March 15, 2017

Comments from the Natural Resources Defense Council (NRDC) on the TSCA Review and Scoping for Tetrachloroethylene (PERC, CAS# 127-18-4) and Trichloroethylene (TCE, CAS# 79-01-6)

Submitted to the following two dockets:

Tetrachloroethylene (perchloroethylene; PERC, tet)
Docket ID: EPA-HQ-OPPT-2016-0732-0003
https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0732

Trichloroethylene (TCE)
Docket ID: EPA-HQ-OPPT-2016-0737-0003
https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0737

The Natural Resources Defense Council (NRDC) is a national, non-profit environmental organization of lawyers, scientists, and other professionals. NRDC presents these comments on behalf of our 1.3 million members and online activists. NRDC does not have any financial interest in the topic of these comments.

NRDC is pleased that TCE and PERC were selected among the first ten chemicals for EPA to evaluate and regulate under the New TSCA. TCE and PERC are both chlorinated hydrocarbons, can be manufactured using the same or similar processes (such as oxychlorination of ethylene, see PERC scoping report, p. 5), and are in products serving similar functions (sealants, lubricants, cleaners, degreasers, and adhesives). TCE and PERC, like many solvents, are highly volatile, environmentally persistent, and toxic to people and wildlife. Their legacy and continuing use in common industrial and consumer products leads to

widespread contamination of waterways and air, and harmful exposures to workers, consumers, and families.

Health hazards of TCE and PERC

Acute poisoning and long-term or chronic adverse health effects from PERC and TCE exposure are extremely well-characterized and have been extensively reviewed in previous assessments by EPA and other authoritative bodies.[1] [2] Once in the blood stream, PERC and TCE travels through the whole body and can access all the organs, cross the placenta to access the fetal circulation, and pass through the blood brain barrier into the brain.[3] [4] For this reason, the adverse health effects are not exposure route-specific; that is, systemic effects are similar, whether exposure is through oral or inhalation routes.[5] Short-term inhalation exposures to high but realistic levels of PERC or TCE in people have been reported to cause neurological effects including blurred vision, impaired hearing, dizziness and loss of balance, muscle weakness and tremors, impaired cognitive function, and altered heartbeat.[6] [7] Short term dermal exposures such as from spills or splashing have been reported to cause skin rashes. [8] [9]

Chronic workplace exposures to solvents including PERC and TCE in women and men can lead to reproductive effects: in men, this includes reduced sex drive, poor sperm quality, and altered reproductive hormone levels; in women, menstrual disorders and spontaneous abortions. [10] [11]

TCE is a multisite human carcinogen (IARC Group 1), based on evidence of kidney cancers in people, and rodent studies reporting cancer of the liver, kidney, lung, testes, and blood by both the oral and

[1] ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf
[2] ATSDR 2014. Toxicological Profile for Tetrachloroethylene (PERC). https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=265&tid=48
[3] ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf
[4] ATSDR 2014. Toxicological Profile for Tetrachloroethylene (PERC). https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=265&tid=48
[5] ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf
[6] ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf
[7] ATSDR 2014. Toxicological Profile for Tetrachloroethylene (PERC). https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=265&tid=48
[8] ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf
[9] ATSDR 2014. Toxicological Profile for Tetrachloroethylene (PERC). https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=265&tid=48
[10] ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf
[11] ATSDR 2014. Toxicological Profile for Tetrachloroethylene (PERC). https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=265&tid=48

inhalation routes of exposure.[12] [13] PERC is classified by IARC as probably carcinogenic to humans (Group 2A).[14]

Conditions of use generally under TSCA

EPA interprets the revised TSCA as requiring the Agency to consider all uses encompassed within conditions of use during risk evaluation, and accordingly structures the risk prioritization and scoping processes to obtain and assess information based on this "comprehensive approach" to chemical management.[15] This reading conforms to EPA's proposed risk evaluation rule, where EPA outlines its interpretation that the amended TSCA requires EPA to evaluate all uses of a chemical that constitute the conditions of use, as the best way to meet its statutory obligations and the purpose underlying the revisions of the law.[16] EPA has already formalized this interpretation in denying a citizen petition under TSCA.[17]

This interpretation is correct, and we believe compelled by the plain reading of the law. [18] A contrary interpretation providing the Agency discretion to ignore any condition of use would violate the statutory directive concerning the designation of low-priority substances under Section 6(b)(1)(B)(ii) of TSCA. By definition, low-priority substances are chemicals found by EPA as not presenting an unreasonable risk to health and the environment, including to a potentially exposed or susceptible subpopulation, "because of a potential hazard and a potential route of exposure under the conditions of use." (Emphasis added). A single hazard or exposure under the conditions of use, broadly defined in the statute, is sufficient to compel a high-priority designation.[19] Where EPA lacks sufficient information regarding a substance, the default designation is "high priority," under Section 6(b)(1)(C)(iii) of TSCA. This default mechanism

[12] IARC 2014. International Agency for Research on Cancer, Monograph 106. Available here: http://monographs.iarc.fr/ENG/Monographs/vol106/index.php

[13] EPA 2016. Proposed Restrictions on Certain Trichloroethylene Uses under Section 6 of the Amended Toxic Substances Control Act. 81 Federal Register 91592 December 16, 2016. Docket ID EPA-HQ-OPPT-2016-0163

[14] IARC 2014. International Agency for Research on Cancer, Monograph 106. Available here: http://monographs.iarc.fr/ENG/Monographs/vol106/index.php

[15] *See* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control, 82 Fed. Reg. 4825, 4829 (January 17, 2017).

[16] *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7562, 7565-6 (January 19, 2017).

[17] Fluoride Chemicals in Drinking Water; TSCA Section 21 Petition; Reasons for Agency Response, 82 Fed. Reg. 11878, 11880 (February 27, 2017).

