

July 6, 2020

Mr. Andrew R. Wheeler, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington D.C. 20460

SUBJECT: Docket ID# EPA-HQ-OPPT-2019-0502-0001

The California Environmental Protection Agency, the Office of Environmental Health Hazard Assessment (“OEHHA”), and the Department of Toxic Substances Control (“DTSC”) (collectively, “CalEPA”) submit the present comment on the United States Environmental Protection Agency’s (“USEPA”) Draft Risk Evaluation for Perchloroethylene (“PCE”) (Ethene, 1,1,2,2-Tetrachloro) (“Draft PCE Risk Evaluation”). The Draft PCE Risk Evaluation underestimates important risks and disregards others altogether, in violation of the Toxic Substances Control Act (“TSCA”). We urge USEPA to correct these failings and adopt a final PCE risk evaluation that adequately accounts for risks to public health and the environment.

BACKGROUND

As the PCE Draft Risk Evaluation explains, PCE is widely used. Its primary uses are as a chemical intermediate for the production of chlorofluorocarbons and as a solvent used in cleaning operations (metal cleaning, vapor degreasing, and dry cleaning). In addition, numerous household products contain some level of PCE.

PCE is a common environmental contaminant. It persists in the atmosphere for several months.¹ It can last for decades in groundwater² and degrades slowly in surface water, with a half-life of 300 days.³ Due to poor handling and disposal practices, solvents such as PCE have entered the environment through evaporation, leaks, and improper disposal. USEPA has found PCE in at least 945 of the 1,699 current or former National Priority List sites. In California, numerous solvent plumes have originated from dry cleaning facilities in the Central Valley, Southern California, and San Francisco Bay Area.

¹ AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY, TOXICOLOGICAL PROFILE FOR TETRACHLOROETHYLENE 263 (2019), available at <https://www.atsdr.cdc.gov/ToxProfiles/tp18.pdf>

² *Ibid.*

³ Timothy M. Vogel & Perry L. McCarty, *Biotransformation of Tetrachloroethylene to Trichloroethylene, Dichloroethylene, Vinyl Chloride, and Carbon Dioxide under Methanogenic Conditions*, 49 APPLIED & ENVTL. MICROBIOLOGY 1080 (1985), available at <https://aem.asm.org/content/aem/49/5/1080.full.pdf>

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PCE poses significant public health risks. The chemical is readily absorbed through the lungs and gastrointestinal tract, and to a lesser extent, it can be absorbed through the skin. Acute and chronic neurological changes, and liver and kidney toxicity, have been reported in humans and animals exposed to PCE. PCE is a demonstrated carcinogen in rodent studies, inducing liver cancer in mice by inhalation or ingestion, and leukemia in rats by inhalation. Statistically significant increases in the incidence of bladder and other tumors have also been observed in studies of workers in the dry-cleaning industry.

PCE has been a listed carcinogen since 1988 under California's Safe Drinking Water and Toxic Enforcement Act of 1986, known as Proposition 65.⁴ The California Air Resources Board has classified PCE as a toxic air contaminant.⁵ The California State Water Resources Control Board has adopted a Maximum Containment Level for PCE in drinking water, and DTSC has led the cleanup of PCE at numerous sites formerly used for dry cleaning operations.

RECOMMENDATIONS

TSCA mandates that USEPA "shall conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."⁶ If USEPA determines through a risk evaluation "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," it must regulate the chemical substance as dictated by TSCA.

Thus, the failure to conduct a proper risk evaluation could have significant adverse consequences. If USEPA underestimates or fails to account for certain risks in its evaluation, it may conclude that a particular chemical substance poses less risk than is actually the case and, as a result, may not adopt appropriately robust regulations.

The PCE Draft Risk Evaluation could lead to such an outcome. It features flaws that, if not corrected, could lead to improper conclusions in the final risk evaluation. We highlight certain of these flaws below.

⁴ California Code of Regulations, tit. 27, § 27001(b). For a fuller discussion of PCE risks, see OEHHA Public Health Goal for Tetrachloroethylene in Drinking Water (2001), available at <https://oehha.ca.gov/media/downloads/pesticides/report/pceaug2001.pdf>.

