremediation-and-womens-health/>.

⁷⁰ Sophia Sidhu, *1,4-Dioxane, Bioremediation, and Women’s Health*, UCLA Center for the Study of Women (Apr. 23, 2018), <https://csw.ucla.edu/2018/04/23/14-dioxane-bioremediation-and-womens-health/>.

⁷¹ 1,4-Dioxane Draft Supplemental Analysis, at 50.

⁷² *Id.*

⁷³ *Id.* at 77.

Third, EPA discounts the risk to workers on the assumption that workers will use personal protective equipment (“PPE”) and that the PPE will protect against 1,4-dioxane exposure.⁷⁴ EPA states that it “expects there is compliance with federal and state laws, such as worker protection standards, unless case-specific facts indicate otherwise, and therefore existing [Occupational Safety and Health Administration (OSHA)] regulations for worker protection and hazard communication will result in use of appropriate PPE consistent with the applicable [safety data sheets] in a manner adequate to protect workers.”⁷⁵ However, EPA provides no evidence that PPE in the workplace is in fact used and effectively protects against 1,4-dioxane exposure. Indeed, OSHA itself has recognized that many of its 1,4-dioxane standards are “outdated and inadequate for ensuring the protection of worker health.”⁷⁶ Moreover, the Science Advisory Committee on Chemicals (“SACC”), whose information and advice EPA must consider,⁷⁷ repeatedly criticized EPA’s assumptions regarding the use and effectiveness of PPE in calculating exposure risks.⁷⁸ Furthermore, in order for EPA to defer to regulations promulgated by other agencies, EPA must follow the prescriptive requirements of TSCA section 9(a), which EPA did not do. 15 U.S.C. § 2608(a)(1). EPA must consider whether 1,4-dioxane presents an unreasonable risk to exposed workers without discounting that risk by assuming the use and effectiveness of PPE. Through this unsupported assumption, EPA understates the risks for workers.

4. EPA Is Not Subjecting the Supplemental Analysis to Peer Review and Adequate Notice and Comment

EPA is not providing the SACC with the opportunity to review the supplemental analysis and is not providing the public with the requisite time to comment on the supplemental analysis. EPA stated that, because the analytical approaches to assessing the unreasonable risk associated with these conditions of use mirror those used for the conditions of use evaluated in the draft risk evaluation, and because there is no new or novel scientific information to consider, additional peer review is not warranted. 85 Fed. Reg. at 74,342. However, the draft supplemental analysis broadens the scope of the draft risk evaluation to add eight major consumer uses which perforce adds new information to the risk evaluation. As EPA is required to consider information and advice provided by the SACC, the committee must be provided the opportunity for review. 40 C.F.R. § 702.41(b)(3); *see also* 40 C.F.R. § 702.45. In addition, although EPA recognized that it would be appropriate to seek public comment on the supplemental analysis, EPA only provided an inadequate and highly unusual 20-day comment period that does not satisfy TSCA’s notice and comment requirements and itself raises serious questions regarding the agency

⁷⁴ 1,4-Dioxane Draft Risk Evaluation, at 175 n.1.

⁷⁵ *Id.*

⁷⁶ EPA, *Technical Fact Sheet-1,4-Dioxane*, at 4 (Nov. 2017), https://www.epa.gov/sites/production/files/2014-03/documents/ffrro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

⁷⁷ 40 C.F.R. § 702.41(b)(3).

⁷⁸ *See, e.g.*, TSCA Science Advisory Committee on Chemicals July 29-Aug. 2, 2019 Meeting Minutes and Final Report No. 2019-02 on 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD), at 53 (2019).

faithfully carrying out its responsibilities under TSCA to protect the public from exposure. *See* 15 U.S.C. § 2605(b)(4)(H); 40 C.F.R. § 702.49(a).

D. Conclusion

As discussed above, EPA's draft risk evaluation for 1,4-dioxane does not satisfy the requirements of TSCA and EPA's implementing regulations. As a consequence, any risk management actions developed from the flawed evaluation, if not reworked to comply with those applicable legal requirements would fail to comply with TSCA and the Administrative Procedure Act. Left uncorrected, the deficiencies in the draft evaluation will fatally compromise the agency's final risk evaluation and any subsequent risk management of 1,4-dioxane, and fail to protect human health and the environment. Because of this, we urge that EPA withdraw the draft evaluation and re-evaluate the risks posed by 1,4-dioxane in a manner that complies with EPA's obligations under TSCA.

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EXHIBIT B

**Opening Brief for Petitioners State of New York et al.,
Neighbors for Environmental Justice, et al. v. EPA, Case No. 20-72091,
*ECF No. 42 (9th Cir. Jan. 25, 2021)***

20-72091(L), 20-73276(Con)

**United States Court of Appeals
for the Ninth Circuit**

NEIGHBORS FOR ENVIRONMENTAL JUSTICE, et al.,
Petitioners,
v.
U.S. ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents,
and
AMERICAN CHEMISTRY COUNCIL, et al.,
Intervenors.

STATE OF NEW YORK, et al.,
Petitioners,
v.
ANDREW WHEELER, as Administrator of
the U.S. Environmental Protection Agency, et al.,
Respondents.

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

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INTRODUCTION

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. When EPA's evaluation shows that a chemical presents an unreasonable risk to health or the environment, EPA must enact regulatory measures to eliminate such risk.

Methylene chloride is one of the ten highly toxic chemical substances that EPA prioritized for initial review under TSCA. 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. Despite these severe and undisputed health consequences, EPA's final risk evaluation for methylene chloride substantially understated the risks of the chemical and determined that six common uses of methylene chloride pose no unreasonable risk of injury to human health—making it unlikely that

EPA will enact rules to protect individuals exposed to methylene chloride as a result of those activities. State and Municipal Petitioners—New York, Hawai‘i, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, Oregon, Rhode Island, Vermont, the District of Columbia, and the City of New York— challenge EPA’s determination, which leaves their residents and the environment unacceptably exposed to the extreme hazards of methylene chloride.

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, 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.

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.

JURISDICTIONAL STATEMENT

On June 24, 2020, pursuant to TSCA section 6(b)(4), 15 U.S.C. § 2605(b)(4), EPA issued an order determining that six uses of methylene chloride do “not present an unreasonable risk of injury to health or the environment.”¹ EPA, *Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)* (June 2020) (“MC Risk Evaluation”), subsec. 5.4.1

¹ See *Methylene Chloride (MC); Final Toxic Substances Control Act (TSCA) Risk Evaluation*, 85 Fed. Reg. 37,942 (June 24, 2020); 3-NYER-340-42.

(hereafter, “Final Order”); 1-NYER-4-5. EPA’s “no unreasonable risk” determination is 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).