[18] Therefore, we do not believe different readings of the law are possible, as suggested by the Agency at 82 Fed. Reg. 7565.

[19] *See* 82 Fed. Reg. 4830.

demonstrates the statutory obligation to perform a comprehensive chemical evaluation. EPA discretion to ignore some conditions of use would undermine the very purpose of the default mechanism – to confine low priority designations to chemicals which do not present an unreasonable risk under any conditions of use.[20]

A reading of the law requiring consideration of all known, intended, or reasonably foreseeable activities related to a chemical substance is also compelled by further statutory construction and legislative history. Specifically, the statute directs EPA to determine whether a chemical presents an unreasonable risk of injury to health or the environment under "the conditions of use" and to establish a risk evaluation process to conduct this inquiry.[21] In provision after provision, EPA is directed to evaluate the chemical under "the conditions of use."[22]

"Conditions of use" is expressly and broadly defined to mean "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."[23] Under this statutory definition, and in the various applications of the term in the law, including but not limited to the risk evaluation determination, there are no exceptions embedded in either the definition or in the application of the term when it is used. This absence of discretion to ignore uses for risk evaluation purposes is consistent with the legislative history supporting the comprehensive evaluation of a chemical and with the statutory requirements for priority designation.[24]

Furthermore, as EPA notes at 82 Fed. Reg. 4829, EPA is required to evaluate the "chemical substance"[25] as a whole,[26] not particular uses of the chemical in question. If the statute were interpreted to allow EPA to evaluate only a subset of uses of a chemical substance, the chemical substance could be determined

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[20] *See* 82 Fed. Reg. 4830.

[21] 15 U.S.C. § 2605(b)(4)(A), (B).

[22] *See, e.g.,* 15 U.S.C. § 2605(b)(1)(B), (b)(4)(F).

[23] 15 U.S.C. § 2602(4).

[24] *See* Senate Floor Debate, 162 Cong. Rec. S.3511-01, S3516 (Jun. 7, 2016) (Analysis and Views of Democratic Members (Boxer, Markey, Udall, Merkley), in regards to the "conditions of use" definition: "In fact, a new definition added to TSCA explicitly provides such authority [to consider reasonably anticipated uses in evaluating risk] and a *mandate* for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur.") (Emphasis added). If EPA had the discretion to ignore certain uses, there could be no mandate to consider future uses because the discretionary exception would swallow the rule.

[25] NRDC supports EPA's proposal to make clear that any reference to chemical substances in the regulations encompasses categories of chemical substances as defined in the statute, including groups of chemical substances or mixtures which share similar properties. As EPA notes, the statute explicitly states that "[a]ny action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures." 15 U.S.C. § 2625(c).

[26] 15 U.S.C. § 2605(b)(4)(A).

to not pose an unreasonable risk based on the consideration of minor uses of the chemical even when other more significant uses were known or foreseen. This would not facilitate a consideration of the chemical substance as a whole, and would thereby undermine the statutory scheme.

This plain language reading is reinforced by the statutory directive to consider aggregate exposures, where relevant, because aggregate exposure assessments cannot be effectively conducted if all uses contributing to aggregate exposures are not considered. Evaluating the total exposure to a chemical is essential for assessing unreasonable risk to potentially exposed or susceptible populations, as directed by the statute.[27] As EPA notes, Section 6(b)(4)(F)(i) of TSCA requires that, in conducting a risk assessment, the Administrator "shall . . . integrate and assess available information on hazards and exposures . . . including information that is relevant to specific risks of injury to health and information on potentially exposed or susceptible subpopulations." (Emphasis added). A "potentially exposed or susceptible subpopulation" is defined as "a group of individuals within the general population . . . who, due to either greater susceptibility or greater exposure, may be at greater risk" of adverse effects.[28] As the definition makes clear, risks to potentially exposed or susceptible subpopulations are premised on greater exposure or susceptibility. For such a subpopulation, a failure to consider the sum of all known or reasonably foreseeable additive exposures would constitute a failure to meet both the Section 6(b)(4)(F)(i) obligation to assess information relevant to susceptible populations, and the fundamental Section 6 obligation to protect potentially exposed or susceptible populations from unreasonable risk. Indeed, in assessing exposures, the statute imposes an explicit "requirement" that EPA "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance,"[29] and repeatedly refers to the EPA's consideration of whether a "combination of activities" involving the chemical presents a risk to health or the environment.[30] To consider the aggregate exposure from the frequency and number of exposures

[27] 15 U.S.C. § 2605(b)(4)(A).
[28] 15 U.S.C. § 2602(12) (emphasis added).
[29] 15 U.S.C. § 2605(b)(4)(F)(iv) (emphasis added).
[30] *See, e.g.,* 15 U.S.C. § 2605(a) (stating that "If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that *any combination of such activities*, presents an unreasonable risk of injury to health or the environment . . .") (emphasis added); § 2605(d)(3)(A) (referring to the Administrator's consideration of the effects of "the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or *any combination of such activities*") (emphasis added); § 2604(b)(2)(B) (requiring manufacturers or processors of new chemicals or of significant new uses of a chemical to submit information showing that "the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or *any combination of such activities* will not present an unreasonable risk of injury to health or the environment") (emphasis added).

considered or the "combination of activities," EPA must look across the full spectrum of a chemical's use and disposal. [31]

In sum, in light of the plain language of the statute requiring consideration of "the conditions of use," without exception; the requirement to evaluate chemical substances, not particular uses; and the requirement to consider aggregate exposures, where relevant, TSCA as revised compels EPA to evaluate all known, intended, and reasonably foreseeable activities associated with a chemical, as embodied in "the conditions of use."

