State of Rhode Island and Providence Plantations

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Peter F. Kilmartin, Attorney General

August 15, 2018

Via Electronic Filing

EPA-HQ-OPPT-2016-0736 (Asbestos)
EPA-HQ-OPPT-2016-0741 (1-Bromopropane)
EPA-HQ-OPPT-2016-0723 (1,4-Dioxane)
EPA-HQ-OPPT-2016-0733 (Carbon Tetrachloride)
EPA-HQ-OPPT-2016-0735 (Cyclic Aliphatic Bromide Cluster, also known as HBCD)
EPA-HQ-OPPT-2016-0742 (Methylene Chloride)
EPA-HQ-OPPT-2016-0743 (N-Methylpyrrolidone (NMP))
EPA-HQ-OPPT-2016-0725 (Pigment Violet 29)
EPA-HQ-OPPT-2016-0732 (Tetrachloroethylene, also known as Perchloroethylene)
EPA-HQ-OPPT-2016-0737 (Trichloroethylene (TCE))
EPA-HQ-OPPT-2018-0210 (Application of Systemic Review in TSCA Risk Evaluations)

Charlotte Bertrand, Acting Principal Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: Notice of Availability on Problem Formulations for the Risk Evaluations to be Conducted Under the Toxic Substances Control Act for Asbestos, 1-Bromopropane, 1,4 Dioxane, Carbon Tetrachloride, Cyclic Aliphatic Bromide Cluster, also known as HBCD, Methylene Chloride, N-Methylpyrrolidone (NMP), Pigment Violet 29, Tetrachloroethylene, also known as Perchloroethylene, and Trichloroethylene (TCE) and General Guiding Principles to Apply Systematic Review in TSCA Risk Evaluations (83 Fed. Reg. 26,998 (Jun. 11, 2018))

Dear Acting Principal Deputy Assistant Administrator Bertrand:

Rhode Island Attorney General Peter F. Kilmartin hereby submits this comment letter, joining the August 3, 2018 comment letter from the Attorneys General of Massachusetts, California, Hawaii, Maine, Maryland, New Jersey, New York, Oregon, Vermont, Washington, and the District of Columbia regarding the U.S. Environmental Protection Agency's ("EPA") problem formulations of the risk evaluations for the ten chemical substances (the "Initial Ten TSCA Chemicals") that are the subject of EPA's initial chemical risk evaluations required under the

Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Act"), amending the Toxic Substances Control Act (TSCA). A copy of that letter is attached hereto as "Exhibit A."

Thank you for this opportunity to submit these comments on this important matter, which will help to protect the health of millions of Americans.

PETER F. KILMARTIN
Attorney General of Rhode Island

/s/ Gregory S. Schultz

GREGORY S. SCHULTZ
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Exhibit A

THE ATTORNEYS GENERAL OF MASSACHUSETTS, CALIFORNIA, HAWAII, MAINE, MARYLAND, NEW JERSEY, NEW YORK, OREGON, VERMONT, WASHINGTON, AND THE DISTRICT OF COLUMBIA

August 3, 2018

Via Electronic Filing

EPA-HQ-OPPT-2016-0736 (Asbestos)
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Re: Notice of Availability on Problem Formulations for the Risk Evaluations to be Conducted Under the Toxic Substances Control Act for Asbestos, 1-Bromopropane, 1,4 Dioxane, Carbon Tetrachloride, Cyclic Aliphatic Bromide Cluster, also known as HBCD, Methylene Chloride, N-Methylpyrrolidone (NMP), Pigment Violet 29, Tetrachloroethylene, also known as Perchloroethylene, and Trichloroethylene (TCE) and General Guiding Principles to Apply Systematic Review in TSCA Risk Evaluations (83 Fed. Reg. 26,998 (Jun. 11, 2018))

Dear Acting Principal Deputy Assistant Administrator Bertrand:

The Attorneys General of Massachusetts, California, Hawaii, Maine, Maryland, New Jersey, New York, Oregon, Vermont, Washington, and the District of Columbia appreciate this opportunity to comment on the U.S. Environmental Protection Agency's ("EPA") problem formulations of the risk evaluations for the ten chemical substances (the "Initial Ten TSCA Chemicals")[1] that are the subject of EPA's initial chemical risk evaluations required under the

[1] *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*,

Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Act"),[2] amending the Toxic Substances Control Act (TSCA).[3]

In its notice dated June 11, 2018, EPA requested comments on the problem formulation documents for the Initial Ten TSCA Chemicals (the "Problem Formulations") to assist the agency in developing its draft risk evaluations for these chemical substances.[4]

The Attorneys General submit the following comments for EPA's consideration as EPA proceeds with its risk evaluations of the Initial Ten TSCA Chemicals.[5]

SUMMARY OF COMMENTS

The undersigned Attorneys General support the goal that motivated the Lautenberg Act amendments to TSCA, signed into law on June 22, 2016: the goal of reforming TSCA to remove obstacles that had prevented EPA from playing a more robust role in protecting public health and the environment from toxic chemicals.

Unfortunately, the Problem Formulations are antithetical to that purpose. EPA takes the position that TSCA authorizes the agency to consider in its risk evaluation a mere subset of the uses for which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed. That interpretation would result in EPA's risk evaluations being woefully incomplete by ignoring significant exposure pathways for the chemical substances. This unlawfully restrictive application of TSCA ignores that Congress intended for EPA to assess a chemical in its entirety, based on all identifiable conditions of use, including ongoing and legacy uses, like the ubiquitous continued use of notoriously hazardous asbestos, in its risk evaluations. For this reason, the Problem Formulations would produce deeply flawed risk evaluations that would make it impossible for EPA to fulfill its statutory mandate under Section 6 of TSCA of establishing requirements for the Initial Ten TSCA Chemicals to ensure that none of the chemical substances presents "an unreasonable risk of injury to health or the environment."[6]

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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 Ten TSCA Chemicals are: Asbestos, 1-Bromopropane, 1,4-Dioxane, Carbon Tetrachloride, Cyclic Aliphatic Bromide Cluster, also known as HBCD, Methylene Chloride, N-Methylpyrrolidone (NMP), Pigment Violet 29, Tetrachloroethylene, also known as Perchloroethylene, 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).

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

[3] 15 U.S.C. § 2601, et seq.

[4] *See* 83 Fed. Reg. 26,998 (Jun. 11, 2018). EPA also solicited comments on its "*Application of Systematic Review in TSCA Risk Evaluations*," dated May 2018, which these comments do not address.

[5] The framework rules that EPA issued to implement the amendments to TSCA, Section 6, including with respect to the procedures for conducting risk evaluations, are currently under review in the Ninth Circuit. *See Safer Chemicals, Healthy Families, et al., v. EPA, et al.*, Docket No. 17-72260 (9th Cir.).

[6] *See* 15 U.S.C. § 2605(a).

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We thus urge EPA to issue revised Scopes of the Risk Evaluation, which the Problem Formulations are meant to refine,[7] for each of the Initial Ten TSCA Chemicals to address the agency's fatally flawed approach to identifying the conditions of use as that term is understood under TSCA and to ensure that the data EPA considers in the process satisfies TSCA's "best available science" standards. Given the well-documented hazards of many of the Initial Ten TSCA Chemicals, we fully expect that after conducting appropriate risk evaluations, EPA will impose new protective restrictions, and in some cases bans, for the chemical substances in this group.

