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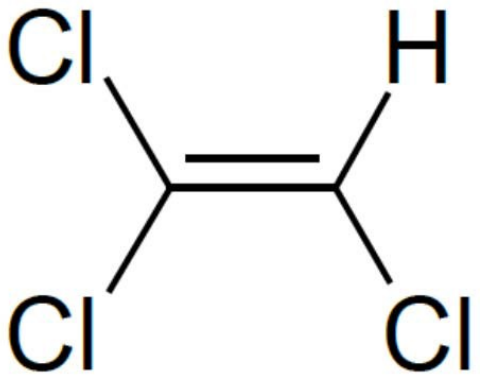
Office of Chemical Safety and
Pollution Prevention

# Scope of the Risk Evaluation for Trichloroethylene

## CASRN: 79-01-6




*June 2017*

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# ACKNOWLEDGEMENTS

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Supporting information can be found in public docket (Docket: EPA-HQ-OPPT-2016-0737).

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# ABBREVIATIONS

| | |
|---|---|
| $\varepsilon_0$ | Vacuum Permittivity |
| AQS | Air Quality System |
| ATSDR | Agency for Toxic Substances and Disease Registries |
| BAF | Bioaccumulation Factor |
| BCF | Bioconcentration Factor |
| CAA | Clean Air Act |
| CASRN | Chemical Abstracts Service Registry Number |
| CBI | Confidential Business Information |
| CCR | California Code of Regulations |
| CDR | Chemical Data Reporting |
| CEHD | Chemical Exposure Health Data |
| CERCLA | Comprehensive Environmental Response, Compensation, and Liability Act |
| CFC | Chlorofluorocarbon |
| CFR | Code of Federal Regulations |
| CNS | Central Nervous System |
| COC | Concentration of Concern |
| CPCat | Chemical and Product Categories |
| CWA | Clean Water Act |
| CYP2E1 | Cytochrome P450 2E1 |
| DMR | Discharge Monitoring Report |
| ECHA | European Chemicals Agency |
| EDC | Ethylene Dichloride |
| EG | Effluent Guidelines |
| EPA | Environmental Protection Agency |
| EPCRA | Emergency Planning and Community Right-to-Know Act |
| ESD | Emission Scenario Document |
| FDA | Food and Drug Administration |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FIFRA | Federal Insecticide, Fungicide, and Rodenticide Act |
| FR | Federal Register |
| GACT | Generally Available Control Technology |
| GST | Glutathione-S-transferase |
| HAP | Hazardous Air Pollutant |
| HCFC | Hydrochlorofluorocarbon |
| HCl | Hydrochloric Acid |
| HEC | Human Equivalent Concentration |
| HFC | Hydrofluorocarbon |
| HHE | Health Hazard Evaluation |
| HPV | High Production Volume |
| ICIS-NPDES | Integrated Compliance Information System-National Pollutant Discharge Elimination System |
| IMIS | Integrated Management Information System |
| IRIS | Integrated Risk Information System |
| $K_{oc}$ | Soil Organic Carbon-Water Partitioning Coefficient |
| $K_{ow}$ | Octanol/Water Partition Coefficient |

| | |
|---|---|
| MATC | Maximum Acceptable Toxicant Concentration |
| MCL | Maximum Contaminant Level |
| MCLG | Maximum Contaminant Level Goal |
| MSDS | Material Safety Data Sheet |
| NAICS | North American Industry Classification System |
| NATA | National Scale Air-Toxics Assessment |
| NCEA | National Center for Environmental Assessment |
| NCP | National Contingency Plan |
| NEI | National Emissions Inventory |
| NESHAP | National Emission Standards for Hazardous Air Pollutants |
| NHANES | National Health and Nutrition Examination Survey - CDC |
| NICNAS | National Industrial Chemicals Notification and Assessment Scheme |
| NIH | National Institute of Health |
| NIOSH | National Institute of Occupational Safety and Health |
| NPDWR | National Primary Drinking Water Regulation |
| NRC | National Research Council |
| NTP | National Toxicology Program |
| OCSPP | Office of Chemical Safety and Pollution Prevention |
| OECD | Organisation for Economic Co-operation and Development |
| OPPT | Office of Pollution Prevention and Toxics |
| OSHA | Occupational Safety and Health Administration |
| OST | Office of Science and Technology |
| OW | Office of Water |
| PCE | Perchloroethylene |
| PEL | Permissible Exposure Limit |
| POD | Point of Departure |
| POTW | Publicly Owned Treatment Works |
| QC | Quality Control |
| QSAR | Quantitative Structure Activity Relationship |
| RCRA | Resource Conservation and Recovery Act |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| SDS | Safety Data Sheet |
| SDWA | Safe Drinking Water Act |
| SIDS | Screening Information Dataset |
| SNUN | Significant New Use Notice |
| SNUR | Significant New Use Rule |
| STORET | STOrage and RETrieval |
| TCCR | Transparent, Clear, Consistent, and Reasonable |
| TCE | Trichloroethylene |
| TRI | Toxics Release Inventory |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average |
| U.S. | United States |
| UV | Ultraviolet |
| USGS | United States Geological Survey |
| VOC | Volatile Organic Compound |

# EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed 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 as relevant to the risk evaluation by the Administrator under the conditions of use." In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). Trichloroethylene was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. This document fulfills the TSCA § 6(b)(4)(D) requirement for TCE.

This document presents the scope of the risk evaluation to be conducted for TCE. If a hazard, exposure, condition of use or potentially exposed or susceptible subpopulation has not been discussed, EPA, at this point in time, is not intending to include it in the scope of the risk evaluation. As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, with respect to conditions of use in conducting a risk evaluation under TSCA, EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for TCE. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

TCE is a volatile organic liquid that is classified as a human carcinogen. TCE is subject to numerous federal and state regulations and reporting requirements. In 2014, EPA assessed inhalation risks from TCE in vapor and aerosol degreasing, spot cleaning at dry cleaning facilities and arts and craft uses and also completed four supplemental analyses. Based on these analyses, EPA published two proposed rules to address the unreasonable risks presented by TCE use in vapor degreasing and in commercial and consumer aerosol degreasing and for spot cleaning at dry cleaning facilities. TCE is designated as a Hazardous Air Pollutant (HAP) under the Clean Air Act (CAA), a regulated drinking water contaminant under the Safe Drinking Water Act (SDWA), and a toxic pollutant under the Clean Water Act (CWA).

TCE is widely used in industrial and commercial processes. Scenarios previously examined in the 2014 publication will not be re-evaluated.

Information on domestic manufacture, processing, use, and disposal of TCE is available to EPA through its Chemical Reporting (CDR) Rule, issued under the TSCA, as well as through the Toxics Release Inventory (TRI). In 2015, approximately 172 million pounds of TCE was manufactured or imported in the US. An estimated 83.6% of TCE's annual production volume is used as an intermediate in the manufacture of hydrofluorocarbon (HFC-134a – an alternative to the refrigerant CFC-12). Another 14.7% of TCE production volume is used as a degreasing solvent, leaving approximately 1.7% for other uses, including consumer uses. Based on 2015 TRI data, most reported environmental releases of TCE are to air, with much lower volumes disposed to land or released to water.

The initial conceptual models presented in Section 2 identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed populations, including potentially exposed or susceptible subpopulations; and hazards EPA expects to evaluate based on the inherent hazards of TCE. It is expected that inhalation will be the primary route of exposure to all populations.

This document presents the occupational scenarios in which workers and occupational non-users may be exposed to TCE during a variety of conditions of use, such as a degreasing solvent or lubricant. It also presents the consumer model which indicates exposures occurring from TCE containing products in either indoor or outdoor environments. For TCE, EPA believes that workers, consumers, and bystanders as well as certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) or have greater susceptibility than the general population, and should therefore be considered relevant potentially exposed or susceptible subpopulations for purposes of this risk evaluation.

Exposures to the general population may occur from industrial releases. The manufacturing, processing, and use of TCE can result in releases to air, water, sediment and soil. EPA expects to consider exposures to the general population and the environment via inhalation of air emitted from manufacturing, processing, use facilities and from water, sediments, soils that may receive releases or wastes from such facilities.

Trichloroethylene has been the subject of numerous human health reviews including the EPA's Integrated Risk Information System (IRIS) Toxicological Review, the Agency for Toxic Substances and Disease Registry's (ATSDR's) Toxicological Profile and the 2014 risk assessment and supplemental analyses. Along with other reasonably available information, EPA will use the existing TSCA risk assessments to inform its development of the TCE risk evaluation. A number of targets of toxicity from exposures to TCE have been identified in animal and human studies for both oral and inhalation exposures. For non-cancer effects, TCE exposure has been associated with acute toxicity, liver toxicity, kidney toxicity, reproductive/developmental toxicity, neurotoxicity, immunotoxicity, and sensitization. TCE is also carcinogenic to humans by all routes of exposures, as documented in the TCE IRIS assessment, through both genotoxic and non-genotoxic mechanisms. These hazards will be evaluated based on the specific exposure scenarios identified.

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation for TCE. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of TCE.

# 1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for trichloroethylene. If a condition of use has not been discussed, EPA, at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. Moreover, during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation. Any condition of use that will not be evaluated will be clearly described in the problem formulation document.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, was signed into law. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed 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 as relevant to the risk evaluation by the Administrator under the conditions of use."

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the ten chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the ten chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for trichloroethylene.