Intended, known, or reasonably foreseeable circumstances

We now turn to what are considered "intended, known, or reasonably foreseeable" circumstances under the law. These are three separate and independent descriptors of the circumstances constituting conditions of use, therefore EPA must give meaning to each of the descriptors when identifying conditions of use for a particular chemical.

Some have suggested these descriptors preclude EPA's consideration of conditions of use which violate federal environmental or workplace regulations, exposures inconsistent with labels, and/or uses inconsistent with the manufacturer's intended use of a chemical or product.[32] However, as explained below, such limitations would violate the statute since they fail to give independent meaning to each of the descriptors. Moreover, EPA's mandate to protect "potentially exposed or susceptible populations," as the term is defined in the law, precludes EPA from summarily dismissing such conditions of use without considering whether existing regulations adequately protect such populations.

For example, the manufacturer's intended use of a chemical or product is only one descriptor applying to the conditions of use. Where the manufacturer knows the chemical or product is actually used in other ways, the public knows of other uses, and/or the Administrator can reasonably foresee other uses (based upon the chemical or product's properties and functionality), the statute compels EPA to identify such conditions of use. The reality is chemicals and products are often used in multiple ways, particularly if there are no legal constraints against such uses, and these conditions of use cannot be rejected simply because the manufacturer alleges it never intended those uses (while profiting from the sales).[33]

The same legal analysis holds true for chemical or product labels, which may largely reflect manufacturer intent. Moreover, in the case of labels for consumer products particularly, adherence to

[31] Accordingly, we fully expect the Analysis Plan in the scoping documents, as proposed in 40 CFR 702.39(c)(5), to expressly identify the aggregate exposure scenarios EPA intends to include in a chemical's risk evaluation.

[32] *See*, *e.g.*, Comments of the American Chemistry Council to Inform EPA's Rulemaking on the Conduct of Risk Evaluations Under the Lautenberg Chemical Safety Act, August 24, 2016, p. 10.

[33] Indeed, one potential outcome of the Section 6 regulatory process is a risk management rule prohibiting the very uses the manufacturer claims it does not intend.

label use instructions cannot be assumed as a factual matter, particularly where the public and EPA "knows," or EPA can reasonable foresee, exposure scenarios inconsistent with labels. Indeed, EPA recently identified 48 relevant studies or meta-analyses concluding consumers and professionals do not follow the advice on the label for a variety of reasons.[34]

Even in the case where federal environmental or workplace standards apply, the relevant considerations are what is known to the Agency or the public, or what EPA can reasonably foresee, regarding uses and exposures related to the chemical. This will be a fact-based, chemical-specific inquiry, which may lead EPA to conclude exposures can exceed the relevant standards, or that the regulations themselves were not set (or adequately complied with) to protect the susceptible populations EPA is charged to protect under Section 6 of TSCA. The reality is some standards are either outdated or intended to protect the general population, not the vulnerable populations specially targeted for protection under the revised TSCA.

The presence of a chemical in a product or waste stream as an impurity or byproduct does not affect the conditions of use definition or scope. Its existence will generally be "known" or "reasonably foreseen" by the manufacturer or EPA. The uses and exposures associated with impurities or byproducts can be significant and their contribution to overall exposure and risk must be accounted for in EPA's risk evaluations.

EPA must also consider uses and potential routes of exposure that are not under EPA's regulatory jurisdiction under TSCA, including in food processing and packaging, and via use in such items as personal care products and cosmetics. The risk evaluations conducted by EPA cannot accurately assess whether a chemical poses an unreasonable risk if all such uses and potential sources of exposure are not accounted for. Whether and how to address uses and potential sources of exposure that are found to contribute to an unreasonable risk is a matter for the risk management stage of the process, including potential exercise of the Agency's authority under Section 9 of TSCA.

Conditions of use and exposure scenarios as applied to TCE and PERC

Below we provide some examples of the following use and exposure scenarios for two highly hazardous solvents, TCE and PERC, which contribute to unsafe human exposures and widespread environmental

[34] Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91592, 91601 (December 16, 2016).

contamination. The scope of the risk evaluation that EPA conducts for these two chemicals must include at a minimum:

- consideration of risk from aggregate exposures;
- ongoing exposures to chemicals from both current and legacy uses;
- consideration of exposures from substances not regulated under TSCA;
- consideration of uses for which hazard and/or exposure data are limited; and
- consideration of risk from cumulative exposures.

By comprehensively considering all information regarding conditions of use, EPA's risk evaluation can take into account the full range of ways in which vulnerable and chemically over-burdened populations are put at risk by these chemicals.

Below are some examples of use/exposure scenarios that EPA should include, at a minimum, in its assessment:

Uses and indoor residential exposures

Indoor residential uses put families at risk of unsafe exposures, such as from breathing, absorption through skin, and ingestion of residues on hands. Vulnerable family members may be present, including reproductive aged men and women, pregnant women, infants and young children, elders, and people with health conditions. The following are examples of realistic residential exposure scenarios using solvent products that would likely expose vulnerable family members to TCE and PERC:

Many of the products that are degreasers, brake cleaners and other products used for home auto repair etc are used in residential attached garages and workshops where, during cold weather, doors and windows would most likely be closed, blocking ventilation. Moreover, doorways connecting the residence and the garage will be opened, leading to contaminant vapor migration directly into the home. Solvent vapors may also escape through walls into the home, particularly to rooms above the garage or workshop area, much the way carbon monoxide auto fumes are known to do.[35] Auto repair tasks are done by reproductive-aged adults, often but not exclusively by the men of the family. Adults

[35] Graham LA, Noseworthy L, Fugler D, et al. 2004. Contribution of vehicle emissions from an attached garage to residential indoor air pollution levels. J Air Waste Manage Assoc 54:563-584. Reported in ATSDR https://www.atsdr.cdc.gov/toxprofiles/tp201.pdf

can be accompanied by children that learn by helping or fixing up their own cars as teenagers. These uses can lead to inhalation and dermal exposures for adults, and likely also teenagers and possibly younger children.