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, State and Municipal Petitioners timely filed a petition for review of the Final Order in the United States Court of Appeals for the Second Circuit. *See New York v. EPA*, No. 20-2729 (2d Cir. 2020), ECF No. 1; 4-NYER-627-33. On November 4, 2020, the petition for review was transferred to this Court 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, ECF No. 30.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Whether EPA acted unlawfully in: (a) evaluating the risks of methylene chloride on a use-by-use basis as opposed to evaluating the risks of the chemical holistically and comprehensively; (b) excluding from

the risk evaluation major sources of exposure to methylene chloride; and (c) considering as part of the risk evaluation extra statutory protections that TSCA precludes EPA from considering.

2. Whether EPA lacked substantial evidence in support of its determination that six “conditions of use” of methylene chloride do “not present unreasonable risk of injury to health or the environment.”

STATUTORY ADDENDUM

State and Municipal Petitioners attach a separate Statutory Addendum to their Opening Brief. 9th Cir. R. 28-2.7.

STATEMENT OF THE CASE

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) (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.

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). 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. 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.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, such as persistence and bioaccumulation.² *See* 15 U.S.C. § 2605(b)(1); 40 C.F.R. §§ 702.1-702.17.

² *See* EPA, TSCA Work Plan Chemicals, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals#select>. All websites last visited on Jan. 24, 2021.

On December 19, 2016, EPA published its initial list of 10 such high-priority chemical substances, which included methylene chloride.³

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

³ 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); 3-NYER-587.

[EPA] 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 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.* 15 U.S.C. 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. No. 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 final 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). 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).

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

1. 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 State and Municipal Petitioners.⁴ Over 260 million pounds of methylene chloride are produced each year in the United States. *See* 85 Fed. Reg. at 37,944; 3-NYER-342. 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”); 3-NYER-569

⁴ *See* EPA, *Nontechnical Summary of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)*, at 3 (June 2020); 3-NYER-419.

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.⁵ See MC Problem Formulation, at 45; 3-NYER-577. 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.⁶ See MC Risk Evaluation, at 33, & App. J; 2-NYER-12, 293. Other acute nervous system effects include sensory impairment and loss of consciousness. See *MC Risk Evaluation*, at 33, App. J; 2-NYER-12, 293.

⁵ 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); 3-NYER-590; 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); 3-NYER-598-605, 4-NYER-608-13.

⁶ 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); 3-NYER-582-85.

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.⁷ See MC Risk Evaluation, App. J; 2-NYER-293. Of these fatalities, over 80% were occupational users. *Id.*; 2-NYER-293. 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,⁸ and a worker in Massachusetts who died while cleaning a 250-gallon reactor vessel with methylene chloride.⁹

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

⁷ See also Safer Chemicals, Healthy Families, *U.S. Deaths from Methylene Chloride* (Mar. 2018), <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”).

⁸ See 82 Fed. Reg. at 7,482; 3-NYER-582.

⁹ Safer Chemicals, Healthy Families, *supra*.

and attention deficits. *See* MC Risk Evaluation, at 288-89; 2-NYER-243-44, 82 Fed. Reg. at 7,483; 3-NYER-583. 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; 3-NYER-577-78; MC Risk Evaluation, at 33, App. L.4; 2-NYER-12, 313; 82 Fed. at 7,471; 3-NYER-580.

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.¹⁰ 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

¹⁰ *See* TSCA Work Plan, at 88-89; 3-NYER-593-94.

responders required hospitalization following their exposure to the toxic chemical. *See* 82 Fed. Reg. at 7,482-83; 3-NYER-582-83.

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. 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.¹¹

2. State and Municipal Petitioners' residents are exposed to methylene chloride through diverse pathways

The State and Municipal Petitioners' 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; 2-NYER-85-86. Individuals may

¹¹ *See* EPA, *Health and Environmental Effects of Ozone Layer Depletion*, <https://www.epa.gov/ozone-layer-protection/health-and-environmental-effects-ozone-layer-depletion>.

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.¹² See MC Problem Formulation, at 40-41; 3-NYER-572-73; MC Risk Evaluation, at 74-226 (assessing human and environmental exposure pathways); 2-NYER-29-181.

Residents of State and Municipal Petitioners 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.¹³ In New York alone, there are 57 environmental remediation sites where methylene chloride is listed as a chemical of concern.¹⁴ Five of these sites are located in Nassau and Suffolk Counties, where groundwater is the sole source of

¹² See also EPA, *Draft Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)* (Oct. 2019) (“Draft MC Risk Evaluation”), at 35-36; 3-NYER-539-40; Toxicological Profile, at 3; 3-NYER-597.

¹³ Toxicological Profile, at 3; 3-NYER-597.

¹⁴ See N.Y. State Dep’t of Env’tl. Conservation, *Environmental Remediation Sites*, <https://data.ny.gov/Energy-Environment/Environmental-Remediation-Sites/c6ci-rzpg>.

drinking water for almost 3 million residents.¹⁵ Methylene chloride is also released in surface waters, which can cause exposures to amphibians and fish. *See* MC Risk Evaluation, at 102-08; 2-NYER-57-63; *see also* Draft MC Risk Evaluation, at 290, 389, 569-91; 3-NYER-542, 544, 545-67.

In light of the significant public health and environmental risks of methylene chloride, the State and Municipal Petitioners 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. Env'tl. Conserv. Law §§ 39-0103, 39-0105(1)-(2).

¹⁵ *See* N.Y. State Dep't of Env'tl. Conservation, *supra*.

The State has also set a health-based guideline to limit methylene chloride in indoor air.¹⁶

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

¹⁶ *See* N.Y. State Dep't of Health, *Tenant Notification Fact Sheet for Dichloromethane*, <https://www.health.ny.gov/environmental/indoors/air/contaminants/dichloromethane.htm>.

toxic chemicals and complete 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.

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 State and Municipal Petitioners 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).

C. EPA’s Risk Evaluation for Methylene Chloride

On June 24, 2020, EPA published the final MC Risk Evaluation for methylene chloride.¹⁷ The 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; 2-NYER-290-92. 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; 2-NYER-290-91. EPA concluded that six

¹⁷ In October 2019, EPA published the Draft MC Risk Evaluation. 3-NYER-577. Several of the Municipal and State Petitioners submitted timely comments to EPA identifying deficiencies in the agency’s draft. *See* 3-NYER-482-514 (States); 3-NYER-515-20 (City of New York).

significant uses of methylene chloride do not pose unreasonable risk to the health of workers, occupational non-users, consumers, or bystanders. MC Risk Evaluation, at 517-18; 1-NYER-4-5. 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, at 517-18; 1-NYER-4-5. EPA also found no unreasonable risk to the environment from any use of methylene chloride. *See* MC Risk Evaluation, at 517-20; 2-NYER-289-92; 85 Fed. Reg. at 37,943; 3-NYER-341.