As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, in conducting a risk evaluation under TSCA EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. Based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities may not generally be considered to be conditions of use. In exercising its discretion, for example, EPA would not generally consider that a single

unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. In addition, EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Furthermore, in exercising its discretion under section 6(b)(4)(D) to identify the conditions of use that EPA expects to consider in a risk evaluation, EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. Consequently, EPA may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern meriting an unreasonable risk consideration. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping, in order to determine which risk evaluation the potential risks from the chemical substance should be addressed in. As an additional example, EPA may, on a case-by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

The situations identified above are examples of the kinds of discretion that EPA will exercise in determining what activities constitute conditions of use, and what conditions of use are to be included in the scope of any given risk evaluation. See the preamble to *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)* for further discussion of these issues.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. The first 10 chemical substances were not subject to the prioritization process that will be used in the future in

accordance with amendments to TSCA. EPA expects to collect and screen much of the relevant information about chemical substances that will be subject to the risk evaluation process during and before prioritization. The volume of data and information about the first 10 chemicals that is available to EPA is extremely large and EPA is still in the process of reviewing it, since the Agency had limited ability to process the information gathered before issuing the scope documents for the first 10 chemicals. As a result of the statutory timeframes, EPA had limited time to process all of the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. For these reasons, EPA's initial screenings and designations with regard to applicability of data (e.g., on-topic vs. off-topic information and data) may change as EPA progresses through the risk evaluation process. Likewise, the Conceptual Models and Analysis Plans provided in the first 10 chemical scopes are designated as "Initial" to indicate that EPA expects to further refine them during problem formulation.

The aforementioned time constraints and uncertainty associated with developing the risk evaluation process rule has resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents. For these reasons, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

## 1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to TCE. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. EPA will evaluate and consider the impact of these existing laws and regulations in the problem formulation step to determine what, if any, further analysis might be necessary as part of the risk evaluation.

***Federal Laws and Regulations***

TCE is subject to federal statutes or regulations, other than TSCA, that are implemented by other offices within EPA and/or other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A.1.

***State Laws and Regulations***

TCE is subject to state statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A.2.

***Laws and Regulations in Other Countries and International Treaties or Agreements***

TCE is subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these laws, regulations, treaties and/or agreements is provided in Appendix A.3.

## 1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations—information useful to EPA in preparing this scope for risk evaluation. Table 1-1 shows the assessments that have been conducted. In addition to using this information, EPA intends to conduct a full review of the data collected [see *Trichloroethylene (CASRN 79-01-6) Bibliography: Supplemental File for the TSCA Scope Document,* EPA-HQ-OPPT-2016-0737) using the literature search strategy (see *Strategy for Conducting Literature Searches for Trichloroethylene: Supplemental File for the TSCA Scope Document,* EPA-HQ-OPPT-2016-0737] to ensure that EPA is considering information that has been made available since these assessments were conducted.

In its final TCE Risk Assessment U.S. EPA (2014b), risks from use of TCE in commercial and consumer solvent degreasing (aerosol and vapor), consumer use as a spray-applied protective coating for arts and crafts and commercial use as a spot remover at dry-cleaning facilities were assessed. The final TCE Risk Assessment was used to support two proposed rules under TSCA section 6 (81 FR 91592; December 12, 2016; 82 FR 7432; January 19, 2017) to address risks from use of TCE. It was also considered in development of a Significant New Use Rule (SNUR) for TCE (81 FR 20535: April 8, 2016). Along with other reasonably available information, EPA will use the existing TSCA risk assessments to inform its development of the TCE risk evaluation.

**Table 1-1. Assessment History of TCE**

| Authoring Organization | Assessment |
|---|---|
| **EPA Assessments** | |
| Office of Chemical Safety and Pollution Prevention (OCSPP)/ Office of Pollution Prevention and Toxics (OPPT) | TSCA Work Plan Chemical Risk Assessment Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Use (2014b) |
| OCSPP/OPPT | Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Aerosol Degreasing (2016d) |
| OCSPP/OPPT | Supplemental Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Consumer Aerosol Degreasing (2016c) |
| OCSPP/OPPT | Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Spot Cleaning (2016e) |
| OCSPP/OPPT | Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Vapor Degreasing [RIN 2070-AK11] (2016f) |

| Authoring Organization | Assessment |
|---|---|
| Integrated Risk Information System (IRIS) | Toxicological Review of Trichloroethylene (2011) |
| National Center for Environmental Assessment (NCEA) | Sources, Emission and Exposure for Trichloroethylene (TCE) and Related Chemicals (2001) |
| Office of Water (OW)/ Office of Science and Technology (OST) | Update of Human Health Ambient Water Quality Criteria: Trichloroethylene (TCE) 79-01-6 (2015) |
| **Other U.S.-Based Organizations** | |
| Agency for Toxic Substances and Disease Registries (ATSDR) | Draft Toxicological Profile for Trichloroethylene (2014) |
| National Research Council (NRC) | Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues (2006) |
| Office of Environmental Health Hazard Assessment (OEHHA), Pesticide and Environmental Toxicology Section | Public Heath Goal for Trichloroethylene in Drinking Water (Cal/EPA, 2009) |
| **International** | |
| Institute for Health and Consumer Protection, European Chemicals Bureau | European Union Risk Assessment Report, Trichloroethylene (2004) |
| Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) | Trichloroethylene: Priority Existing Chemical Assessment Report No. 8 (NICNAS, 2000) |

## 1.3 Data and Information Collection

EPA/OPPT generally applies a process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific data used in risk assessments developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk evaluation.

***Data Collection: Data Search***

EPA/OPPT conducted chemical-specific searches for data and information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations; ecological hazard, human health hazard, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies

from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the National Toxicology Program's (NTP) *Report on Carcinogens,* to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for Trichloroethylene: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0737)provides details about the data sources and search terms that were used in the initial search.

***Data Collection: Data Screening***

Following the data search, references were screened and categorized using selection criteria outlined in the *Strategy for Conducting Literature Searches for Trichloroethylene: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0737). Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical and chemical properties; environmental fate and transport; chemical use/conditions of use information; human and environmental exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard), but within each data set, there are two broad categories or data tags: (1) o*n-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. O*ff-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. The *Strategy for Conducting Literature Searches for Trichloroethylene: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0737) discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic*.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information – for example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, cancer, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in the *Strategy for Conducting Literature Searches for Trichloroethylene: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0737). and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization can be found in the *Trichloroethylene (79-01-6) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0737). This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence,

additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

# 2 SCOPE OF THE EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA is including an initial life cycle diagram and initial conceptual model that describe the actual or potential relationships between TCE and human and ecological receptors. An initial analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks under the conditions of use of TCE. As noted previously, EPA intends to refine this analysis plan during the problem formulation phase of risk evaluation.

## 2.1 Physical and Chemical Properties

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes and hazards that EPA intends to consider. For scope development, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1.

**Table 2-1. Physical and Chemical Properties of TCE**

| Property | Value[a] | References |
|---|---|---|
| Molecular Formula | $C_2HCl_3$ | |
| Molecular Weight | 131.39 g/mole | |
| Physical Form | Colorless, liquid, sweet, pleasant odor, resembles chloroform | O'Neil et al. (2006) |
| Melting Point | -84.7°C | Lide (2007) |
| Boiling Point | 87.2°C | Lide (2007) |
| Density | 1.46 g/cm$^3$ at 20°C | EC (2000) |
| Vapor Pressure | 73.46 mmHg at 25°C | Daubert and Danner (1989) |
| Vapor Density | 4.53 | O'Neil et al. (2006) |
| Water Solubility | 1,280 mg/L at 25°C | Horvath et al. (1999) |
| Octanol/Water Partition Coefficient (Log $K_{ow}$) | 2.42 (Estimated) | U.S. EPA (2012) |
| Henry's Law Constant | 9.85E-03 atm·m$^3$/mole | Leighton and Calo (1981) |
| Flash Point | 90°C (closed cup) | EC (2000) |
| Auto Flammability | 410°C (Estimated) | U.S. EPA (2012) |
| Viscosity | 0.53 mPa·s at 25°C | Weast and Selby (1966) |
| Refractive Index | 1.4775 at 20°C | O'Neil et al. (2001) |
| Dielectric Constant | 3.4 $\varepsilon_0$ at 16°C | Weast and Selby (1966) |

[a] Measured unless otherwise noted

## 2.2 Conditions of Use

TSCA § 3(4) defines the conditions of use as ''the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.''

### 2.2.1 Data and Information Sources

As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of available data sources (e.g., *Use and Market Profile for Trichloroethylene*, EPA-HQ-OPPT-2016-0737). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use (see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Trichloroethylene*, EPA-HQ-OPPT-2016-0737) prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings has been incorporated into this scope document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents.

### 2.2.2 Identification of Conditions of Use

As part of the scope, an initial life cycle diagram is provided (Figure 2-1) depicting the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer; when distinguishable), distribution and disposal. The information is grouped according to Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses), in combination with other data sources (e.g., published literature and consultation with stakeholders), to provide an overview of conditions of use. EPA notes that some subcategories of use may be grouped under multiple CDR categories.

For the purposes of this scope, CDR definitions were used. CDR use categories include the following: "industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use (U.S. EPA, 2016b).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the life cycle diagram includes the production volume associated with each stage of the life cycle, as reported in the 2016 CDR reporting (U.S. EPA, 2016b) when the volume was not claimed confidential business information (CBI). The 2016 CDR reporting data for TCE are provided

in Table 2-2 for TCE from EPA's CDR database (U.S. EPA, 2016b). For the 2016 CDR reporting period, non-confidential data indicate a total of 13 manufacturers and importers of TCE in the United States.

