

**THE ATTORNEYS GENERAL OF NEW YORK, CALIFORNIA, DISTRICT OF
COLUMBIA, HAWAI‘I, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS,
MINNESOTA, NEW JERSEY, NORTH CAROLINA, OREGON, RHODE
ISLAND, VERMONT, AND WASHINGTON**

July 6, 2020

Via Electronic Filing

EPA-HQ-OPPT-2019-0502

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: *Perchloroethylene; Draft Toxic Substances Control Act (TSCA) Risk Evaluation and TSCA Science Advisory Committee on Chemicals (SACC) Meetings; Notice of Availability, Public Meetings, and Request for Comment, 85 Fed. Reg. 26,464 (May 4, 2020)*

Dear Administrator Wheeler:

The Attorneys General of New York, California, District of Columbia, Hawai‘i, Illinois, Maine, Maryland, Massachusetts, Minnesota, New Jersey, North Carolina, Oregon, Rhode Island, Vermont, and Washington submit these comments regarding the U.S. Environmental Protection Agency’s (“EPA”) draft risk evaluation for perchloroethylene (“PERC”),¹ for which notice was published on May 4, 2020. Perchloroethylene is one of the 10 chemical substances² that are the subject of EPA’s initial chemical risk evaluations required under the Frank R.

¹ Other names include tetrachloroethene and tetrachloroethylene.

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, also known as HBCD, Methylene Chloride, N-Methylpyrrolidone (NMP), Pigment Violet 29, 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).

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 PERC as one of the initial 10 chemical substances because of its potential for substantial harm to human health and the environment.⁵ PERC is widely used in, among other things, dry cleaning and metal degreasing. EPA recognizes that PERC is present in various environmental media such as groundwater, surface water, and air. According to EPA, PERC is likely to be carcinogenic to humans by all routes of exposure.⁶ If EPA fails to fully identify the risks posed by the many uses of this chemical as it fails to do here, the agency cannot then effectively manage those risks to protect human health and the environment.

In the draft risk evaluation for PERC, EPA failed to correct the deficiencies a number of state Attorneys General and other commenters identified in the PERC problem formulation⁷ and instead has produced a fatally flawed draft risk evaluation. Among other deficiencies, the draft excludes numerous significant exposure pathways in which the general population and environment are exposed to PERC, ignores the well-documented risks to those who live near dry-cleaning facilities and hazardous waste sites, as well as the risks to infants, children, and pregnant women, and underestimates the overall risk of PERC exposure. Residents of low-income and/or communities of color face greatest exposure to PERC making EPA’s failure to comply with TSCA and the EPA implementing regulations particularly egregious from the perspective of environmental justice.

Accordingly, we request that EPA withdraw the draft risk evaluation for PERC and re-evaluate the risks posed by PERC in a manner that fully complies with its obligations under TSCA to conduct the necessary, thorough evaluation of the risks presented by this chemical before issuing its final risk evaluation.

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

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

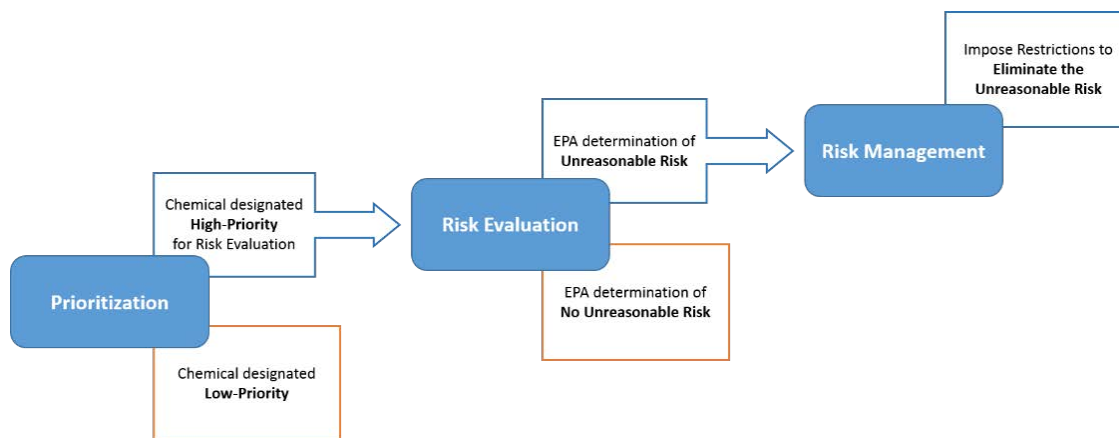
⁴ 15 U.S.C. § 2601 *et seq.*

⁵ 81 Fed. Reg. 91,927.