These comments proceed as follows. In Part I, we describe TSCA's requirements for the risk evaluations. In Part II, we provide a summary of our states' interests with regard to the risk evaluations. In Part III, we offer analysis supporting our call for EPA to reconsider its approach to its conditions of use characterizations and to ensure that data consistent with TSCA's requirements are considered in the risk evaluation process. Finally, we suggest an appropriate risk evaluation path forward that will satisfy Congress's mandate under TSCA that EPA act to eliminate unreasonable risks of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations.

I. Risk Evaluations for the Initial Ten TSCA Chemicals

Under TSCA, as amended, EPA is required to prioritize chemical substances for regulatory review and then assess the risks posed by the chemicals identified as priorities. Risk is a function of hazard and exposure, and to evaluate the risks posed by a chemical as TSCA requires it is necessary to consider the full range of exposures. However, in the Problem Formulations EPA has, without basis in law or fact, eliminated from its risk evaluation process many significant sources of chronic exposure to these toxic chemical substances.

Section 6 of TSCA requires EPA systematically to prioritize for risk evaluation, and to evaluate the potential risks presented by, the manufacture, processing, distribution in commerce, use, or disposal of chemical substances or mixtures.[8] Within 180 days of enactment of the 2016 TSCA amendments, that is by December 19, 2016, EPA was required to begin risk evaluations on ten chemical substances drawn from the agency's *TSCA Work Plan for Chemical Assessments: 2014 Update* (the "2014 TSCA Work Plan Update")[9] and to publish the list of such

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[7] 83 Fed.Reg. 26,998 at 26,999.

[8] 15 U.S.C. § 2605.

[9] In 2012, EPA identified 83 chemicals for assessment as part of its chemical safety program. According to EPA, the screening process for identifying the chemicals was based on a combination of hazard, exposure (including via uses), and persistence and bioaccumulation characteristics, and in developing the 2014 Update the agency continued to use the process, which focused on chemicals that meet one or more of the following factors: (i) potential concern for children's health (for example, because of reproductive or developmental effects); (ii) neurotoxic effects; (iii) persistent, bioaccumulative and toxic; (iv) probable or known carcinogens; (v) used in children's products or in products to which children may be highly exposed; and (vi) detected in biomonitoring programs. *See 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.

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chemical substances during the 180-day period.[10] On December 19, 2016, EPA designated the Initial Ten TSCA Chemicals for risk evaluation: Asbestos, 1-Bromopropane, 1,4-Dioxane, Carbon Tetrachloride, Cyclic Aliphatic Bromide Cluster (also known as HBCD), Methylene Chloride, N-Methylpyrrolidone (NMP), Pigment Violet 29, Tetrachloroethylene (also known as Perchloroethylene), and Trichloroethylene (TCE).[11]

Under TSCA, Section 6(b)(4)(A), EPA is required to conduct a risk evaluation for each of the Initial Ten TSCA Chemicals, and for chemicals later designated as "high-priority," to determine whether the

> . . . chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of cost or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.[12]

And under TSCA, Section 6(b)(4)(D), EPA was required to publish the scope of the risk evaluation to be conducted for each of the Initial Ten TSCA Chemicals within six months after the initiation of the risk evaluation.[13]

On July 7, 2017, EPA published its Notice of Availability for the Scopes of the Risk Evaluations To Be Conducted for the First Ten Chemical Substances Under the Toxic Substances Control Act.[14] Under TSCA, those scopes must include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in his or her analysis.[15] Thereafter, EPA published the subject Problem Formulations in the Federal Register on June 11, 2018,[16] with the Problem Formulations being said to function to refine the earlier-published scope documents.[17]

II. The Interests of the Participating States

Our states have a significant interest in ensuring that the risk evaluations for the Initial Ten TSCA Chemicals are conducted in accordance with TSCA. The Initial Ten TSCA

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[10] 15 U.S.C. § 2605(b)(2)(A).

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

[12] 15 U.S.C. § 2605(b)(4)(A).

[13] 15 U.S.C. § 2605(b)(4)(D).

[14] 82 Fed. Reg. 31,592 (Jul. 7, 2017).

[15] *See* 15 U.S.C. § 2605(b)(4)(D).

[16] 83 Fed. Reg. 26,998 (Jun. 11, 2018).

[17] *Id.* at 26,999.

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Chemicals were drawn from the agency's 2014 TSCA Work Plan Update,[18] as required by TSCA,[19] and were selected based on their hazard and potential exposure, as well as other factors such as persistence and bioaccumulation.[20] For example, asbestos is a known carcinogen, with acute and chronic toxicity associated with inhalation exposures; tetrachloroethylene (also known as perchloroethylene or perc) is a probable human carcinogen with high reported releases to the environment; and n-methylpyrrolidone (NMP) has high reported releases to the environment and is associated with reproductive toxicity.[21] The potential for substantial harm to public health and the environment associated with the Initial Ten TSCA Chemicals resulted in their being chosen as the first candidates for risk evaluation. Thus, the consequences for our states' residents of a federal failure to identify those risks and to regulate accordingly may be dire, with the potential for even greater risk to susceptible subpopulations, where the failure to perform a full analysis may have the most severe adverse impact.

As evidenced by the following overview of actions by many of the participating states and the District of Columbia, the unreasonable risks to human health and the environment that the Initial Ten TSCA Chemicals pose justifies governmental response. In fact, it is just such health- and environment-protective regulation at the federal level that informed the 2016 amendments to TSCA.

Additionally, the data listed below that demonstrates the prevalence of the Initial Ten TSCA Chemicals in our states further confirms the states' significant interest in ensuring that EPA implements TSCA as it was revised by the Lautenberg Act: to eliminate "unreasonable risk of injury to health or the environment" from the "intended, known, or reasonably foreseen" manufacturing, processing, distribution in commerce, use, or disposal of chemicals.[22]

Massachusetts

Under the Massachusetts Toxics Use Reduction Act, G.L. c. 21I ("TURA"), large-quantity chemical users in the Commonwealth are required to report annually on their use of toxic chemicals and conduct toxics use reduction planning every two years. Each of the Initial Ten TSCA Chemicals, with the exception of Cyclic Aliphatic Bromide Cluster, also known as HBCD, and Pigment Violet 29, are on the TURA chemicals list and are subject to TURA's requirements.[23] Moreover, the TURA program may designate "Higher" or "Lower Hazard Substances" within the larger TURA list of Toxic or Hazardous Substances. If a chemical is designated as a Higher Hazard Substance (HHS) under TURA, the thresholds for reporting for

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[18] *See 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.

[19] *See* 15 U.S.C. § 2605(b)(2)(A).

[20] 81 Fed. Reg. 91,927 (Dec. 19, 2016), at 91,928–91,929.

[21] *Id.*

[22] 15 U.S.C. § 2602(4) and § 2605(b)(4)(A).

[23] That HBCD and Pigment Violet 29 are not listed does not represent any judgment of the toxicity of these chemicals. It simply means that they have not been taken up for consideration and possible addition to the TURA list and they may later be added to the TURA list.

