5. UNREASONABLE RISK DETERMINATION

TSCA section 6(b)(4) requires EPA to conduct a risk evaluation 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 by EPA as relevant to this Risk Evaluation, under the conditions of use.

EPA has determined that perchloroethylene (PCE) presents an unreasonable risk of injury to health under the conditions of use. This determination is based on the information in previous sections of this Risk Evaluation, the appendices and supporting documents of PCE, in accordance with TSCA section 6(b), as well as TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

The full list of conditions of use evaluated for PCE are listed in Table 1-4 of this Risk Evaluation (Ref. 1). EPA's unreasonable risk determination for PCE is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing (Domestic Manufacture)
- Manufacturing (Import)
- Processing as a reactant/intermediate
- Processing into formulation, mixture or reaction product for cleaning and degreasing products
- Processing into formulation, mixture or reaction product for adhesive and sealant products
- Processing into formulation, mixture or reaction product for paint and coating products
- Processing into formulation, mixture or reaction product for other chemical products and preparations
- Processing by repackaging
- Recycling
- Industrial and commercial use as solvent for open-top batch vapor degreasing
- Industrial and commercial use as solvent for closed-loop batch vapor degreasing
- Industrial and commercial use as solvent for in-line conveyorized vapor degreasing
- Industrial and commercial use as solvent for in-line web cleaner vapor degreasing
- Industrial and commercial use as solvent for cold cleaning
- Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
- Industrial and commercial use as a solvent for aerosol lubricants
- Industrial and commercial use as a solvent for penetrating lubricants and cutting tool coolants
- Industrial and commercial use in solvent-based adhesives and sealants
- Industrial and commercial use in solvent-based paints and coatings
- Industrial and commercial use in maskants for chemical milling

- Industrial and commercial use as a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing
- Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing
- Industrial and commercial use in wipe cleaning
- Industrial and commercial use in other spot cleaning and spot removers, including carpet cleaning
- Industrial and commercial use in mold release
- Industrial and commercial use in dry cleaning and spot cleaning post-2006 dry cleaning
- Industrial and commercial use in dry cleaning and spot cleaning 4th/5th gen only dry cleaning
- Industrial and commercial use in automotive care products (*e.g.,* engine degreaser and brake cleaner);
- Industrial and commercial use in non-aerosol cleaner
- Industrial and commercial use in metal (*e.g.,* stainless steel) and stone polishes
- Industrial and commercial use in laboratory chemicals
- Industrial and commercial use in welding
- Industrial and commercial use in other textile processing
- Industrial and commercial use in wood furniture manufacturing
- Industrial and commercial use in foundry applications
- Industrial and commercial use in specialty Department of Defense uses (oil analysis and water pipe repair)
- Commercial use in inks and ink removal products (based on printing)
- Commercial use in inks and ink removal products (based on photocopying)
- Commercial use for photographic film
- Commercial use in mold cleaning, release and protectant products
- Consumer use in cleaners and degreasers (other)
- Consumer use as a dry cleaning solvent
- Consumer use in automotive care products (brake cleaner)
- Consumer use in automotive care products (parts cleaner)
- Consumer use in aerosol cleaner (vandalism mark and stain remover)
- Consumer use in non-aerosol cleaner (*e.g.,* marble and stone polish)
- Consumer use in lubricants and greases (cutting fluid)
- Consumer use in lubricants and greases (lubricants and penetrating oils)
- Consumer use in adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive, gun ammunition sealant)
- Consumer use in adhesives for arts and crafts (livestock grooming adhesive)
- Consumer use in adhesives for arts and crafts (column adhesive, caulk and sealant)
- Consumer use in solvent-based paints and coatings (outdoor water shield (liquid))
- Consumer use in solvent-based paints and coatings (coatings and primers (aerosol))
- Consumer use in solvent-based paints and coatings (rust primer and sealant (liquid))
- Consumer use in solvent-based paints and coatings (metallic overglaze)
- Consumer use in metal (*e.g.,* stainless steel) and stone polishes
- Consumer use in inks and ink removal products

- Consumer use in welding
- Consumer use in mold cleaning, release and protectant products
- Disposal

The following conditions of use do not drive EPA's unreasonable risk determination for PCE:

- Distribution in commerce

EPA is not making a condition-of-use-specific risk determination for this condition of use, is not issuing a final order under TSCA section 6(i)(1) for the condition of use that does not drive the unreasonable risk, and does not consider the revised risk determination for PCE to constitute a final agency action at this point in time.

Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management regulatory action to the extent necessary so that PCE no longer presents an unreasonable risk. EPA expects to focus its risk management action on the conditions of use that drive the unreasonable risk. However, it should be noted that, under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management requirements in section 6(a) related to manufacture (including import), processing, distribution in commerce, commercial use, and disposal as part of its regulatory options to address the unreasonable risk. As a general example, EPA may regulate upstream activities (e.g., processing, distribution in commerce) to address downstream activities (e.g., consumer uses) driving unreasonable risk, even if the upstream activities do not drive the unreasonable risk.

5.1 Background

5.1.1 Background on Policy Changes Relating to the Whole Chemical Risk Determination and Assumption of PPE Use by Workers

From June 2020 to January 2021, EPA published risk evaluations on the first ten chemical substances, including for PCE. The risk evaluations included individual unreasonable risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1).

In accordance with Executive Order 13990 ("Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 2, 3, 4, and 5), EPA reviewed the risk evaluations for the first ten chemical substances to ensure that they meet the requirements of TSCA, including conducting decision-making in a manner that is consistent with the best available science and weight of the scientific evidence.