**Table 2-2. Production Volume of TCE in CDR Reporting Period (2012 to 2015) [a]**

| Reporting Year | 2012 | 2013 | 2014 | 2015 |
|---|---|---|---|---|
| Total Aggregate Production Volume (lbs) | 220,536,812 | 198,987,532 | 191,996,578 | 171,929,400 |

[a] The CDR data for the 2016 reporting period is available via ChemView (https://java.epa.gov/chemview). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the scope document is more specific than currently in ChemView.

Figure 2-1 depicts the initial life cycle diagram for TCE from manufacture to the point of disposal. This diagram does not distinguish between industrial, commercial and consumer uses; EPA will further investigate and define the differences between these uses during problem formulation. Most information on the production volume associated with the various uses is shown as "Volume CBI" in the life cycle diagram, based on CBI claims in the 2016 CDR (U.S. EPA, 2016b). As reported in the Use Document [EPA-HQ-OPPT-2016-0737-0003 (U.S. EPA, 2017a)], as well as in The 2014 TCE risk assessment U.S. EPA (2014b), an estimated 83.6% of TCE's annual production volume is used as an intermediate in the manufacture of the hydrofluorocarbon, HFC-134a, an alternative to the refrigerant chlorofluorocarbon, CFC-12. Another 14.7% of TCE production volume is used as a degreasing solvent, leaving approximately 1.7% for other uses. Also reflected in the life cycle diagram is the fact that TCE, as a widely used solvent, has numerous applications across industrial, commercial and consumer settings.

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR and included in the life cycle diagram (Figure 2-1) are summarized below (U.S. EPA, 2016b). The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacture, processing, use and disposal category. The descriptions provided below are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions from the 2016 CDR and can be found in EPA's Instructions for Reporting 2016 TSCA Chemical Data Reporting (U.S. EPA, 2016a).

The following describes several categories where TCE has been used; Appendix B provides additional process-related information on the remaining categories and life cycle stages.

The **"Solvents for Cleaning and Degreasing"** category encompasses chemical substances used to dissolve oils, greases and similar materials from a variety of substrates including metal surfaces, glassware and textiles. This category includes the use of TCE in vapor degreasing, cold cleaning and in industrial and commercial aerosol degreasing products.

The **"Lubricants and Greases"** category encompasses chemical substances contained in products used to reduce friction, heat generation and wear between solid surfaces. This category includes the use of TCE in penetrating lubricants, and tap and die fluids for industrial, commercial and consumer uses.

The **“Adhesives and Sealants”** category encompasses chemical substances contained in adhesive and sealant products used to fasten other materials together. This category includes the use of TCE in mirror-edge sealants, lace wig and hair extension glues and other adhesive products.

The “**Functional Fluids (closed system)”** category encompasses liquid or gaseous chemical substances used for one or more operational properties in a closed system. Examples are heat transfer agents (e.g., coolants and refrigerants).

The **“Paints and Coatings”** category encompasses chemical substances contained in paints, lacquers, varnishes and other coating products that are applied as a thin continuous layer to a surface. Coating may provide protection to surfaces from a variety of effects such as corrosion and ultraviolet (UV) degradation; may be purely decorative; or may provide other functions. EPA anticipates that the primary subcategory to be the use of TCE in solvent-based coatings. This category covers industrial, commercial and consumer uses of paints and coatings.

The **“Cleaning and Furniture Care Products”** category encompasses chemical substances contained in products that are used to remove dirt, grease, stains and foreign matter from furniture and furnishings, or to cleanse, sanitize, bleach, scour, polish, protect or improve the appearance of surfaces. This category includes the use of TCE for spot cleaning and carpet cleaning.

The **“Laundry and Dishwashing Products”** category encompasses chemical substances contained in laundry and dishwashing products and aids formulated as a liquid, granular, powder, gel, cakes, and flakes that are intended for consumer or commercial use.

The **“Arts, Crafts and Hobby Materials”** category encompasses chemical substances contained in arts, crafts, and hobby materials that are intended for consumer or commercial use.

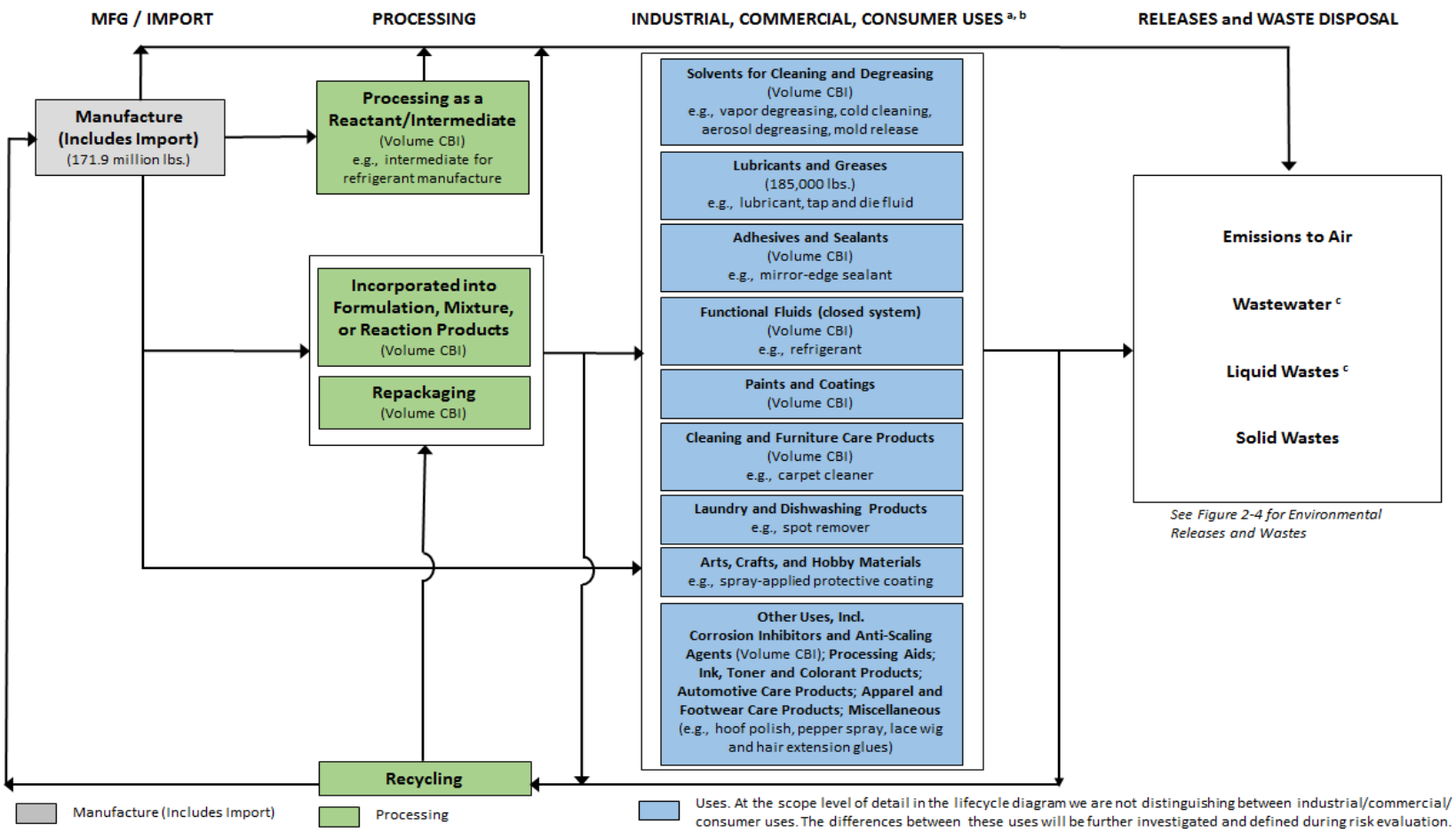


**Figure 2-1. Initial TCE Life Cycle Diagram**

The initial life cycle diagram depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer), distribution and disposal. The production volumes shown are for reporting year 2015 from the 2016 CDR reporting period. Activities related to distribution (e.g., loading and unloading) will be considered throughout the TCE life cycle, rather than using a single distribution scenario.

[a] See Table 2-3 for additional uses not mentioned specifically in this diagram.

[b] Includes uses assessed in the U.S. EPA (2014b) risk assessment.

[c] Wastewater: combination of water and organic liquid, where the organic content is <50%. Liquid wastes: combination of water and organic liquid, where the organic content is >50%.

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of conditions of use for TCE that EPA expects to consider in the risk evaluation. Using the 2016 CDR, EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories (U.S. EPA, 2016b). EPA identified the subcategories by supplementing CDR data with other published literature and information obtained through stakeholder consultations. For risk evaluations, EPA intends to consider each life cycle stage (and corresponding use categories and subcategories) and assess relevant potential sources of release and human exposure associated with that life cycle stage.

