Trichloroethylene (TCE)

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 non-risk 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 Trichloroethylene (TCE) presents an unreasonable risk of injury to health under the conditions of use. This determination is based on the information in previous sections of the Risk Evaluation, the appendices and supporting documents of TCE, 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 TCE are listed in Tables 1-3 and 1-4 of the risk evaluation (Ref. 1). EPA's unreasonable risk determination for TCE 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: processing as a reactant/intermediate
- Processing: incorporation into a formulation, mixture or reaction product
- Processing: incorporation into articles
- Processing: repackaging
- Processing: recycling
- Industrial and commercial use as a solvent for open-top batch vapor degreasing
- Industrial and commercial use as a solvent for closed-loop batch vapor degreasing
- Industrial and commercial use as a solvent for in-line conveyorized vapor degreasing
- Industrial and commercial use as a solvent for in-line web cleaner vapor degreasing
- Industrial and commercial use as a solvent for cold cleaning
- Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release
- Industrial and commercial use as a lubricant and grease in tap and die fluid
- Industrial and commercial use as a lubricant and grease in penetrating lubricant
- Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants; tire repair cement/sealer; mirror edge sealant
- Industrial and commercial use as a functional fluid in heat exchange fluid

- Industrial and commercial use in paints and coatings as a diluent in solvent-based paints and coatings
- Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning
- Industrial and commercial use in laundry and dishwashing products in spot remover
- Industrial and commercial use in arts, crafts, and hobby materials in fixatives and finishing spray coatings
- Industrial and commercial use in corrosion inhibitors and anti-scaling agents
- Industrial and commercial use in processing aids in process solvent used in battery manufacture; process solvent used in polymer fabric spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture
- Industrial and commercial use as ink, toner and colorant products in toner aid
- Industrial and commercial use in automotive care products in brake parts cleaner
- Industrial and commercial use in apparel and footwear care products in shoe polish
- Industrial and commercial use in hoof polish; gun scrubber; pepper spray; other miscellaneous industrial and commercial uses
- Consumer use as a solvent in brake and parts cleaner
- Consumer use as a solvent in aerosol electronic degreaser/cleaner
- Consumer use as a solvent in liquid electronic degreaser/cleaner
- Consumer use as a solvent in aerosol spray degreaser/cleaner
- Consumer use as a solvent in liquid degreaser/cleaner
- Consumer use as a solvent in aerosol gun scrubber
- Consumer use as a solvent in liquid gun scrubber
- Consumer use as a solvent in mold release
- Consumer use as a solvent in aerosol tire cleaner
- Consumer use as a solvent in liquid tire cleaner
- Consumer use as a lubricant and grease in tap and die cleaner
- Consumer use as a lubricant and grease in penetrating lubricant
- Consumer use as an adhesive and sealant in solvent-based adhesives and sealants
- Consumer use as an adhesive and sealant in mirror edge sealant
- Consumer use as an adhesive and sealant in tire repair cement/sealer
- Consumer use as a cleaning and furniture care product in carpet cleaner
- Consumer use as a cleaning and furniture care product in aerosol spot remover
- Consumer use as a cleaning and furniture case product in liquid spot remover
- Consumer use in arts, crafts, and hobby materials in fixative and finishing spray coatings
- Consumer use in apparel and footwear products in shoe polish
- Consumer use in fabric spray
- Consumer use in film cleaner
- Consumer use in hoof polish
- Consumer use in toner aid
- Disposal

EPA will initiate risk management for TCE by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that TCE no longer presents an unreasonable risk. 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 options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities are not unreasonable risk drivers.

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 TCE in November 2020. 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 is reconsidering two key aspects of the risk determinations for TCE published in November 2020. First, EPA proposes that the appropriate approach to these determinations is to make an unreasonable risk determination for TCE 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 proposes that the risk determination shall 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]

Separately, EPA is conducting a screening approach to assess potential risks from the air and water pathways for several of the first 10 chemicals, including this chemical. For TCE the exposure pathways that were or could be regulated under other EPA administered statutes were excluded from the final risk evaluation for this chemical. This resulted in the ambient air and ambient water pathways for TCE not being assessed. The goal of the recently-developed screening approach is to remedy this exclusion and to identify if there are risks that were unaccounted for in the TCE risk evaluation. While this analysis is underway, EPA is not incorporating the screening-level approach into this draft revised unreasonable risk determination. If the results suggest there is additional risk, EPA will determine if the risk management approaches being contemplated for TCE will protect against these risks, or if the risk evaluation will need to be formally supplemented or revised.