As a result of this review, EPA announced plans to revise specific aspects of certain of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby can help ensure the protection of health and the environment (Ref. 6). To that end, EPA has reconsidered two key aspects of the risk determinations for PCE published in December 2020. First, EPA has determined that the appropriate approach to these determinations is to make an unreasonable risk determination for PCE as a whole chemical

substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation. Second, EPA has determined that the risk determination explicitly state that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6; rather, the use of PPE will be considered during risk management. Making unreasonable risk determinations based on the baseline scenario without assuming PPE should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location or that there is widespread noncompliance with applicable OSHA standards. EPA understands that there could be occupational safety protections in place at workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health,"[1] or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

Separately, EPA is conducting a screening approach to assess risks from the air and water pathways for several of the first 10 chemicals, including this chemical. For PCE the exposure pathways that were or could be regulated under another EPA-administered statute were excluded from the final risk evaluation (see Section 1.4.2 of the December 2020 PCE Risk Evaluation). This resulted in the ambient air and ambient water pathways for PCE not being assessed. The goal of the recently-developed screening approach is to remedy this exclusion and to determine if there are risks that were unaccounted for in the PCE risk evaluation. The screening-level approach has gone through public comment and independent external peer review through the SACC. The Agency received the final peer review report on May 18, 2022, and has reviewed public comments and SACC comments. EPA expects to describe its findings regarding the chemical-specific application of this screening-level approach in the forthcoming proposed rule under TSCA section 6(a) for PCE.

Further discussion of the rationale for the whole chemical approach is found in the Federal Register Notice in the docket accompanying this revised PCE unreasonable risk determination and further discussion of the decision to not rely on assumptions regarding the use of PPE is provided in the Federal Register Notice and in Section 5.2.4 below. With respect to the PCE risk evaluation, EPA did not amend, nor does a whole chemical approach or change in assumptions regarding PPE require amending, the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation.

With regard to the specific circumstances of PCE, as further explained below, EPA has determined that a whole chemical approach is appropriate in order to protect health and the environment. The whole chemical approach is appropriate for PCE because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical

[1] As noted on OSHA's Annotated Table of Permissible Exposure Limits: "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time" (Ref. 7).

lifecycle–from manufacturing (including import), processing, commercial and industrial use, consumer use, and disposal) for human health, and risk of severe health effects (specifically neurotoxicity and cancer) is associated with PCE exposures. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, and a substantial amount of the conditions of use drive the unreasonable risk, it is therefore appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk. In addition, as discussed below in Section 5.2.4, in making this risk determination, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. EPA is revising the assumption for PCE that workers always and properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents. PPE use will be considered as part of risk management.

As explained in the Federal Register Notice, the revisions to the unreasonable risk determination (Section 5 of this Risk Evaluation) follow the issuance of a draft revision to the TSCA PCE unreasonable risk determination (87 FR 39085, June 30, 2022) (Ref. 8) and the receipt of public comment. A response to comments document is also being issued with this final revised unreasonable risk determination for PCE (Ref. 9). As noted in the Federal Register Notice, the revisions to the unreasonable risk determination are based on the existing risk characterization section of this Risk Evaluation (Section 4), and do not involve additional technical or scientific analysis. The discussion of the issues in this revision to the risk determination supersedes any conflicting statements in the prior PCE risk evaluation (December 2020) and the response to comments document (*Summary of External Peer Review and Public Comments and Disposition for Perchloroethylene (PCE) Response to Support Risk Evaluation for Perchloroethylene (PCE*), December 2020). EPA also views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence, per TSCA sections 26(h) and (i).

5.1.2 Background on Unreasonable Risk Determination

In each risk evaluation under TSCA section 6(b), EPA determines whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use. The unreasonable risk determination does not consider costs or other nonrisk factors. In making the unreasonable risk determination, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations (PESS)); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA also takes into consideration the Agency's confidence in the data used in the risk estimate. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. This approach is in keeping with the Agency's final rule, *Procedures for*

Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726, July 20, 2017).[2]

This section describes the revised unreasonable risk determination for PCE, under the conditions of use in the scope of the Risk Evaluation for PCE. This revised unreasonable risk determination is based on the risk estimates in the final Risk Evaluation, which may differ from the risk estimates in the draft Risk Evaluation due to peer review and public comments.

5.2 Unreasonable Risk to Human Health

5.2.1 Human Health

EPA's PCE risk evaluation identified risks for non-cancer adverse effects from acute and chronic inhalation and dermal exposures to PCE, and cancer from chronic inhalation and dermal exposures to PCE. The health risk estimates for all conditions of use are in Tables 4-125 and 4-126 of Section 4.4.2 of this Risk Evaluation.

In developing the exposure assessment for the PCE risk evaluation, EPA identified the following groups as Potentially Exposed or Susceptible Subpopulations (PESS): workers and occupational non-users (ONUs),[3] consumers and bystanders, developing fetus (and by extension, women of childbearing age); and those with pre-existing health conditions, higher body fat content, or particular genetic polymorphisms (Section 4.3.1 and Tables 4-125, 4-126 of this Risk Evaluation).

EPA evaluated exposures to workers, ONUs, children of workers at dry cleaners, consumer users, and bystanders using reasonably available monitoring and modeling data for inhalation and dermal exposures, as applicable. For example, EPA assumed that ONUs and bystanders do not have direct contact with PCE; therefore, risks from non-cancer effects and cancer from dermal exposures to PCE are not expected and were not evaluated. The description of the data used for human health exposure is in Section 2.4 of this Risk Evaluation. Other PESS risk considerations, including that EPA determined bystanders may include lifestages of any age, are discussed in Section 4.3.1 of this Risk Evaluation. Uncertainties in the analysis are discussed in Sections 4.2.5 and 4.4 of this Risk Evaluation and are considered in the unreasonable risk determination presented below, including the fact that the dermal model used for occupational exposures does not address variability in exposure duration and frequency.

5.2.2 Non-Cancer Risk Estimates

The risk estimates of non-cancer effects (expressed as margins of exposure or MOEs) refer to adverse health effects associated with health endpoints other than cancer, including to the body's organ systems, such as reproductive/developmental effects, cardiac and lung effects, and kidney

[2] This risk determination is being issued under TSCA section 6(b) and the terms used, such as unreasonable risk, and the considerations discussed are specific to TSCA. Other EPA programs have different statutory authorities and mandates and may involve risk considerations other than those discussed here.