**Table 2-3. Categories and Subcategories of Conditions of Use for TCE**

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| Manufacture | Domestic manufacture | Domestic manufacture | U.S. EPA (2016b) |
| | Import | Import | U.S. EPA (2016b) |
| 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) | U.S. EPA (2016b); EPA-HQ-OPPT-2016-0737-0013; EPA-HQ-OPPT-2016-0737-0026; EPA-HQ-OPPT-2016-0737-0027 |
| | Processing - Incorporation into formulation, mixture or reaction product | Solvents (for cleaning or degreasing) | U.S. EPA (2016b) |
| | | Adhesives and sealant chemicals | U.S. EPA (2016b) |
| | | Solvents (which become part of product formulation or mixture) (e.g., lubricants and greases, paints and coatings, other uses) | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | Processing – incorporated into articles | Solvents (becomes an integral components of articles) | U.S. EPA (2016b) |
| | Repackaging | Solvents (for cleaning or degreasing) | U.S. EPA (2016b) |
| | Recycling | Recycling | U.S. EPA (2017b) |
| Distribution in commerce | Distribution | Distribution | |
| Industrial/commercial/ consumer use | Solvents (for cleaning or degreasing) | Batch vapor degreaser (e.g., open-top, closed-loop) [c] | Use Document, EPA-HQ-OPPT-2016-0737-0003, U.S. EPA (2014b), (2016f) |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| Industrial/commercial/ consumer use | Solvents (for cleaning or degreasing) | In-line vapor degreaser (e.g., conveyorized, web cleaner) [c] | Use Document, EPA-HQ-OPPT-2016-0737-0003, U.S. EPA (2014b), (2016f) |
| | | Cold cleaner | Use Document, EPA-HQ-OPPT-2016-0737-0003; U.S. EPA (2017c) |
| | | Aerosol spray degreaser/cleaner [c] | Use Document, EPA-HQ-OPPT-2016-0737-0003, U.S. EPA (2014b), (2016d), (2016c) |
| | | Mold release | Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | Lubricants and greases/lubricants and lubricant additives | Tap and die fluid | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0737-0003; EPA-HQ-OPPT-2016-0737-0028 |
| | Lubricants and greases/lubricants and lubricant additives | Penetrating lubricant | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0737-0003; EPA-HQ-OPPT-2016-0737-0028 |
| | Adhesives and sealants | Solvent-based adhesives and sealants | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | | Tire repair cement/sealer | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | | Mirror edge sealant | Use Document, EPA-HQ-OPPT-2016-0737-0003; U.S. EPA (2014b) |
| | Functional fluids (closed systems) | Heat exchange fluid | U.S. EPA (2017c) |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| Industrial/commercial/ consumer use | Paints and coatings | Diluent in solvent-based paints and coatings | U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0737-0003; EPA-HQ-OPPT-2016-0737-0010; EPA-HQ-OPPT-2016-0737-0015; EPA-HQ-OPPT-2016-0737-0027 |
| | Cleaning and furniture care products | Carpet cleaner | Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | | Cleaning wipes | Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | Laundry and dishwashing products | Spot remover [c] | Use Document, EPA-HQ-OPPT-2016-0737-0003, U.S. EPA (2014b), (2016e) |
| | Arts, crafts and hobby materials | Fixatives and finishing spray coatings [c] | U.S. EPA (2014b) |
| | Corrosion inhibitors and anti-scaling agents | Corrosion inhibitors and anti-scaling agents | U.S. EPA (2016b) |
| | Processing aids | Process solvent used in battery manufacture | U.S. EPA (2017c) |
| | | Process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture | U.S. EPA (2017c) |
| | | Extraction solvent used in caprolactam manufacture | U.S. EPA (2017c) |
| | | Precipitant used in beta-cyclodextrin manufacture | U.S. EPA (2017c) |
| | Ink, toner and colorant products | Toner aid | Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | Automotive care products | Brake and parts cleaner | Use Document, EPA-HQ-OPPT-2016-0737-0003 |

| Life Cycle Stage | Category [a] | Subcategory [b] | References |
|---|---|---|---|
| Industrial/commercial/ consumer use | Apparel and footwear care products | Shoe polish | U.S. EPA (2017c) |
| | Other uses | Hoof polishes | Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | | Pepper spray | Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | | Lace wig and hair extension glues | Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | | Gun scrubber | Use Document, EPA-HQ-OPPT-2016-0737-0003 |
| | | Other miscellaneous industrial, commercial and consumer uses | U.S. EPA (2017c) |
| Disposal | Emissions to air | Air | U.S. EPA (2017b) |
| | Wastewater | Industrial pre-treatment | |
| | | Industrial wastewater treatment | |
| | | Publicly owned treatment works (POTW) | |
| | | Underground injection | |
| | Solid wastes and liquid wastes | Municipal landfill | |
| | | Hazardous landfill | |
| | | Other land disposal | |
| | | Municipal waste incinerator | |
| | | Hazardous waste incinerator | |
| | | Off-site waste transfer | |

[a] These categories appear in the Life Cycle Diagram, reflect CDR codes and broadly represent conditions of use of TCE in industrial and/or commercial settings.
[b] These subcategories reflect more specific uses of TCE.
[c] This includes uses assessed in the U.S. EPA (2014b) risk assessment and therefore those uses are out of scope for the risk evaluation.

EPA assessed inhalation risks from TCE in vapor and aerosol degreasing, spot cleaning at dry cleaning facilities and arts and craft uses U.S. EPA (2014b) and also completed four supplemental analyses as identified in Table 1-1. Based on these analyses, EPA published two proposed rules to address the unreasonable risks presented by TCE use in vapor degreasing and in commercial and consumer aerosol degreasing and for spot cleaning at dry cleaning facilities (82 FR 7432, January 19, 2017; 81 FR 91592, December 16, 2016). Scenarios already assessed in the 2014 document will not be re-evaluated in the risk evaluation to which this scope applies.

## 2.3 Exposures

For TSCA exposure assessments, EPA expects to evaluate exposures and releases to the environment resulting from the conditions of use applicable to TCE. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of TCE and the exposure to human receptors, including potentially exposed or susceptible subpopulations and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures TCE.

### 2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation. Table 2-4 provides environmental fate data that EPA has identified and considered in developing the scope for TCE.

**Table 2-4. Environmental Fate Characteristics of TCE**

| Property or Endpoint | Value [a] | References |
|---|---|---|
| Indirect photodegradation | 5.5-8 days (atmospheric degradation based on measured hydroxyl radical degradation)<br>1-11 days (atmospheric degradation based on measured hydroxyl radical degradation) | ECB (2004)<br><br>U.S. EPA (2014b) |
| Hydrolysis half-life | Does not undergo hydrolysis at pH 7 | EC (2000) |
| Biodegradation | 19% in 28 days (aerobic in water, OECD 301D)<br>2.4% in 14 days (aerobic in water, OECD 301C)<br><br>25% degradation after 10 days, 95% degradation after 30 days (anaerobic biodegradation in subsurface sediment with methanol)<br><br>65% degradation after 10 days, 99% degradation after 30 days (anaerobic biodegradation in subsurface sediment with glucose) | ECB (2004) |

| Property or Endpoint | Value [a] | References |
|---|---|---|
| | TCE removed slowly with a reduction of 40% after 8 weeks (TCE (200 µg/L) incubated with batch bacterial cultures under methanogenic conditions) | |
| Bioconcentration factor (BCF) | 4-17 (carp) | U.S. EPA (2014b) |
| Bioaccumulation factor (BAF) | 23.7 (estimated) | U.S. EPA (2014b) |
| Organic carbon:water partition coefficient (Log $K_{oc}$) | 2.17 (measured in silty clay Nebraska loam);<br>1.94 (measured in silty clay Nevada loam);<br>1.86 (measured in a forest soil)<br>1.8 (estimated) | U.S. EPA (2014b) |
| [a] Measured unless otherwise noted | | |

If released to the air, TCE does not absorb radiation well at wavelengths that are present in the lower atmosphere (>290 nm) so direct photolysis is not a main degradation process. Degradation by reactants in the atmosphere has a half-life of several days meaning that long range transport is possible.

If released to water, sediment or soil, the fate of TCE is influenced by volatilization from the water surface or from moist soil as indicated by its physical chemical properties (e.g. Henry's law constant) and by microbial biodegradation under some conditions. The biodegradation of TCE in the environment is dependent on a variety of factors and thus, a wide range of degradation rates have been reported (ranging from days to years). TCE is not expected to accumulate in aquatic organisms due to low measured BCFs and estimated BAF.

### 2.3.2 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

A source of information that EPA expects to consider in evaluating exposure are data reported under the Toxics Release Inventory (TRI) program. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 rule, TCE is a TRI-reportable substance effective January 1, 1987.

Table 2-5 provides production-related waste managed data (also referred to as waste managed) for TCE reported by industrial facilities to the TRI program for 2015. Table 2-6 provides more detailed information on the quantities released to air or water or disposed of on land. Release quantities in Table 2-6 are more representative of actual releases during the year. Production-related waste managed shown in Table 2-5 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), while release quantities shown in Table 2-6 include both production-related and non-routine quantities (TRI section 5 and 6 data). Table 2-5 counts all release quantities reported to TRI, while Table 2-6 counts releases once at final disposition, accounting for transfers of chemical waste

from one TRI reporting facility and received by another TRI reporting facility for final disposition. As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017b) .

**Table 2-5. Summary of TCE TRI Production-Related Waste Managed in 2015 (lbs)**

| Number of Facilities | Recycling | Energy Recovery | Treatment | Releases [a, b, c] | Total Production Related Waste |
|---|---|---|---|---|---|
| 172 | 76,090,421 | 2,585,262 | 10,540,042 | 1,967,576 | 91,183,301 |

Data source: 2015 TRI Data (updated March 2017).
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

In 2015, 172 facilities reported a total of 91 million pounds of TCE waste managed. Of this total, 76 million pounds were recycled, 2.5 million pounds were recovered for energy, 10.5 million pounds were treated, and nearly 2 million pounds were released into the environment (Table 2-5). Of these releases, 96% were released to air; nearly 1.9 million pounds were released to air (stack and fugitive air emissions), 52 pounds were released to water (surface water discharges), 50 thousand pounds were released to land (of which disposal to Resource Conservation and Recovery Act (RCRA) Subtitle C landfills is the primary disposal method) and nearly 37 thousand pounds were released in other forms such as to waste brokers (Table 2-6).