PERC and TCE can be in miscellaneous paint-related products, including paints, paint strippers, and coatings. They are also used in mold removers. It is likely that several of these products will be used for the same home improvement project.[36] [37] These paint products are used indoors in people's homes where ventilation may or may not be available. Use of these products will likely expose all family members to fumes contaminating the air.

Carpet cleaners and spot removers are all used indoors in people's homes where ventilation may or may not be available. These uses pose risks to family members through inhalation from off-gassing and possible dermal exposure risk from direct contact.

Lubricants are used indoors on rusty or old metal parts like squeaky door hinges, exposing all family members to possible dermal exposures from touching the treated area during or shortly after application, as well as fumes that off-gas.

Coil cleaners are intended to be used to clean the coil in HVAC units, which are often located in small, cramped, unventilated basements. It is sprayed on – making inhalation unavoidable – and then the dirty liquid is mopped up, making dermal exposures also likely.

Adhesives used for arts and crafts (for example, 'shoe dazzle', and jewelry and bead glue) will be used by children, possibly with their reproductive-aged mothers, in a small craft room or basement with no ventilation, putting beads and decorations on their clothing with these toxic products.

Hair extension glues are used indoors, either in salons where mostly women of reproductive age are employed, or in private homes indoors with poor ventilation. These hair treatments involve mostly women of reproductive age doing the treatments and receiving the treatments. If done at home, then children, elders, and people with health conditions may be present. Treatments can last all day,

[36] http://scorecard.goodguide.com/chemical-profiles/consumer-products.tcl?edf_substance_id=127-18-4
[37] http://scorecard.goodguide.com/chemical-profiles/consumer-products.tcl?edf_substance_id=79-01-6

involving multiple chemically-intensive procedures that include their hair braiding, straightening, extensions, and coloring. Hair extensions are frequently used by African American women, making its increasing use a significant concern for a population already at higher risk for co-exposures to other chemicals, and socio-economically vulnerable. The market in the US is reported to be expanding to women of all races and ethnic backgrounds, driven by music and movie stars using hair extensions to add volume as well as length to hair. Great Lengths Hair Extensions, one of the largest human hair vendors in the industry, reports a 70 percent growth over the past five years, according to a 2015 market research report.[38]

Oven cleaners are used in kitchens, and specifically in the small confined area of an oven, where the cleaning person may be in close contact with fumes, posing an inhalation and dermal exposure risk, for the time it takes to clean the appliance, and then exposed from continuing off-gassing of the cleaning materials. This use is especially concerning for pregnant and reproductive aged women, since women still do most of the housework including cleaning in American families, according to the most recent data from the US Bureau of Labor Statistics.[39] EPA didn't list oven cleaners as containing PERC, but they are listed as a possible consumer use on Scorecard.[40]

Household hard surface cleaners – both aerosol and liquid – will expose the person doing the cleaning through both inhalation and dermal routes, and possibly also by ingestion if the cleaning person does not properly wash hands before eating. If the cleaner is also parenting at the time, then the chemical residues from the product may easily be transferred to the child through direct contact such as by holding the child, preparing food for the child, etc. Other family members may be exposed through off-gassing into poorly ventilated rooms.

On its public webpage on PERC toxicity, CDC ATSDR warns that, "accidental ingestions or spills, and use of products in small, enclosed spaces, may place unsuspecting persons at risk. For example, a spot remover containing tetrachloroethylene, used to clean a carpet in a poorly ventilated area, can produce dangerously high levels of the chemical in the air."[41] Such spills around the home while doing household

[38] http://finalstepmarketing.com/wp-content/uploads/2015/07/Hair-Extensions-Market-Research.pdf
[39] https://www.bloomberg.com/news/articles/2015-06-26/women-in-the-u-s-still-do-way-more-housework-than-men
[40] http://scorecard.goodguide.com/chemical-profiles/consumer-products.tcl?edf_substance_id=127-18-4
[41] https://www.atsdr.cdc.gov/csem/csem.asp?csem=14&po=7

repair projects, car maintenance, painting projects, and cleaning are routine and to be expected. Just today I've already spilled my morning coffee on the couch, and the day isn't over yet.

Residential exposures from dry cleaning

Living above dry cleaners – higher risk for minority households

Fugitive tetrachloroethylene (PCE, perc) emissions from dry cleaners operating in apartment buildings can contaminate residential indoor air. The American Cancer Society warns that, "people who live near dry cleaning or metal degreasing operations, people using coin-operated laundries where dry cleaning machines are present, and people who live in buildings where dry cleaning shops are located are exposed to higher amounts of tetrachloroethylene [PERC] in the air."[42]

A study conducted by the New York State Department of Health (NYSDOH) measured indoor air PERC levels from 2001 to 2003 in 65 apartments located in 24 buildings that housed dry cleaning shops in New York City.[43] While the study provided welcomed evidence that regulations to limit PERC use were effective in dramatically reducing levels in residential apartments by 10-fold (from an average of 340-260 µg/m3 before the 1997 restrictions to 34 µg/m3 after restrictions), some apartments still exceeded the NYSDOH residential guideline of 100 µg/m3 and four apartments exceeded 1,000 µg/m3. And, worse, ethnically minority households were four-fold higher than nonminority households, highlighting both a continuing exposure problem and an environmental justice inequity.