EPA has stated that it is 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 has up to one year—i.e., until June 2021—to propose and take public comments on any such action.¹⁸ 15 U.S.C. § 2605(c)(1)(A). With respect to the six

¹⁸ EPA, *Risk Management for Methylene Chloride*, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride>.

conditions of use for which EPA found no unreasonable risk, EPA does not plan to propose any risk management measures.

SUMMARY OF ARGUMENT

I. EPA's final risk evaluation must be set aside because it is arbitrary and capricious, without substantial evidence, and violates TSCA in several ways. First, EPA evaluated the risks of methylene chloride on a use-by-use basis in violation of Congress's clear directive to analyze the risks posed by a chemical's "conditions of use" comprehensively and collectively. *See* 15 U.S.C. § 2605(b)(4)(A). Congress enacted TSCA to give EPA the power to address the risks of a chemical substance as a whole, and EPA's use-by-use approach contravenes this mandate. EPA's contrary arguments misread the relevant language of TSCA and otherwise rely on inapposite provisions of the statute.

Second, EPA failed to assess the risks that methylene chloride poses to human health and the environment from air, water, and soil pollution, violating TSCA's requirement that EPA assess the cumulative hazards from all known exposure pathways. *See* 15 U.S.C. § 2605(b)(4)(F). Although EPA claims that it had discretion to ignore these exposure pathways because other regulatory regimes address environmental

pollutants, TSCA forbids EPA from considering such provisions during the risk evaluation stage, and the other statutes to which EPA points are limited in scope and do not authorize EPA to undertake the comprehensive evaluation of health and environmental risks that TSCA requires. Other statutes are therefore an inadequate substitute for regulation under TSCA.

Third, EPA improperly credited certain occupational safety regulations and thus significantly understated the risks of methylene chloride to workers. As part of the risk evaluation, EPA assumed that all workers are protected by personal protective equipment, such as respirators, based on an existing OSHA regulation. But TSCA prohibits EPA from considering the effects of such regulations during the risk evaluation stage, and those regulations have been shown to be insufficient to protect workers.

Finally, for the reasons articulated in the brief by Neighbors for Environmental Justice et al. (at Argument, Section II), EPA failed to satisfy TSCA's requirement that the agency evaluate the unique risks that a chemical poses to potentially exposed or susceptible subpopulations, including people who live or work near sites that are

likely to produce substantial methylene chloride pollution, and individuals who are genetically predisposed to develop cancer as a result of exposure to methylene chloride.

II. Independently, the risk evaluation should be set aside because EPA lacked substantial evidence to support its determination that six uses of methylene chloride do not pose an unreasonable risk of injury to human health. TSCA requires EPA's risk determination to be based on reliable and unbiased scientific evidence. But EPA's risk evaluation lacked a basis in the administrative record, or the evidence was otherwise biased, unrepresentative, or unreliable.

III. State and Municipal Petitioners have standing to bring this Petition. EPA's numerous violations of TSCA caused EPA to significantly understate the risks of methylene chloride and to avoid triggering TSCA's mandatory risk management provisions for six conditions of use. If EPA's risk evaluation is not set aside, State and Municipal Petitioners will incur higher costs to address the severe public health and environmental harms caused by methylene chloride.

STANDARD OF REVIEW

TSCA’s judicial review provision, *see* 15 U.S.C. § 2618(c)(1), generally provides for judicial review under the standards of the APA. Under the APA, the Court must “hold unlawful and set aside” agency action that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2). Agency action is arbitrary and capricious if the agency relied on factors which Congress did not intend it to consider, failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. *See Ctr. for Biological Diversity v. Nat’l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1193 (9th Cir. 2008). Judicial review under the APA is “deferential,” but it must also be “thorough, probing, [and] in-depth.” *Ranchers Cattleman Action Legal Fund United Stockgrowers of Am. v. United States Dep’t of Agric.*, 415 F.3d 1078, 1093 (9th Cir. 2005) (quotation marks omitted). The Court “need not defer to the agency when the agency’s decision is without substantial basis in fact.” *Ctr. for Biological Diversity v. Zinke*,

900 F.3d 1053, 1067 (9th Cir. 2018) (quotation marks and citation omitted).

TSCA also requires courts to “hold unlawful and set aside” final agency action under TSCA section 6(i)(1) that is “not supported by substantial evidence in the record taken as a whole.” 15 U.S.C. § 2618(c)(1)(B)(i)(II). “Substantial evidence means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” *ASSE Int’l, Inc. v. Kerry*, 803 F.3d 1059, 1072 (9th Cir. 2015) (quoting *Bonnichsen v. United States*, 367 F.3d 864, 880 n.19 (9th Cir. 2004)). “The substantial evidence standard mandated by [TSCA] is generally considered to be more rigorous than the arbitrary and capricious standard normally applied to informal rulemaking, and afford[s] a considerably more generous judicial review than the arbitrary and capricious test.” *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214 (5th Cir. 1991) (quotation marks and citations omitted). While EPA’s expert decisions are still owed some deference, “a reviewing court must give careful scrutiny to agency findings.” *Id.*

ARGUMENT

POINT I

EPA’S METHYLENE CHLORIDE RISK EVALUATION VIOLATES TSCA

In conducting the methylene chloride risk evaluation, EPA failed to comply with several statutory requirements and improperly considered factors that TSCA prohibits it from considering. EPA’s final determination is therefore arbitrary and capricious, without substantial evidence, and contrary to law, and it must be set aside. *See* 15 U.S.C. § 2618(c)(1); 5 U.S.C. § 706(2).

A. EPA Failed to Comprehensively Evaluate the Risks Posed by Methylene Chloride.

EPA’s final risk evaluation separately assessed the risks of methylene chloride for each of 53 “conditions of use,” meaning that it made discrete determinations of the risks posed by each of the distinct activities in which methylene chloride is manufactured, processed, distributed, or used. *See* MC Risk Evaluation, at 39-41; 2-NYER-18-20; *see also* 15 U.S.C. § 2602(4) (defining “conditions of use”). Based on that analysis, EPA determined that six conditions of use do not pose an unreasonable risk of injury to human health or the environment—

essentially guaranteeing that EPA will not enact rules to protect individuals exposed to methylene chloride as a result of those activities. See MC Risk Evaluation, at 39; 2-NYER-18. EPA's use-by-use approach violates TSCA's clear command to analyze the risk of each chemical substance comprehensively and collectively.

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, this fundamental purpose remained intact. See S. Rep. No. 114-67, at 7.

The text of section 6 reflects Congress's purpose of ensuring 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 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.

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. 114-67, at 17 (emphasis added).