**Table 2-6. Summary of TCE TRI Releases to the Environment in 2015 (lbs)**

| | Number of Facilities | Air Releases | | Water Releases | Land Releases | | | Other Releases [a] | Total Releases [b, c] |
|---|---|---|---|---|---|---|---|---|---|
| | | Stack Air Releases | Fugitive Air Releases | | Class I Under-ground Injection | RCRA Subtitle C Landfills | All other Land Disposal [a] | | |
| Subtotal | 172 | 689,627 | 1,190,942 | 52 | 122 | 49,500 | 405 | 36,890 | 1,967,538 |
| Totals | | 1,880,569 | | | 50,027 | | | | |

Data source: 2015 TRI Data (updated March 2017).
[a] Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points.
[b] These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes.
[c] Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

While production-related waste managed shown in Table 2-5 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-6 include both production-related and non-routine quantities (TRI section 5 and 6 data). As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2016g).

Other sources of information provide evidence of releases of TCE, including EPA effluent guidelines (EGs) promulgated under the Clean Water Act (CWA), National Emission Standards for Hazardous Air

Pollutants (NESHAPs) promulgated under the Clean Air Act (CAA), or other EPA standards and regulations that set legal limits on the amount of TCE that can be emitted to a particular media. EPA expects to consider these data in conducting the exposure assessment component of the risk evaluation for TCE.

There are additional agency resources for TCE emissions data, including National Emissions Inventory (NEI) (U.S. EPA, 2017d) and the Discharge Monitoring Report (DMR) Pollutant Loading Tool (U.S. EPA, 2010), which provide additional release data specific to air and surface water, respectively. NEI provides comprehensive and detailed estimates of air emissions for criteria pollutants, criteria precursors, Hazardous Air Pollutants (HAPs) on a 3-year cycle. Recent TCE air emissions data from NEI will be pulled and analyzed for point and non-point sources in the next phase of risk evaluation. The DMR loading tool calculates pollutant loadings from permit and DMR data from EPA's Compliance Information System for the National Pollutant Discharge Elimination System (ICIS-NPDES) Compliance Information System for the National Pollutant Discharge Elimination System (ICIS-NPDES). DMR data are available for the years 2007 to present and will be pulled and analyzed in the next phase of risk evaluation

### 2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

Monitoring and biomonitoring data were identified in EPA's data search for TCE.

***Environment***

TCE is widely detected in a number of environmental media. While the primary fate of TCE released to surface waters or surface soils is volatilization, TCE is more persistent in air and ground water, where it is commonly detected through national and state-level monitoring efforts. TCE is frequently found at Superfund sites as a contaminant in soil and ground water.

TCE has been detected in ambient air across the United States, though ambient levels vary by location and proximity to industrial activities. EPA's Air Quality System (AQS) is EPA's repository of Criteria Pollutant and HAP monitoring data. A summary of the ambient air monitoring data for TCE (i.e., measured data) in the United States from 1999 to 2006 suggests that TCE levels in ambient air have remained fairly constant in ambient air for the United States since 1999, with an approximate mean value of 0.23 $\mu g/m^3$ (U.S. EPA, 2011, 2007) . EPA also compiles modeled air concentrations in its National-scale Air Toxics Assessments (NATA) using NEI data for the Criteria Pollutants and HAPs, like TCE. Recent ambient air concentration data from both sources, as well as those identified in open literature, will be reviewed and considered for risk evaluation.

The presence of TCE in indoor air may result from ambient air releases from industrial and commercial activities, volatilization from tap water and household uses of TCE-containing consumer products. Additionally, TCE in ground water may volatilize through soil and into indoor environments of overlying buildings in a process called vapor intrusion. There are a number of studies that have reported indoor air levels of TCE in residences, schools and stores, and recent indoor air data from open literature, agency databases (e.g., EPA's Vapor Intrusion Database) and other authoritative documents addressing

vapor intrusion will be reviewed during problem formulation. Additional sources of data related to vapor intrusion, especially as related to ongoing TSCA uses, will also be reviewed and considered for risk evaluation.

TCE is one of the most frequently detected organic solvent in U.S. ground water. The U.S. Geological Survey (USGS) conducted a national assessment of VOCs in ground water, including TCE. Between 1985 and 2001, the detection frequency of TCE was 2.6%, with a median concentration of 0.15 µg/$m^3$ (U.S. EPA, 2011; Zogorski et al., 2006). Recent sources of national and state-level ground water monitoring data, along with any sources identified in the open literature, will be reviewed and considered in the risk evaluation. Approximately 90% of the public drinking water systems in the United States are ground water systems (U.S. EPA, 2011).

TCE has been detected in drinking water systems through national and state-wide monitoring efforts. EPA's second and third Six-Year Review (Six-Year Review 2 and 3) contains a compilation of state drinking water monitoring data from 1998-2005 and 2006-2011, which are available through EPA's Six-Year Review 2 Contaminant Occurrence Data site and EPA's Six-Year Review 3 Contaminant Occurrence Data Site. As part of risk evaluation, EPA intends to review data from EPA's Six-Year Review 2, as well as additional drinking water monitoring data from states and/or the open literature, to inform the magnitude and extent of TCE's presence in drinking water.

EPA's STOrage and RETrieval (STORET) is an electronic data system for water quality monitoring data. Based on a relatively recent search of the STORET database in 2008, TCE was detected in three of 150 samples (U.S. EPA, 2011). STORET data from 2008 to present, as well as data from other sources, will be reviewed for a better understanding of current levels of TCE in surface water. EPA's STORET database will also be examined for recent data on TCE levels in sediment.

Compared with other environmental media, there is a relative lack of nationally-representative monitoring data on levels of TCE in soil.

***Biota***

Biological studies have detected TCE in human blood and urine in the United States and several other countries, with those exposed through occupational degreasing activities reporting the highest frequency of positive detections (U.S. EPA, 2011; IARC, 1995). The Third National Health and Nutrition Examination Survey (NHANES III) analyzed blood concentrations of TCE in non-occupationally exposed individuals in the United States and found that 10% of those sampled had TCE levels in whole blood at or above the detection limit of 0.01 ppb (U.S. EPA, 2011). These and other sources of TCE biomonitoring data will be reviewed and considered for risk evaluation.

### 2.3.4 Environmental Exposures

The manufacturing, processing, use and disposal of TCE can result in releases to air, water, sediment and soil. EPA expects to consider exposures to the environment and ecological receptors that occur via these exposure pathways or media shown in Figure 2-4 in conducting the risk evaluation for TCE.

### 2.3.5 Human Exposures

EPA expects to consider three broad categories of human exposures: occupational exposures, consumer exposures and general population exposures. Subpopulations within these exposure categories will also be considered as described herein.

#### 2.3.5.1 Occupational Exposures

EPA expects to consider worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA expects to consider exposure to occupational non-users, who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment (PPE) have on occupational exposure levels.

In the previous 2014 risk assessment (U.S. EPA, 2014b), EPA assessed inhalation exposures to TCE for occupational use in degreasing and spot cleaning in dry cleaning facilities which will not be re-evaluated. For the included occupational scenarios, acute and chronic risks to workers and bystanders at small degreasing facilities and dry cleaning facilities were assessed, including adults of both sexes and pregnant women. During this scoping, additional uses were identified and described in Section 2.2 and will be considered during the risk evaluation and will be considered during the risk evaluation.

Workers and occupational non-users may be exposed to TCE when performing activities associated with the conditions of use described in Section 2.2, including, but not limited to:

- Using TCE in process equipment (e.g., vapor degreasing machine);
- Applying formulations and products containing TCE onto substrates (e.g., spray applying coatings or adhesives containing TCE);
- Handling, transporting and disposing waste containing TCE; and
- Performing other work activities in or near areas where TCE is used.

Based on these activities, EPA expects to consider inhalation exposure to vapor and mists and dermal exposure, including skin contact with liquids and vapors for workers and occupational non-users. EPA also expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed.

The United States has several regulatory and non-regulatory exposure limits for trichloroethylene: an Occupational Safety and Health Administration (OSHA) permissible exposure limit (PEL) of 100 ppm 8-hour time-weighted average (TWA), an acceptable ceiling concentration of 200 ppm provided the 8-hour PEL is not exceeded, and an acceptable maximum peak of 300 ppm for a maximum duration of 5 minutes in any 2 hours (OSHA, 1997), and an American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 10 ppm 8-hour TWA and a short-term exposure level (STEL) of 25 ppm (ACGIH, 2010). Also, the National Institute for Occupational Safety and Health (NIOSH) has classified trichloroethylene as a potential occupational carcinogen and established an immediately dangerous to life or health (IDLH) value of 1,000 ppm (NIOSH, 2016).

Key data that inform occupational exposure assessment and which EPA expects to consider include: the OSHA Chemical Exposure Health Data (CEHD) and NIOSH Health Hazard Evaluation (HHE) program data. OSHA data are workplace monitoring data from OSHA inspections. The inspections can be random or targeted, or can be the result of a worker complaint. OSHA data can be obtained through the OSHA Integrated Management Information System (IMIS) at https://www.osha.gov/oshstats/index.html. Table_Apx B-1 in Appendix B provides a summary of industry sectors with TCE personal monitoring air samples obtained from OSHA inspections conducted between 2003 and 2017. NIOSH HHEs are conducted at the request of employees, union officials, or employers and help inform

potential hazards at the workplace. HHEs can be downloaded at https://www.cdc.gov/niosh/hhe/. During the problem formulation, EPA will review these data and evaluate their utility in the risk evaluation.

#### 2.3.5.2 Consumer Exposures

TCE can be found in consumer products and commercial products that are readily available for public purchase at common retailers [EPA-HQ-OPPT-2016-0737-003, Sections 3 and 4, (U.S. EPA, 2017a)] and can therefore result in exposures to consumers.