Off gassing from dry cleaning hanging in cars and closets puts children at risk

Dry-cleaned fabrics can off-gas PERC during transport in cars, bringing them in close contact with families. For example, a parent will often pick up children from day care or school, and pick up dry cleaning on the way home, placing the clothing and children in close quarters with poor ventilation. Once home, dry-cleaned textiles including clothing and curtains may continue to off-gas PERC at harmful levels – an especially worrisome risk since curtains and clothing are hung in bedrooms where people will

[42] https://www.cancer.org/cancer/cancer-causes/tetrachlorethylene-perchloroethylene.html
[43] 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. Environ Health Perspect. 2005 Oct;113(10):1336-43.

spend 8 hours per day sleeping. CDC also highlights two medical case studies of poisoning from residential exposure to dry cleaning: "In one report, a 53-year-old male dry cleaner died after being overcome by tetrachloroethylene fumes (Levine, Fierro et al. 1981). A 2-year-old boy found dead 1.5 hours after he was placed in his room with curtains that had been incorrectly dry cleaned in a coin-operated dry cleaning machine (Garnier, Bedouin et al. 1996)."[44]

A 2017 study reported that PERC release rates from dry-cleaned leather and furs such as fox, rabbit, raccoon and sheepskin are especially high, and can last over a week.[45] The American Cancer Society warns that although professional dry cleaners are supposed to remove PERC before the clothing is given back to the customer, clothing may be returned to the customer still smelling of solvent.[46]

Take home exposures from dry cleaner workers poisons families

Off-gassing of clothing from dry cleaners can contaminate families. A 1994 study in Italy reported that the indoor air in the homes of PERC-exposed dry-cleaner workers was contaminated with PERC at levels nearly 10-times higher than in the homes of unexposed workers, demonstrating significant take-home exposure levels.[47] The CDC warns of take-home exposures from solvents on its public webpage on solvents, warning that, "Solvents can be carried into the home on shoes and clothing."[48] The CDC webpage on take-home exposures warns that, "Chemicals from your work can come home on your skin, hair, clothes and shoes. When you go home, these chemicals can get onto your floors, your furniture, or in your car where your family members or pets can be exposed. We call this take-home exposure. Some of these chemicals might be dangerous, especially for children."[49]

<u>Schools and workplaces</u>

[44] https://www.atsdr.cdc.gov/csem/csem.asp?csem=14&po=7
[45] Fu K, Wang L, BAo Q, Zhou W. 2017. Determination and release rate of tetrachloroethylene residues in dry-cleaned fur garments. Fibers and Polymers, 18(1):196-201. https://link-springer-com.proxygw.wrlc.org/article/10.1007/s12221-017-6395-5
[46] https://www.cancer.org/cancer/cancer-causes/tetrachlorethylene-perchloroethylene.html
[47] Aggazzotti G, Fantuzzi G, Predieri G, Righi E, Moscardelli S. Indoor exposure to perchloroethylene (PCE) in individuals living with dry-cleaning workers. Sci Total Environ. 1994;156(2):133–137
[48] https://www.cdc.gov/niosh/topics/repro/solvents.html
[49] https://www.cdc.gov/niosh/topics/repro/takehome.html

On construction sites, once the outer walls are put up but before the HVAC systems are installed, workers use portable heaters to recirculate the air in the building. Thus, there is no ventilation at all – it is in fact a closed system. Construction adhesives will concentrate in the air, along with other volatile chemical products like paints, caulking, flooring adhesives and finishes.

Embalming fluids are used to preserve cadavers that are used by gross anatomy students in Universities (students of medical, dental, physical therapy, nursing, physical education, etc.) that may spend a half-day or longer bent closely over the tank holding the cadaver and fluid when doing dissections. When I used to teach gross anatomy it was routine for the medical and dental students to spend 4-5 hours dissecting over a tank containing the corpse soaked in embalming fluids, take a few hours break to eat and rest, and return later the same day or evening for another few hours of dissecting. Instructors, including graduate students like myself would be exposed in close quarters with no more ventilation than an open window - and not even that in the winter time when it was too cold to open the windows - for several half-days each week. Even when windows were opened, the hallway doors were always closed, thus preventing a cross-breeze, so that people walking down the hallways wouldn't be disturbed by the accidental sighting of a cadaver. And, we were all reproductive age – the undergraduate students, the professional school students, and the graduate students like me, and most of the faculty. One of our graduate students that taught in the anatomy lab was pregnant, and both she and I had young children at home; our clothing, hair, and skin would reek of solvents when we arrived home, making take-home exposures a certainty.

Environmentally sensitive areas

Products advertised to remove paint and graffiti can be used on riverbanks where vandals have painted the rocky shoreline, or on bridges over waterways (railroad bridges tend to be a favorite for graffiti 'artists').[50] The paint removal is often done by local governments or volunteer groups that either don't know how or don't have the money to pay for a costly cleanup that would prevent products from washing into the water and soil below. In these cases the chemicals will all go directly into the water. I unfortunately know this personally, having been involved in one such volunteer "cleanup" in the recent past, along the Potomac Riverbank.

[50] See for example Austin Railroad Graffiti Bridge over Lady Bird Lake, Austin, Texas. http://herronstock.photoshelter.com/image/I0000aF6JRlDiHVI

Unfortunately, both TCE and PERC, like other chlorinated compounds, are extremely persistent in the environment, and may remain in high concentrations in water and soil for decades.