⁶ PERC Draft Risk Evaluation, p. 294.

⁷ *Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro)* (May 2018), available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0080>.

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>.



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

The first stage in EPA’s process for evaluating the safety of existing chemicals is prioritization. The prioritization process focuses EPA’s limited resources on the 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. Part 702, Subpart A.

The second stage is risk evaluation. *See* 15 U.S.C. § 2605(b)(2)-(4); 40 C.F.R. Part 702, Subpart B. 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).

The risk evaluation stage has three linked components: (1) a scope document that provides the public with information on the focus of the risk evaluation, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations; (2) hazard and exposure assessments and a risk characterization to inform the risk determination; and (3) a risk determination stating whether or not a chemical presents an unreasonable risk to health or the environment under its existing conditions of use. *See* 40 C.F.R. § 702.41(a)(1).

As pertinent here, in the hazard assessment, EPA must identify the potential adverse human health or environmental effects caused by exposure to the chemical. 40 C.F.R. § 702.41(d)(2). Hazards may include, but are not limited to, toxicity with respect to cancer, mutation, reproductive, developmental, respiratory, immune, cardiovascular impacts, and neurological impairments.⁹ Hazard information related to potential health and environmental hazards of the chemical 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). Relevant potential human and environmental hazards must be evaluated. 40 C.F.R. § 702.41(d)(3). The relationship between the dose of the chemical substance and the occurrence of health and environmental effects or outcomes must also be evaluated. 40 C.F.R. § 702.41(d)(4). The human health hazard

⁹ *See* <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#determination>.

assessment must also consider all potentially exposed and susceptible subpopulations. 40 C.F.R. § 702.41(d)(7).

In the exposure assessment, EPA must identify, where relevant, the likely duration, intensity, frequency, and number of exposures to a chemical under the broad conditions of use as defined by 40 C.F.R. § 702.3.¹⁰ 40 C.F.R. § 702.41(e)(1). EPA must examine chemical-specific factors, including physical-chemical properties and environmental fate and transport parameters. 40 C.F.R. § 702.41(e)(2). EPA must also review exposure information related to potential human health or ecological hazards of the chemical in a manner consistent with best available science and weight of scientific evidence. 40 C.F.R. § 702.41(e)(3). EPA's exposure assessment must include a human health exposure assessment that considers all potentially exposed and susceptible subpopulations determined to be relevant. 40 C.F.R. § 702.41(e)(4). EPA's exposure assessment must further include an environmental health exposure assessment that characterizes and evaluates the interaction of the chemical with the ecological receptors and considers populations and communities. 40 C.F.R. § 702.41(e)(5).

In turn, EPA must formulate a risk characterization by integrating and assessing the reasonably available information on hazard and exposure and include considerations of information quality and alternative interpretations. 40 C.F.R. § 702.43. EPA must ultimately make a risk determination as to whether the chemical, under the conditions of use, presents an unreasonable risk to health or the environment. *See* 15 U.S.C. § 2605(b)(4)(A); 40 C.F.R. § 702.47.

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 action 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 States' Interests in Evaluating the Risk of PERC

TSCA requires that EPA choose the first 10 chemical substances from the list of 90 chemical substances on the 2014 update of the TSCA Work Plan for Chemical Assessments.¹¹ TSCA Work Plan chemicals were selected based on their hazard and potential for exposure, as 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.¹²

¹⁰ “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.” 40 C.F.R. § 702.3.

¹¹ 81 Fed. Reg. at 91,928.

¹² *Id.* at 91,928-29.