⁵ California Code of Regulations, tit. 17, § 93001.

⁶ 15 U.S.C. § 2605(b)(4)(A).

I. USEPA Should Use Appropriate Assumptions

A. USEPA Should Use an Appropriately Health-Protective Point of Departure

To estimate cancer risk from inhalation exposure to PCE, the PCE Draft Risk Evaluation uses the unit risk factor (“IUR”) developed by the IRIS program in 2012. This value is 3×10^{-7} per $\mu\text{g}/\text{m}^3$, or 2×10^{-3} per ppm. (Note that the TSCA evaluation refers to the IUR as a point of departure, or “POD”).

Section 3.2.6.3 of the draft TSCA evaluation discusses some of the uncertainty associated with this choice:

There is uncertainty concerning the selected POD for cancer dose-response. [...] EPA selected the male mouse data for hepatocellular adenoma/carcinoma to use as the representative cancer POD based on the majority recommendation from the NRC [National Research Council] peer review panel of the IRIS Assessment [...] However, the NRC panel was not unanimous and some members believed that the MCL [mononuclear cell leukemia] data was better representative. The MCL IUR for the combined male and female dataset is 35x higher than the hepatocellular cancer IUR selected for use as the representative cancer POD. An adjustment was not made to account for the additional risk from MCL or hemangiomas and therefore the selected cancer POD may underestimate total cancer risk from tetrachloroethylene.⁷

Further on in the draft, at Section 3.2.5.4, USEPA states:⁸

For cancer, there is evidence of carcinogenicity in multiple tissues. The IUR (Inhalation Unit Risk) was developed from a High-quality animal study, however the limited available human data was ambiguous. Overall, there is medium confidence in the cancer endpoint.

We agree with USEPA that there is evidence—we would say *strong evidence*—that PCE is carcinogenic in multiple tissues. However, we are concerned that USEPA has decided, in this instance, to use a dataset from a single study in male mice to define its cancer POD. We believe that inclusion of dose-response data for other tumor types in mice and rats would increase confidence that the cancer risk assessment was not underestimating, and therefore ignoring, various unreasonable risks to workers and the general public.

We therefore urge USEPA to reconsider its cancer POD determination by including, at a minimum, the rat MCL data along with the male mouse liver data in its quantitative POD estimate. We would point out that USEPA’s 2012 IRIS Toxicological Review for tetrachloroethylene provided relatively strong support for using the MCL data quantitatively.⁹ For example, the IRIS review summarized that:

⁷ PCE Draft Risk Evaluation, pp. 316-317.

⁸ PCE Draft Risk Evaluation, p. 308.

⁹ USEPA, Toxicological Review of PCE (CAS No. 127-18-4) In Support of Summary Information on the Integrated Risk Information System (February 2012) (“IRIS Review”) available at https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0106tr.pdf.

the available bioassay evidence and statistical analyses, together with a limited database of studies that characterize the biologic plausibility of tetrachloroethylene as a leukemogen, provide sufficient support of the conclusion that tetrachloroethylene causes MCL in the F344 rat. No mechanistic or other data are available that would rule out the relevance of the F344 MCL for assessing potential carcinogenic hazard to humans.¹⁰

One simple approach to incorporating the rat MCL data would be to give equal weight to each of the two data sets, which would imply setting a POD at the midpoint between the individual IUR values. Since USEPA obtains an IUR of 1×10^{-5} per $\mu\text{g}/\text{m}^3$ using the rat MCL data, and reiterating the value of 3×10^{-7} per $\mu\text{g}/\text{m}^3$ based on mouse liver tumors, the revised POD would be 5×10^{-6} per $\mu\text{g}/\text{m}^3$.

An alternative approach that we could recommend would be to adopt the methodology that OEHHA used to develop an IUR for tetrachloroethylene.¹¹ OEHHA's value is based upon the same rodent-tumor data set and the same physiologically-based pharmacokinetic model as was used by USEPA in its 2012 IRIS Review. However, OEHHA took a more data-inclusive approach for dose-response estimation, using information for multiple tumor types in both sexes of mice and rats. In addition, to offset analytical uncertainty regarding the metabolism of tetrachloroethylene in rodents and humans, OEHHA interpreted the information from the toxicokinetic model in a more health-protective way than did USEPA. OEHHA's IUR for tetrachloroethylene is 6×10^{-6} per $\mu\text{g}/\text{m}^3$, approximately 20 times more health-protective than USEPA's proposed POD.