Substance abuse

The NIH National Institute on Drug Abuse warns that solvents are frequently used as inhalants by substance abusers, particular in products that commonly contain PERC or TCE.[51] The NIH lists the following products as common forms of inhalants: Paint thinners or removers, degreasers, dry-cleaning fluids, glue, spray paint, fabric protector sprays, aerosol computer cleaning products, and refrigerant gases.[52] EPA lists all these products as ones that may contain TCE or PERC, and emphasizes that since 2011 an estimated 84 percent of TCE is used to manufacture refrigerants.[53]

Solvents are mainly inhaled through the mouth, leading to rapid access to the blood stream and from there to the brain and other organs. The CDC NIOSH reports that there have been medical case reports of toxicity from deliberately inhaling TCE-containing consumer products in an effort to get "high"; it induces a state of euphoria and can be addictive.[54] [55] A recently published review of medical cases of sniffing deaths from TCE highlighted the need for more attention and better diagnostics to what is likely to be an under reported cause of death.[56]

Routes of Exposure

Dermal absorption from skin contact

The TCE and Perc chemical assessments under TSCA should include dermal exposures as part of the aggregate exposure assessment. Many chemicals, including solvents like TCE and Perc are absorbed

[51] NIH National Institute on Drug Abuse. Inhalants. https://www.drugabuse.gov/publications/drugfacts/inhalants
[52] https://www.drugabuse.gov/drugs-abuse/commonly-abused-drugs-charts#inhalants
[53] TCE scoping report, page 9. EPA-HQ-OPPT-2016-0737-0003
[54] Litt, I.F. and Cohen, M.I.: Danger - Vapor Harmful: Spot-Remover Sniffing. New Eng J Med, 281:543-44, 1969. Hepple, N.V. Sniffing of a Shoe-Cleaner. Brit Med J, November 9, 1968, p. 387
[55] https://www.cdc.gov/niosh/docs/1970/78127_2.html
[56] Da Broi U, Colatutto A, Sala P, Desinan L. Medico legal investigations into sudden sniffing deaths linked with trichloroethylene. J Forensic Leg Med. 2015 Aug;34:81-7. doi: 10.1016/j.jflm.2015.05.016. Review.

through the skin, entering the blood and lymphatic circulation directly, without passing through the liver and thus avoiding potential detoxification. NIOSH estimates that over 13 million US workers are potentially exposed to chemicals that can be absorbed through the skin.[57] Such dermal exposures can lead to a variety of debilitating diseases and disorders that can reduce quality of life, prevent continued working, and can cause permanent and deadly developmental disorders. Occupational Skin Disorders (OSD's) can include skin irritation, skin allergies, skin infections, and even skin cancers.

Breathing contaminated air

The TCE and Perc chemical assessments under TSCA should include air pollution exposures as part of the aggregate exposure assessment. The use of these chemicals in paint strippers and other products generates hazardous waste and toxic fugitive releases into the air, which can contribute to elevated exposures and ill health in communities. This exposes the general population – including women, children, older adults, environmental justice communities and fenceline communities.

There is increasing concern among communities that TCE contaminated soils and groundwater can release vapors into air, including indoor air of nearby homes or buildings, leading to vapor intrusion (EPA 2012). Mean TCE levels in ambient outdoor air across the US are generally between 0.01 and 0.3 ppb, although mean levels as high as 3.4 ppb have been reported, according to ASDR (2014). [58] ATSDR reports that levels of TCE as high as 0.02 ppm have been measured in air inside homes and public places.

Although TCE and PERC are broken down rapidly in air, people that live near facilities that use TCE or near waste sites containing TCE or PERC are at risk of elevated inhalation exposures.

Dietary exposures from contaminated drinking water – current and legacy pollution

Both TCE and PERC are frequent water contaminants, due to both continuing and legacy uses of the chemicals. For example, Camp Lejeune, in Jacksonville, North Carolina is an active naval military base, and one of the Department of Defense's 141 Superfund sites, with its drinking water sources polluted with terrifyingly high levels of TCE and PERC from historical military and dry cleaning uses. The solvents

[57] https://www.cdc.gov/niosh/topics/skin/
[58] ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf

percolated through the soil and into the aquifer, where residents unknowingly used poisoned water to drink, cook, and bathe for decades. Now there is justifiable outrage among the affected military families, many claiming that their chronic and acute health effects are the result of that poisoning – the area is now believed to have elevated numbers of male breast cancer cases among the sons born on the base.[59]

TCE is frequently found in drinking water samples at many locations in the United States, usually at levels below 0.03 ppm (30 ppb).[60] EPA reports that between 4.5 and 18% of source water for drinking water in the US has measurable levels of TCE, most below 30 ppb, but still above the drinking water Maximum Contaminant Level (MCL) for TCE of 5 ppb (µg/L).[61]

Similarly, PERC was detected in 130 of 1,179 well samples in the drinking water from domestic wells in the United States.[62] The drinking water MCL for PERC is 5 ppb (µg/L).[63]

TCE and PERC break down slowly in water, and are mainly dissipated as a vapor into air, or slowly leached into soil.

Once in soil, TCE and PERC can leach underground to contaminated groundwater, including sources of drinking water, where they last for decades since evaporation is not possible.[64] [65] A survey by the USGS reported detecting PERC in 4% of almost 3,500 aquifer samples used for drinking water; 0.7% of samples exceeded the MCL of 5 ppb (5 µg/L) (USGS 2006).

<u>Dietary exposure from contaminated food – non TSCA uses</u>

TCE has been detected in table-ready foods in the low ppb range, although ATSDR notes that levels as high as 140 ppb have been reported.