PERC is a manufactured chemical that is widely used, including in the production of fluorinated compounds, and as a solvent in dry cleaning and vapor degreasing.¹³ PERC is also used in various consumer and commercial products such as adhesives (for arts and crafts and light repairs), degreasing aerosols, brake cleaners, aerosol lubricants, sealants, stone polish, stainless steel polish, and wipe cleaners.¹⁴ The best known use of PERC is as a commercial dry-cleaning solvent.¹⁵ Approximately 70 percent of dry cleaners in the United States still use PERC.¹⁶ The yearly production volume for PERC, which includes imported volumes, ranged from 388 million to 324 million pounds between 2012 and 2015.¹⁷

PERC can be released into air, water, and soil at places where it is produced or used, or at disposal facilities and sites.¹⁸ PERC breaks down very slowly in the air, facilitating long distance transport by air.¹⁹ PERC also evaporates quickly from water into air.²⁰ PERC may also evaporate from shallow soils and groundwater and cause extensive contamination in the vapor phase. Once in groundwater, PERC is very persistent and can travel long distances as part of a groundwater plume, leading to extensive areas of contaminated drinking water.²¹ Furthermore, PERC breaks down into other degradation compounds, including dichloroethene and vinyl chloride, both of which are known to be persistent in groundwater. Soil vapor intrusion from groundwater plumes contaminated with PERC have led to widespread human exposures in New York and other states. In fact, discovery of soil vapor intrusion led to the installation of vapor mitigation systems in over 450 homes and businesses in Endicott, New York and many other communities in New York,²² and spurred Massachusetts to recently publish its comprehensive guidance for addressing soil vapor intrusion at contaminated sites.²³

People working in the dry cleaning industries or using metal degreasing products may be exposed to elevated levels of PERC.²⁴ Dry cleaning workers have been reported to be some of the lowest paid workers in the United States and may face unsafe working conditions.²⁵ People

¹³ PERC Draft Risk Evaluation, p. 28.

¹⁴ *Id.*

¹⁵ EHS Daily Advisor, *EPA Evaluation of Perchloroethylene (PCE) Reveals Many Risks* (May 15, 2020), available at <https://ehsdailyadvisor.blr.com/2020/05/epa-evaluation-of-perchloroethylene-pce-reveals-many-risks/>.

¹⁶ *Id.*

¹⁷ PERC Draft Risk Evaluation, p. 28.

¹⁸ Agency for Toxic Substances & Disease Registry, ToxFAQs™ for Tetrachloroethylene (PERC) (2020), available at <https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=264&tid=48>.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² See <https://nyassembly.gov/comm/Encon/20050302/>

²³ See <https://www.mass.gov/files/documents/2016/10/nu/vapor-intrusion-guidance-10-14-2016.pdf>.

²⁴ Agency for Toxic Substances & Disease Registry, ToxFAQs™ for Tetrachloroethylene (PERC) (2020), available at <https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=264&tid=48>.

²⁵ Grant Suneson, *What are the 25 Lowest Paying Jobs in the US? Women Usually Hold Them*, USA Today (Apr. 4,

residing near PERC contaminated sites or dry cleaning locations may be exposed to higher levels of PERC than the general population.²⁶ Residential apartments and other buildings near dry cleaners have been shown to have high PERC concentrations caused by vapors which travel through elevator shafts and air vents.²⁷

For example, in New York City, approximately 10,000 people work in 3,500 dry cleaners.²⁸ The majority of the 1,200 dry cleaners in New York City that do their work on-premises use PERC.²⁹ An estimated 2.3 million people also live within 650 feet of New York City's approximately 400 PERC dry cleaners located in apartment buildings.³⁰ A 2013 study in the journal *Environmental Research* showed average PERC readings of more than triple the limit recommended by the New York State Department of Health in low-income New York City households located near dry cleaners.³¹

Furthermore, an analysis of environmental justice programs adopted by the South Coast Air Quality Management District as part of its regulation to phase out PERC used by dry cleaners found that, even with financial incentives available to dry cleaners to make the shift from PERC to greener technologies, dry cleaners in low-income, predominantly communities of color were less likely to receive a grant to switch to these technologies despite the effort to set aside half of the funding for applicants from these communities.³²

EPA has found PERC in at least 945 of the 1,699 current or former hazardous waste sites on the National Priorities List ("NPL"), which EPA targets for federal clean-up activities.³³ The

2019), available at <https://www.usatoday.com/story/money/2019/04/04/25-lowest-paying-jobs-in-us-2019-includes-cooking-cleaning/39264277/>; see also Fabrice Robinet, *\$7 an Hour, 72 Hours a Week: Why Laundry Workers Have Had Enough*, *The New York Times* (Aug. 23, 2019), available at <https://www.nytimes.com/2019/08/23/nyregion/nyc-laundry-workers-unionizing.html>; Amir Khafagy, *New York City Laundry Workers Struggle in the Face of Covid-19*, *The Appeal* (June 26, 2020), available at <https://theappeal.org/new-york-city-laundry-workers-struggle-in-the-face-of-covid-19/>.

