THE ATTORNEYS GENERAL OF NEW YORK, HAWAI'I, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, NEW JERSEY, 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 chemicals[2] 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 formulation[7] 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.

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

[4] 15 U.S.C. § 2601 *et seq.*

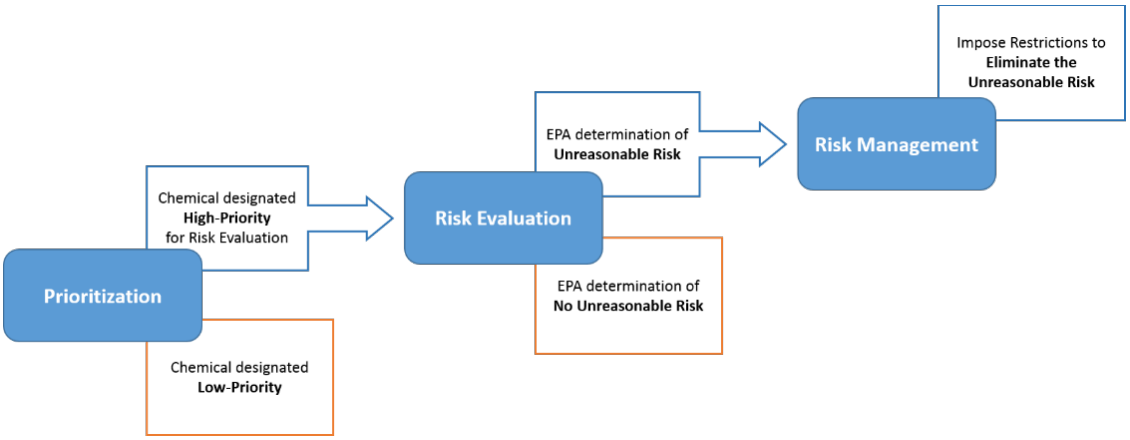
[5] 81 Fed. Reg. 91,927.

[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

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[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 UMCR 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

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[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,

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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

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[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.

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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

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[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]

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chemical/98/i43.

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

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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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