Exposures routes that EPA may consider for consumers using TCE-containing products include dermal exposure through skin contact with liquids and vapors; oral exposure through mists that deposit in the upper respiratory tract and are swallowed. Although less likely given the physical-chemical properties, oral exposure may also occur from incidental ingestion of residue on hand/body.

The final 2014 TCE TSCA Work Plan Chemical Risk Assessment characterized inhalation exposures to TCE for consumer use in aerosol degreasing and as a spray-applied protective coating for arts and crafts. These scenarios will not be reassessed. For the included consumer scenarios, acute risks to consumers and bystanders in the home were also assessed.

#### 2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of TCE could result in potential pathways for oral, dermal or inhalation exposure to the general population. EPA will consider each media, route and pathway to estimate general population exposures.

The final 2014 TCE risk assessment (U.S. EPA, 2014b) limited its assessment to worker and consumer exposures; however, general population exposures via all identified potential pathways will be considered for risk evaluation, including oral ingestion through presence in drinking water or other media, inhalation of the chemical through presence in outdoor or indoor air and dermal absorption of TCE through direct or indirect contact.

***Inhalation***

Based on TRI data and TCE physical-chemistry and fate properties, it is expected that inhalation represents the primary route of exposure for the general population from ongoing industrial and/or commercial activities. As noted in Section 2.3.3, Presence in the Environment and Biota, levels of TCE in ambient air vary based on proximity to industrial and commercial activities and urban environments and there are a number of possible sources that may contribute to TCE levels in indoor air. Like other VOCs, TCE in water can also contribute to general population inhalation exposures from volatilization from water during activities such as showering, bathing or washing (McKone and Knezovich, 1991). EPA intends to evaluate the potential of inhalation exposures that may result from vapor intrusion into an overlying home or indoor space from contaminated soil or ground water, especially as related to the activities within scope, leading to elevated indoor air concentrations for some segments of the general population.

Based on these potential sources and pathways of exposure, EPA expects to consider TCE inhalation exposures of the general population that may result from the conditions of use of TCE.

***Oral***
The general population may ingest TCE via contaminated drinking water and other ingested media.

It is anticipated that ingestion of drinking water containing TCE, for on-going TSCA uses, represents the primary route of oral exposure for this chemical. TCE's presence in drinking water may also contribute, to a lesser degree, to oral ingestion through showering or other non-drinking activities. Possible contributions from ingestion of other TCE-containing media or biota will be considered where applicable and based on the available data.

Based on these potential sources and pathways of exposure, EPA expects to consider oral exposures to the general population that may result from the conditions of use of TCE.

***Dermal***
Dermal exposures are expected to primarily result from dermal contact with TCE-containing tap water during showering, bathing and/or washing. EPA will need to determine if this exposure is possible as a result of ongoing uses and not merely legacy uses.

Based on these potential sources and pathways of exposure, EPA expects to consider dermal exposures to the general population that may result from the conditions of use of TCE.

#### 2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."

In this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure* that EPA expects to consider in the risk evaluation:

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. TCE has been identified as being used in products available to consumers; however, only some individuals within the general population may use these products. Therefore, those who do use these products are a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or disposal sites).

In developing exposure scenarios, EPA will evaluate available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006).

In summary, in the risk evaluation for TCE, EPA expects to consider the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use. As described above, EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

## 2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of TCE, as described in supplemental document: *Strategy for Conducting Literature Searches for Trichloroethylene: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0737). Based on initial screening, EPA expects to consider the hazards of TCE identified in this scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

### 2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the following sources of environmental hazard data for TCE: European Chemicals Agency (ECHA) and EPA Chemical Test Rule Data.

EPA expects to consider the hazards of TCE to aquatic organisms including fish, aquatic invertebrates and algae exposed under acute and chronic exposure conditions. Toxicological data are available in the ECHA Database (ECHA, 2017) and EPA Chemical Test Rule Data. The summarized data supported acute toxicity to fish (mortality) and aquatic invertebrates (mortality and immobilization) from TCE. Toxicity to algae was also observed (growth rate) when exposed to TCE. Chronic toxicity to fish (growth and survival) was observed when exposed to TCE.

EPA expects to consider the hazards of TCE to terrestrial organisms including amphibians, earthworms, and aquatic plants exposed under acute and chronic exposure conditions. Mortality was observed in amphibians and no mortality was observed in earthworms. Growth and reproduction effects to aquatic plants were observed.

The European Union Risk Assessment Report, Trichloroethylene (EC, 2004) concluded that there was hazard to plants from air emissions of TCE from production, processing as an intermediate, formulation of solvent use and use in metal degreasing. The 2014 TCE Risk Assessment U.S. EPA (2014b) did not consider or assess environmental exposures from the selected TCE uses due to TCE's moderate persistence, low bioaccumulation and low hazard for aquatic toxicity, as well as the expectation that low levels of TCE would be present in surface water (U.S. EPA, 2014b). However, environmental exposures and environmental receptors are being considered in this scope document for inclusion in

the risk evaluation since summarized environmental hazard data indicates toxicity to environmental receptors and the European Union Risk Assessment Report, Trichloroethylene (EC, 2004) concluded that there was hazard to plants from air emissions of TCE.

### 2.4.2 Human Health Hazards

TCE has an existing EPA IRIS Assessment (U.S. EPA, 2011) and an ATSDR Toxicological Profile (U.S. EPA, 2014c); hence, many of the hazards of TCE have been previously compiled and systematically reviewed. Furthermore, OPPT previously reviewed data/information on health effects endpoints, identified hazards and conducted dose-response analysis in the 2014 TSCA Work Plan Chemical Risk Assessment for TCE (U.S. EPA, 2014b). EPA has relied heavily on these comprehensive reviews in preparing this scope. EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for TCE [*Trichloroethylene (CASRN 79-01-6) Bibliography: Supplemental File for the TSCA Scope Document*) (EPA-HQ-OPPT-2016-0737]. EPA expects to consider all potential hazards associated with TCE. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

#### 2.4.2.1 Non-Cancer Hazards

***Acute Toxicity***

Human volunteers reported mild nose and throat irritation in TCE inhalation studies (U.S. EPA, 2014b) and laboratory studies have also demonstrated acute effects of TCE on the respiratory tract in the form of both localized irritation and broad fibrosis as well as labored breathing (U.S. EPA, 2011). Acute exposures to TCE have additionally shown to cause central nervous system depression and cardiac arrhythmias while there are also reports of deaths following accidental exposure (NAC/AEGL, 2009). An Acute Exposure Guideline Level (AEGL) has been derived for TCE (NAC/AEGL, 2009).

***Liver Toxicity***

Several available human studies have reported clinical and functional evidence of TCE-induced liver toxicity. The primary effect of TCE on liver in laboratory rodents is hepatomegaly (which has also been observed in humans), with only mild effects seen in other indicators of toxicity such as necrosis and enzyme changes (U.S. EPA, 2011).

***Kidney Toxicity***

Multiple lines of evidence in human and animal studies support the conclusion that TCE induces toxic nephropathy. Visible effects resulting from TCE exposure include both histopathological and weight changes in the kidney (U.S. EPA, 2011) .

***Reproductive/Developmental Toxicity***

Human studies have reported TCE exposure to be associated with increased sperm density and decreased sperm quality, altered sexual drive or function, and altered serum endocrine levels. Male reproductive effects have been corroborated by several laboratory animal studies reporting effects on sperm, libido/copulatory behavior and serum hormone levels, while histopathological lesions in testis or epididymis, altered sperm-oocyte binding and reduced fertilization have also been observed. Evidence for female reproductive toxicity is more limited, however a critical effect was identified for delayed parturition (giving birth) (U.S. EPA, 2011). Both epidemiology and experimental animal studies of TCE have reported increases in total birth defects, central nervous system (CNS) defects, oral cleft

defects, eye/ear defects, kidney/urinary tract disorders, musculoskeletal birth anomalies, lung/respiratory tract disorders, skeletal defects, developmental immunotoxicity, and cardiac defects (U.S. EPA, 2011).

***Neurotoxicity***

Both epidemiologic and animal studies have reported abnormalities in trigeminal nerve function and psychomotor effects in association with TCE exposure. Laboratory animal studies have demonstrated additional critical effects from TCE exposure including auditory impairment and decreased wakefulness (U.S. EPA, 2011) .

***Immunotoxicity***

TCE promotes both immunosuppressive and auto-immune effects in humans and animals. Sensitive markers of immunosuppression that have been observed include decreased thymus weight and cellularity as well as reduced immune cell response. Auto-immune effects include hypersensitivity (discussed in sensitization section) and increased anti dsDNA/ssDNA antibodies (U.S. EPA, 2011).

***Sensitization***

Limited epidemiological data do not support an association between TCE exposure and allergic respiratory sensitization or asthma; however, there is strong human evidence for severe skin sensitization resulting in dermatitis, mucosal lesions and often systemic effects such as hepatitis. Skin sensitization tests on rodents corroborate the contact allergenicity potential of TCE and its metabolites along with the resulting immune-mediated hepatitis (U.S. EPA, 2011).

#### 2.4.2.2 Genotoxicity and Cancer Hazards

Studies in humans have shown convincing evidence of a causal association between TCE exposure in humans and kidney cancer as well as human evidence of TCE carcinogenicity in the liver and lymphoid tissues. Further support for TCE's carcinogenic characterization comes from positive results in multiple rodent cancer bioassays in rats and mice of both sexes, similar toxicokinetics between rodents and humans, mechanistic data supporting a mutagenic mode of action for kidney tumors, and the lack of mechanistic data supporting the conclusion that any of the mode(s) of action for TCE-induced rodent tumors are irrelevant to humans (U.S. EPA, 2011). TCE is considered to have both genotoxic and non-genotoxic mechanisms. Following EPA's Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005), including a weight of evidence judgement, TCE is considered "carcinogenic to humans" by all routes of exposure and calculated quantitative estimates of risk from oral and inhalation exposures (U.S. EPA, 2011).