Finally, we note that the above arguments also hold for the oral slope factor that USEPA proposes to use as PODs for estimating the cancer risk from oral and dermal exposures to tetrachloroethylene. The slope factor developed by the IRIS program was based upon the same inhalation dataset as was the IUR.

B. USEPA Should Use Reliable Uncertainty Factors

TSCA requires USEPA to identify potentially exposed or susceptible subpopulations and then to determine whether a particular chemical substance presents an unreasonable risk to the identified subpopulations. The Draft PCE Risk Assessment fails to adequately identify subpopulations, as discussed below, and even for the subpopulations that it does identify, USEPA arbitrarily assesses the risks posed to them.

To calculate the risks, the Draft PCE Risk Assessment assumes an uncertainty factor of $10 \times \text{UF}_H$ for intraspecies variability.¹² But it expressly and repeatedly recognizes that this uncertainty factor does not have a rational basis:

¹⁰ IRIS Review, p. 4-271.

¹¹ OEHHA, Perchloroethylene: Inhalation Cancer Unit Risk Factor. Technical Support Document for Cancer Potency Factors. Appendix B. September 2016 (2016).

¹² PCE Draft Risk Evaluation, pp. 402-403.

- “some differences among lifestages or between working and at-rest individuals may not have been accounted for by this value.”¹³
- “most but not all of these factors are expected to be covered by the inclusion of a 10x UF_H.”¹⁴
- “[US] EPA was unable to directly account for all possible PESS considerations and subpopulations in the risk estimates.”¹⁵
- “It is unknown whether the 10x UF to account for human variability will cover the full breadth of human responses.”¹⁶
- “subpopulations with particular disease states or genetic predispositions may fall outside the range covered by this UF.”¹⁷
- “[US] EPA can also not rule out that certain subpopulations, whether due to elevated exposure or biological susceptibility, may be at risk for hazards that were not fully supported by the weight of the evidence or could not be quantified.”¹⁸

We urge USEPA to incorporate a reliable uncertainty factor or factors in the final risk evaluation.

II. USEPA Should Evaluate All Applicable Exposure Scenarios

TSCA requires that, in conducting a risk evaluation, USEPA “integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified.”¹⁹ The PCE Draft Risk Evaluation falls short of this requirement in that it fails to consider potential injuries to the environment or human health injuries that could occur as a result of exposure to PCE through environmental media.

A. USEPA Should Evaluate Scenarios for Injuries to the Environment

TSCA requires a risk evaluation to consider whether a chemical substance presents “an unreasonable risk of injury to . . . *the environment*.”²⁰ TSCA does not allow USEPA to limit its evaluation only to particular parts of the environment. In the PCE Draft Risk Evaluation, USEPA recognizes this:

To assess environmental risk, EPA identifies and evaluates environmental hazard data for aquatic, sediment-dwelling, and terrestrial organisms exposed under acute and chronic exposure conditions.²¹

¹³ *Id.*, p. 403.

¹⁴ *Ibid.*

¹⁵ *Ibid.*

¹⁶ *Ibid.*

¹⁷ *Ibid.*

¹⁸ *Ibid.*

¹⁹ 15 U.S.C. § 2605(b)(4)(F).

²⁰ *Ibid.* (emphasis added.)

²¹ PCE Draft Risk Evaluation, p. 457.

Moreover, USEPA has recognized that PCE in particular poses environmental risk. It has previously discussed the extent of PCE contamination in different environmental media:

- General Contamination: “Perchloroethylene has been found in air, soil, surface water, salt water, drinking water, aquatic organisms and terrestrial organisms (WHO, 2006). Historic industrial, commercial and military use of perchloroethylene, including unregulated or improper disposal of perchloroethylene wastes, has resulted in location-specific soil and ground water contamination. Perchloroethylene is a common ground water contaminant at hazardous waste sites in the U.S. (ATSDR, 2014) and a common drinking water contaminant.”²²
- Air Contamination: “EPA air monitoring data from 2013 reported detection of perchloroethylene in 77% of ambient air samples, with 58% of detects above the method detection limit.”²³
- Drinking Water Contamination: “EPA and the USGS National Water Quality Assessment Program (Cycle 1, 1992-2001) reported perchloroethylene contamination in U.S. surface water and ground water in 19.6% of samples (n=5,911) and at 13.2% of sites (n=4,295) . . . The Second Six-Year Review data showed perchloroethylene occurrence in 2.5% of roughly 50,000 public water systems, with thirty-six states reporting drinking water systems with at least one detection above the maximum contaminant level (MCL: 5 µg/L) (U.S. EPA, 2009).”²⁴
- Groundwater Contamination: “Groundwater levels are usually below 10 µg/l, but concentrations as high as 1300 µg/l have been reported for a legacy contaminated site.”²⁵
- Terrestrial Animals: “Terrestrial species populations living near industrial and commercial facilities using perchloroethylene may be exposed via multiple routes such as ingestion of surface waters and inhalation of outdoor air.”²⁶

In spite of these known and recognized risks, the PCE Draft Risk Evaluation considers risks only for one environmental medium – aquatic species.²⁷ It fails to consider risks to air, soil, surface water quality, groundwater, or terrestrial animals.

USEPA attempts to justify this failure by contending that it need not consider pathways that fall under other environmental statutes.²⁸ But the PCE Draft Risk Evaluation does not identify any authority that would allow USEPA to disregard its TSCA obligations merely because they may overlap with

²² USEPA, Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro) CASRN: 127-18-4 (May 2018) (“Problem Formulation”), p. 40.

²³ *Id.*, p. 40.

²⁴ *Id.*, p. 41.

²⁵ *Id.*, p. 42.

²⁶ *Id.*, p. 43.

²⁷ See PCE Draft Risk Evaluation, pp. 86-87, 94, 249-255, 318, 459.

²⁸ E.g., *id.*, p. 459; see also Problem Formulation, p. 54.

obligations under other environmental laws.²⁹ Reading TSCA in this light would have the effect of rewriting the requirement that USEPA conduct risk evaluations “without consideration of costs or other nonrisk factors.” We therefore urge USEPA to comply with TSCA by considering the risk of injury to all applicable environmental media in the final risk evaluation.³⁰

B. USEPA Should Evaluate Scenarios for Human Exposures Through Environmental Media

As discussed above, the PCE Draft Risk Evaluation recognizes that PCE is present in various environmental media.³¹ It further recognizes that humans may be exposed to PCE through environmental media³² and that these exposures could result in adverse health impacts.³³ Additionally, the Science Advisory Committee on Chemicals (“SACC”) has repeatedly urged the USEPA to consider under TSCA all exposure pathways, including drinking water ingestion and air inhalation. For example, in the peer review for EPA Draft Risk Evaluations for 1,4-Dioxane, the SACC states “there was concern with excluding general human and biota exposures from air and water from this TSCA evaluation and ‘assigning’ them to other EPA regulatory processes (that is, not considering general population and environmental exposures as TSCA-related uses.”³⁴

Despite this, the PCE Draft Risk Evaluation does not evaluate scenarios in which humans could be exposed to PCE through environmental media.³⁵ The PCE Draft Risk Evaluation attempts to excuse this failure on the ground that environmental pathways “are regulated under other environmental statutes administered by EPA which adequately assess and effectively manage exposures.”³⁶ But as discussed above, the existence of other media-specific statutes does not alter USEPA’s obligations under TSCA. We therefore urge USEPA to evaluate scenarios concerning human exposure to PCE through environmental media.³⁷

²⁹ E.g., *Connecticut Nat. Bank v. Germain* 503 U.S. 249, 253 (1992) (“Redundancies across statutes are not unusual events in drafting, and where, as here, there is no positive repugnancy between two laws, a court must give effect to both”).

³⁰ See 15 USCA § 2605(b)(4)(A).

³¹ See also PCE Draft Risk Evaluation, p. 29 (“PCE is present in various environmental media, such as groundwater, surface water, and air”).

³² *Id.*, p. 33 (“[g]eneral population exposures to PCE may occur from . . . releases to air, water or land”).