Further discussion of the rationale for the whole chemical approach is found in the Federal Register notice in the docket accompanying this revised TCE unreasonable risk determination and further discussion of the proposed 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 TCE 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 TCE, as further explained below, EPA proposes that a whole chemical is appropriate for TCE in order to protect health and the environment. The whole chemical approach is appropriate for TCE, because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (including import), processing, commercial and consumer use, and disposal) for health, and the health effects associated with TCE exposures are irreversible. 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. As explained in the Federal Register Notice, the revisions to the unreasonable risk determination would be based on the existing risk characterization section of the risk evaluation (section 4 of this risk evaluation) and do not involve additional technical or

[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).

scientific analysis. The discussion of the issues in this draft revision to the risk determination supersedes any conflicting statements in the prior TCE risk evaluation (November 2020) and the response to comments document (*Summary of External Peer Review and Public Comments and Disposition for Trichloroethylene (TCE), November 2020*). 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 TCE that workers always or properly use PPE, although the Agency does not question the information received regarding the occupational safety practices often followed by industry respondents. 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 non-risk 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 draft revised unreasonable risk determination for TCE, under the conditions of use in the scope of the Risk Evaluation for TCE. This draft 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.

[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.

5.2 Unreasonable Risk to Human Health

5.2.1 Human Health

EPA's TCE risk evaluation identified non-cancer adverse effects from acute and chronic inhalation and dermal exposures to TCE, and cancer from chronic inhalation and dermal exposures to TCE. The endpoint identified by EPA was immunosupression effects for acute inhalation and dermal exposures, and autoimmunity effects for chronic inhalation and dermal exposures, discussed in further detail below in Section 5.2.4 of this Risk Evaluation. The health risk estimates for all conditions of use are in Tables 4-59 and 4-60 of Section 4.5 of this Risk Evaluation.

In developing the exposure assessment for TCE, EPA analyzed reasonably available information to ascertain whether some human receptor groups may have greater exposure or susceptibility than the general population to the hazard posed by TCE. Exposures of TCE would be expected to be higher among workers who use TCE as part of typical processes and groups who have greater age-and route-specific intake rates compared to the general population. For the TCE risk evaluation, EPA identified the following groups as Potentially Exposed or Susceptible Subpopulations (PESS): workers and occupational non-users (ONUs), [3] including men and women of reproductive age, adolescents, and biologically susceptible subpopulations; and consumer users (age 11 and older) and bystanders (of any age group, including infants, toddlers, children, and elderly), including biologically susceptible subpopulations (Section 2.3.3 of this Risk Evaluation).

EPA evaluated exposures to workers, ONUs, consumer users, and bystanders to consumer use 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 TCE; therefore, non-cancer effects and cancer from dermal exposures to TCE are not expected and were not evaluated. Additionally, EPA did not evaluate chronic exposures for consumer users and bystanders because EPA considered the frequency of consumer product use to be too low to create chronic risk concerns. The description of the data used for human health exposure is in Section 2.3 of this Risk Evaluation. Uncertainties in the analysis are discussed in Section 4.3 of this Risk Evaluation and are considered in the unreasonable risk determination, including the fact that the dermal model used does not address variability in exposure duration and frequency. For the human health risk estimation, key assumptions and uncertainties are related to data on exposures, exposure model input parameters, and the estimates for ONU inhalation exposures for COUs in which monitoring data or probabilistic modeling data were not reasonably available.

EPA currently is examining whether there are risks not accounted for in the risk evaluation by analyzing exposures to fenceline communities. As described earlier, in Section 5.1.1, while this

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

234 analysis is underway, EPA is not incorporating the screening-level approach into this draft
235 revised unreasonable risk determination.