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those chemicals are lowered. To date, the TURA program has designated 14 chemicals or chemical categories as HHS.[24] Four of the Initial Ten TSCA Chemicals are designated as HHS under TURA: trichloroethylene, perchloroethylene, 1-bromopropane, and methylene chloride.[25]

In Massachusetts, the Toxics Use Reduction Institute ("TURI"), created under TURA, Section 6, and the Massachusetts Office of Technical Assistance and Technology ("OTA"), its partner agency, work with Massachusetts businesses to reduce the use of toxic chemicals in the state. TURI and OTA are engaged in on-going work to help Massachusetts businesses and communities reduce their use of toxic solvents including trichloroethylene, perchloroethylene, methylene chloride, 1-bromopropane, and n-methylpyrrolidone, as well as helping businesses adopt safer alternatives to toxic flame retardants, among other efforts. This work to assist Massachusetts businesses and communities complements other regulatory activities within the Commonwealth to protect workers, communities and the environment from these and other toxic chemicals.

Massachusetts also comprehensively regulates asbestos through a set of overlapping state and delegated federal programs involving multiple state agencies. From 2011–2015, the U.S. Centers for Disease Control and Prevention (CDC) reports there were 441 new cases of mesothelioma in Massachusetts, resulting in 366 deaths.[26] Asbestos exposure is the known cause of mesothelioma.

- The Massachusetts Department of Environmental Protection ("MassDEP") is authorized by the Massachusetts Clean Air Act, M.G.L. c. 111, §§ 142A-O, and the federal Clean Air Act, 42 U.S.C. § 7401, et seq., to prevent air pollution by regulating asbestos handling, transport, and disposal.
- MassDEP requires notice and remediation of releases of asbestos to the environment as a hazardous material under the state's "superfund" law, M.G.L. c. 21E.
- MassDEP also regulates the disposal of asbestos under the Massachusetts Solid Waste Management Act, M.G.L. c. 111, § 150A.
- The Massachusetts Department of Labor Standards ("DLS") ensures worker safety in Massachusetts by licensing asbestos-related work and requiring the use of proper work practices and safety equipment pursuant to M.G.L. c. 149.
- DLS is also delegated authority under the Asbestos Hazard Emergency Response Act, 15 U.S.C. § 2641, et seq., to regulate asbestos in schools for the safety of the school community.

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[24] *See Designation of TURA Higher and Lower Hazard Substances in Massachusetts*, MASS. EXEC. OFFICE OF ENERGY & ENVTL. AFFAIRS (2016), https://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets/Higher_and_Lower_Hazard_Substances.

[25] That six of the Initial Ten TSCA Chemicals are not designated as HHS in Massachusetts does not mean that the TURA program considers them to be less toxic than others. Rather, it means that those chemicals have not yet been addressed under this regulatory process.

[26] *See* https://gis.cdc.gov/Cancer/USCS/DataViz.html (last accessed July 26, 2018).

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- The Massachusetts Office of the Attorney General is empowered to initiate litigation to enforce these state statutes and to seek court orders for compliance and civil penalties.

The Attorney General also conducts other work to encourage the safe use and public awareness of asbestos, such as leading a multi-party stakeholder effort to create a comprehensive online public database of asbestos information about Massachusetts schools in response to a report by the Office of Senator Edward J. Markey identifying a lack of this information nationally.

California

Because of the significant harm to human health and the environment that the Initial Ten TSCA Chemicals pose, California has implemented regulatory measures including, but not limited to: prohibiting the sale, supply, and manufacturing for use of specified consumer product categories that contain any of the following compounds: TCE, PCE, or methylene chloride;[27] regulating exposure to asbestos in construction work,[28] general industry,[29] shipyards[30] and prohibiting sale of brake pads with asbestiform fibers above .1% weight.[31] California has proposed regulation of methylene chloride in varnish and paint strippers under its Safer Consumer Products regulations (Cal. Code Regs., tit. 22, § 69501, et seq.). With the exception of HBCD and Pigment Violet 29, each of the Initial Ten TSCA Chemicals is listed as either a carcinogen and/or reproductive toxin under California's Safe Drinking Water and Toxic Enforcement Act of 1986 known as "Proposition 65."[32] The adverse impacts to California these substances cause are further demonstrated by the following:

- From 2011–2015, the CDC reports there were 1,716 new cases of mesothelioma in California, resulting in 1,318 deaths.[33] Asbestos exposure is the known cause of mesothelioma.
- There have been at least two deaths in California caused by exposure to paint strippers containing methylene chloride since 2012.[34]
- There are 37 sites in California with TCE contamination that have been or are on the National Priorities List (NPL) under the Comprehensive Environment Response, Compensation and Liability Act (CERCLA), 29 with PCE contamination, 6 with asbestos contamination, 10 with 1,4-dioxane contamination,

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[27] California Code of Regulations ("Cal. Code Regs."), tit. 17, §§ 93111(d), 94509(m), and 94552(e).

[28] *Id.* tit. 8, § 1529.

[29] *Id.* tit. 8, § 5208.

[30] *Id.* tit. 8, § 8358.

[31] California Health and Safety Code ("Health & Saf. Code"), § 25250.51.

[32] *Id.* § 25249.5, et seq.

[33] *See* https://gis.cdc.gov/Cancer/USCS/DataViz.html (last accessed July 26, 2018).

[34] *See* https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/Pages/MeClLinks.aspx (last accessed July 27, 2018).

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36 with methylene chloride contamination, and 25 with carbon tetrachloride contamination. [35]

- In 2016, the most current Toxic Release Inventory (TRI) reporting year, a combined total of 2,124,369 pounds of 1,4-dioxane, asbestos, carbon tetrachloride, NMP, PCE and TCE was reported as having been disposed of or released in California.[36]

Maine

Under the Maine Priority Toxic Chemical Use Reduction law, 38 Maine Revised Statutes ("M.R.S.") §§ 2331-2330, and corresponding rule, 06-096 Code of Maine Rules ("CMR") ch. 82, commercial and industrial facilities using more than 1,000 pounds/year of a priority toxic chemical listed in Maine's rule, 06-096 CMR ch. 81, must report their usage of the chemical and must develop a pollution prevention plan, which must be updated every two years. Maine has identified five chemicals as priority toxic chemicals under this law, two of which are on the list of Initial Ten TSCA Chemicals—perchloroethylene and trichloroethylene.

Maine regulates several of the chemicals on the list of Initial Ten TSCA Chemicals as hazardous matter and hazardous substances.[37] In addition, Maine regulates control technology for dry cleaners using perchloroethylene.[38]

Maine also comprehensively regulates asbestos abatement activities to ensure safe working conditions pursuant to its asbestos law, 38 M.R.S. §§ 1271-1284, and its corresponding rule, 06-096 CMR ch. 425, and the disposal and transportation of asbestos under its Solid Waste Management Rules, 06-096 CMR ch. 401 (disposal); 06-096 CMR ch. 411 (transportation). Additionally, in Maine, all sellers of residential real property are required to disclose the presence of asbestos or the prior removal of asbestos to potential buyers.[39] From 2011–2015, the CDC reports there were 128 new cases of mesothelioma in Maine, resulting in 107 deaths.[40]

Moreover, the Maine Department of Environmental Protection has been delegated by the U.S. Environmental Protection Agency to conduct periodic Asbestos Hazard Emergency Response Act (AHERA) compliance inspections in Maine's non-profit school systems.

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[35] Data reflected by searching California for all active NPL sites for these contaminants via EPA's Superfund Enterprise Management System at https://cumulis.epa.gov/supercpad/CurSites/srchsites.cfm.

[36] Data reflected by searching the TRI for California as to release or disposal of Initial Ten TSCA Chemicals via EPA's TRI Explorer at https://iaspub.epa.gov/triexplorer/tri_release.chemical (last accessed August 2, 2018).