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[59] http://www.newsweek.com/2014/07/25/us-military-supposed-protect-countrys-citizens-and-soldiers-not-poison-them-259103.html
[60] https://www.atsdr.cdc.gov/phs/phs.asp?id=171&tid=30
[61] https://www.epa.gov/ground-water-and-drinking-water/table-regulated-drinking-water-contaminants
[62] Rowe BL, Toccalino PL, Moran MJ, et al. 2007. Occurrence and potential human-health relevance of volatile organic compounds in drinking water from domestic wells in the United States. Environ Health Perspect 115(11):1539-1546.
[63] https://www.epa.gov/ground-water-and-drinking-water/table-regulated-drinking-water-contaminants
[64] ATSDR 2014 Draft Toxicological Profile for Trichloroethylene. https://www.atsdr.cdc.gov/toxprofiles/tp19.pdf
[65] ATSDR 2014. Toxicological Profile for Tetrachloroethylene (PERC). https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=265&tid=48

ATSDR (2014) summarized a number of studies of PERC detections in various common store-bought foods at levels ranging from 1 to 230 ppb (ng/g), with a mean of 12 ppb. [66] Contaminated foods included corn muffin mix, corn meal, fudge brownie mix, dry lima beans, lasagna noodles, and uncooked rice.[67] Levels of PERC in margarine from several stores in the Washington, DC, area were 50 ppm in 10.7% of the products sampled.[68] The highest levels (500–5,000 ppb) were found in samples taken from a grocery store located near a dry cleaning shop; because levels were highest on the ends of the margarine stick and decreased toward the middle, the authors suggested that the contamination occurred after manufacturing. [69] PERC has also been detected in fatty foods such as butter, cream, vegetable oil, margarine, sausage, and cheese in residences or food stores near dry cleaners.[70]

In addition to unintentional contamination, there are also FDA-approves uses of TCE that lead to detectable levels in foods. FDA has established tolerances for residues of TCE resulting from its use as a solvent in the manufacture of decaffeinated ground coffee (25 ppm), decaffeinated soluble instant coffee extract (10 ppm), and spice oleoresins (30 ppm) (FDA 2016 21CFR173.290).[71] TCE is also approved by FDA as a food additive in modified hop extract that is used in beer. The hop extract is manufactured by an extraction and fractionation process that can include trichloroethylene, methylene chloride, and other solvents (FDA 2016 21CFR172.560).[72] Both these solvents are being reviewed by EPA under TSCA at this time. Regular beer consumers, including pregnant and under-age consumers, are likely to be exposed to TCE and methylene chloride, and other solvents, supporting their inclusion together in a cumulative exposure assessment.

An FDA-approved slimicide used to coat food-contact paper and paperboard can include residual amounts of 1,2-dichloroethane and PERC (tetrachloroethylene), both of which are carcinogenic, as

[66] ATSDR 2014. Toxicological Profile for Tetrachloroethylene (PERC). https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=265&tid=48
[67] Heikes DL, Hopper ML. 1986. Purge and trap method for determination of fumigants in whole grains, milled grain products, and intermediate grain-based foods. J Assoc Off Anal Chem 69:990-998.
[68] Entz RC, Diachenko GW. 1988. Residues of volatile halocarbons in margarines. Food Addit Contam 5:267-276.
[69] ATSDR 2014. Toxicological Profile for Tetrachloroethylene (PERC). https://www.atsdr.cdc.gov/toxprofiles/TP.asp?id=265&tid=48
[70] Schreiber JS, House S, Prohonic E, et al. 1993. An investigation of indoor air contamination in residences above dry cleaners. Risk Anal 13(3):335-344.
[71] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=173.290
[72] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.560

impurities (FDA 1999).[73] FDA notes that these are commonly found as contaminants in chemical products, including food additives. These non-TSCA dietary exposures must be included in the aggregate assessment of each chemical.

Potential susceptible populations of concern, based on conditions of use and exposures

Virtually the entire population is at risk of exposures. Both TCE and PERC are considered high production volume (HPV) chemicals, used at over a million pounds annually. In fact, each are used at hundreds of millions of pounds annually in the US, according to the EPA scoping reports. Their use at such a high volume in common consumer and industrial products contributes to contamination of soil, water, ambient air, food, and people's homes and bodies.[74] The widespread environmental and occupational contamination means that virtually the entire US population is routinely and even daily exposed to these toxic solvents, including reproductive aged men and women, pregnant women, infants and children, elders, people with health conditions, and people exposed to co-contaminants including other toxic chemicals. EPA must consider all populations, including the following vulnerable and chemically over-burdened populations:

<u>Reproductive aged men and women</u>

The chemical assessments for TCE, PERC, and other solvents under TSCA should consider possible effects on male reproductive fitness include reproductive aged men as a vulnerable population.
Workplace studies report an increased risk of childhood brain tumors associated with maternal (mother's) occupational exposure to chlorinated solvents (like TCE and PERC), and within a year before conception the paternal (father's) exposure to aromatic solvents like benzene, toluene, and xylene.[75] It is now fairly well established that solvent exposure in men can result in damaged sperm causing birth defects and low birth weight.[76] Thus, exposures to men or women can lead to developmental disorders.

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[73] FDA 1999. Final Rule. Federal Register: December 15, 1999 (Volume 64, Number 240) https://www.fda.gov/OHRMS/DOCKETS/98fr/121599a.txt

[74] https://www.atsdr.cdc.gov/phs/phs.asp?id=171&tid=30

[75] Peters S, Glass DC, Greenop KR, et al. Childhood brain tumours: associations with parental occupational exposure to solvents. *British Journal of Cancer*. 2014;111(5):998-1003. doi:10.1038/bjc.2014.358. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4150269/

[76] University of Alberta. "Solvent Exposure Linked To Birth Defects In Babies Of Male Painters." ScienceDaily. ScienceDaily, 27 September 2006. https://www.sciencedaily.com/releases/2006/09/060926183059.htm

Children and Families exposed to occupational take-home contamination

The TCE and Perc chemical assessments under TSCA should include risk estimates for children and other vulnerable family members from occupational take home exposures. Solvents used in the workplace can travel home with workers by getting into the clothing, skin, hair, and even on the exhaled breathe of workers. In other words, occupational exposure to solvents can wind up as residential exposure to families, posing a risk of reproductive, developmental, and other harm. This risk has long been known to those within those industries, as well as to government experts.

Worker populations of women and minorities

Over 60 percent of people employed in laundry and dry-cleaning facilities where PERC and TCE spot cleaners are used, are non-white, and are predominantly women (see Bureau of Labor Statics, 2015). [77] This represents a vulnerable population requiring protection.