To be sure, TSCA requires EPA to identify and evaluate the risks of each chemical’s conditions of use as part of its risk evaluation.¹⁹ See 15 U.S.C. § 2605(b)(4)(F). Congress imposed this 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 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

¹⁹ 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.

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 7. Under the 2016 amendments, however, EPA must 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.²⁰ See

²⁰ To grant an exemption, EPA must determine that (1) the condition of use “is a critical or essential use for which no technically and

15 U.S.C. § 2605(g). 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).

To justify its approach, EPA has mistakenly relied (MC Risk Evaluation, at 57; 2-NYER-22) on TSCA section 6(b)(4)(D)—an inapposite provision governing EPA’s preparation of the initial scope document for the risk evaluation.²¹ A separate provision of TSCA—section 6(b)(4)(F)—governs the substance of the risk evaluation, 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).

²¹ 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).

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 EPA’s 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 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.

B. EPA Failed to Consider Major Sources of Methylene Chloride Exposure.

Separate from EPA's failure to holistically assess the risks of methylene chloride, the final risk evaluation should be set aside because EPA failed to consider the risks of methylene chloride exposure arising from environmental pollution. In the final risk evaluation, EPA acknowledged that methylene chloride permeates our surroundings and that "the general population may be exposed to the chemical from "releases to air, water, or land."²² MC Risk Evaluation, at 32, 37; 2-NYER-11, 16. EPA has also recognized that these documented exposure pathways are significant. It has acknowledged, for example, that "[l]evels of methylene chloride in the ambient air are widespread and shown to be increasing." *MC Problem Formulation*, at 39; 3-NYER-571.²³

²² See also MC Risk Evaluation 437 (acknowledging "documented background exposures of methylene chloride in residential or consumer environments"); 2-NYER-275. MC Problem Formulation, at 12 (recognizing that methylene chloride is released "from industrial and/or commercial uses; industrial releases to air, water or land; and other conditions of use," and that these exposure pathways may result in exposures to the general population); 3-NYER-570.

²³ See also, e.g., MC Problem Formulation, at 39 (concluding that methylene chloride may be present in indoor air due to its variety of uses, including consumer uses); 3-NYER-571-72; MC Problem Formulation, at

Nonetheless, EPA excluded from its analysis the risks to workers, consumers, and other populations from exposure to methylene chloride via contaminated air, water, and land. *See* MC Risk Evaluation, at 31-32, 37; 2-NYER-10-11, 16. That violates TSCA.

As Congress made clear when it enacted TSCA, “[i]ntelligent standards for regulating exposures to a chemical in the workplace, the home or elsewhere in the environment cannot be set unless the full extent of human or environmental exposure is considered.”²⁴ H.R. Rep. No. 94-1341, at 6. Accordingly, Congress designed TSCA to ensure that EPA evaluates all of the health and environmental risks arising from environmental exposure pathways. Among other things, TSCA directs EPA to determine whether a substance poses an “unreasonable risk” to

39 (concluding that wastewater/liquid wastes and solid waste could result in potential pathways for exposure to the general population); 3-NYER-572; MC Problem Formulation, at 40 (concluding that “[t]he general population may ingest methylene chloride via contaminated drinking water, ground water, and/or surface water”); 3-NYER-572; MC Problem Formulation, at 40 (concluding that methylene chloride may be ingested through contaminated breast milk); 3-NYER-572.

²⁴ For example, “[p]eople who work in a factory in which dangerous substances are handled in high concentration may live in an adjacent area in which the same or other substances are dispersed, thus increasing overall exposure.” H.R. Rep. No. 94-1341, at 6-7.

“the environment,” 15 U.S.C. § 2605(b)(4)(A), which is defined to “include[] water, air, land, and all living things,” *id.* § 2602(4). And it also requires EPA to evaluate risks to human health based on cumulative exposures, which must include known “exposures” from environmental pollution. *See, e.g.*, 15 U.S.C. § 2605(b)(4)(F)(i), (iv) (directing EPA to consider “the likely duration, intensity, frequency, and number of exposures” to a chemical).

By excluding releases of methylene chloride to the air, water, and soil from its risk analysis, EPA violated TSCA and substantially understated the overall risk of methylene chloride.²⁵ *See TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report*, No. 2020-1, at 15 (Dec. 2019) (“SACC Report”) (stating that the risk

²⁵ *See Response to Support Risk Evaluation of Methylene Chloride* (June 2020) (“EPA Response”), at 41 (admitting that “the risk estimations in the Risk Evaluation may be underestimations, because background exposures and risk are not incorporated to the risk estimations for each [condition of use]”); 3-NYER-431; EPA Response, at 67 (stating that “EPA did not consider background exposure that workers and consumers using products containing MC might be exposed to” which “may result in an underestimation of risk”); 3-NYER-433; MC Risk Evaluation, at 92 (stating that the environmental exposure characterization only “focuses on aquatic releases of methylene chloride from facilities that use, manufacture, or process methylene chloride under industrial and/or commercial conditions of use”); 2-NYER-47.

evaluation only paints “a partial picture of risks” of methylene chloride); 3-NYER-472.

There is no merit to any of the explanations that EPA has offered to justify its failure to consider these sources of exposure. *First*, EPA has incorrectly argued (MC Risk Evaluation, at 57; 2-NYER-22) that TSCA section 6(b)(4)(D) gives the agency discretion to exclude environmental exposure pathways. As explained above (at 35-37), that provision “simply refers to the Agency’s role in determining” all of the relevant exposure pathways for a chemical. *See Safer Chems.*, 943 F.3d at 419. A different provision, section 6(b)(4)(F), governs the substance of the risk evaluation, and it requires EPA to “integrate and assess” the cumulative effects of all sources of exposure. *See* 15 U.S.C. § 2605(b)(4)(F).

Second, EPA has mistakenly argued (MC Risk Evaluation, at 57-59; 2-NYER-22-24) that TSCA section 9(b)(1) empowers it to disregard the risks of environmental pollution. But section 9(b)(1) has nothing to do with EPA’s risk *evaluation*. Rather, that provision deals exclusively with the risk *management* stage, authorizing EPA to “coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by” EPA *after* the agency “determines”

that the chemical presents “a risk to health or the environment.” *See* 15 U.S.C. § 2608(b)(1). As the legislative history confirms, “the requirement to examine other EPA laws and to make determinations applies *only* when the [agency] takes regulatory action to protect against an unreasonable risk under this Act.”²⁶ H.R. Rep. No. 94-1679, at 85 (1976) (Conf. Rep.) (emphasis added).

Third, EPA has erroneously insisted (MC Risk Evaluation, at 60-63; 2-NYER-25-28) that it need not analyze major exposure pathways because other EPA-administered statutes—such as the Safe Drinking Water Act and Clean Air Act—already “well-regulate” those pathways. None of the other regulatory regimes on which EPA relies comprehensively addresses the suite of risks posed by methylene chloride. The Safe Drinking Water Act, for example, authorizes EPA to regulate only certain kinds of public water systems, *see* 42 U.S.C.