[3] ONUs are workers who do not directly handle PCE but perform work in an area where PCE is present. (Executive Summary of this Risk Evaluation).

and liver effects. The MOE is the point of departure (POD) (an approximation of the no-observed adverse effect level (NOAEL) or benchmark dose level (BMDL)) and the corresponding human equivalent concentration (HEC) for a specific health endpoint divided by the exposure concentration for the specific scenario of concern. Section 3.2.5 of this Risk Evaluation presents the PODs for non-cancer effects for PCE and Section 4.2.2 and 4.2.3 of this Risk Evaluation presents the MOEs for non-cancer effects.

The MOEs are compared to a benchmark MOE. The benchmark MOE accounts for the total uncertainty in a POD, including, as appropriate: (1) the variation in sensitivity among the members of the human population (i.e., intrahuman/intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a lowest observed adverse effect level (LOAEL) rather than from a NOAEL. A lower benchmark MOE (e.g., 30) indicates greater certainty in the data (because fewer of the default uncertainty factors (UFs) relevant to a given POD as described above were applied). A higher benchmark MOE (e.g., 1000) would indicate more uncertainty for specific endpoints and scenarios. However, these are often not the only uncertainties in a risk evaluation. The benchmark MOE for acute non-cancer risks for CNS effects from PCE exposure is 10 (accounting for intraspecies variability). The benchmark MOE for chronic non-cancer risks for CNS effects from PCE exposure is 100 (accounting for intraspecies and LOAEL to NOAEL variability). Additional information regarding the non-cancer hazard identification is in Section 3.2.3.1 and 3.2.5.4 and the benchmark MOE is in Section 3.2.6 of this Risk Evaluation.

5.2.3 Cancer Risk Estimates

Cancer risk estimates represent the incremental increase in probability of an individual in an exposed population developing cancer over a lifetime (excess lifetime cancer risk (ELCR)) following exposure to the chemical. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (i.e., $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed. For example, in this risk evaluation, EPA used $1x10^{-4}$ as the benchmark for the cancer risk to individuals in industrial and commercial workplaces. The $1x10^{-4}$ value is not a bright line and EPA has discretion to make an unreasonable risk determination for the chemical substance based on other benchmarks as appropriate. Additional information regarding the cancer benchmark is in Section 3.2.5.1.3 and 4.2.1 of this Risk Evaluation, with a discussion of uncertainties in Section 3.2.6.3.

5.2.4 Determining Unreasonable Risk of Injury to Health

Calculated risk estimates (MOEs or cancer risk estimates) can provide a risk profile of PCE by presenting a range of estimates for different health effects for different conditions of use. A calculated MOE that is less than the benchmark MOE supports a determination of unreasonable risk of injury to health, based on noncancer effects. Similarly, a calculated cancer risk estimate that is greater than the cancer benchmark supports a determination of unreasonable risk of injury to health from cancer. Whether EPA makes a determination of unreasonable risk for the chemical substance depends upon other risk-related factors, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (e.g., duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

In the PCE risk characterization, neurotoxicity was identified as the most robust and sensitive endpoint for non-cancer adverse effects from acute and chronic inhalation and dermal exposures for all conditions of use. Additional risks associated with other adverse effects (e.g., kidney, liver, immune system and developmental toxicity) were identified for acute and chronic exposures. Addressing unreasonable risk by using the neurotoxicity endpoint will also address the risk from other endpoints resulting from acute or chronic inhalation and dermal exposures.

In accordance with EPA's Guidelines for Carcinogen Risk Assessment, in this risk evaluation EPA concluded that PCE is considered "likely to be carcinogenic in humans" by all routes of exposure and EPA calculated cancer risk estimates with a linear model. The cancer analysis is described in Section 3.2. EPA considered cancer risks estimates for workers from chronic dermal or inhalation exposures and risk estimates for ONUs from chronic inhalation exposures in the unreasonable risk determination.

When making a determination of unreasonable risk for the chemical substance, the Agency has a higher degree of confidence where uncertainty is low. For example, EPA has high confidence in the hazard and exposure characterizations when the basis for characterizations is measured data or monitoring data or a robust model and the hazards identified for risk estimation are relevant for conditions of use. This Risk Evaluation discusses major assumptions and key uncertainties. The PCE unreasonable risk determination considers the uncertainties associated with reasonably available information, including assumptions and uncertainties related to having only one monitoring or modeling data source available for the majority of occupational exposure scenarios (OES) and estimates for ONU inhalation exposures because monitoring data were not reasonably available for many of the conditions of use evaluated. Important assumptions and key sources of uncertainty in the risk characterization are described in more detail in Section 4.2.5 and 4.4.2 of this Risk Evaluation.

When determining the unreasonable risk for a chemical substance, EPA considers the central tendency and high-end exposure levels in occupational settings, and low, moderate and high intensity of use for consumer uses. Risk estimates based on high-end exposure levels or high intensity use scenarios (e.g., 95th percentile) are generally intended to cover individuals or sub-populations with greater exposure (PESS) as well as to capture individuals with sentinel exposure, and risk estimates at the central tendency exposure are generally estimates of average or typical exposure (Section 4.3 of this Risk Evaluation).

As shown in Section 4 of this Risk Evaluation, when characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations (workers and ONUs) who may not be covered by Occupational Safety and Health Administration (OSHA) standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. In addition, EPA risk evaluations may characterize

the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA's evaluation of risk under scenarios that, for example, incorporate use of engineering or administrative controls, or personal protective equipment, serves to inform its risk management efforts. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used to tailor risk mitigation appropriately to address worker exposures where the Agency has found unreasonable risk. In particular, EPA can use the information developed during its risk evaluation to determine whether alignment of EPA's risk management requirements with existing OSHA requirements or industry best practices will adequately address unreasonable risk as required by TSCA.

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that an applicable OSHA requirement or industry practice is consistently and always properly applied. Mitigation scenarios included in the PCE risk evaluation (e.g., scenarios considering use of various personal protective equipment (PPE)) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities will have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that is not based on an assumption of compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread noncompliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health,"[4] or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

The revised unreasonable risk determination for PCE is based on the peer reviewed risk characterization of the December 2020 Risk Evaluation, which was developed according to TSCA section 26(h) requirements to make science-driven decisions, consistent with best available science. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation.