³³ *Id.*, p. 262-268.

³⁴ TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2019-02, Peer Review for EPA Draft Risk Evaluations for 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD), p. 39, available <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0237-0064>.

³⁵ PCE Draft Risk Evaluation, p. 38 (“[US] 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”).

³⁶ *Id.*, p. 38.

³⁷ USEPA raises two additional arguments in passing. First, it argues that “PCE has low bioconcentration potential and moderate potential to accumulate in wastewater biosolids, soil, or sediment.” *Id.*, p. 459. But it does not explain the reason that these factors would allegedly absolve it of its obligations to evaluate the risk of environmental injuries. Second, it argues that, for terrestrial animals, it “has determined that data are sufficient to characterize the environmental hazards of PCE and that the exposure pathways to the terrestrial environment are not likely.” *Id.*, p. 400. But USEPA does not state its basis for this conclusion.

III. USEPA Should Clearly and Comprehensively Evaluate Risks to Potentially Exposed or Susceptible Subpopulations

TSCA mandates that a risk evaluation consider risks “to a potentially exposed or susceptible subpopulation.”³⁸ It defines the term “potentially exposed or susceptible subpopulation” to mean “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.”³⁹

The PCE Draft Risk Evaluation divides potentially exposed and susceptible subpopulations into two broad categories – subpopulations “identified as relevant based on *greater exposure*” and “subpopulations identified as relevant based on *greater susceptibility*.”⁴⁰ But for the reasons discussed below, it fails to adequately assess the risks of PCE for either category.

A. USEPA Should Clearly Identify Potentially Susceptible Subpopulations

The Draft PCE Risk Evaluation does not identify exactly which subpopulations it considers to be susceptible.⁴¹ It states, in relevant part:

Factors affecting susceptibility examined in the available studies on PCE include lifestage, biological sex, genetic polymorphisms, race/ethnicity, preexisting health status, lifestyle factors, and nutrition status . . . Subpopulations that may have higher body fat composition, and therefore may be more highly exposed to sustained internal PCE concentrations/doses, include pubescent and adult women (including women of child-bearing age) as well as any individual with an elevated body-mass-index. Based on evidence of developmental toxicity from PCE exposure, pregnant women, the developing fetus and newborn infants are all considered highly susceptible subpopulations, and therefore women of childbearing age are susceptible by proxy. Effects on male fertility are more likely to present in older men, while kidney and liver effects are of most concern to subpopulations with pre-existing liver or kidney dysfunction. The partitioning of PCE to fatty tissue is of particular concern for those with fatty liver disease. Neurological endpoints are primarily related to visual function, pattern recognition, and memory. Therefore, subpopulations with poor vision or neurocognitive deficiencies may be especially susceptible to these hazards.⁴²

In this passage, the Draft PCE Risk Evaluation identifies as potential relevant factors “lifestage, biological sex, genetic polymorphisms, race/ethnicity, preexisting health status, lifestyle factors, and nutrition status.” It then discusses the potential implications of lifestage (“child-bearing age”),

³⁸ 15 USCA § 2605(b)(4)(A).

³⁹ *Id.*, § 2602(12).

⁴⁰ PCE Draft Risk Evaluation, p. 245.

⁴¹ See *id.*, p. 300.

⁴² *Ibid.*

biological sex (“pregnant women”), preexisting health status (“live or kidney dysfunction,” “poor vision or neurocognitive deficiencies”), and nutrition status (but only regarding body fat composition). But it fails to address the race/ethnicity, lifestyle factors, and nutrition status (other than body fat composition).

Moreover, it arbitrarily identifies specific susceptible subpopulations. For example, after stating that “pubescent and adult women (including women of child-bearing age)” may be more susceptible, it identifies as a susceptible subpopulation only “women of childbearing age.” It fails to articulate a reason for its exclusion of women who are not of childbearing age. Similarly, it recognizes that “[e]ffects on male fertility are more likely to present in older men” but does not identify men of a particular age as a susceptible subpopulation. And while it states that “kidney and liver effects are of most concern to subpopulations with pre-existing liver or kidney dysfunction,” it does not clearly designate such subpopulations as susceptible under TSCA.