²⁶ *See also* S. Rep. No. 94-1302, at 85 (1976) (stating that the requirement of deference to other EPA authorities is limited to “regulatory action to protect against an unreasonable risk”); 162 Cong. Rec. S3517 (June 7, 2016) (stating that TSCA section 9(b)(2) “only applies where [EPA] has already determined that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by additional actions taken under other EPA authorities”).

§§ 300f(4), 300g, and requires EPA to consider the costs associated with limiting exposures and risks, *see id.* § 300f(1)(C)(i)-(ii). Only TSCA grants EPA authority to evaluate the hazards of a substance without considering nonrisk factors, and to enact comprehensive risk management solutions, like a complete ban on a chemical substance. *See* S. Rep. No. 94-698, at 1-2.

Finally, EPA has erroneously argued (MC Risk Evaluation, at 59-60; 2-NYER-24-25) that TSCA sections 2(c) and 18(d) authorize the agency to ignore recognized exposure pathways and hazards. Section 2(c) is part of a general statement of intent and simply directs EPA to carry out TSCA in a “reasonable and prudent manner” and to “consider the environmental, economic, and social impact of its actions under TSCA.” *See* 15 U.S.C. § 2601(c). Nothing in that precatory provision overrides the statute’s more specific mandate to address the cumulative risks to health from environmental sources. *See id.* § 2605(b)(4)(F). TSCA section 18(d) is similarly inapposite. That provision provides certain exceptions to TSCA’s general preemption provision; it addresses the legal status of state and local laws and cannot be read to limit the scope of what EPA must do.

C. EPA Improperly Considered Nonrisk Factors When Assessing the Risks of Methylene Chloride to Workers.

Workplace users of methylene chloride—including both direct users and “occupational bystanders” whom EPA says do not use products containing methylene chloride but who may be exposed to its toxic fumes—face some of the most severe and imminent health risks from methylene chloride exposure due to risk of prolonged exposures at high concentrations.²⁷ EPA has determined that workers face acute and chronic risks from methylene chloride for all 53 conditions of use under high-end inhalation or dermal exposure estimates. *See* MC Risk Evaluation, at 34; 2-NYER-13. In addition, it has determined that workers face cancer risks for most industrial and commercial conditions of use under high-end inhalation or dermal exposure estimates. *See* MC Risk Evaluation, at 34; 2-NYER-13.

In evaluating the risks to workers, however, EPA substantially downplayed the risks by assuming the use of personal protective

²⁷ Indeed, OSHA has recognized that workers who are exposed to methylene chloride face significant health risks, including cancer, central nervous system and cardiac effects, and sensory impairment. *See* 62 Fed. Reg. 1,494, 1,577 (Jan. 10, 1997); 4-NYER-625.

equipment (“PPE”). Specifically, EPA relied (EPA Response, at 163-64, 171; 3-NYER-440-41, 448) on a longstanding OSHA regulation that addresses occupational uses of methylene chloride and requires use of PPE in certain circumstances. 29 C.F.R. § 1910.1052. Based on that regulation, EPA assumed exposure risks were lower under numerous conditions of use because workers would use respirators and gloves. *See* MC Risk Evaluation, at 34, 455-56; 2-NYER-13, 2-NYER-276-77. This assumption, however, is forbidden by TSCA.

TSCA section 6(b)(4)—which governs the risk evaluation process—directs EPA “to determine whether a chemical substance 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) (emphasis added). Specifically, EPA must make its risk determination “based solely on risk to human health and the environment—the integration of hazard and exposure information about a chemical—and not on the basis of other factors such as consideration of the costs or benefits of the substance or of *possible restrictions on the substance*” under other statutes. S. Rep. No. 114-67, at 17 (emphasis added). By prohibiting the agency from considering these factors, Congress intended

to “de-couple[]’ the Agency’s science-based risk decision about a chemical’s safety under its intended conditions of use from the Agency’s decision on how to manage unreasonable risks where chemicals do not meet the safety standard under intended conditions of use.” *Id.* EPA’s assumption that workers are protected by PPE improperly imports a risk *management* consideration into the risk *evaluation* stage, violating TSCA’s clear division of such considerations.

Furthermore, TSCA section 9(a) is also inconsistent with EPA’s approach. That provision authorizes EPA to consider whether an unreasonable “risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered” by EPA “[i]f the Administrator determines that the . . . chemical substance . . . presents an unreasonable risk,” 15 U.S.C. § 2608(a)(1) (emphasis added). Rather than grant EPA broad power to consider risk mitigation under other statutes, this language narrowly cabins EPA’s authority, precluding the agency from considering existing restrictions on a substance until after EPA has determined that a chemical poses an unreasonable risk. Like TSCA section 9(b) (see *supra* at 40-41), TSCA section 9(a) permits EPA

to consider the effects of other regulatory restrictions only during the risk *management* stage.

Moreover, the OSHA regulation on which EPA relied requires the use of respirators only in limited circumstances, providing an insufficient basis for EPA's assumption that workers are protected by PPE. The OSHA regulation provides that employers must implement engineering controls²⁸ and work practices controls²⁹ to reduce employee exposure to or below certain permissible exposure limits ("PELs"), to the extent such controls are feasible, if exposure to methylene chloride exceeds certain PELs. *See* 29 C.F.R. § 1910.1052(f)(1). Workers are required to use respiratory protection, such as respirators, only if other controls do not reduce exposure to or below the PELs. *See id.*

²⁸ "Examples of engineering controls are local exhaust ventilation, general and special isolation devices, and enclosures. These controls reduce employee exposure in the workplace by either removing or isolating the hazard or isolating the worker from it." OSHA, *Methylene Chloride*, OSHA 3144-06R3144, at 11-12, <https://www.osha.gov/Publications/osha3144.pdf>.

²⁹ "Work practice controls reduce the likelihood of exposure by altering the way a task is performed. One example is having a worker keep his or her face out of the methylene chloride vapor zone above a dip tank. Another safe practice is to prohibit employees from eating, drinking, smoking, taking medication, or applying cosmetics inside the work area where methylene chloride is used." OSHA, *supra* at 12.