[4] As noted on OSHA's Annotated Table of Permissible Exposure Limits: "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time" (Ref. 5).

Section 4.4.2 and Table 4-125 of this Risk Evaluation summarize the risk estimates with and without PPE, and informed the revised unreasonable risk determination.

5.3 Unreasonable Risk to the Environment

5.3.1 Environment

EPA calculated a risk quotient (RQ) to compare environmental concentrations against an effect level. The environmental concentration is determined based on the levels of the chemical released to the environment (e.g., surface water, sediment, soil, biota) under the conditions of use, based on the fate properties, release potential, and reasonably available environmental monitoring data. The effect level is calculated using concentrations of concern that represent hazard data for aquatic organisms. Section 4.1 of this Risk Evaluation provides more detail regarding the environmental risk characterization for PCE.

5.3.2 Determining Unreasonable Risk of Injury to the Environment

Calculated risk quotients (RQs) can provide a risk profile by presenting a range of estimates for different environmental hazard effects for different conditions of use. An RQ equal to 1 indicates that the exposures are the same as the concentration that causes effects. An RQ less than 1, when the exposure is less than the effect concentration, generally indicates that there is not risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. An RQ greater than 1, when the exposure is greater than the effect concentration, generally indicates that there is risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. Consistent with EPA's human health evaluations, the RQ is not treated as a bright line and other risk-based factors may be considered (e.g., confidence in the hazard and exposure characterization, duration, magnitude, uncertainty) for purposes of making an unreasonable risk determination.

PCE has low bioaccumulation potential and moderate potential to accumulate in wastewater biosolids, soil, or sediment. EPA considered the effects on the aquatic organisms, including immobilization from acute exposure, growth effects from chronic exposure, and mortality to algae. Site-specific RQs that were calculated from modeled surface water concentrations of PCE based on release data did not exceed 1 for acute PCE exposures to aquatic organisms or for PCE exposures to algae. For chronic PCE exposures, two out of 18 facilities identified as processing PCE as a reactant for which releases to water were assessed using the direct release to water scenario and one out of three facilities identified as processing PCE for incorporation into formulation for which releases to water were assessed using the indirect release to water scenario had releases indicating risk to aquatic organisms. All of the facilities for which water releases were assessed that were identified as processing as a reactant or processing into a formulation and from which exceedances occurred had NPDES permits and are subject to effluent limitations under the CWA. Risks to aquatic organisms from chronic PCE exposures were not identified for other facilities for which releases to water were assessed. EPA provides estimates for environmental risk in Section 4.4.1 and Table 4-124 of this Risk Evaluation. There were major limitations in the model associated with uncertainties, including the lack of flow data based on representative industry sector. Assumptions and key sources of uncertainty in the risk characterization are detailed in Section 4.1.5 of this Risk Evaluation.

When making a determination of unreasonable risk, EPA has a higher degree of confidence where uncertainty is low. For example, EPA has high confidence in the hazard and exposure characterizations when the basis for the characterizations is measured or representative monitoring data or a robust model and the hazards identified for risk estimation are relevant for conditions of use. Where EPA has made assumptions in the scientific evaluation, the degree to which these assumptions are conservative (i.e., more protective) is also a consideration.

Therefore, based on this Risk Evaluation, including the risk estimates, the environmental effects of PCE, the exposures, physical-chemical properties of PCE, and consideration of uncertainties, EPA did not identify risk of injury to the environment that would drive the unreasonable risk determination for PCE.

5.4 Additional Information Regarding the Basis for the Unreasonable Risk Determination

Table 5-1, Table 5-2, and Table 5-3 summarize the basis for the revised determination of unreasonable risk of injury to health presented by PCE. In these tables, a checkmark indicates the risk of the type of effect and the exposure route to the population evaluated for each condition of use that drives the unreasonable risk determination. As explained in Section 5.2, for the revised unreasonable risk determination, EPA considered the effects on human health of exposure to PCE at the central tendency and high-end, the exposures from the condition of use, the risk estimates, and the uncertainties in the analysis. See Section 4.4.1 and 4.4.2 of the Risk Evaluation for a summary of risk estimates.

Table 5-1. Supporting Basis for the Revised Unreasonable Risk Determination for Human Health (Occupational Conditions of Use)[5]

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Manufacture	Domestic manufacture	Domestic manufacture	Worker	Inhalation	✓		✓		✓	
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation						
Manufacture	Import	Import [c, d]	Worker	Inhalation	✓		✓	✓	✓	
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A	✓	N/A	
Processing	Processing as a reactant or intermediate	Intermediate in industrial gas manufacturing; Intermediate in basic organic chemical manufacturing; Intermediate in petroleum refineries; Reactant use [e]	Worker	Inhalation	✓		✓		✓	
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation						
Processing	Incorporated into formulation,	Cleaning and degreasing products [c, f]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓

[5] The checkmarks indicate the risk of the type of effect and the exposure route to the population evaluated for each condition of use that support the revised unreasonable risk determination for PCE. This table is based on Table 4-125 of this Risk Evaluation.