²⁶ Agency for Toxic Substances & Disease Registry, ToxFAQs™ for Tetrachloroethylene (PERC) (2020), available at <https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=264&tid=48>.

²⁷ Aaron Elstein, *The Toxic Chemical New York's Dry Cleaners Can't Quit*, *Crain's New York* (May 8, 2016), available at <https://www.crainsnewyork.com/article/20160508/SMALLBIZ/160509884/perchloroethylene-used-by-new-york-city-dry-cleaners-under-the-name-perc-has-been-a-concern-for-decades-leading-t>.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² Ong, Paul, *Environmental Justice and Green-Technology Adoption*, *Journal of Policy Analysis and Management*, Vol. 31, No. 3 (Summer 2012), pp. 578-97, available at <https://www.jstor.org/stable/41653815>.

³³ Agency for Toxic Substances & Disease Registry, ToxFAQs™ for Tetrachloroethylene (PERC) (2020), available at <https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=264&tid=48>.

total number of NPL sites evaluated for PERC is not known.³⁴ As more sites are evaluated, the number of sites at which PERC is found may increase.³⁵

PERC is also present in many other non-NPL sites with air, water, and soil contamination.³⁶ The concern for PERC in non-NPL sites may be particularly strong since NPL sites represent only a small fraction of the total hazardous waste sites with PERC contamination.³⁷ For example, there are over 57,000 inactive hazardous waste sites in New York, almost 1,400 of which have PERC as a contaminant of concern. Over 23,000 of these sites are located in Nassau and Suffolk counties, 600 of which have PERC as a contaminant of concern.³⁸ Groundwater contaminated with PERC is of particular concern in Nassau and Suffolk counties, where groundwater provides the sole source of drinking water to its almost 3 million residents.

Significantly, hazardous waste sites are not dispersed evenly throughout communities.³⁹ Often, those most at risk of living near hazardous waste sites are low-income and/or communities of color.⁴⁰

PERC poses numerous health risks. Possible direct links between PERC and cancer have been extensively studied. PERC is likely to be carcinogenic in humans by all routes of exposure based on conclusive evidence in animals and suggestive evidence in humans.⁴¹ In 2012, EPA reviewed epidemiological data pertaining to the carcinogenicity of PERC and found that there was a pattern of evidence associating PERC exposure with cancer of the bladder, non-Hodgkin's lymphoma, and multiple myeloma.⁴² Other data support a suggestive effect with respect to esophageal, kidney, lung, liver, cervical, and breast cancer.⁴³ The International Agency for Research on Cancer lists PERC as "probably carcinogenic to humans."⁴⁴ Non-cancer effects

³⁴ Agency for Toxic Substances & Disease Registry, *Public Health Statement Tetrachloroethylene* (Oct. 2014), available at <https://www.atsdr.cdc.gov/ToxProfiles/tp18-c1-b.pdf>.

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ See <https://data.ny.gov/Energy-Environment/Environmental-Remediation-Sites/c6ci-rzpg>.

³⁹ Chloe Reichel, *Toxic Waste Sites and Environmental Justice: Research Roundup*, Journalist's Resource (Sept. 24, 2018), available at <https://journalistsresource.org/studies/environment/superfund-toxic-waste-race-research/>.

⁴⁰ *Id.*

⁴¹ PERC Draft Risk Evaluation, p. 294.

⁴² *Id.* at 272-73.

⁴³ *Id.* at 272-73.