[37] 38 M.R.S. § 1362(1); 06-096 CMR ch. 800, 801.

[38] 06-096 CMR ch. 125.

[39] 33 M.R.S. § 173(4).

[40] *See* https://gis.cdc.gov/Cancer/USCS/DataViz.html (last accessed July 26, 2018).

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Maryland

Maryland regulates the manufacture, sale, use, and disposal of chemicals—including some of the substances to be addressed in EPA's initial risk evaluations—in a variety of ways. For instance, businesses engaged in the removal or encapsulation of asbestos may do so only pursuant to a license issued by the Maryland Department of the Environment—which, in turn, has prescribed strict procedures governing such activities.[41] From 2011–2015, the CDC reports there were 258 new cases of mesothelioma in Maryland, resulting in 207 deaths.[42]

More broadly, the Department regulates the disposal of hazardous waste, including substances included in EPA's Initial Ten TSCA Chemicals.[43] Maryland Department of the Environment regulations generally prohibit the sale, supply, offer for sale, or manufacture for use in the state of adhesives, cleaners, and other products containing methylene chloride, perchloroethylene, or trichloroethylene.[44] Additionally, the Maryland Secretary of Health may declare a substance to be "hazardous material" and establish labeling requirements or, where appropriate, ban the substance.[45] The Secretary has exercised this authority by incorporating by reference Parts 1500 and 1505 of Title 16 of the Code of Federal Regulations (implementing the Federal Hazardous Substances Act).[46] The Secretary is authorized to inspect facilities where hazardous material may be manufactured, processed, packaged, or stored, as well as vehicles used to transport or hold such material.[47]

New York

New York regulates the manufacture, sale, use and disposal of chemicals, including some at issue in the Problem Formulations, in a variety of ways. For example, New York has a de facto ban on the use of 1-bromopropane, also known as n-propyl bromide, in dry cleaning.[48] New York will not issue an Air Facility Registration to any facility proposing to use that chemical as an alternative dry cleaning solvent as it is not an approved alternative solvent. New York has spent millions of dollars cleaning up tetrachloroethylene (perc) and trichloroethylene at hazardous waste sites. To help remove 1,4-dioxane from drinking water on Long Island, New York has conditionally approved a new treatment technology.[49] As regards asbestos, New York

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[41] *See* Annotated Code of Maryland ("Md. Code Ann."), Env't tit. 6 subtit. 4; Code of Maryland Regulations ("Md. Code Regs.") tit. 26, subtit. 11, ch. 21.

[42] *See* https://gis.cdc.gov/Cancer/USCS/DataViz.html (last accessed July 26, 2018).

[43] Md. Code Regs. tit. 26, subtit. 13.

[44] Md. Code Regs. 26.11.32.08 to .09.

[45] Md. Code Ann., Health § 22-502.

[46] Md. Code Regs. 10.19.02.01.

[47] Md. Code Ann., Health § 22-506.

[48] *See* NEW YORK STATE DEP'T OF ENVTL. CONSERVATION, *Approved Alternative Solvents for Dry Cleaning, available at* http://www.dec.ny.gov/chemical/72273.html.

[49] *See* Governor's Office, "*Governor Cuomo Announces Conditional Approval For New Drinking Water Treatment Technology in Suffolk County*," *available at* https://www.governor.ny.gov/news/governor-cuomo-announces-

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has a number of regulatory programs in place: the Department of Health certifies and trains employees who perform asbestos abatement; the Department of Labor regulates asbestos abatement and removal projects; and the Department of Environmental Conservation regulates the transportation and disposal of asbestos waste.[50]

Oregon

Oregon has adopted, and is considering, several state-specific statutes and regulations to manage the impacts of toxic and hazardous pollutants that encompass the majority of the Initial Ten TSCA Chemicals. These programs include:

- Asbestos emissions, disposal, licensing and certification requirements.[51] From 2011–2015, the CDC reports there were 245 new cases of mesothelioma in Oregon, resulting in 223 deaths.[52]
- Air toxics permits and benchmarks for industrial facilities.[53] In addition, Oregon is currently in the process of developing new rules on industrial air emissions that would regulate emissions based on health risks to neighboring communities. The proposed rules will regulate emissions of hundreds of chemicals, including several of the Initial Ten TSCA Chemicals: asbestos, 1-bromopropane, carbon tetrachloride, 1,4 dioxane, tetrachloroethylene, and trichloroethylene. Oregon is relying on federal guidance and expertise to help define potential health risks for communities that are exposed to these emissions and to ensure that communities are protected from cumulative risks from other potential exposure pathways.
- Toxics Use and Hazardous Waste Reduction planning requirements,[54] which apply to large and small quantity generators of hazardous waste and Toxic Release Inventory reporters.
- State cleanup and remedial actions for hazardous substances,[55] and separate rules for dry cleaning facilities with perchloroethylene (tetrachloroethylene).[56] In addition, legacy contamination from industrial sites is still a potential source of exposure to several of the Initial Ten TSCA Chemicals. The Oregon Health Authority's Environmental Health Assessment Program evaluates potential public health risks from contaminated sites across our state. In the last year alone, the program has been asked to evaluate public health risks from sites where

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conditional-approval-new-drinking-water-treatment-technology-suffolk.

[50] *See* New York State Department of Environmental Conservation, Asbestos Regulation, at https://www.dec.ny.gov/chemical/8791.html.

[51] Oregon Revised Statutes (ORS) 468A.700 to 468A.760 and Oregon Administrative Rules (OAR) ch. 340, div. 248).

[52] *See* https://gis.cdc.gov/Cancer/USCS/DataViz.html (last accessed July 26, 2018).

[53] OAR ch. 340, div. 246.

[54] ORS 465.003 to 465.037 and OAR 340-135.

[55] ORS 465.200 through 465.455 and 465.900, and OAR ch.340, div. 122.

[56] ORS 465.200 and 465.500 through 465.548, and OAR 340-124.

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environmental monitoring projects detected at least one of the Initial Ten TSCA Chemicals, including 1,4 dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and/or trichloroethylene.

- Oregon adopted the Toxic Free Kids Act in 2015, requiring manufacturers of children's products to report the presence of specific chemicals of concern in products sold in Oregon.[57] Several of the Initial Ten TSCA Chemicals are being reported in that program, including 1,4 dioxane, methylene chloride, tetrachloroethylene, and hexabromocyclododecane.[58] Oregon relies on information from federal agencies to evaluate potential health risks of chemicals of concern for children, to identify new chemicals of concern to add to the reporting list, and to help address cumulative risks from these chemicals through other routes of exposure.

Across all of these programs, Oregon has compiled data documenting the presence of the majority of the Initial Ten TSCA Chemicals in various environmental media. EPA must consider the full scope of impacts from these chemicals in states like Oregon in determining the scope of TSCA risk evaluations for the Initial Ten TSCA Chemicals.

Washington

The Washington State Waste Reduction Act ("WRA") was enacted "[i]n the interest of protecting the public health, safety, and the environment[.]"[59] Under the WRA, any person generating over 2,640 pounds of hazardous waste annually is required to "prepare a plan for the voluntary reduction of the use of hazardous substances and the generation of hazardous wastes."[60] The Revised Code of Washington 70.95C.020 provides that both dangerous waste and extremely hazardous waste "shall specifically include those wastes designated as dangerous by rules adopted pursuant to chapter 70.105 RCW."[61] Accordingly, pursuant to RCW 70.105, the Washington State Department of Ecology ("Ecology") has designated five of the Initial Ten TSCA Chemicals as dangerous wastes subject to voluntary reduction plans.[62]

Within Ecology, the WRA establishes an office of waste reduction (also referred to as Ecology).[63] Ecology's duties, in part, include encouraging the reduction of hazardous waste use, coordinating with all state agency programs to provide technical assistance, and coordinating public education programs on waste reduction.[64] Additionally, Ecology provides technical

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[57] ORS 431A.250 through 431A.280.