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
	mixture or reaction product		ONU	Inhalation	N/A	✓	N/A	✓	N/A	✓
Processing	Incorporated into formulation, mixture or reaction product	Adhesive and sealant products [c, g]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A	✓	N/A	✓	N/A	✓
Processing	Incorporated into formulation, mixture or reaction product	Paint and coating products [c, h]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A	✓	N/A	✓	N/A	✓
Processing	Incorporated into formulation, mixture or reaction product	Other chemical products and preparations [c, i]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A	✓	N/A	✓	N/A	✓
Processing	Repackaging	Solvent for cleaning or degreasing; Intermediate [c]	Worker	Inhalation	✓		✓	✓	✓	
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A	✓	N/A	
Processing	Recycling	Recycling [c]	Worker	Inhalation						
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A		N/A	
Industrial/ Commercial	Solvents (for cleaning or degreasing)	Batch vapor degreaser (open-top) [j]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial/ Commercial use	Solvents (for cleaning or degreasing)	Batch vapor degreaser (closed-loop) [k]	Worker	Inhalation			✓			
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation						
Industrial/ Commercial use	Solvents (for cleaning or degreasing)	In-line vapor degreaser (conveyorized) [l]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ Commercial use	Solvents (for cleaning or degreasing)	In-line vapor degreaser (web cleaner) [m]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓	✓	✓	
Industrial/ Commercial use	Solvents (for cleaning or degreasing)	Cold cleaner [n]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓		✓	
Industrial/ Commercial use	Solvents (for cleaning or degreasing)	Aerosol spray degreaser/ cleaner [o]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓		✓	
Industrial/ Commercial use	Lubricants and greases	Lubricants and greases (aerosol lubricants) [o]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓		✓	

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial/ Commercial use	Lubricants and greases	Lubricants and greases (*e.g.*, penetrating lubricants, cutting tool coolants) [c, p]	Worker	Inhalation						
			Worker	Dermal			✓	✓	✓	
			ONU	Inhalation	N/A		N/A		N/A	
Industrial/ Commercial use	Adhesives and sealant chemicals	Solvent-based adhesives and sealants [c, q]	Worker	Inhalation	✓		✓		✓	
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A		N/A	
Industrial/ Commercial use	Paints and coatings including paint and coating removers	Solvent-based paints and coatings [c, q]	Worker	Inhalation	✓		✓	✓	✓	
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A	✓	N/A	
Industrial/ Commercial use	Paints and coatings including paint and coating removers	Maskant for chemical milling	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ Commercial use	Processing aids, not otherwise listed	Pesticide, fertilizer and other agricultural chemical manufacturing	Worker	Inhalation	✓		✓		✓	
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A		N/A	

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial/ Commercial use	Processing aids, specific to petroleum production	Catalyst regeneration in petrochemical manufacturing	Worker	Inhalation	✓		✓		✓	
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A		N/A	
Industrial/ Commercial use	Cleaning and furniture care products	Cleaners and degreasers (other) (wipe cleaning) [r]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓		✓	
Industrial/ Commercial use	Cleaning and furniture care products	Cleaners and degreasers (other) (Other Spot Cleaning/Spot Removers (Including Carpet Cleaning) [s]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation						
Industrial/ Commercial use	Cleaning and furniture care products	Cleaners and degreasers (other) (Mold Release) [c]	Worker	Inhalation						
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A		N/A	

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial/ Commercial use	Cleaning and furniture care products	Dry Cleaning and Spot Cleaning Post-2006 Dry Cleaning [t, u]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓	✓	✓	
			Children of workers present at dry cleaners	Inhalation	✓	✓	N/A	N/A	N/A	N/A
Industrial/ Commercial use	Cleaning and furniture care products	Dry Cleaning and Spot Cleaning 4th/5th Gen Only Dry Cleaning [u, v]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation						
			Children of workers present at dry cleaners	Inhalation			N/A	N/A	N/A	N/A
Industrial/ Commercial use	Cleaning and furniture care products	Automotive care products (*e.g.,* engine degreaser and brake cleaner) [w]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓		✓	
Industrial/ Commercial use	Cleaning and furniture care products	Non-aerosol cleaner [x]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓		✓	
Industrial/ Commercial use	Other uses	Metal (*e.g.,* stainless steel) and stone polishes [x]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓		✓	

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Industrial/ Commercial use	Other uses	Laboratory chemicals [y]	Worker	Inhalation						
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation						
Industrial/ Commercial use	Other uses	Welding [z]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓		✓	
Industrial/ Commercial use	Other uses	Textile processing (other) [c]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A	✓	N/A	✓	N/A	✓
Industrial/ Commercial use	Other uses	Wood furniture manufacturing [c]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A	✓	N/A	✓	N/A	✓
Industrial/ Commercial use	Other uses	Foundry applications [c]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A	✓	N/A	✓	N/A	✓
Industrial/ Commercial use	Other uses	Specialty Department of Defense uses [c]	Worker	Inhalation	✓	✓	✓	✓		
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A	✓	N/A	✓	N/A	
Commercial use	Other uses	Inks and ink removal products (based on printing) [c]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A	✓	N/A	✓	N/A	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
Commercial use	Other uses	Inks and ink removal products (based on photocopying) [c]	Worker	Inhalation						
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A		N/A	
Commercial use	Other uses	Photographic film [c]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A	✓	N/A	✓	N/A	✓
Commercial use	Other uses	Mold cleaning, release and protectant products [c]	Worker	Inhalation						
			Worker	Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	N/A		N/A		N/A	
Disposal	Disposal	Industrial pre-treatment; Industrial wastewater treatment;	Worker	Inhalation						
			Worker	Dermal	✓	✓	✓	✓	✓	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
		Publicly owned treatment works (POTW); Underground injection; Municipal solid waste landfill; Hazardous waste landfill; Other land disposal; Municipal waste incinerator; Hazardous waste incinerator; Off-site waste transfer [c]	ONU	Inhalation	N/A		N/A		N/A	