⁴⁴ Agency for Toxic Substances & Disease Registry, ToxFAQs™ for Tetrachloroethylene (PERC) (2020), available at <https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=264&tid=48>.

include acute toxicity, neurotoxicity, kidney toxicity, liver toxicity, reproductive/developmental toxicity, immune and hematological effects, and irritation.⁴⁵

The health risks posed by PERC are also particularly severe with respect to certain subpopulations. For example, a 2009 study conducted of New York City residents living in areas where there are many PERC dry cleaners showed that an increase in PERC exposure was associated with an increased risk of kidney cancer.⁴⁶ The results of a 2002 residential study of families living in apartment buildings in New York City co-located with dry cleaning facilities on the ground floors and a study of workers in a day care facility co-located with a dry cleaning facility suggested that chronic, environmental exposure to airborne PERC adversely affects neurobehavioral function in healthy individuals.⁴⁷

Given its widespread use, multiple exposure scenarios, and associated environmental and human health hazards, it is imperative that EPA evaluate the risks of PERC thoroughly, comprehensively, and in full accordance with the requirements of TSCA and the EPA implementing regulations.

C. The Draft Scope and Problem Formulation

On August 3, 2018, the Attorneys General of 10 states and the Attorney General of the District of Columbia submitted comments to EPA identifying deficiencies in the agency's problem formulation for PERC ("AG Problem Formulation Comments").⁴⁸ In the AG Problem Formulation Comments, the Attorneys General identified, among other infirmities, that EPA's PERC problem formulation presented an incomplete and inadequate characterization of the conditions of use the risk evaluation, an approach contradicting TSCA's plain language and Congress' intent that EPA's risk evaluations assess each chemical in its entirety, based on all identifiable conditions of use.

The Attorneys General urged EPA to issue revised scopes of the risk evaluations for the first 10 chemical substances, including for PERC, in order to address the agency's erroneous approach to identifying the conditions of use, as that term is defined under TSCA, and to ensure

⁴⁵ PERC Draft Risk Evaluation, p. 256.

⁴⁶ Ma, Jing, Lessner, Lawrence, Schreiber, Judith and Davod O. Carpenter, *Association between Residential Proximity to PERC Dry Cleaning Establishments and Kidney Cancer in New York City*, Journal of Environmental and Public Health (Nov. 2009), available at <https://doi.org/10.1155/2009/183920>.

⁴⁷ Schreiber, Judith S., et al., *Environmental Health Perspectives*, Vol. 110, No. 7 (July 2002).

⁴⁸ Comments of the Attorneys General of Massachusetts, California, Hawaii, Maine, Maryland, New Jersey, New York, Oregon, Vermont, Washington, and the District of Columbia, submitted electronically to Charlotte Bertrand, Acting Principal Deputy Assistant Administrator, EPA Office of Chemical Safety and Pollution Prevention, *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)), Aug. 3, 2018, available at <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), available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0096>.

that the data EPA considers in its risk evaluation process satisfies TSCA's "best available science" standards. EPA has not responded the AG Problem Formulation Comments as it must. Rather, EPA produced a deficient draft risk evaluation that does not comport with TSCA, as described below.

D. EPA's PERC Draft Risk Evaluation Fails to Satisfy TSCA and the Agency's Implementing Regulations

The deficiencies the Attorneys General identified in their Problem Formulation Comments remain unaddressed in the draft risk evaluation, leading to numerous deficiencies that result in a serious underestimate of the risk posed by PERC. EPA must correct these deficiencies in order to fulfill the legal requirements of TSCA and the EPA implementing regulations.

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 PERC "is present in various environmental media, such as groundwater, surface water, and air."⁴⁹ EPA further recognizes that exposures to human and environmental receptors by PERC "may occur from industrial and/or commercial uses, industrial releases to air, water or land; and other conditions of use."⁵⁰ In turn, these exposures can lead to serious health risks, as discussed above. For example, as EPA recognizes, exposure to drinking water contaminated by PERC can cause developmental effects such as pre-term birth, low birth weight, eye and ear anomalies, and oral clef defects,⁵¹ and affect neurodevelopment.⁵²

However, in contravention of TSCA and the EPA implementing regulations, EPA excludes numerous exposure pathways in its risk evaluation:

The conclusions of the problem formulation were that risk would not be evaluated for sediment, soil and land-applied biosolid pathways leading to exposure to terrestrial and aquatic organisms. Risks would not be evaluated for land-applied biosolids because [PERC] is currently being addressed in the Clean Water Act (CWA) regulatory analytical process. EPA also excluded from risk evaluation ambient air, drinking water, land disposal, ambient water, and waste incineration pathways leading to exposures to the general population and terrestrial organisms . . . [.]⁵³

⁴⁹ PERC Draft Risk Evaluation, p. 29.