[58] OAR 333-016-2020.

[59] Revised Code of Washington ("RCW") 70.95C.010.

[60] RCW 70.95C.200(1); Washington Administrative Code ("WAC") 173-305-015.

[61] RCW 70.95C.020(3), (5).

[62] *See* WAC 173-303-090(8), -9903, -9904, -9905 (listing 1,4-dioxane, carbon tetrachloride, methylene chloride, tetrachloroethylene, and trichloroethylene).

[63] RCW 70.95C.030(1).

[64] *See* RCW 70.95C.030.

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assistance in preparing plans pursuant to WRA in an effort to reduce the use of such dangerous wastes.[65]

In the context of hazardous waste and toxics reduction, Washington State has additional statutes that authorize Ecology to regulate asbestos and many Initial Ten TSCA Chemicals due to their associated harms to public health and the environment.[66] For example, Washington's Better Brakes Law mandates a phase out of asbestos in brake friction material that is sold, or offered for sale, in Washington State.[67] From 2011–2015, the CDC reports there were 463 new cases of mesothelioma in Washington State, resulting in 394 deaths.[68] In addition, under Washington's Children's Safe Products Act, manufacturers whose products contain certain chemicals, like N-Methylpyrrolidone, methylene chloride, tetrachloroethylene, and HBCD, must annually report to Ecology.[69] With respect to children's products containing HBCD, a flame retardant, Ecology is required to evaluate "potential impacts on human health and the environment resulting from . . . [chemical] exposure" when developing policies and recommendations.[70]

Ecology collaborates with many state agencies, such as the Washington State Department of Health, and works with industries and environmental stakeholders, to identify chemicals that pose the highest risks to human health and the environment. Thereafter, Ecology develops and enforces policies, toxic chemical regulations, and plans to reduce or eliminate the use of toxic chemicals.

District of Columbia

The District of Columbia's Hazardous Waste Management Act includes provisions for toxic chemical source reporting and reduction.[71] Businesses identified by the Standard Industrial Classification (SIC) as the largest generators or within the top 25% of all hazardous waste generators within the District, or that release a toxic chemical subject to regulation are required to file an annual Toxic Release Inventory (TRI) Form R for each TRI-listed chemical it manufactures, processes or otherwise uses in quantities above the threshold reporting quantity.[72] In addition, reporting facilities must prepare and submit a toxic chemical source reduction plan which must be updated every four years.[73] TRI-listed chemicals include the following toxic substances included in the Initial Ten TSCA Chemicals: trichloroethylene, 1-bromopropane and n-methylpyrrolidone.

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[65] *Id.*

[66] *See* RCW 70.285, .240.

[67] RCW 70.285; WAC 173-901-010.

[68] *See* https://gis.cdc.gov/Cancer/USCS/DataViz.html (last accessed July 26, 2018).

[69] RCW 70.240; *see also* WAC 173-334-130 (list of chemicals of high concern to children).

[70] RCW 70.240.035(3), .010(8).

[71] Code of the District of Columbia ("D.C. Code"), Chapter 13, Subchapter II.

[72] D.C. Code § 8-1317.

[73] D.C. Code § 8-1318.

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The District also regulates the removal and abatement of asbestos through its own licensing and permitting requirements to ensure the safe removal and disposal of asbestos-containing material and the safety of asbestos abatement workers and the surrounding community.[74]

III. Analysis

A. The Problem Formulations Reflect a Fatally Flawed Conditions-of-Use Approach

Under Section 6(b)(4)(A) of TSCA, EPA conducts risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . under the conditions of use."[75] And the term "conditions of use" is defined as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[76]

So, under TSCA, EPA must conduct risk evaluations to determine whether a "chemical substance" presents an unreasonable risk under the circumstances under which that substance is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[77] The plain language of the statue requires EPA to evaluate the risks of each chemical substance identified for evaluation under all circumstances for which exposures can be anticipated, including the so-called "legacy" uses, which clearly are circumstances under which these chemicals are "known . . . to be . . . used or disposed of."[78] Without basis in law or fact, the risk evaluation scheme reflected in the Problem Formulations fails to evaluate the risks for each chemical under all circumstances for which exposures can be anticipated and by failing to do so frustrates TSCA's purposes by ignoring exposures and underestimating risks posed by the chemical substances. For example, where the hazard posed by a chemical may relate to multiple exposure pathways, ignoring one of these pathways may result in underestimating the total, cumulative risk posed by the chemical. Such underestimation may adversely impact determinations of risk to certain populations, including those who are particularly exposed or sensitive to the chemical's adverse effects. Therefore, any risk evaluations conducted under the risk evaluation scheme reflected in the Problem Formulations cannot satisfy EPA's mandate under TSCA.

1. EPA is Ignoring Highly Risky "Legacy Uses," Putting Public Health and the Environment in Grave Peril

In the Problem Formulations, EPA has eliminated from its analysis many of the most important sources of chronic exposure to these toxic chemicals by defining away these exposure

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[74] 20 D.C. Municipal Regulations § 20-800.

[75] 15 U.S.C. § 2605(b)(4)(A).

[76] Section 3(4) of TSCA; 15 U.S.C. § 2602(4).

[77] *Id.*

[78] *Id.*

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pathways through the agency's unjustified narrowing of the conditions of use it will consider. Most significant, perhaps, is EPA's irrational decision to eliminate so-called "legacy" uses from its evaluations. This willful ignorance is both unlawful and patently dangerous based on the hazards both to people and the environment presented by unaccounted-for exposures to any of the Initial Ten TSCA Chemicals.

The most glaring and egregious example of this dereliction of EPA's statutory obligations comes in the Problem Formulation for asbestos. Asbestos is a known carcinogen and there is no safe level of exposure to this highly toxic material ubiquitous in our built environment.[79] The potential for harm posed by asbestos is universally recognized and addressing its risks was a priority in reforming TSCA:

> Asbestos, for example, is one of the most harmful chemicals known to humankind, and it takes 15,000 lives a year. It is linked to a deadly form of lung cancer called mesothelioma. People can breathe in these fibers deep into their lungs where they cause serious damage. We have addressed asbestos in this bill. We didn't ban it on this bill, which I support . . . but we have made asbestos a priority in this bill.[80]

EPA's failure to consider so-called "legacy" uses of asbestos (e.g., asbestos currently in place in buildings and on pipes and equipment) in its risk evaluation process, and the agency's failures otherwise to identify properly the conditions of use for asbestos, means EPA will not consider the risks from, among others, aging asbestos-containing tiles, adhesives, and piping in millions of homes, commercial buildings, and in underground infrastructure nationwide.[81] By failing to identify and assess exposures from the full range of known and likely uses, EPA is failing to characterize the full range of risks posed by asbestos and thus cannot possibly satisfy its mandate under TSCA to eliminate unreasonable risks of injury to health or the environment, without consideration of costs or other non-risk factors, including unreasonable risks to a potentially exposed or susceptible subpopulation.