a. These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of PCE.
b. These subcategories reflect more specific information regarding the conditions of use of PCE.
c. Based on EPA's analysis, the data for worker and ONU inhalation exposures could not be distinguished; however, ONU inhalation exposures are assumed to be lower than inhalation exposures for workers directly handling the chemical substance. To account for this uncertainty, EPA also considered the workers' central tendency risk estimates from inhalation exposures when determining ONUs' unreasonable risk.
d. For import of PCE, inhalation exposures were assessed based on monitoring data using the repackaging occupational exposure scenario.
e. For processing of PCE as a reactant/intermediate, inhalation exposures were assessed using PCE personal breathing zone monitoring data collected at facilities manufacturing PCE as a surrogate for facilities processing PCE as reactant.
f. For processing of PCE into formulation, mixture, or reaction product for cleaning and degreasing products, two exposures scenarios apply to this condition of use. EPA made its determination based on the processing of a dry cleaning solvent scenario, which was more representative of the condition of use.
g. For processing of PCE into formulation, mixture, or reaction product for adhesive and sealant products, two exposure scenarios apply to this condition of use. EPA made its determination based on the degreasing solvent scenario, which was more representative of this condition of use.
h. For processing of PCE into formulation, mixture, or reaction product for paint and coating products, two exposure scenarios apply to this condition of use. EPA made its determination based on the degreasing solvent scenario, which was more representative of this condition of use.
i. For processing of PCE into formulation, mixture, or reaction product for other chemical products and preparations, EPA made its determination based on the aerosol packing scenario assessed for Incorporation into Formulation, Mixture, or Reactant Product, which used personal breathing zone monitoring data.
j. For industrial and commercial use of PCE as a solvent for open-top batch vapor degreasing (OTVD), inhalation exposures for workers and ONUs were assessed using monitoring data from NIOSH investigations at five sites using PCE as a degreasing solvent in OTVDs. Due to the large variety in shop types that may use PCE as a vapor degreasing solvent, it is unclear how representative these data are of a "typical" shop.
k. For industrial and commercial use of PCE as a solvent for closed-loop batch vapor degreasing, inhalation exposures for workers and ONUs were assessed using monitoring data from NIOSH investigations at two sites using PCE as a degreasing solvent in closed loop batch vapor degreasers. Due to the large variety in shop types that may use PCE as a vapor degreasing solvent, it is unclear how representative these data are of a "typical" shop.
l. For industrial and commercial use of PCE as a solvent for in-line conveyorized vapor degreasing, EPA assessed inhalation exposures during conveyorized degreasing using the Conveyorized Degreasing Near-Field/Far-Field Inhalation Exposure Model. Workers' risk estimates are based on concentrations in the near-field where the conveyorized degreasing work occurs, and ONU exposures are based on concentrations in the far-field, away from the conveyorized degreaser.
m. For industrial and commercial use of PCE as a solvent for in-line web vapor degreasing, EPA assessed inhalation exposures during web degreasing using the Web Degreasing Near-Field/Far-Field Inhalation Exposure Model. Workers' risk estimates are based on concentrations in the near-field where the web degreasing work occurs, and ONU exposures are based on concentrations in the far-field, away from the web degreaser.
n. For industrial and commercial use of PCE as a solvent for cold cleaning, EPA assessed inhalation exposures for workers using monitoring data supplemented by the Cold Cleaning Near-Field/Far-Field Inhalation Exposure Model. The estimates based on monitoring data only include values for workers as monitoring data for ONUs were not identified. To account for lack of monitoring data for ONUs, EPA considered risk estimates from exposure modeling when determining ONU risk.
o. For industrial and commercial use of PCE as a solvent for aerosol spray degreaser/cleaner and industrial and commercial use of PCE as a solvent for aerosol lubricants, inhalation exposures for workers were assessed using monitoring data supplemented by the Brake Servicing Near-Field/Far-Field inhalation Exposure Model. The estimates based on monitoring data only include values for workers as monitoring data for ONUs were not identified. To account for lack of monitoring data for ONUs, EPA considered risk estimates from exposure modeling when determining ONU risk. EPA's inhalation exposure modeling is based on a near-field/far-field approach, where vapor generation source located inside the near-field diffuses into the surrounding environment. Workers are assumed to be exposed to PCE vapor concentrations in the near-field, while ONUs are exposed at concentrations in the far-field.

p. For industrial and commercial use of PCE as a solvent for penetrating lubricants and cutting tool coolants, EPA made its determination based on the metalworking fluids occupational exposure scenario.
q. For industrial and commercial use of PCE in solvent-based adhesives and sealants and in solvent-based paints and coatings, EPA identified inhalation exposure monitoring data related to the use of PCE-based adhesives, sealants, paints, and coatings. The results in the monitoring data only include values for workers, as monitoring data for ONUs were not identified. To account for this uncertainty when using monitoring data, EPA considered the central tendency estimate when determining ONU risk. Due to the large variety in shop types that may use PCE-based adhesives and coatings, it is unclear how representative these data are of a "typical" site using these products.
r. For industrial and commercial use of PCE in wipe cleaning, EPA identified inhalation exposure monitoring data from NIOSH investigations at two sites using PCE for wipe cleaning and stone/metal polish. EPA separately calculated risk estimates for ONUs and workers based on monitoring data. Due to the large variety in shop types that may use PCE as a wipe cleaning solvent, it is unclear how representative these data are of a "typical" shop. EPA does not have a model for estimating exposures from wipe cleaning; therefore, the assessment is based on the identified monitoring data.
s. For industrial and commercial use of PCE in other speat cleaning/spot removers (including carpet cleaning), EPA separately calculated risk estimates for ONUs and workers based on monitoring data. EPA identified inhalation exposure monitoring data from a single NIOSH investigation at a garment manufacturer. Worker samples were determined to be any sample taken on a person while directly handling PCE. ONUs samples were determined to be any sample taken on a person in the same location as the PCE use but not handling PCE. ONU exposure data did not distinguish central tendency and high-end. There is some uncertainty in how representative this data are of exposure at other facilities performing carpet cleaning or spot remover tasks.
t. For industrial and commercial use of PCE in dry cleaning and spot cleaning post-2006 dry cleaning, EPA made its determination on workers using monitoring data. Because the monitoring data only contained one data point representing an ONU for this scenario, EPA made its determination on ONUs using modeled data. Modeled ONU exposures are based on concentrations in the far-field which corresponds to any area outside the near-field zones.
u. EPA separately evaluated risks to consumers from dry-cleaned articles as part of the condition of use, consumer use as a dry cleaning solvent.
v. For industrial and commercial use of PCE in dry cleaning and spot cleaning $4^{th}/5^{th}$ gen only dry cleaning, EPA based its risk determination on monitoring data. When comparing the model results to the fourth/fifth generation monitoring data results for workers, the model high-end and central tendency are both an order of magnitude greater than the monitoring data. This is expected as the model captures exposures from facilities with third and fourth/fifth generation machines.
w. For the industrial and commercial use of PCE in automotive care products (*e.g.*, engine degreaser and brake cleaning), inhalation exposures for workers were assessed using monitoring data supplemented by the Brake Servicing Near-Field/Far-Field inhalation Exposure Model. The estimates based on monitoring data only include values for workers as monitoring data for ONUs were not identified. To account for lack of monitoring data for ONUs, EPA considered risk estimates from exposure modeling when determining ONU risk. EPA's inhalation exposure modeling is based on near-field/far-field approach, where a vapor generation source located inside the near-field diffuses into the surrounding environment. Workers are assumed to be exposure to PCE vapor concentrations in the near-field, while ONUs are exposed at concentrations in the far-field.
x. For industrial and commercial use in non-aerosol cleaner and in metal (e.g., stainless steel) and stone polishes, inhalation exposure for workers and ONUs were assessed using monitoring data from NIOSH investigations at two sites using PCE for wipe cleaning and metal/stone polish. EPA separately calculated risk estimates for ONUs and workers based on monitoring data. Due to the large variety in shop types that may use PCE as a wipe cleaning solvent, it is unclear how representative these data are of a "typical" shop. EPA does not have a model for estimating exposures from wipe cleaning; therefore, the assessment is based on the identified monitoring data.
y. For industrial and commercial use of PCE in laboratory chemicals, while EPA quantitatively and qualitatively assessed worker inhalation exposures to PCE during industrial and commercial use in laboratory chemicals, EPA has low confidence in the quantitative assessment. Due to the expected safety practices