#### 2.4.2.3 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." In developing the hazard assessment, EPA will evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to TCE's hazards.

The IRIS assessment for TCE indicates that there is some evidence that certain populations may be more susceptible to exposure to TCE and examined life stage, gender-specific, genetic variation, race/ethnicity, preexisting health status, lifestyle factors and nutrition status. However, the IRIS assessment concluded that except for toxicokinetic variability, there are inadequate chemical-specific data to quantify the degree of differential susceptibility due to such factors.

As for toxicokinetic variability, increased enzymatic activity of cytochrome P450 2E1 (CYP2E1) and glutathione-S-transferase (GST) polymorphisms may influence TCE susceptibility due to effects on the production of toxic metabolites (U.S. EPA, 2011). In the 2014 risk assessment (U.S. EPA, 2014b), EPA performed a population analysis to systematically estimate uncertainty and variability including human variability related to glutathione conjugation as a result of GST activity, which resulted in a distribution of human equivalent concentrations (HEC) for each endpoint. HEC99 values representing the most sensitive 1% of the population, a susceptible subpopulation, were used for risk evaluation, and EPA expects to perform a similar analysis for this assessment.

## 2.5 Initial Conceptual Models

A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of the conditions of use, exposures (pathways and routes), hazards and receptors. As part of the scope for TCE, EPA developed three conceptual models, presented here.

### 2.5.1 Initial Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

Figure 2-2 presents the initial conceptual model for human receptors from industrial and commercial activities and uses of TCE. EPA anticipates that workers and occupational non-users may be exposed to TCE via inhalation and dermal routes. In the final TCE risk assessment (U.S. EPA, 2014b), inhalation exposures to vapor and mist were assessed as the most likely exposure route; however, there is also potential dermal exposure for some conditions of use, such as maintenance of industrial degreasing tanks. EPA expects to consider potential worker exposure through mists that deposit in the upper respiratory tract and are swallowed.

The industrial, commercial and consumer activities depicted in Figure 2-2 and Figure 2-3 may result in emissions of TCE to outdoor air, as well as liquid and solid wastes containing TCE. Pathways previously assessed in U.S. EPA (2014b) are shaded in green in these figures.

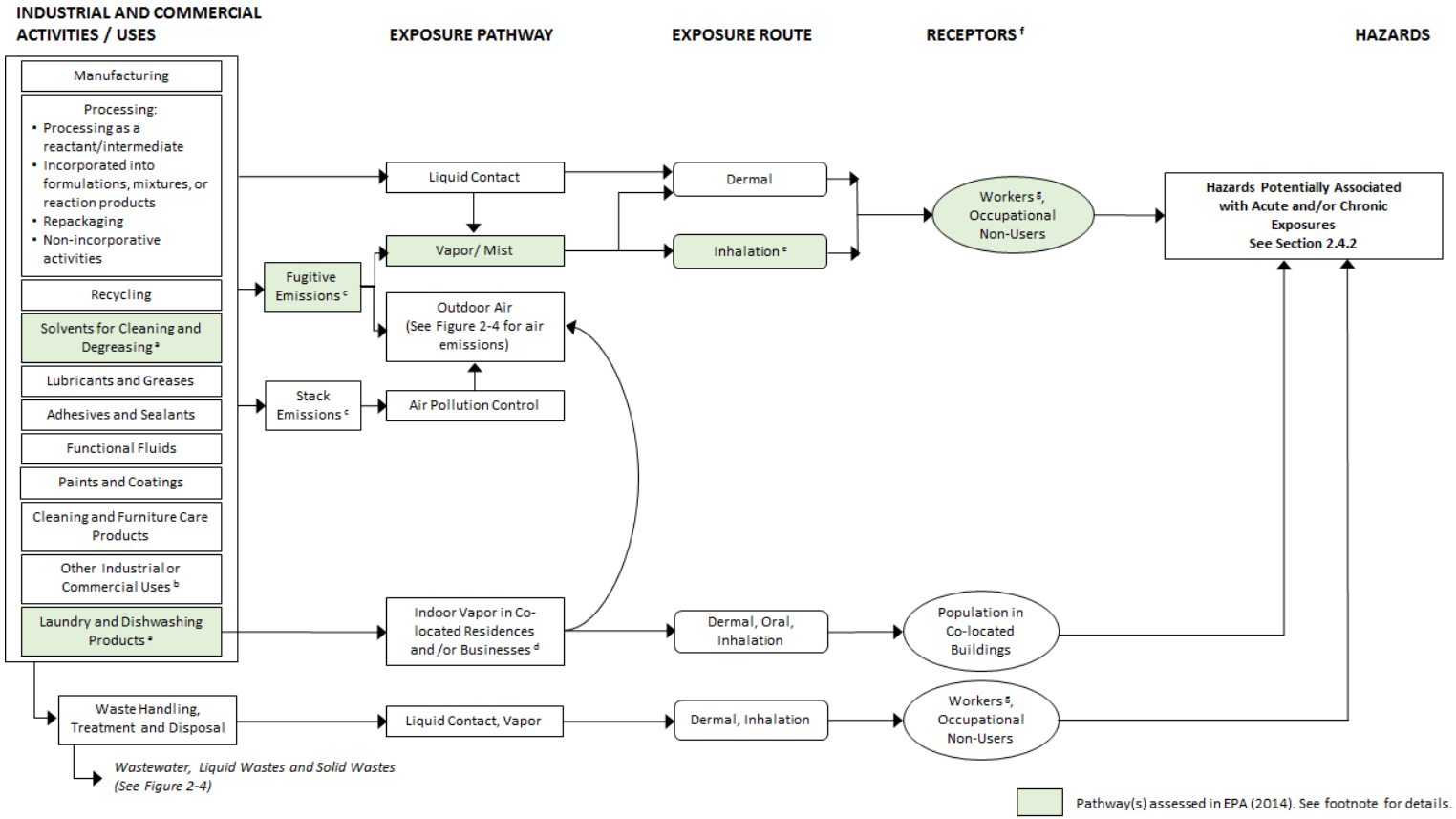


**Figure 2-2. Initial TCE Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards**

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of TCE.

[a] U.S. EPA (2014b) assessed vapor degreasing in commercial settings, as well as TCE use in spotting agents at dry cleaning facilities and will not reassess these activities.

[b] Some products are used in both commercial and consumer applications. Additional uses of TCE are included in Table 2-3.

[c] Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions, and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

[d] TCE vapor in air, soil or ground water may migrate to indoor air in co-located residences, co-located businesses or other nearby buildings.

[e] Exposure may occur through mists that deposit in the upper respiratory tract and are swallowed.

[f] Receptors include potentially exposed or susceptible subpopulations.

[g] When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

### 2.5.2 Initial Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

Figure 2-3 presents the initial conceptual model for human receptors from consumer uses of TCE. Similar to Figure 2-2, EPA expects that consumers and bystanders may be exposed via inhalation, dermal and oral routes, with inhalation of vapor and mist being the most likely exposure route. It should be noted that some consumers may purchase and use products primarily intended for commercial use over the Internet.