Aggregate and cumulative exposure

In order to guarantee that ample information is collected and data gaps appropriately identified, EPA must identify all potential sources of information related to, but not limited to, chemical properties (e.g., physical and chemical characteristics, related chemistries, metabolic potential, etc.), sources of hazard and dose response information (e.g., animal, non-animal, epidemiologic, mechanistic studies, etc.), sources of aggregate and cumulative exposure information (e.g., sources of near- and far-field exposure including environmental release information, production volume, presence in consumer and household products, dietary intake, occupational exposure, modeling tools with mechanisms for quantifying uncertainty and variability, etc.), and sensitive and/or vulnerable subpopulations should be outlined for each condition of use for each chemical or class of chemicals.

Aggregate exposures

For TCE and PERC, we have identified the following aggregate exposures that EPA should include, but is not limited to, in its assessment:

[77] https://www.bls.gov/cps/cpsaat11.htm

1. The general population is exposed to TCE or PERC by the aggregation of consumption of contaminated foods, drinking water, ambient air, and contact with consumer products containing the compound.

2. Residential exposures should be aggregated for all potential routes of exposure to susceptible subpopulations identified above, including indoor air contamination from TCE or PERC vapor intrusion, ambient air levels, food and drinking water, consumer products, and dry cleaning related-activities (through occupational take home and finished product-related routes of exposure).

3. In addition to the above exposure scenarios, infants can also be exposed to TCE and PERC in breast milk.[78] [79] These solvents can be higher in the breast milk than in blood because breast tissue doesn't eliminate solvents as quickly as blood.[80] Using a PBPK model that presumes an infant's exposure at the maximum breast milk levels, Schreiber (1993) predicted that for women exposed under occupational conditions, breast milk concentrations would range from 857 to 8,440 ppb (µg/L) - up to 1600 times higher than the 5 ppb MCL for PERC.[81] Studies have reported PERC at levels in breast milk that are 3-fold higher than maternal blood. [82]

4. Adults of reproductive age, including and in many cases especially men, can be exposed to the aggregate of both residential (described in #2 above) and occupational exposures. For example, an auto mechanic is exposed to TCE, PERC and other halogenated VOC solvents through routine daily tasks in the workplace, and then again on weekends at home maintaining family vehicles and possibly also fixing up old cars as a hobby or for extra money. Dry cleaning workers may be exposed at work and at home. The aggregate of occupational and residential exposures must be included in EPA's analysis for these workers.

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[78] Pellizzari ED, Hartwell TD, Harris BS, et al. 1982. Purgeable organic compounds in mother's milk. Bull Environ Contam Toxicol 28:322-328.

[79] Solomon GM, Weiss PM. Chemical contaminants in breast milk: time trends and regional variability. Environmental Health Perspectives. 2002;110(6):A339-A347.

[80] Fisher J, Mahle D, Bankston L, Greene R, Gearhart J. Lactational transfer of volatile chemicals in breast milk. Am Ind Hyg Assoc J 58:425–431 (1997).

[81] Schreiber JS. 1993. Predicted infant exposure to tetrachloroethylene in human breast milk. Risk Anal 13(5):515-524.

[82] Fisher J, Mahle D, Bankston L, Greene R, Gearhart J. Lactational transfer of volatile chemicals in breast milk. Am Ind Hyg Assoc J 58:425–431 (1997).

Cumulative exposures should consider exposure to other solvents

The halogenated VOCs should be considered as a cumulative group given that they share the same or similar human hazard characteristics (carcinogenic, reproductive toxicity, developmental toxicity, acute toxicity, neurotoxicity, systemic toxicity), ecological fate (highly persistent in water), and often are used together or are interchangeable in consumer products.

TCE and PERC are frequent co-contaminants with other halogenated volatile organic compounds (VOCs) including methylene chloride and carbon tetrachloride, both of which are included in EPA's first ten chemicals to be assessed under new TSCA. These and many other halogenated VOCs can typically co-occur in, "burn pits, chemical manufacturing plants or disposal areas, contaminated marine sediments, disposal wells and leach fields, electroplating/metal finishing shops, firefighting training areas, hangars/aircraft maintenance areas, landfills and burial pits, leaking collection and system sanitary lines, leaking storage tanks, radioactive/mixed waste disposal areas, oxidation ponds/lagoons, paint stripping and spray booth areas, pesticide/herbicide mixing areas, solvent degreasing areas, surface impoundments, and vehicle maintenance areas."[83]

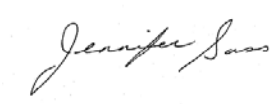
The environmental degradation products of TCE and PERC should also be included in the cumulative assessment. Degradation of highly chlorinated solvents including TCE and PERC occurs most efficiently under strictly anaerobic (chemically reducing) conditions that favor the microbial consortia capable of reductive dehalogenation. PERC, for example, though strictly non-biodegradable under aerobic conditions, can be microbially transformed to TCE, cis-dichloroethylene (cDCE), vinyl chloride (VC), and ethene in a highly reducing ground water environment.[84] These can then contaminate drinking water sources, and off-gas to air, leading to possible ingestion and inhalation exposures to families.

Thank you for your consideration of these comments. We look forward to working with EPA to ensure that unreasonable risks of these and related toxic solvents are properly identified and fully mitigated to protect the environment and human health.

[83] FRTR Remediation Technologies Screening Matrix and Reference Guide. 2.4 Halogenated Volatile Organic Compounds. https://frtr.gov/matrix2/section2/2_4.html

[84] Minnesota Pollution Control Agency (2006). Guidelines for the natural attenuation of chlorinated solvents in ground water. https://www.pca.state.mn.us/sites/default/files/c-s4-05.pdf

Respectfully,



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