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
when using chemicals in a laboratory setting, PCE is expected to be applied in small amounts under a fume hood, thus reducing the potential for inhalation exposures. z. For industrial and commercial use of PCE in welding, inhalation exposures for workers were assessed using monitoring data supplemented by the Brake Servicing Near-Field/Far-Field inhalation Exposure Model. The estimates based on monitoring data only include values for workers as monitoring data for ONUs were not identified. To account for lack of monitoring data for ONUs, EPA considered risk estimates from exposure modeling when determining ONU risk. EPA's inhalation exposure modeling is based on a near-field/far-field approach, where a vapor generation source located inside the near-field diffuses into the surrounding environment. Workers are assumed to be exposed to PCE vapor concentrations in the near-field, while ONUs are exposed at concentrations in the far-field.											

Table 5-2. Supporting Bases for the Revised Unreasonable Risk Determination for Human Health (Consumer Conditions of Use) [6]

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health		
					Acute Non-cancer		
					High Intensity Use	Moderate Intensity Use	Low Intensity Use
Consumer use	Cleaning and furniture care products	Cleaners and degreasers [c,d]	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓		
			Bystander	Inhalation	✓	✓	
Consumer use	Cleaning and furniture care products	Automotive care products (brake cleaner) [c,d]	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓		
			Bystander	Inhalation	✓	✓	✓
Consumer use	Cleaning and furniture care products	Automotive care products (parts cleaner) [c,d]	Consumer user	Inhalation	✓	✓	
			Consumer user	Dermal	✓		
			Bystander	Inhalation	✓	✓	
Consumer use	Cleaning and furniture care products	Aerosol cleaning (vandalism mark and stain remover) [c,d]	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓		
			Bystander	Inhalation	✓	✓	
Consumer use	Cleaning and furniture care products	Non-aerosol cleaner (*e.g.*, marble and stone polish) [c,d]	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	

[6] The checkmarks indicate the risk of the type of effect and the exposure route to the population evaluated for each condition of use that support the revised unreasonable risk determination for PCE. This table is based on Table 4-126 of this Risk Evaluation.

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health		
					Acute Non-cancer		
					High Intensity Use	Moderate Intensity Use	Low Intensity Use
Consumer use	Lubricants and greases	Lubricants and greases (cutting fluid) [c,d]	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓		
			Bystander	Inhalation	✓	✓	
Consumer use	Lubricants and greases	Lubricants and greases (lubricants and penetrating oil) [c,e]	Consumer user	Inhalation	✓	✓	
			Consumer user	Dermal	✓		
			Bystander	Inhalation	✓	✓	
Consumer use	Adhesives and sealant chemicals	Adhesives for arts and crafts (includes industrial adhesive, arts and crafts adhesive, gun ammunition sealant) [c,e]	Consumer user	Inhalation	✓	✓	
			Consumer user	Dermal	✓	✓	
			Bystander	Inhalation	✓		
Consumer use	Adhesives and sealant chemicals	Adhesives for arts and crafts (livestock grooming adhesive) [c,e]	Consumer user	Inhalation	✓		
			Consumer user	Dermal	✓		
			Bystander	Inhalation	✓		
Consumer use	Adhesives and sealant chemicals	Adhesives for arts and crafts (column adhesive, caulk, and sealant) [c,e,f]	Consumer user	Inhalation	✓	✓	
			Consumer user	Dermal	✓	✓	
			Bystander	Inhalation	N/E	N/E	N/E

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health		
					Acute Non-cancer		
					High Intensity Use	Moderate Intensity Use	Low Intensity Use
Consumer use	Paints and coatings	Solvent-based paints and coatings (outdoor water shield (liquid)) [c,e]	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓	✓	✓
			Bystander	Inhalation	✓	✓	
Consumer use	Paints and coatings	Solvent-based paints and coatings (coatings and primers (aerosol)) [c,e]	Consumer user	Inhalation	✓		
			Consumer user	Dermal	✓	✓	
			Bystander	Inhalation			
Consumer use	Paints and coatings	Solvent-based paints and coatings (rust primer and sealant (liquid)) [c,e]	Consumer user	Inhalation			
			Consumer user	Dermal	✓	✓	✓
			Bystander	Inhalation			
Consumer use	Paints and coatings	Solvent-based paints and coatings (metallic overglaze) [c,e]	Consumer user	Inhalation			
			Consumer user	Dermal	✓		
			Bystander	Inhalation			
Consumer use	Other uses	Metal (*e.g.*, stainless steel) and stone polishes) [c,d]	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health		
					Acute Non-cancer		
					High Intensity Use	Moderate Intensity Use	Low Intensity Use
Consumer use	Other uses	Inks and ink removal products [c,d]	Consumer user	Inhalation	✓	✓	✓
			Consumer user	Dermal	✓		
			Bystander	Inhalation	✓	✓	
Consumer use	Other uses	Welding [c,e]	Consumer user	Inhalation	✓	✓	
			Consumer user	Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	
Consumer use	Other uses	Mold cleaning, release and protectant products [c,e]	Consumer user	Inhalation	✓	✓	
			Consumer user	Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	