The vast majority of the asbestos currently in place in the U.S. is in the form of "legacy" materials. The relatively small amounts of new asbestos being introduced into the United States,

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[79] *See Occupational Safety and Health Administration Safety and Health Topics: Asbestos, available at https://www.osha.gov/SLTC/asbestos/.*

[80] Sen. Barbara Boxer speaking in support of H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, 114th Congress, Second Session, 162 Cong. Rec. S3511 (Jun. 7, 2016).

[81] Legacy uses of asbestos excluded from the scope of the risk evaluation include: asbestos arc chutes; asbestos packings; asbestos pipeline wrap; asbestos protective clothing; asbestos separators in fuel cells and batteries; asbestos-cement flat sheet: asbestos-cement pipe and fittings; asbestos-cement shingles; asbestos-reinforced plastics; automatic transmission friction components; beater-add gaskets; clutch facings; corrugated asbestos-cement sheet; extruded sealant tape; filler for acetylene cylinders; high-grade electrical paper; millboard; missile liner; roofing felt; and vinyl-asbestos floor tile. *See* Scope of the Risk Evaluation for Asbestos, Jun. 2017, pp. 24-25, *available at*: https://www.epa.gov/sites/production/files/2017-06/documents/asbestos_scope_06-22-17.pdf.

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as documented by EPA in the asbestos Problem Formulation[82] pales in comparison to the amount of asbestos currently in place in buildings, vehicles, underground, and elsewhere. While only approximately 300 metric tons, or 661,387 pounds, of asbestos was imported into the U.S. in 2017,[83] an amount of approximately 11,598 metric tons, or 25,568,292 pounds, of asbestos containing materials has been documented as having been disposed of as solid waste or otherwise released in the U.S. in 2015.[84] These so-called "legacy" use materials continue to present very significant exposure risks, both in the asbestos abatement process and as a result of environmental releases from the disturbance of "legacy" materials that are not subject to the abatement process. For example, the cutting and beveling of asbestos cement pipe leads to extremely high airborne concentrations of asbestos fibers putting workers at risk.[85]

EPA does not even attempt to provide a rationale for ignoring exposures related to the current widespread and most common uses of asbestos by excluding so-called "legacy" uses from its risk evaluations under Section 6 of TSCA.[86] Rather than providing either legal or data-based justifications for its decision, the agency merely states:

> EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on current and prospective uses for which manufacture, processing, or distribution in commerce is intended, known or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context (TSCA section 6(b)(4)(B)). In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their life cycle. Consistent with this rationale, EPA has excluded certain uses from the scope of the risk evaluation, as identified below.[87]

Another "legacy" use not included in EPA's Scope of the Risk Evaluation for Asbestos is the use of Libby Amphibole asbestos (which EPA describes as "a mixture of several mineral fibers such as winchite, richterite, and tremolite found in vermiculite ore near Libby, Montana).[88] This notwithstanding that EPA readily admits Libby Amphibole has the potential for human exposure:

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[82] *Problem Formulation of the Risk Evaluation for Asbestos*, pp. 21–22.

[83] *Id.* at p. 22.

[84] *Id.* at p. 28.

[85] Kumagi S. et al. 1993. "Estimation of Asbestos Exposure Among Workers Repairing Asbestos Cement Pipes Used for Conduits." *Japan Journal of Industrial Health*, 178-87; Noble W.M. et al. 1977. *Asbestos Exposures During the Cutting and Machining of Asbestos Cement Pipe*. Report prepared for the A/C Pipe Producers Association. Berkeley, CA: Equitable Environmental Health, Inc.

[86] There are reports that a Russian mining company recently praised the Trump Administration for downplaying the health risks of the cancer-causing mineral. *See, e.g.*, http://www.newsweek.com/trumps-face-stamped-russian-asbestos-products-tied-putin-donald-our-side-1018327 (last accessed Jul. 11, 2018).

[87] *Problem Formulation of the Risk Evaluation for Asbestos*, p. 20.

[88] *Scope of the Risk Evaluation for Asbestos*, dated Jun. 2017, p. 25.

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> Although vermiculite contaminated with the Libby Amphibole remains in buildings as an insulating material and therefore presents the potential for human exposure, vermiculite containing the Libby Amphibole is no longer manufactured or processed for use in the United States and therefor is not considered a condition of asbestos use for the purpose of risk evaluation under TSCA."[89]

Here, EPA is arbitrarily and capriciously limiting the uses that qualify as conditions of use to future applications, even while confirming the potential for human exposure as well as the risks to human health presented by such exposures.

Moreover, EPA is taking inconsistent and irreconcilable positions with respect to how it views conditions-of-use determinations.

On February 17, 2017, the current administration's EPA announced[90] the availability of EPA's response to a petition EPA received in November 2016 under Section 21 of TSCA[91] from a group of organizations, including Fluoride Action Network, Food & Water Watch, and the Organic Consumers Association, asking EPA to exercise its TSCA Section 6 authority to ban the purposeful fluoridation of U.S. water supplies.

In its denial of the petition, EPA interpreted TSCA's requirements for determining "conditions of use" for risk evaluations under Section 6 of TSCA as appropriately very broad consistent with the intent of Congress in reforming TSCA. In its finding issued less than eighteen months ago, EPA announced:

> Unless EPA establishes an exemption under TSCA section 6(g) (whereby certain unreasonable risks may be allowed to persist for a limited period) or EPA is addressing a persistent, bioaccumulative, and toxic substance as set forth in TSCA section 6(h), the standard for an adequate rule under TSCA section 6(a) is that it regulates "so that the chemical substance or mixture no longer presents" unreasonable risks under the conditions of use. 15 U.S.C. 2605(a). Prior to the 2016 amendment of TSCA, EPA completed risk assessments that were limited to selected uses of chemical substances. The amended TSCA authorizes EPA to issue TSCA section 6 rules that are not comprehensive of the conditions of use, so long as they are consistent with the scope of such pre-amendment risk assessments. 15 U.S.C. 2625(l)(4). But *EPA has interpreted the amended TSCA as requiring that forthcoming risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities that the Administrator determines are intended, known or reasonably foreseen.*[92]

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[89] *Id.*

[90] 82 Fed. Reg. 11,878 (Feb. 17, 2017)

[91] 15 U.S.C. § 2620.

[92] 82 Fed. Reg. 11,878 (Feb. 17, 2017), at 11,879–11,880 (emphasis supplied).

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Following EPA's denial of the petition, the petitioners challenged the denial in federal district court.[93]

EPA moved to dismiss the federal court challenge because the petitioners did not address conditions of use other than fluoridation of drinking water. As EPA stated in its denial of the petition: "Rather than comprehensively addressing the conditions of use that apply to a particular chemical substance, the petition requests EPA to take action on a single condition of use (water fluoridation) that cuts across a category of chemical substances (fluoridation chemicals)."[94]

The court denied EPA's motion, recognizing that a citizen petitioner under Section 21 of TSCA need not evaluate all conditions of use for the chemical substance at issue. However, for TSCA Section 6 chemical substance risk evaluations by EPA, as opposed to Section 21 determinations regarding citizens' petitions, TSCA requires the agency comprehensively to address the conditions of use that apply to that particular substance. EPA's retreat from its broad interpretation of the conditions of use that must be considered under Section 6 of TSCA is both contrary to law and represents what appears to be a mere impermissible convenient reinterpretation of the statute by the agency to avoid adequately regulating chemical substances under Section 6.