236 ### 5.2.2 Non-Cancer Risk Estimates

237 The risk estimates for non-cancer effects (expressed as margins of exposure or MOEs) refer to
238 adverse health effects associated with health endpoints other than cancer, including to the body's
239 organ systems, such as reproductive/developmental effects, cardiac and lung effects, and kidney
240 and liver effects. The MOE is the point of departure (POD) (an approximation of the no-
241 observed adverse effect level (NOAEL) or benchmark dose level (BMDL)) and the
242 corresponding human equivalent concentration (HEC) for a specific health endpoint divided by
243 the exposure concentration for the specific scenario of concern. Section 3.2.5 of this Risk
244 Evaluation presents the PODs for acute and chronic non-cancer effects for TCE and Section 4.2
245 of this Risk Evaluation presents the HEC and MOEs for acute and chronic non-cancer effects.
246
247 The MOEs are compared to a benchmark MOE. The benchmark MOE accounts for the total
248 uncertainty in a POD, including, as appropriate: (1) the variation in sensitivity among the
249 members of the human population (i.e., intrahuman/intraspecies variability); (2) the uncertainty
250 in extrapolating animal data to humans (i.e., interspecies variability); (3) the uncertainty in
251 extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure
252 (i.e., extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating
253 from a lowest observed adverse effect level (LOAEL) rather than from a NOAEL. A lower
254 benchmark MOE (e.g., 30) indicates greater certainty in the data (because fewer of the default
255 uncertainty factors (UFs) relevant to a given POD as described above were applied). A higher
256 benchmark MOE (e.g., 1000) would indicate more uncertainty for specific endpoints and
257 scenarios. However, these are often not the only uncertainties in a risk evaluation. The
258 benchmark MOE for acute non-cancer risks for TCE is 10. The benchmark MOE for chronic
259 non-cancer risks for TCE is 30. Additional information regarding the non-cancer hazard
260 identification is in Section 3.2.3.1 and the benchmark MOE is in Section 4.2.1 of this Risk
261 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 work places. 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 4.2 of this Risk Evaluation.

5.2.4 Determining Unreasonable Risk of Injury to Health

Calculated risk estimates (MOEs or cancer risk estimates) can provide a risk profile of TCE 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. These calculated risk estimates alone are not bright-line indicators of unreasonable risk. 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 TCE risk characterization, EPA identified several acute and chronic endpoints for non-cancer effects of TCE (e.g., developmental toxicity, reproductive toxicity, liver toxicity, kidney toxicity, neurotoxicity, and immunotoxicity). In Section 3.2.5.4.1, EPA identified the best overall non-cancer endpoints to be immunosuppression effects for acute inhalation and dermal exposures, and autoimmunity effects for chronic inhalation and dermal exposures. EPA determined that these were the best overall endpoints for Risk Evaluation under TSCA, based on the best available science, weight of the scientific evidence, and confidence in the POD, and were used as the basis of risk conclusions in Section 4.5.2 and risk determinations in Section 5.

Consistent with EPA guidance, in this Risk Evaluation EPA concluded that TCE is carcinogenic to workers and ONUs by all routes of exposure. This is most strongly supported by the data on kidney cancer. The cancer hazard analysis is described in Section 3.2.4.2. EPA considered cancer risk estimates from chronic inhalation or dermal 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 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, whether or not those assumptions are protective is also a consideration. Important assumptions and key sources of uncertainty in the risk characterization are described in more detail in Section 4.3.2 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 in environmental media 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 4.4 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 TCE 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," or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

The draft revised unreasonable risk determination for TCE is based on the peer reviewed risk characterization (Section 4 of this 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. Section 4.5.2 and Table 4-59 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, sediment-dwelling, and terrestrial organisms. Due to the volatile properties of TCE, EPA also considered when it was more likely for acute or chronic exposure durations to occur. Section 4.1 provides more detail regarding the environmental risk characterization for TCE.

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.

EPA used a screening-level approach to integrate relevant pathways of environmental exposure with available environmental hazard data to evaluate unreasonable risk to relevant environmental receptors. EPA assessed environmental exposures derived from predicted and measured concentrations of TCE in surface water in the U.S. Specifically, the aquatic exposures associated with the industrial and commercial conditions of use were predicted through modeling, and the aquatic exposure assessment also includes an analysis of collected measured surface water concentrations from monitoring data. EPA considered the biological relevance of the species to determine the concentrations of concern for the location of surface water concentration data to produce RQs, as well as frequency and duration of the exposure. EPA determined that the evaluation does not support an unreasonable risk determination to aquatic organisms.