⁵⁰ *Id.* at 59.

⁵¹ *Id.* at 268.

⁵² *Id.* at 264.

⁵³ *Id.* at 38. As EPA removed "most environmental exposure pathways" from its risk evaluation, EPA excluded as off-topic, 7,091 of 7,170 studies (98.9%) that it identified through its literature search results for the environmental

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, such as the Clean Air Act, Safe Drinking Water Act, Clean Water Act, and Resource Conservation and Recovery Act.⁵⁴ EPA concluded:

Exposure pathways to the general population are covered by other statutes and consist of: the ambient air pathway (i.e., [PERC] is listed as a hazardous air pollutant (HAP) in the Clean Air Act (CAA)), the drinking water pathway (i.e., National Primary Drinking Water Regulations (NPDWRs) are promulgated for [PERC] under the Safe Drinking Water Act), ambient water pathways (i.e., [PERC] is a priority pollutant with recommended water quality criteria for protection of human health under the CWA), biosolids pathways (i.e., [PERC] has been identified in biosolids biennial reviews under the CWA), disposal pathways ([PERC] disposal is managed and prevented from further environmental release by RCRA and SDWA regulations). As described above other environmental statutes administered by EPA adequately assess and effectively manage these exposures. EPA believes that the TSCA risk evaluation should focus on those exposure pathways associated with TSCA conditions of use that are not subject to the regulatory regimes discussed above because those pathways are likely to represent the greatest areas of concern to EPA. Therefore, EPA did not evaluate hazards or exposures to the general population in this risk evaluation, and there is no risk determination for the general population.⁵⁵

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 cumulatively. Nothing in TSCA justifies EPA 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. In fact, there is no indication that existing environmental laws have adequately addressed the risks of PERC.⁵⁶

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

fate and transport of PERC. *Id.* at 55.

⁵⁴ *Id.* at 460.

⁵⁵ *Id.*

⁵⁶ See, e.g., Lisa Sorg, *A Superfund Cleanup in Jacksonville Failed. Without Federal Funding for a Fix, Contamination is Spreading*, NC Policy Watch (June 21, 2020), available at <http://www.ncpolicywatch.com/2020/02/21/a-superfund-cleanup-in-jacksonville-failed-without-federal-funding-for-a-fix-contamination-is-spreading/>.

toxics legislation that resulted in TSCA's passage in 1976,⁵⁷ 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."⁵⁸ 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.

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 PERC to the environment.

2. EPA Does Not Evaluate the Risk of PERC 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 PERC on several relevant potentially exposed or susceptible subpopulations.

a. Subpopulations within Proximity of Dry-Cleaning Facilities

It is well-documented that people living near industrial or dry-cleaning operations may be exposed to higher levels of PERC than the general population.⁵⁹ Even EPA has acknowledged, "Residents living in the same building as an area source dry cleaner may receive significantly higher exposure than other non-collocated receptors due to their close proximity to the source."⁶⁰

⁵⁷ *See Report to Senate from the Committee on Commerce*, S. Rep. No. 94-698 (Mar. 16, 1976).

⁵⁸ *Id.*

⁵⁹ <https://www.health.ny.gov/environmental/chemicals/tetrachloroethene>; *see also* Agency for Toxic Substances & Disease Registry, ToxFAQs™ for Tetrachloroethylene (PERC) (2020), available at <https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=264&tid=48>.

⁶⁰ EPA, *Perchloroethylene Dry Cleaners Refined Human Health Risk Characterization* (Nov. 2005), p. 4 (citing Schreiber, Judith S. *et. al.*, *Apartment Residents' and Day Care Workers' Exposures to Tetrachloroethylene and Deficits in Visual Contrast Sensitivity*, *Environmental Health Perspectives* 110:655-664 (2002); New York Department of Health Bureau of Toxic Substance Assessment, *Investigation of Indoor Air Contamination in Residences Above Dry Cleaners* (Oct. 1991)), available at https://www.epa.gov/sites/production/files/2015-06/documents/riskassessment_dry_cleaners.pdf.