2. Risk Evaluations Must Assess Exposure Pathways For All Uses, Including Those Addressed Under Other Statutes

EPA is also failing to identify properly the conditions of use by not considering exposures resulting from uses of the chemical purportedly addressed within the context of other statutory schemes.[95]

EPA claims in the Problem Formulation for perchloroethylene that it is not excluding any conditions of use for the chemical,[96] while ignoring in the risk evaluation significant pathways for exposure to that chemical, finding that the chemical is adequately regulated under other identified regulatory programs under other statutes.[97] While the protections under other regulatory schemes may reduce exposure potential, it is EPA's charge under TSCA to eliminate unreasonable risk to human health and the environment posed by the chemical, a mandate that only can be satisfied if EPA includes in its risk evaluations all known exposure pathways assessed cumulatively. Without a sound evaluation of those exposure pathways, whether potentially addressed by other regulatory schemes or not, EPA cannot fulfill its mandate to

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[93] *Food and Water Watch v. EPA*, Docket No. 3:17-cv-02162-EMC (N.D. Ca.).

[94] 82 Fed. Reg. 11,878 (Feb. 17, 2017), at pp. 11,881–11,882.

[95] Under TSCA, Section 9(b), 15 U.S.C.§ 2608(b), EPA "shall coordinate actions taken under this chapter with actions taken under other Federal laws administered in whole or in part by the Administrator." However, this does not authorize the Administrator to rely on these other actions without evaluating the risks in the context of TSCA's requirements that EPA eliminate unreasonable risks of injury to health or the environment.

[96] *See Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro), CASRN: 127-18-4 (May 2018),* p. 22

[97] *Id.* at p. 59.

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evaluate and eliminate unreasonable risks posed by these chemicals.[98]

Perchloroethylene, known as perc, is a dry cleaning solvent and is also used as a metal degreaser, a chemical intermediate and an ingredient in consumer products, such as automotive aerosol parts cleaners and degreasers. Perc has been reported to be the chemical most widely found in groundwater contamination at Superfund sites.[99] Acute exposures to perchloroethylene have been associated with dizziness, confusion, headache, nausea, and irritation of the eyes and mucous tissue, while exposure to extremely high levels of perc may lead to unconsciousness and, in extreme cases, death from respiratory depression.[100] Long term exposure to perc may cause liver, kidney or central nervous system damage, and perc has been characterized by the International Agency on Research on Cancer (IARC) as "probably carcinogenic to humans."[101]

In the perchloroethylene Problem Formulation, Section 2.5.3.2, EPA carves out recognized exposure pathways from its analysis:

> **Pathways That EPA Does Not Expect to Include in the Risk Evaluation**
>
> Exposures to receptors may occur from industrial and/or commercial uses, industrial releases to air, water or land; and other conditions of use. As described in [this section], pathways under other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist will not be included in the risk evaluation.[102]

The Problem Formulation then identifies the statutory schemes under which perchloroethylene is regulated: (i) the Clean Air Act (regulates perc as a hazardous air pollutant and prescribes technology-based standards and other limitations as required for stationary source emissions of perchloroethylene); (ii) the Safe Drinking Water Act (sets Maximum Contaminant Levels for perc in drinking water); (iii) the federal Clean Water Act (perchloroethylene is a "priority pollutant" requiring the adoption of numeric criteria and discharge permit limits to protect surface water quality and perchloroethylene has been identified in biosolids reviews that EPA says it plans to address in the future); and (iv) the Resource Conservation and Recovery Act (RCRA) (perchloroethylene is a listed hazardous waste, the treatment, storage, and disposal of

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[98] 15 U.S.C. § 2605.

[99] *Perchloroethylene Fact Sheet*, MASS. EXEC. OFFICE OF ENERGY & ENVTL. AFFAIRS (2007), *available at* https://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets/Perchloroethylene_PCE_Fact_Sheet/PCE_Details/PCE-Fact-Sheet-pdf.

[100] *Id.*

[101] *Id.*

[102] *See Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro), CASRN: 127-18-4 (May 2018)*, p. 59.

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which is regulated under the act).[103]

However, EPA's charge under TSCA is to evaluate the risks from the full range of exposures in the circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of, to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment.[104] Even if EPA's actions under its separate regulatory programs for perchloroethylene described above serve to meet each statute's requirements for protections under that statute, relying on each of those individual mandates for addressing the chemical as a pollutant (mandates designed to reduce impacts and exposures but not eliminate them), provides no assurance that TSCA's mandate for eliminating unreasonable risks will be met because the potential cumulative effect of exposures to the chemical across environmental media must be considered in its evaluations. The standard for an adequate rule under TSCA section 6(a)[105] is that it regulate so that the chemical substance no longer presents unreasonable risks to public health and the environment, and it necessarily follows that EPA must evaluate the potential for exposure and risk associated with perchloroethylene being regulated under those schemes, and make appropriate TSCA regulatory determinations that account for those anticipated exposures, in order to regulate the chemical as Section 6 requires.

This flaw is also highlighted in the Problem Formulation of the Risk Evaluation for Methylene Chloride.[106] Methylene chloride is a chlorinated solvent commonly used as a metal degreaser, a chemical intermediate, a reaction extraction solvent, a paint stripper, and as a component of adhesives, found in consumer products that can be purchased at local automotive and hardware stores.[107] Methylene chloride exposure can result in serious adverse health effects,

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[103] *Id.* at pp. 59–63.

[104] *See* Section 6(b)(4)(A) of TSCA; 15 U.S.C. § 2605(b)(4)(A) and Section 3(4) of TSCA; 15 U.S.C. § 2602(4).

[105] 15 U.S.C. § 2605(a).

[106] Note that on May 10, 2018, EPA announced its intention to finalize a rule making for methylene chloride. *See EPA Announces Action on Methylene Chloride*, U.S. ENVTL. PROT. AGENCY, https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride (last accessed Jul. 10, 2018). To our knowledge, EPA has not specified the action it plans to take and it is not clear whether EPA plans to adopt a ban of the chemical and if so, the extent of such ban. However, the Environmental Defense Fund has argued that to protect public health, the final rule should "Ban distribution in commerce and use of methylene chloride for paint and coating removal; extend to both consumer and commercial uses . . . ; not provide exemptions based on training, labeling or use of protective equipment; be finalized and implemented quickly; [and] require full compliance within as short as possible a period." *See* Richard Denison, Ph.D., Lead Senior Scientist, Environmental Defense Fund, *Critical 'blanks' in EPA's methylene chloride announcement need to be filled in if it is to be health protective,* May 10, 2018, http://blogs.edf.org/health/2018/05/10/critical-blanks-in-epas-methylene-chloride-announcement-need-to-be-filled-in-if-it-is-to-be-health-protective/ (last accessed Jul. 10, 2018). Home Depot, Loews, and Sherwin-Williams have committed to phasing out methylene chloride and NMP based paint strippers by the end of 2018. *See* Chemical Watch, *Campaigners secure third paint stripper victory with Home Depot*," Jun. 20, 2018, https://chemicalwatch.com/67874/campaigners-secure-third-paint-stripper-victory-with-home-depot (last accessed Jul. 10, 2018).

[107] *Methylene Chloride Fact Sheet*, MASS. TOXICS USE REDUCTION INST. (2014), *available at* https://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets/Methylene_Chloride_Fact_Sheet/Fact_Sheet_Methylene_Chloride.2014.