For sediment-dwelling invertebrates, the toxicity of TCE is similar to the toxicity to aquatic invertebrates. TCE is expected to remain in aqueous phases and not adsorb to sediment due to its water solubility and low partitioning to organic matter. TCE has relatively low partitioning to organic matter and biodegrades slowly, so TCE concentrations in sediment pore water are expected to be similar to the concentrations in the overlying water or lower in the deeper part of sediment where anaerobic condition prevails. Thus, the TCE detected in sediments is likely from the pore water. Therefore, for sediment-dwelling organisms, the risk estimates, based on the highest ambient surface water concentration, do not support an unreasonable risk determination to sediment-dwelling organisms from acute or chronic exposures. For terrestrial organisms, TCE exposure is expected to be low since physical-chemical properties do not support an exposure pathway through water and soil pathways to these organisms. Therefore, for terrestrial organisms, the risk estimates, based on the EPA 2003 Guidance for Ecological Soil Screening Levels, do not support an unreasonable risk determination from acute or chronic exposures.

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. Additionally, EPA considers the central tendency and high-end scenarios when determining the unreasonable risk. High-end risk estimates (*e.g.*, 90th percentile) are generally intended to cover organisms or populations with greater exposure (those inhabiting ecosystems near industries) and central tendency risk estimates are generally estimates of average or typical exposure.

EPA considered uncertainties in its determination of unreasonable risk for TCE. Key assumptions and uncertainties in the environmental risk estimation are related to uncertainties regarding the hazard data used for aquatic species, uncertainties around surface water concentrations used to determine the environmental risk, and the variable effect of TCE volatilization as site-specific depending on stream flow and environmental conditions. Additionally, the reasonably available environmental monitoring data was limited temporally and geographically. Assumptions and key sources of uncertainty in the risk characterization are detailed in Section 4.3.1. of this Risk Evaluation.

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

5.4 Additional Information regarding the Basis for the Unreasonable Risk Determination

Table 5-1 and Table 5-2 summarize the basis for the draft revised determination of unreasonable risk of injury to health presented by TCE. In these tables, a checkmark indicates the type of effect and the exposure route to the population evaluated for each condition of use that drive the unreasonable risk determination. As explained in Section 5.2, for the draft revised unreasonable risk determination, EPA considered the effects on human health of exposure to TCE for occupational conditions of use at the central tendency and high-end, and the human health effects of exposure to TCE for consumer conditions of uses at low-, moderate-, and high-intensity uses, the exposures from the condition of use, the risk estimates, and the uncertainties in the analysis. See Section 4.5.2 of this Risk Evaluation for a summary of risk estimates.

Table 5-1. Conditions of Use Included in the Unreasonable Risk Determination for Human Health (Occupational Conditions of Use)[4]

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					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	✓		✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]		ND[d]	✓	ND[d]	✓
Manufacture	Import	Import	Worker	Inhalation	✓		✓		✓	
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation						
Processing	Processing as a reactant/intermediate	Intermediate in industrial gas manufacturing (e.g., manufacture of fluorinated gases used as refrigerants, foam blowing agents and solvents)	Worker	Inhalation	✓		✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]		ND[d]	✓	ND[d]	✓
Processing	Processing – incorporation into formulation, mixture or reaction products	Solvents (for cleaning or degreasing)	Worker	Inhalation	✓		✓		✓	
		Adhesives and sealant chemicals		Dermal	✓	✓	✓	✓	✓	✓

[4] The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that supports the draft revised unreasonable risk determination for TCE. This table is based on Table 4-59 of this Risk Evaluation.