The record is also devoid of evidence that workers will be able to use respirators, even when required by employers. As EPA’s Science Advisory Committee noted, there are numerous “known factors that affect workers’ or [occupational non-users] use of PPE, such as discomfort, limitations in movement, [and effects on] sensory perception.” SACC Report, at 72; 3-NYER-480. And as EPA has previously acknowledged, even where employers provide respirators and adequate training, “not all workers may be able to wear [them],” or to wear them safely and effectively.³⁰ 82 Fed. Reg. at 7,481; 3-NYER-581 (proposed rule banning paint-stripping uses of methylene chloride under TSCA). Accordingly,

³⁰ For example, “[i]ndividuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease . . . may be physically unable to wear a respirator.” 82 Fed. Reg. at 7,481; 3-NYER-581. Likewise, “[i]ndividuals with facial hair . . . that interfere[s] with a proper face-to-face respirator seal, cannot wear tight fitting respirators.” *Id.*; 3-NYER-581. And “respirators may also present communication problems, vision problems, worker fatigue, and reduced work efficiency.” *Id.*; 3-NYER-581; *see also ASARCO, Inc. v. OSHA*, 746 F.2d 483, 496 n.27, 497 (9th Cir. 1984) (concluding that the many “problems associated with respirators”—including “problems with adequate facial fit, increased heat stress, reduced vision,” and more—“render respirators woefully inadequate, standing alone, to protect worker health”).

“EPA’s assumptions of PPE use likely do not reflect actual conditions in most workplaces.” *See* SACC Report, at 17; 3-NYER-474.

Finally, the OSHA regulation only attempts to limit methylene chloride exposure to the extent of the PELs—25 parts per million (ppm)—and significant health risks remain even below that exposure level.³¹ *See Occupational Exposure to Methylene Chloride*, 62 Fed. Reg. 1,494, 1,575 (Jan. 10, 1997); 4-NYER-623. Specifically, OSHA found that even at its PEL of 25 ppm, workers exposed to methylene chloride would face an additional 3.6 deaths per 1,000 over a working lifetime. *See id.*; 4-NYER-623. OSHA adopted the 25 ppm PEL because that was the lowest level at which exposures could then be feasibly controlled without reliance on respirators—not based on health risk, as TSCA requires. *See id.*; 4-NYER-623; *see Pub. Citizen Health Research Group v. United States Dep’t of Labor*, 557 F.3d 165, 183 (3d Cir. 2009). As EPA itself recognized “the PEL is a technology-based limit, rather than a risk-based limit,” and

³¹ OSHA defines the PELs as an airborne concentration of methylene chloride in excess of 25 parts of methylene chloride per million parts of air (25 ppm) as an 8-hour time weighted average or 125 parts of methylene chloride per million parts (125 ppm) of air as determined over a sampling period of 15 minutes. *See* 29 C.F.R. § 1910.1052(c).

“there may be health risks in some cases from exposures below the PEL.”

EPA Response, at 192; 3-NYER-469.

POINT II

EPA’S CONCLUSION THAT SIX CONDITIONS OF USE OF METHYLENE CHLORIDE DO NOT PRESENT AN UNREASONABLE RISK IS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE

EPA’s analysis is also deficient for a further reason. EPA lacked substantial evidence in support of its conclusion that six “conditions of use” do not present an unreasonable risk of injury to health or the environment. *See* 15 U.S.C. § 2618(c)(1)(B)(i)(II).

When determining whether methylene chloride poses an unreasonable risk of injury to human health or the environment, TSCA requires EPA to use the “best available science” and all “reasonably available information,” and to make risk determinations based on the “weight of scientific evidence.” 15 U.S.C. § 2625(h), (i), (k); 40 C.F.R. § 702.33. “Best available science” means “science that is reliable and unbiased.” 40 C.F.R. § 702.33. These standards do not allow EPA to rely on “one or two individual cherry-picked studies, and forces a much greater level of transparency[.]” 162 Cong. Rec. S3522 (June 7, 2016).

EPA failed to meet these evidentiary standards with respect to each of the conditions of use for which EPA found no unreasonable risk.

First, EPA repeatedly relied on unrepresentative and self-serving data to diminish the risk of methylene chloride to workers. For example, with respect to the condition of use that involves domestic manufacturing, EPA acknowledged that workers may be exposed to methylene chloride through a variety of activities, such as routine production monitoring. *See* EPA, *Final Risk Evaluation for Methylene Chloride; Supplemental File; Supplemental Information on Releases and Occupational Exposure Assessment*, at 31 (June 2020) (“Supplemental Exposure Information”); 3-NYER-346. EPA also recognized that exposure levels resulting from these activities may vary “substantially depending on the facility’s operation, process enclosure, level of automation, engineering control, and PPE.” *Id.*; 3-NYER-346. Nonetheless, when analyzing the risk to manufacturing workers, EPA relied entirely on monitoring data submitted by a single trade group, the Halogenated Solvents Industry Alliance—an intervenor in this action. *See* MC Risk

Evaluation, at 131; 2-NYER-86.³² EPA admitted that this “data may not be representative.” MC Risk Evaluation, at 464; 2-NYER-280. Indeed the data covered only two out of as many as fourteen manufacturing facilities nationwide. EPA did not make any effort to establish the reliability of the data, or explain why it did not seek available data from other facilities. Under OSHA, all manufacturing facilities are required to collect and maintain monitoring data on methylene chloride exposure,³³ and EPA could have readily obtained this information under TSCA.³⁴ *See* 15 U.S.C. § 2625(k); 40 C.F.R. § 702.33(5).

³² EPA noted one other source of data, which indicated lethal levels of exposure to workers, but excluded this data in favor of the self-serving data provided by the Alliance. Supplemental Exposure Information, at 129, 146-47; 2-NYER-84, 101-02.

³³ OSHA requires employers who use methylene chloride to conduct initial monitoring of exposure levels. *See* 29 C.F.R. § 1910.1052(d)(2). If exposures exceed half the PEL, employers must continue periodic monitoring. *Id.* § 1910.1052(d)(3). Monitoring records must be accompanied by detailed industrial hygiene data, including on the use of respirators. *Id.* § 1910.1052(m)(2)(ii)(E). And employers must retain this data for 30 years. *Id.* § 1910.1052(m)(2)(iv).

³⁴ *See also Asbestos Disease Awareness Org. v. Wheeler*, No. 19-cv-00871, 2020 WL 7625445, at *10 (N.D. Cal. Dec. 22, 2020) (EPA is obligated “to collect reasonably available information to inform and facilitate its regulatory obligations under TSCA”).

EPA also used unrepresentative data to conclude that workers face no unreasonable risks from other conditions of use. For example, with respect to processing methylene chloride for recycling, EPA relied on personal breathing-zone monitoring data provided by two sources that EPA admitted “may not be representative of exposures across the range of facilities that recycle methylene chloride.” MC Risk Evaluation, at 468; 2-NYER-283. Similarly, with respect to processing methylene chloride as a reactant, EPA relied on personal breathing-zone monitoring data provided by one manufacturing facility, and EPA admitted “uncertainty regarding how well the data represent activities at all processing facilities.” MC Risk Evaluation, at 465; 2-NYER-281. And with respect to industrial and commercial uses of methylene chloride as a laboratory chemical, EPA acknowledged uncertainties regarding “the representativeness of the monitoring data toward the true distribution of inhalation concentrations for the industries and sites covered by this condition of use.” MC Risk Evaluation, at 494-95; 2-NYER-284-85. Moreover, EPA relied on the data without attempting to justify its reliance or explain why it was confident in its conclusion that these

conditions of use posed no unreasonable risk to workers. *See* MC Risk Evaluation, at 465, 467-68, 494-95; 2-NYER-281-85.