This subpopulation may also be more likely to be comprised of low-income populations and communities of color, presenting potential environmental injustice.⁶¹

EPA must consider the risk to subpopulations with elevated exposures because of proximity to dry cleaning operations. These subpopulations include residents of apartments near or above dry cleaners and occupants of nearby homes and business. Although EPA has previously acknowledged the risk to these subpopulations, the agency's draft risk evaluation does not address these subpopulations. EPA's failure to do so results in an underestimation of the overall risk of exposure to PERC.

b. Subpopulations within Proximity of Hazardous Waste Sites

It is also well-documented that people within the proximity of hazardous waste sites may be exposed to higher levels of PERC than the general population.⁶² As mentioned above, EPA has found that at least 945 hazardous waste sites on the NPL are contaminated with PERC. PERC is also present at numerous other non-NPL hazardous waste sites throughout the country. Significantly, hazardous waste sites are often in low-income and/or communities of color again presenting potential environmental injustice.⁶³

EPA must consider the risk to subpopulations with elevated exposures because of their proximity to hazardous waste sites. These subpopulations include occupants of nearby homes, businesses, schools, and daycares. EPA's failure to address the risk to these subpopulations results in an underestimation of the overall risk of exposure to PERC.

c. Infants, Children, and Pregnant Women

Infants, children, and pregnant women are additional subpopulations that are susceptible to the adverse health effects posed by PERC exposure. Pregnant women exposed to PERC may experience problems with pregnancy, including miscarriage, birth defects, and slowed growth of the baby.⁶⁴ EPA identifies developing fetuses as being potentially exposed to PERC.⁶⁵ Studies

⁶¹ McDermott MJ, Mazor KA, Shost SJ, Narang RS, Aldous KM, Storm JE, *Tetrachloroethylene (PCE, PERC) Levels in Residential Dry Cleaner Buildings in Diverse Communities in New York City*, Environmental Health Perspectives 113(10):1336-43 (Oct. 2005), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1281276>; see also Aaron Elstein, *The Toxic Chemical New York's Dry Cleaners Can't Quit*, Crain's New York (May 8, 2016), available at <https://www.crainsnewyork.com/article/20160508/SMALLBIZ/160509884/perchloroethylene-used-by-new-york-city-dry-cleaners-under-the-name-perc-has-been-a-concern-for-decades-leading-t>.

⁶² See Agency for Toxic Substances & Disease Registry, ToxFAQs™ for Tetrachloroethylene (PERC) (2020), available at <https://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=264&tid=48>; see also Attorney General of the State of New York, *Daycare Centers and Superfund: A Parent's Right to Know* (Jan. 2003), available at https://ag.ny.gov/sites/default/files/press-releases/archived/tutor_time.pdf.

⁶³ Chloe Reichel, *Toxic Waste Sites and Environmental Justice: Research Roundup*, Journalist's Resource (Sept. 24, 2018), available at <https://journalistsresource.org/studies/environment/superfund-toxic-waste-race-research/>.

⁶⁴ Agency for Toxic Substances & Disease Registry, *Public Health Statement for Tetrachloroethylene (PERC)* (2015), available at <https://www.atsdr.cdc.gov/phs/phs.asp?id=263&tid=48>.

⁶⁵ PERC Draft Risk Evaluation, p. 248.

have shown that organic chemicals, such as PERC can be transported from breastmilk.⁶⁶ EPA recognizes that infants fed breastmilk are potentially exposed to PERC if their mothers have been exposed.⁶⁷ EPA further recognizes that infants fed by formula are potentially exposed to PERC when PERC is present in the drinking water used to make the formula.⁶⁸ According to EPA, “pregnant women, the developing fetus and newborn infants are all considered highly susceptible subpopulations, and therefore women of childbearing age are susceptible by proxy.”⁶⁹

Children are also potentially susceptible to adverse health effects posed by PERC through inhalation exposure because of greater lung surface area:body weight ratios and increased minute volumes:weight ratios.⁷⁰ In addition, children may inhale higher levels of PERC because of their short stature and the higher levels of PERC vapor found nearer to the ground.⁷¹ Children are also more vulnerable to PERC absorbed through the skin because of their relatively larger surface:body weight ratio.⁷²

Although EPA has recognized the susceptibility of many of these subpopulations, EPA fails to evaluate the risk PERC poses to these subpopulations and, therefore, cannot determine whether that risk is reasonable or unreasonable. EPA must evaluate the risk to particularly susceptible populations, including infants, children, and pregnant women. EPA’s failure to do so results in an underestimation of the overall risk of exposure to PERC.