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and high, short-term exposures can be lethal, with its extreme volatility making it especially dangerous because unsafe airborne concentrations can readily be created through evaporation.[108] As noted in the Problem Formulation, in its IRIS (Integrated Risk Information System) assessment, "EPA concluded that methylene chloride is 'likely to be carcinogenic in humans by all routes of exposure.'"[109] The International Agency for Research on Cancer (IARC) classifies methylene chloride as a possible human carcinogen (Group 2B),[110] and the National Toxicology Program of the U.S. Department of Health and Human Services classifies methylene chloride as "reasonably anticipated to be a human carcinogen."[111]

Methylene chloride is a widespread contaminant in our environment. For example, the problem formulation notes that "[d]ata compiled between 1992 and 2001 from NAWQA [the U.S. Geological Survey's National Water Quality Assessment Program] showed methylene chloride to be found in 6% of all ground water and surface water samples, with occurrences more common in surface water. Methylene chloride was detected in 20% of sediment samples in the [EPA] STORET database."[112]

And yet, EPA plans to exclude exposure pathways for methylene chloride that allegedly are addressed under other statutes although these pathways have been identified for regulation precisely because they are known or suspected to pose a serious concern.[113] For example, EPA plans to exclude from consideration: (i) "stationary source releases of methylene chloride to ambient air," as methylene chloride is regulated as a hazardous air pollutant (HAP) under the Clean Air Act;[114] and (ii) exposures through drinking water because these are regulated under the Safe Drinking Water Act.[115] EPA also plans to exclude from consideration "methylene chloride-based extraction solvents for oils, waxes, fats, spices, and hops" because they "meet the definition of food additive" under the Federal Food, Drug and Cosmetic Act, and so would ignore potentially significant exposure pathways.[116] By excluding consideration of exposures to methylene chloride through drinking water and other pathways of chronic exposure, it will not be possible for EPA to conduct an adequate risk evaluation for methylene chloride under Section 6 of TSCA.

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[108] *Id.*

[109] *See Problem Formulation of the Risk Evaluation for Methylene Chloride (May 2018),* p. 46 (references omitted).

[110] *See* International Agency for Research on Cancer, Agents Classified by the *IARC Monographs*, Volumes 1–121, p. 12, at: http://monographs.iarc.fr/ENG/Classification/ClassificationsAlphaOrder.pdf (last accessed Jul. 25, 2018).

[111] U.S. DEP'T OF HEALTH AND HUMAN SVCS., National Toxicology Program, Report on Carcinogens (RoC), Fourteenth Edition, Dichloromethane, *available at* https://ntp.niehs.nih.gov/ntp/roc/content/profiles/dichloromethane.pdf (last accessed Jul. 25, 2018).

[112] *Id.* at p. 36 (references omitted).

[113] *Id.* at p. 47.

[114] *Id.* at p. 54.

[115] *Id.*

[116] *Id.* at p. 21.

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Through this misguided approach of ignoring uses that are subject to other regulatory schemes, EPA has essentially eliminated from consideration those pathways that Congress has prioritized for regulation to date.

B. Scientific Standards: Best Available Science/Scientific Weight of Evidence

The approach to science expressed by EPA as reflected in the Problem Formulations fails to satisfy TSCA's "best available science" standard for the quality of data that EPA must consider in preparing its risk evaluation, and TSCA's "weight of scientific evidence" standard for decision making under Section 2605.[117]

Under TSCA, Congress expressly required EPA to engage in science-based actions to prevent unreasonable risk of injury to health or the environment as result of exposures to hazardous chemical substances:

> **(h) Scientific standards**
>
> In carrying out section [2605] of this title . . . the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner *consistent with the best available science* . . . .
>
> **(i) Weight of scientific evidence**
>
> The Administrator shall make decisions under section [2605] of this title based on the weight of the scientific evidence.[118]
>
> * * *
>
> (k) Reasonably available information
>
> In carrying out sections 2603, 2604, and 2605 of this title, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is *reasonably available* to the Administrator.[119]

EPA is failing to account for some of the most significant, generally recognized pathways

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[117] On April 30, 2018, EPA published the so-called *Strengthening Transparency in Regulatory Science* proposed rule limiting the body of scientific evidence that EPA will consider when adopting regulatory standards to protect human health and the environment. 83 Fed. Reg. 18768 (Apr. 30, 2018). While the comment period on the proposed rule is still open, the proposed rule raises concerns about the ability of EPA to satisfy its mandate under TSCA with respect to the quality of data that it will consider in carrying out its mandate to eliminate unreasonable risks of injury to health or the environment.

[118] TSCA, Section 26(h) and (i) (emphasis supplied); 15 U.S.C. § 2625(h) and (i) (emphasis supplied).

[119] *Id.* at § 2625(k) (emphasis supplied).

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of exposure in the Problem Formulations.[120] It follows that it is impossible for EPA to satisfy the "best available science" standard because it is choosing to put on blinders and ignore some of the most meaningful data with respect to risks of exposure to the chemical substance.

Additionally, in its evaluation of uses in the Problem Formulations EPA fails to satisfy its statutory duties to review all reasonably available information. The Problem Formulations are rife with examples of instances where it appears that EPA stopped short of complete data collection, failing to satisfy its statutory obligation to consider the information "reasonably available" to it.[121] Unfortunately, notwithstanding Congress's express requirement that EPA use the "best available science" in regulating toxic chemicals, the Problem Formulations on their face make it impossible for EPA to conduct the risk evaluations as required in this regard. The recent overhaul of TSCA was designed to address the recognized failures of traditional risk assessment to consider the big picture of toxic chemicals exposures and address the landscape of the many uses and exposure pathways affecting different people in different ways.[122] TSCA, as amended by the Lautenberg Act, addresses this by mandating comprehensive risk evaluations in which EPA reviews chemical substances broadly in the context of the chemical substances' known, intended, and reasonably foreseen uses across the full spectrum of potentially exposed populations. The Problem Formulations, which would restrict EPA's reviews to certain uses and exposures that do not reflect the pathways through which people and the environment are affected by these chemical substances, will not meet the express purpose of TSCA as amended and should be abandoned in this regard.

CONCLUSION

We believe that the risk evaluations that EPA proposes to conduct for the Initial Ten TSCA Chemicals, in which the agency plans to consider only a subset of the uses for which the chemical substances are intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed, fails to satisfy the requirements for risk evaluations under TSCA. We therefore urge EPA to issue revised Scopes of the Risk Evaluation for each of the Initial Ten TSCA Chemicals to address the concerns we raise above regarding the agency's unlawful approach to identifying the conditions of use as that term is properly understood under TSCA and to ensure that the data EPA considers in its risk evaluations satisfies TSCA's "best available science" standards. After conducting appropriate risk evaluations, we expect EPA will impose new protective restrictions, and in some cases bans, for at least some of the Initial Ten TSCA Chemicals.

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[120] *See, e.g.*, Section III(A)(2), above.

[121] 15 U.S.C. § 2625(k).

[122] *See* Richard Denison, Ph.D., Lead Senior Scientist, Environmental Defense Fund, *Final TSCA framework rules retreat from best available* science, http://blogs.edf.org/health/2017/06/29/final-tsca-framework-rules-retreat-from-best-available-science/ (last accessed Jul. 8, 2018).

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We would be pleased to provide further input as EPA continues its Section 6 risk evaluations under TSCA. Please do not hesitate to contact us if you wish to engage us further in this important effort.

Sincerely,

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