Second, EPA simply assumed that certain conditions of use do not pose an unreasonable risk to workers and occupational non-users without any supporting evidence. For example, Congress broadly defined the condition of use termed “distribution in commerce” to encompass any sale, transportation, delivery, or holding of a chemical substance.³⁵ *See* 15 U.S.C. § 2602(5). EPA unilaterally redefined and narrowed the meaning of this term to encompass only the “transportation associated with the moving of methylene chloride in commerce.” MC Risk Evaluation, at 468; 2-NYER-283. It then summarily determined that this condition of use does not present an unreasonable risk based on the unfounded assumption—supported by no data in the record—that “transportation of methylene chloride” is “in compliance with existing regulations for the transportation of hazardous materials, and emissions

³⁵ In full, “[d]istribution in commerce” means “to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.” 15 U.S.C. § 2602(5).

are therefore minimal.” MC Risk Evaluation, at 468; 2-NYER-283; *see also* EPA Response, at 15-16; 3-NYER-428-29.

EPA also failed to assess worker exposures associated with the disposal of methylene chloride. *See* Supplemental Exposure Information, at 110; 3-NYER-364. EPA recognized that over 12,000 workers at waste disposal sites are potentially exposed to methylene chloride via dermal contact or inhalation of vapors. *See* Supplemental Exposure Information, at 107; 3-NYER-361. Moreover, many workers at waste disposal sites are public workers for whom OSHA’s safety protections do not apply. *See* 29 U.S.C. § 652(5) (“The term ‘employer’ . . . does not include . . . any State or political subdivision of a State.”). EPA failed to analyze the extent to which any of these workers are actually exposed to methylene chloride and arbitrarily assumed that disposal processes do not present an unreasonable risk of injury to the health of workers. *See* MC Risk Evaluation, at 513-14; 2-NYER-286-87.

Third, EPA assumed without supporting evidence or explanation that occupational non-users face lower risks of dermal and inhalation

exposure than other workers.³⁶ But as EPA has admitted elsewhere, “[i]t is possible that some employees categorized as ‘occupational non-user’ have exposures similar to those in the ‘worker’ category depending on their specific work activity pattern.” MC Risk Evaluation, at 431-32; 2-NYER-269-70. And as the TSCA Science Advisory Committee has explained, many “workers who do not handle methylene chloride directly, but whose job requires them to be in the same area as users,” are at risk of dermal exposure, including cleaning staff and “office/managerial workers that could be incidentally exposed when visiting a work area.”³⁷ As a result, several members of the TSCA Science Advisory Committee

³⁶ Based on this assumption, EPA averaged all of the data points for inhalation exposures over eight hours and then relied on “central tendency data,” which reflects the 50th percentile of distribution, rather than the “high end” exposure level that EPA used for non-occupational non-users. *See* Supplemental Exposure Information, at 24; 3-NYER-344; *see also* MC Risk Evaluation, at 463; 2-NYER-279 (As to the domestic manufacturing condition of use, “EPA considered the workers’ central tendency risk estimates from inhalation exposures when determining [occupational non-users’] unreasonable risk.”); MC Risk Evaluation, at 465; 2-NYER-281 (same as to the processing as a reactant); MC Risk Evaluation, at 468; 2-NYER-283 (same as to processing for recycling); MC Risk Evaluation, at 494; 2-NYER-284 (same as to industrial and commercial uses as a laboratory chemical); MC Risk Evaluation, at 514; 2-NYER-287 (same as to disposal).

³⁷ SACC Report, at 31; 3-NYER-477.

“expressed concern that the risks to [occupational non-users] could be underestimated.”³⁸

EPA also provided no evidence for its assumption that occupational non-users face lower inhalation exposures compared to direct users.³⁹ EPA concluded that six conditions of use present no unreasonable risk of injury to the health of occupational non-users, purportedly relying on an absence of exposure data. But TSCA requires EPA to obtain reasonably available information, *see* 15 U.S.C. § 2603(a)(2), and EPA received relevant data from the TSCA Science Advisory Committee and commenters that contradicted its no unreasonable risk determinations.⁴⁰ EPA simply ignored that data.

³⁸ *See* SACC Report, at 18; 3-NYER-475.

³⁹ *See, e.g.*, MC Risk Evaluation, at 34; 2-NYER-13; Supplemental Exposure Information, at 32 (“EPA has not identified data on potential [occupational non-user] inhalation exposures from methylene chloride manufacturing.”); 3-NYER-347; Supplemental Exposure Information, at 37 (the same for processing of methylene chloride as a reactant); 3-NYER-352; Supplemental Exposure Information, at 109 (the same for the processing of methylene chloride in recycling); 3-NYER-363.

⁴⁰ *See, e.g., Comments from Academics, Scientists and Clinicians on the Draft Risk Evaluation for Methylene Chloride*, at 20 (Dec. 30, 2019) (citing evidence that occupational non-users have died after entering workplaces where methylene chloride has been used); 3-NYER-523; *Comments from Toxics Use Reduction Institute*, at 2-3 (Dec. 30, 2019)

POINT III

STATE AND MUNICIPAL PETITIONERS HAVE STANDING

To establish standing, State and Municipal Petitioners must demonstrate: (1) an injury, (2) that is traceable to EPA's conduct, and (3) redressable by a favorable decision. *See Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). Here, Congress has expressly given State and Municipal Petitioners, like all other persons, a clear right to seek judicial review of a risk determination by EPA that adversely affects them. *See* 15 U.S.C. § 2618(a)(1). Because of that express grant of a right to obtain judicial review, the typical redressability and traceability requirements of standing are relaxed, and a "litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant." *Massachusetts*, 549 U.S. at 518. Here, the requisite elements are more than satisfied.

(discussing observations of the Massachusetts Toxic Use Reduction Act staff that occupational non-users can have levels of exposure similar to that of occupational users); 3-NYER-534-35.

First, State and Municipal Petitioners will suffer a direct proprietary injury. It is well established that States and municipalities suffer an injury sufficient to establish standing when they expend resources “to mitigate and recover from harms that could have been prevented” absent the challenged regulatory action. *Air Alliance Houston v. EPA*, 906 F.3d 1049, 1059-60 (D.C. Cir. 2018). EPA’s faulty risk evaluation injures State and Municipal Petitioners’ proprietary interests by forcing them to incur additional expenses to (i) address the public health effects of methylene chloride, and (ii) remediate the adverse environmental effects of methylene chloride pollution.