The failure to clearly identify relevant susceptible subpopulations is particularly problematic because potentially susceptible subpopulations may experience their greatest exposures to PCE through contaminated environmental media, which, as discussed above, the PCE Draft Risk Evaluation fails to address. For example, the susceptible subpopulations may drink contaminated water, inhale contaminated air, or live near PCE-contaminated sites. These environmental exposures would compound any occupational or consumer exposures. Thus, we urge USEPA to clearly identify which subpopulations it deems be potentially susceptible and to consider all applicable pathways through which these subpopulations could be exposed to PCE.

B. USEPA Should Evaluate Scenarios for Exposures to Bystanders Through Occupational Use

The PCE Draft Risk Evaluation acknowledges that bystanders are at risk of exposure if they live or work near occupational settings where PCE is used.⁴³ But it does not identify such bystanders as a potentially exposed subpopulation.⁴⁴

USEPA fails to state a rational basis for excluding bystanders associated with occupational use from the Perc Draft Risk Evaluation. We therefore urge USEPA to correct this deficiency in the final risk evaluation by identifying them as a potentially exposed subpopulation and by assessing the risks to them.

⁴³ PCE Draft Risk Evaluation, p. 245 (“Exposures of PCE would be expected to be higher amongst groups living near industrial facilities”). See also Problem Formulation, p. 41 (“Levels can be much higher in buildings housing dry cleaning facilities”), p. 47 (“Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution or use sites”).

⁴⁴ The evaluation identifies only four potentially exposed subpopulations: (1) “workers;” (2) “occupational non-users,” which it defines to mean “workers who do not directly handle PCE but perform work in an area where PCE is present;” (3) “consumers;” and (4) bystanders associated with consumer use. None of these subpopulations encompasses bystanders who live near factories or other settings where PCE is being used or has been used in an occupational capacity. PCE Draft Risk Evaluation, p. 29.

C. USEPA Should Evaluate Scenarios for Chronic Exposures to Consumers

The PCE Draft Risk Evaluation identifies consumers as a potentially exposed or susceptible subpopulation.⁴⁵ And it recognizes that “[US] EPA cannot rule out that consumers at very high frequencies of use may be at risk for chronic hazards, especially if those consumers also exhibit biological susceptibilities.”⁴⁶

Nevertheless, the PCE Draft Risk Evaluation fails to consider the risks of chronic exposure to consumers.⁴⁷ Its stated reasoning is that, “[w]hile inhalation exposure can be acute or chronic in nature, EPA does not expect consumer exposure to be chronic in nature because product use patterns tend to be infrequent with relatively short durations of use.”⁴⁸ But this statement is directly at odds with statements elsewhere acknowledging the risk of chronic exposures to consumers. The failure to evaluate scenarios involving chronic exposures to consumers is thus arbitrary and capricious. We urge USEPA to correct this failure by including such scenarios in the final risk evaluation.

IV. USEPA Should Evaluate Legacy Uses

TSCA requires USEPA to evaluate “legacy uses,”⁴⁹ which USEPA has characterized as referring to “circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution.”⁵⁰ Despite this – and the persistence of PCE, as discussed above – legacy uses do not appear in EPA’s draft risk assessment for PCE. This could result in an underestimation of the exposure risks of PCE. We therefore urge USEPA to examine the legacy uses of PCE in the final risk evaluation.

⁴⁵ PCE Draft Risk Evaluation, p. 246.

⁴⁶ *Id.*, p. 403. The PCE Draft Risk Evaluation further recognizes that “[US] EPA can also not rule out that certain subpopulations, whether due to very elevated exposure or biological susceptibility, may be at risk for hazards that were not fully supported by the weight of evidence or could not be quantified (e.g. immune and blood effect).” *Ibid.*

⁴⁷ *Id.*, p. 31.

⁴⁸ *Id.*, p. 209.

⁴⁹ *Safer Chems. v. United States EPA*, 943 F.3d 397 (9th Cir. 2019).

⁵⁰ Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33726, 33729 (July 20, 2017).

Administrator Wheeler

July 6, 2020

Page 11

CONCLUSION

We appreciate your consideration of these comments and look forward to a final PCE risk evaluation that complies with all applicable TSCA requirements.



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