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
		Solvents (which become part of product formulation or mixture) (e.g., lubricants and greases, paints and coatings, other uses)	ONU	Inhalation	ND[d]		ND[d]		ND[d]	
Processing	Processing – incorporation into articles	Solvents (becomes an integral component of articles)	Worker	Inhalation	✓		✓		✓	
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]		ND[d]		ND[d]	
Processing	Repackaging	Solvents (for cleaning or degreasing)	Worker	Inhalation	✓		✓		✓	
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]		ND[d]		ND[d]	
Processing	Recycling	Recycling	Worker	Inhalation	✓		✓		✓	
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]		ND[d]		ND[d]	
Industrial/ commercial use	Solvent (for cleaning or degreasing)	Batch vapor degreaser (open-top)	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Solvent (for cleaning or degreasing)	Batch vapor degreaser (closed-loop) [f]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]	✓	ND[d]	✓	ND[d]	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					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	In-line vapor degreaser – conveyorized vapor degreasing	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]	✓	ND[d]	✓	ND[d]	✓
Industrial/ commercial use	Solvent (for cleaning or degreasing)	In line vapor degreaser – Web Vapor Degreasing	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Solvent (for cleaning or degreasing)	Cold cleaner	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Solvent (for cleaning or degreasing)	Aerosol spray degreaser/cleaner	Worker	Inhalation	✓	✓	✓	✓	✓	✓
		Mold release		Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓	✓	✓	✓
Industrial/ commercial use	Lubricants and greases/ lubricants and lubricant additives	Tap and die fluid	Worker	Inhalation	✓		✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]		ND[d]	✓	ND[d]	✓
Industrial/ commercial use	Lubricants and greases/ lubricants and lubricant additives	Penetrating lubricant	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓	✓	✓	✓
Industrial/ commercial use	Adhesives and sealants	Solvent-based adhesives and sealants	Worker	Inhalation	✓	✓	✓	✓	✓	✓
		Tire repair cement/ Sealer		Dermal	✓	✓	✓	✓	✓	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
		Mirror edge sealant	ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Functional fluids (closed systems)	Heat exchange fluid	Worker	Inhalation	✓		✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]		ND[d]	✓	ND[d]	✓
Industrial/ commercial use	Paints and coatings	Diluent in solvent-based paints and coatings	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Cleaning and furniture care products	Carpet cleaner	Worker	Inhalation	✓	✓	✓	✓	✓	✓
		Wipe cleaning		Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Laundry and dishwashing products	Spot remover	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Arts, crafts, and hobby materials	Fixatives and finishing spray coatings	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Corrosion inhibitors and anti-scaling agents	Corrosion inhibitors and anti-scaling agents	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Processing aids	Process solvent used in battery manufacture	Worker	Inhalation	✓	✓	✓	✓	✓	✓
		Process solvent used in polymer		Dermal	✓	✓	✓	✓	✓	✓

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
		fabric spinning, fluoroclastomer manufacture and Alcantara manufacture								
		Extraction solvent used in caprolactam manufacture								
		Precipitant used in beta-cyclodextrin manufacture	ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Ink, toner and colorant products	Toner aid	Worker	Inhalation	✓		✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	ND[d]		ND[d]	✓	ND[d]	✓
Industrial/ commercial use	Automotive care products	Brake and parts cleaner	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓		✓	✓	✓	✓
Industrial/ commercial use	Apparel and footwear care products	Shoe polish	Worker	Inhalation	✓	✓	✓	✓	✓	✓
				Dermal	✓	✓	✓	✓	✓	✓
			ONU	Inhalation	✓	✓	✓	✓	✓	✓
Industrial/ commercial use	Other uses	Hoof polishes [c]	Worker	Inhalation	✓	✓	✓	✓	✓	✓
		Gun Scrubber		Dermal	✓	✓	✓	✓	✓	✓
		Pepper spray								

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Effects					
					Acute Non-cancer		Chronic Non-cancer		Cancer	
					High End	Central Tendency	High End	Central Tendency	High End	Central Tendency
		Other miscellaneous industrial and commercial uses	ONU	Inhalation	✓	✓	✓	✓	✓	✓
Disposal	Disposal	Industrial pre-treatment	Worker	Inhalation	✓		✓		✓	
		Industrial wastewater treatment		Dermal	✓	✓	✓	✓	✓	✓
		Publicly owned treatment works (POTW)	ONU	Inhalation	ND[d]		ND[d]		ND[d]	

[a] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent all conditions of use of TCE.
[b] These subcategories reflect more specific information regarding the conditions of use of TCE.
[c] "Hoof polish" would remain within EPA's jurisdiction unless the article in question was also intended for the diagnosis, cure, mitigation, treatment, of disease or intended to affect the structure or function of the body of animals, as described in the FFDCA. EPA identified a single product for hoof polish containing TCE, and this product is intended for only cosmetic and not medical use. Therefore, "hoof polish" was evaluated as a COU, applicable only to products restricted to cosmetic function.
[d] "ND" stands for No Data and is an indication that there was not sufficient data to be analyzed for a category.