a. These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of PCE.
b. These subcategories reflect more specific information regarding the conditions of use of PCE.
c. Inhalation exposures to consumers and bystanders were evaluated with the Consumer Exposure Model Version 2.1 (CEM 2.1). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the concentration of PCE in products used, use patterns (including frequency, duration, amount of product used, room of use, and local ventilation), and application methods.
d. Dermal exposures to consumers were evaluated with the CEM (Permeability). Dermal exposures to consumers result from dermal contact involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including skin surface area, concentration of PCE in product used, permeability coefficient, and dermal exposure duration. The potential for dermal exposures to PCE is limited by several factors including physical-chemical properties of PCE, such as high vapor pressure.
e. Dermal exposures to consumers were evaluated with the CEM (Fraction Absorbed). Dermal exposures to consumers result from dermal contact not involving impeded evaporation while using the product. The magnitude of dermal exposures depends on several factors, including skin surface area, film thickness, concentration of PCE in product used, dermal exposure duration, and estimated fractional absorption. The potential for dermal exposures to PCE is limited by several factors including physical-chemical properties of PCE, such as high vapor pressure.
f. Acute inhalation exposure for bystanders was not evaluated, as the consumer area of use was assumed to be similar conditions as outside the home.

Table 5-3. Supporting Basis for the Revised Unreasonable Risk Determination for Human Health (Consumer Dry Cleaning Condition of Use) [7]

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health		
					Acute Non-Cancer		
					Assumed Dry Cleaning Technology (Events, days after cleaning)		
					2nd and 3rd generation, 1 day after single dry cleaning event	2nd and 3rd generation, 2 days after single dry cleaning event	2nd and 3rd generation, 3 days after single dry cleaning event
Consumer use	Cleaning and furniture care products	Dry cleaning solvent [c, d, e, f]	Consumer user, half-body garments	Dermal	✓		

a. These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of PCE.
b. These subcategories reflect more specific information regarding the conditions of use of PCE.
c. Risk estimates for consumer use of PCE as a dry cleaning solvent due to off-gassing from recently dry cleaned articles was evaluated for two scenarios: direct dermal contact with clothing to consumers and inhalation exposure to bystanders (stay-at-home adult and child) from article storage in a home closet. Modeling was used to estimate dermal and inhalation exposures.
d. Measurements of PCE concentrations in indoor air from storage of recently dry cleaned articles are in good agreement with modeling results. No direct measurements were found for consumer dermal exposure to PCE from dry cleaned fabrics.
e. Inhalation exposures to consumers and bystanders were evaluated with the Multi-Chamber Concentration and Exposure Model (MCCEM). The magnitude of inhalation exposures to consumers and bystanders depends on several factors, including the type (generation) of dry cleaning machine used, residual PCE remaining in dry cleaned clothing, fabric type, frequency of dry cleaning events, and number of dry cleaned articles stored.
f. Dermal exposures to consumers were evaluated with the CEM (Dermal Dose from Skin Contact with Article). Dermal exposures to consumers result from direct contact with residual PCE in recently dry cleaned articles. The magnitude of dermal exposures depends on several factors, including fabric type, number and proximity of dry cleaning events, total number of dry cleaned articles, total article surface area, the type (generation) of dry cleaning machine used, and number of days elapsed since the fabric was dry cleaned.

[7] The checkmarks indicate the risk of the type of effect and the exposure route to the population evaluated for each condition of use that support the revised unreasonable risk determination for PCE. This table is based on Table 4-126 of this Risk Evaluation.

5.5 Order Withdrawing TSCA Section 6(i)(1) Order

The December 2020 risk evaluation for PCE included individual risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present unreasonable risk were issued by order under TSCA section 6(i)(1). Section 5.4.1 of the December 2020 Risk Evaluation stated: "This subsection of the final Risk Evaluation … constitutes the order required under TSCA section 6(i)(1), and the 'no unreasonable risk' determinations in this subsection are considered to be final agency action effective on the date of issuance of this order."

In this revised risk determination, EPA has determined that PCE as a whole chemical substance presents an unreasonable risk of injury to health under the conditions of use. This revised risk determination supersedes the no unreasonable risk determinations in the December 2020 Risk Evaluation that were premised on a condition of use-specific approach to determining unreasonable risk. This subsection of the revised risk determination also constitutes an order withdrawing the TSCA section 6(i)(1) order in the December 2020 Risk Evaluation. EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the to the extent permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Further explanation and justification for this action can be found in the Federal Register Notice announcing the availability of the draft revised risk determination for PCE, 87 Fed. Reg. 39085 (June 30, 2022) (Ref. 8), and in the Federal Register Notice accompanying this revised risk determination.

5.6 References

1. EPA. Risk Evaluation for Perchloroethylene (PCE). December 2020. *https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0502-0058*.

2. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register* (86 FR 7009, January 25, 2021).

3. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register* (86 FR 7037, January 25, 2021).

4. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register* (86 FR 7619, February 1, 2021).

5. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register* (86 FR 8845, February 10, 2021).

6. EPA Press Release. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 30, 2021. *https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations*.

7. Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. *https://www.osha.gov/annotated-pels.*

8. Notice. Perchloroethylene (PCE); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment. *Federal Register* (87 FR 39085, June 30, 2022).

9. EPA. Response to Public Comments to the Revised Unreasonable Risk Determination; Perchloroethylene (PCE). December 2022.