The adverse public health effects of methylene chloride are undisputed. As EPA itself has recognized, long-term exposure to methylene chloride—whether in occupational or consumer settings—can result in various cancers, kidney and liver disease, decreased fertility, and other adverse health effects. Short-term exposures can also be fatal, causing heart attacks, hypoxia, and death. See *supra* at 14-15. See also MC Risk Evaluation, at 239-313 (surveying the human health hazards of methylene chloride exposure); 2-NYER-194-268.

These public health effects impose substantial costs on State and Municipal Petitioners. Work-related illnesses can generate substantial healthcare costs in the form of emergency room visits, long-term care expenses, and medications, among other things.⁴¹ 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 the State and Municipal Petitioners through Medicaid and other programs.⁴² 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, employer-provided benefits.⁴³ Accordingly, the costs of caring for many of these individuals

⁴¹ 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'tl. Med.* 607, 616 (2005); The Pew Charitable Trusts, *States Collectively Spend 17 Percent of their Revenue on Medicaid* (Jan. 9, 2020), <https://www.pewtrusts.org/en/research-and-analysis/articles/2020/01/09/states-collectively-spend-17-percent-of-their-revenue-on-medicaid>.

⁴² See Leigh, *supra* at 749; Schulte, *supra* at 615.

⁴³ 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'tl. Health* 304, 306 (2003).

will fall on State and Municipal Petitioners and are “precisely the kind of ‘pocketbook’” injuries that confer standing. *See Air Alliance*, 906 F.3d at 1059.

Occupational illnesses caused by methylene chloride exposure also harm State and Municipal Petitioners 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 the State and Municipal Petitioners.⁴⁴ *See, e.g., Wyoming v. Oklahoma*, 502 U.S. 437 (1992) (loss of state tax revenue constituted injury in fact).

Independently, State and Municipal Petitioners have borne and will continue to bear the costs of cleaning up methylene chloride pollution within their borders.⁴⁵ As explained above, EPA has acknowledged that

⁴⁴ *See Leigh, supra* at 731; *Schulte, supra* at 616.

⁴⁵ *See, e.g., Richard Maxwell and Toby Miller, The Environmental Ruin of Eastman Kodak*, Psychology Today (Apr. 12, 2018), <https://www.psychologytoday.com/us/blog/greening-the-media/201804/the-environmental-ruin-eastman-kodak>; 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), <https://www.justice.gov/>

air, water, and soil across the United States is polluted with methylene chloride. See *supra* at 37-38. In New York alone, there are scores of environmental remediation sites where methylene chloride is listed as a chemical of concern.⁴⁶ In the past, State and Municipal Petitioners have expended substantial funds to remediate hazardous pollution caused by methylene 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.⁴⁷

EPA's faulty risk evaluation ensures that extensive uses of methylene chloride will continue without significant restrictions. As a result, State and Municipal Petitioners will continue to bear remediation costs in the future, and their reasonable steps to "mitigate" such a "substantial risk" of harm further establish their standing. See *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013); see also *Air Alliance*,

usao-sdny/pr/manhattan-us-attorney-and-epa-announce-agreement-eastman-kodak-company-clean-rochester.

⁴⁶ See N.Y. State Dep't of Env'tl. Conservation, *supra*.

⁴⁷ See, e.g., Maxwell & Miller, *supra*; U.S. Att'y's Office, *supra*.

906 F.3d at 1059 (States had standing to challenge delayed implementation of new chemical safety protections based on “the expenditures states have previously made and may incur again when responding to accidental release during the delay period”).

Second, the State and Municipal Petitioners’ injuries are fairly traceable to the final risk evaluation, and they would be remedied by an order setting the evaluation aside. By ignoring TSCA’s requirements, EPA substantially understated the risks to the State and Municipal Petitioners’ residents and environments and essentially guaranteed the absence of new restrictions addressing severe hazards of methylene chloride. The revised and rigorous evaluation that State and Municipal Petitioners seek will require EPA to better account for methylene chloride releases, exposures, and risks, and to eliminate any risks EPA determines to be unreasonable. *See* 15 U.S.C. § 2605(a); *see also Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1355 (9th Cir. 1994) (causation and redressability established where “environmental consequences might be overlooked, as a result of deficiencies in the government’s analysis under environmental statutes” (quotation marks omitted)).

CONCLUSION

For the reasons stated above, State and Municipal Petitioners respectfully request that the Court grant the petition for review and set aside EPA's Final Order (MC Risk Evaluation, Subsection 5.4.1; 1-NYER-4-5) determining that methylene chloride does not pose an unreasonable risk of injury to health or the environment. *See* 15 U.S.C. § 2618(c)(2).

More specifically, State and Municipal Petitioners request that the Court vacate and remand with instructions for EPA to within 90 days (1) evaluate the hazards and exposures that methylene chloride presents to health and the environment, including to account for all methylene chloride releases to air, water, and soil; (2) evaluate the risk that methylene chloride poses to workers and determine whether the chemical presents unreasonable risk without consideration of the use of PPE; (3) evaluate the risk that methylene chloride poses to potentially exposed or susceptible subpopulations, including the communities neighboring commercial and industrial emitters of methylene chloride and those who have special genetic sensitivity to methylene chloride; (4) revise the risk evaluation to evaluate the hazards and exposures in which people and

the environment may be exposed to methylene chloride through its conditions of use, and evaluate that information to determine whether methylene chloride as a whole, as opposed to its separate conditions of use, presents an unreasonable risk of injury to health or the environment; and (5) revise the risk evaluation on remand in accordance with best available science, the weight of the scientific evidence, and reasonably available information.

Dated: New York, New York
January 25, 2021

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STATEMENT OF RELATED CASES

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

Form 17. Statement of Related Cases Pursuant to Circuit Rule 28-2.6

9th Cir. Case Number(s): 20-73276

The undersigned attorney or self-represented party states the following:

I am unaware of any related cases currently pending in this court.

I am unaware of any related cases currently pending in this court other than the case(s) identified in the initial brief(s) filed by the other party or parties.

I am aware of one or more related cases currently pending in this court. The case number and name of each related case and its relationship to this case are:

Neighbors for Environmental Justice et al. v. EPA, No. 20-72091 (2d Cir. 2020) challenges the same agency order and raises the same or closely related issues.

Signature s/ Sarah K. Kam **Date** January 25, 2021
(use "s/[typed name]" to sign electronically-filed documents)

CERTIFICATE OF COMPLIANCE FOR BRIEFS
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

9th Cir. Case Number(s): 20-73276

I am the attorney or self-represented party.

This brief contains 12,085 words, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this brief (*select only one*):

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