Table 5-2. Conditions of Use Included in the Draft Revised Unreasonable Risk Determination for Human Health (Consumer Conditions of Use) [5]

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 uses	Solvents (for cleaning or degreasing)	Brake and Parts Cleaner	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystanders	Inhalation	✓	✓	✓
Consumer uses	Solvents (for cleaning or degreasing)	Aerosol electronic degreaser/cleaner	User	Inhalation	✓	✓	
				Dermal	✓	✓	
			Bystanders	Inhalation	✓	✓	
Consumer uses	Solvents (for cleaning or degreasing)	Liquid electronic degreaser/cleaner	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystanders	Inhalation	✓	✓	
Consumer uses	Solvents (for cleaning or degreasing)	Aerosol spray degreaser/cleaner	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	✓
			Bystanders	Inhalation	✓	✓	✓
Consumer uses	Solvents (for cleaning or degreasing)	Liquid degreaser/cleaner	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	✓
			Bystanders	Inhalation	✓	✓	✓

[5] The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that support the draft revised unreasonable risk determination for TCE. This table is based on Table 4-60 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 uses	Solvents (for cleaning or degreasing)	Aerosol gun scrubber	User	Inhalation			
				Dermal	✓	✓	✓
			Bystanders	Inhalation			
Consumer uses	Solvents (for cleaning or degreasing)	Liquid gun scrubber	User	Inhalation			
				Dermal	✓	✓	✓
			Bystanders	Inhalation			
Consumer uses	Solvents (for cleaning or degreasing)	Mold Release	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	
Consumer uses	Solvents (for cleaning or degreasing)	Aerosol Tire Cleaner	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	✓
			Bystander	Inhalation	✓	✓	✓
Consumer use	Solvents (for cleaning or degreasing)	Liquid Tire Cleaner	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	✓
			Bystander	Inhalation	✓	✓	✓
Consumer use	Lubricants and greases	Tap and Die Fluid	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	
Consumer use	Lubricants and greases	Penetrating lubricant	User	Inhalation	✓	✓	
				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	Adhesives and sealants	Solvent-based adhesives and sealants	User	Inhalation	✓	✓	
				Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	
Consumer use	Adhesives and sealants	Mirror edge sealant	User	Inhalation	✓	✓	
				Dermal	✓	✓	
			Bystander	Inhalation	✓		
Consumer use	Adhesives and sealants	Tire repair cement/ sealer	User	Inhalation	✓	✓	
				Dermal	✓	✓	✓
			Bystander	Inhalation	✓	✓	
Consumer use	Cleaning and furniture care products	Carpet cleaner	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	✓
Consumer use	Cleaning and furniture care products	Aerosol Spot Remover	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	
Consumer use	Cleaning and furniture care products	Liquid Spot Remover	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	✓
Consumer use	Arts, crafts, and hobby materials	Fixatives and finishing spray and coatings`	User	Inhalation	✓	✓	✓
				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	Apparel and footwear care products	Shoe polish	User	Inhalation	✓	✓	
				Dermal	✓		
			Bystander	Inhalation	✓		
Consumer use	Other consumer uses	Fabric spray	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	
Consumer use	Other consumer uses	Film cleaner	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	✓
Consumer use	Other consumer uses	Hoof polish[c]	User	Inhalation	✓		
				Dermal	✓	✓	
			Bystander	Inhalation			
Consumer use	Other consumer uses	Pepper spray	User	Inhalation			
				Dermal			
			Bystander	Inhalation			
Consumer use	Other consumer uses	Toner aid	User	Inhalation	✓	✓	✓
				Dermal	✓	✓	
			Bystander	Inhalation	✓	✓	

[a] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent all conditions of use of TCE.
[b] These subcategories reflect more specific information regarding the conditions of use of TCE.
[c] "Hoof polish" would remain within EPA's jurisdiction unless the article in question was also intended for the diagnosis, cure, mitigation, treatment, of disease or intended to affect the structure or function of the body of animals, as described in the FFDCA. EPA identified a single product for hoof polish containing TCE, and this product is intended for only cosmetic and not medical use. Therefore, "hoof polish" was evaluated as a COU, applicable only to products restricted to cosmetic function.

5.5 References

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