3. EPA Underestimates the Risk in Other Ways

EPA underestimates the risks posed by PERC in several additional respects, including in the following ways. First, EPA fails to consider aggregate exposures under the conditions of use for workers and 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 states “[i]nhalation and dermal exposures are assumed to occur simultaneously for workers and consumers.”⁷³ EPA, acknowledging that this “may lead to an underestimate of exposure,” states that it evaluated exposures by inhalation and dermal routes separately.⁷⁴ Because inhalation and dermal risks are significant for most

⁶⁶ Schreiber, J., *Transport of Organic Chemicals to Breastmilk: Tetrachloroethene Case Study*, Environmental Toxicology and Pharmacology of Human Development (1997), pp. 95-143.

⁶⁷ PERC Draft Risk Evaluation, p. 248.

⁶⁸ *Id.*

⁶⁹ *Id.* at 300.

⁷⁰ See Agency for Toxic Substances & Disease Registry, *Medical Management Guidelines for Tetrachloroethylene* (2014), available at <https://www.atsdr.cdc.gov/MMG/MMG.asp?id=261&tid=48>.

⁷¹ *Id.*

⁷² *Id.*

⁷³ PERC Draft Risk Evaluation, p. 32.

⁷⁴ *Id.*

PERC conditions of use, EPA's failure to combine exposure across these routes results in an underestimate of risk for workers and consumers.

Second, EPA fails to consider aggregate exposures under the conditions of use for the general population. Exposure to PERC can come from numerous sources, including ambient and indoor air, drinking water, and even food. 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 underestimate of PERC's human health impacts. As no other environmental law enables EPA to evaluate exposure across all environmental media, TSCA must be used to address the additive and cross-media risks of PERC. EPA offers no justification except to state, "Due to deference to existing environmental statutes, administered by EPA, a detailed analysis of environmental pathways to the general population was not deemed appropriate for this risk evaluation."⁷⁵ EPA's entirely conclusive justification has no foundation in law or common sense.

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 PERC exposure.⁷⁶ However, EPA provides no evidence that PPE in the workplace is in fact used and effectively protects against PERC exposure. Moreover, the Science Advisory Committee on Chemicals, whose information and advice EPA must consider,⁷⁷ repeatedly criticized EPA's assumptions regarding the use and effectiveness of PPE in calculating exposure risks. EPA must consider whether PERC presents an unreasonable risk to exposed workers without discounting that risk by assuming the use and effectiveness of PPE. Through this unsupported assumption, EPA underestimates the risks for workers.

Fourth, the draft EPA evaluation only addresses acute inhalation and dermal exposures for consumers.⁷⁸ EPA states, "Risk estimates for chronic exposures were not calculated because it is unknown how the available toxicological data relates to the human exposures expected in consumer exposure scenarios."⁷⁹ EPA's failure to develop risk estimates for chronically exposed consumers underestimates the risks for consumers and further undermines the risk evaluation.

E. Conclusion

As discussed above, EPA's draft risk evaluation for PERC does not satisfy the requirements of TSCA and the EPA implementing regulations at 40 C.F.R. Part 702, Subpart B. As a consequence, any risk management actions developed from the evaluation, if not reworked to comply with those applicable legal requirements would fail to comply with law. Left uncorrected, the deficiencies in the draft evaluation will fatally compromise the agency's risk evaluation and any subsequent risk management of PERC, and fail to protect human health and

⁷⁵ *Id.* at 403.

⁷⁶ *Id.* at 30.

⁷⁷ 40 C.F.R. § 702.41(b)(3).

⁷⁸ PERC Draft Risk Evaluation, p. 386.

⁷⁹ *Id.*

the environment. Because of this, we request that EPA withdraw the draft evaluation and re-evaluate the risks posed by PERC in a manner that complies with EPA's obligations under TSCA.

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