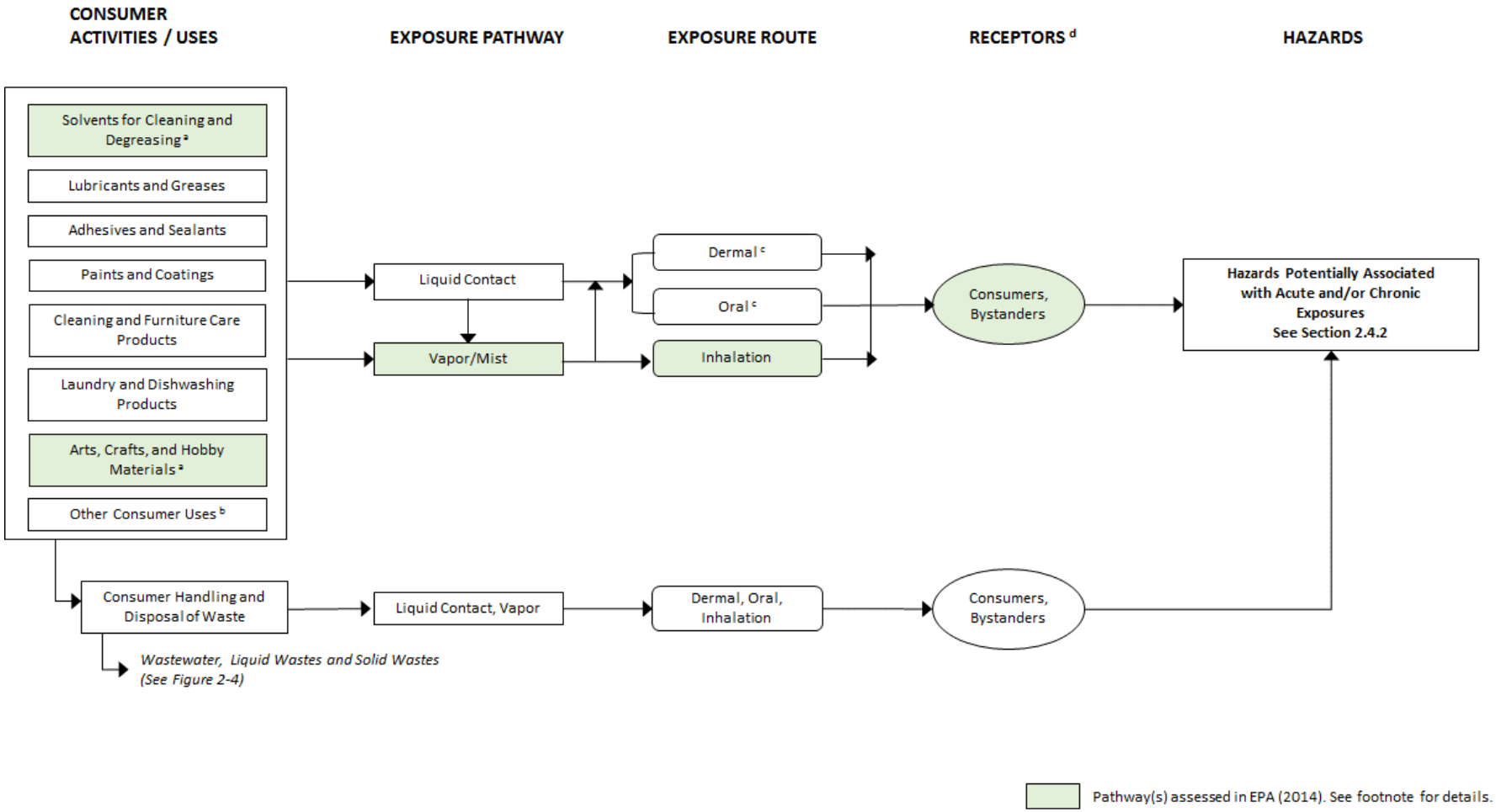


**Figure 2-3. Initial TCE Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards**

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of TCE.

[a] U.S. EPA (2014b) assessed aerosol degreasing and spray applied protective coating uses in consumer settings and will not reassess these activities.

[b] Some products are used in both commercial and consumer applications. Additional uses of TCE are included in Table 2-3.

[c] Dermal exposure may occur through skin contact with liquids and vapors; oral exposure may occur through mists that deposit in the upper respiratory tract and are swallowed. Although less likely given the physical-chemical properties, oral exposure may also occur from incidental ingestion of residue on hand/body.

[d] Receptors include potentially exposed or susceptible subpopulations.

### 2.5.3 Initial Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

Figure 2-4 illustrates exposure pathways for human and environmental receptors from environmental releases and waste disposal activities.

EPA anticipates that general populations living near industrial and commercial facilities using TCE will be exposed via inhalation of outdoor air. In addition, aquatic and terrestrial life may be exposed to TCE-contaminated water, sediment and soil.

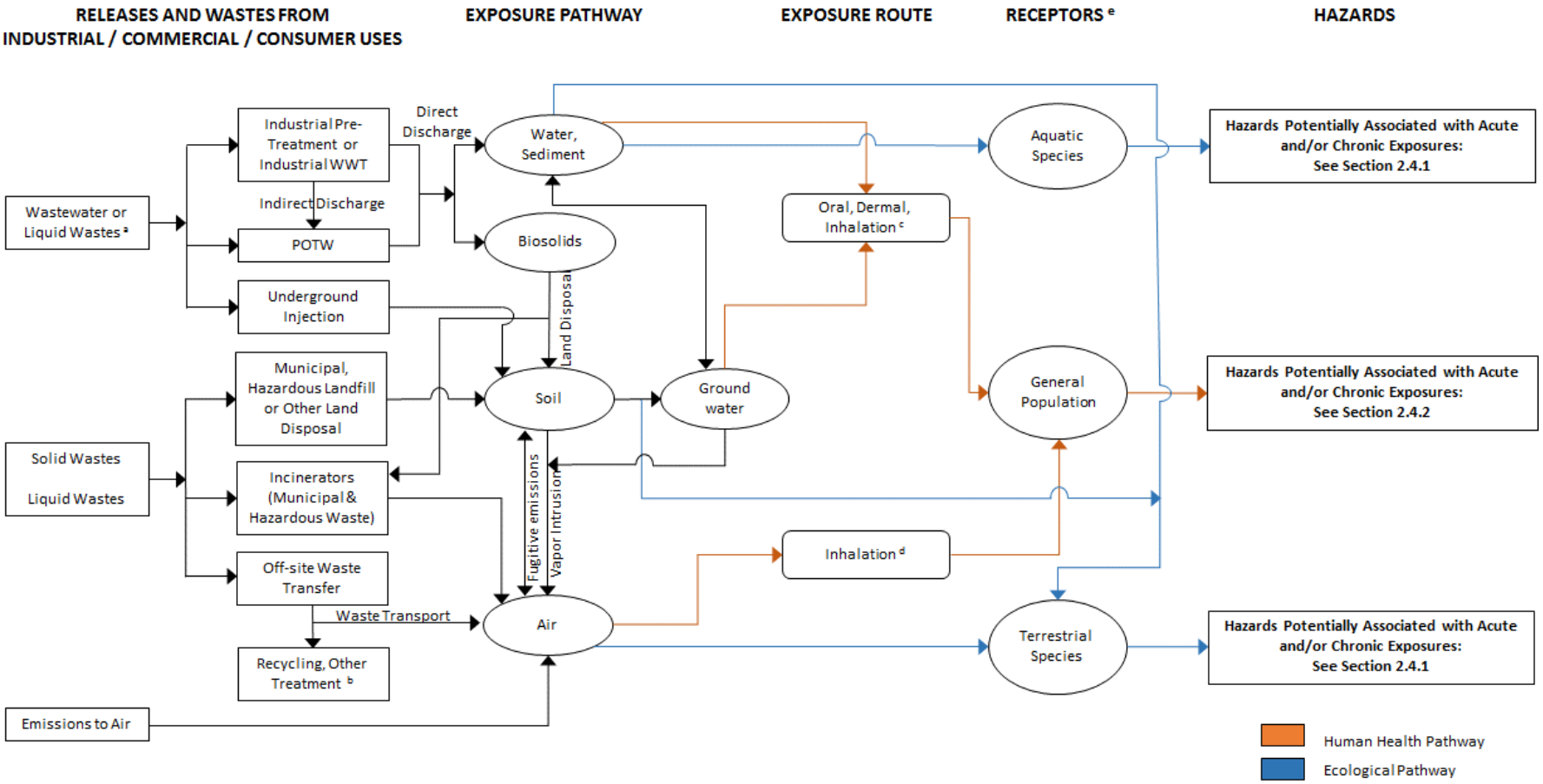


**Figure 2-4. Initial TCE Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards**

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of TCE.

[a] Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

[b] Additional releases may occur from recycling and other waste treatment.

[c] Volatilization from or liquid contact with water in the home during showering, bathing, washing, etc. represents another potential exposure pathway.

[d] Presence of mist is not expected; dermal and oral exposure are negligible.

[e] Receptors include potentially exposed or susceptible subpopulations.

## 2.6 Initial Analysis Plan

The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for readily available data and information from public sources (*Trichloroethylene (CASRN 79-01-6) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0737) as described in Section 1.3, EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations.

The analysis plan outlined here is based on the conditions of use of TCE, as described in Section 2.2 of this scope. The analysis plan may be refined as EPA proceeds with the systematic review of the information in the *Trichloroethylene (CASRN 79-01-6) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0737). EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible, and transparent.

### 2.6.1 Exposure

#### 2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to environmental media as follows:

1) Review reasonably available published literature or information on processes and activities associated with the conditions of use to evaluate the types of releases and wastes generated.
2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI and National Emissions Inventory [NEI] programs).
3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses, volatility, chemical and physical properties.
4) Understand and consider regulatory limits that may inform estimation of environmental releases.
5) Review and determine applicability of Organisation for Economic Co-operation and Development (OECD) Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.
6) Evaluate the weight of the evidence of environmental release data.
7) Map or group each condition(s) of use to a release assessment scenario.

#### 2.6.1.2 Environmental Fate

EPA expects to consider and analyze fate and transport in environmental media as follows:

1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.
2) Using measured data and/or modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.
3) Evaluate the weight of the evidence of environmental fate data.

#### 2.6.1.3 Environmental Exposures

EPA expects to consider the following in developing its environmental exposure assessment of TCE:

1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.
2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: release into the media of interest, fate and transport and characteristics of the environment.
3) Review reasonably available biomonitoring data. Consider whether these monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are available, and characterize exposed aquatic and terrestrial populations.
5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
6) Map or group each condition(s) of use to environmental assessment scenario(s).

#### 2.6.1.4 Occupational Exposures

EPA expects to consider and analyze both worker and occupational non-user exposures as follows:

1) Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and the National Institute of Occupational Safety and Health (NIOSH), and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements).
2) Review reasonably exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to TCE.
3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.
4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.
5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.
6) Evaluate the weight of the evidence of occupational exposure data.
7) Map or group each condition of use to occupational exposure assessment scenario(s).

#### 2.6.1.5 Consumer Exposures

EPA expects to consider and analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) Review reasonably available consumer product-specific exposure data related to consumer uses/exposures.
2) Evaluate the weight of the evidence of consumer exposure data.
3) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.

4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with those reported in monitoring data.
6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined.
7) Map or group each condition of use to consumer exposure assessment scenario(s).

#### 2.6.1.6 General Population

EPA expects to consider and analyze general population exposures as follows:

1) Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected. For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
2) Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
3) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
4) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
5) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further defined.
6) Evaluate the weight of the evidence of general population exposure data.
7) Map or group each condition of use to general population exposure assessment scenario(s).

### 2.6.2 Hazards (Effects)

#### 2.6.2.1 Environmental Hazards

EPA will conduct an environmental hazard assessment of TCE as follows:

1) Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).
2) Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints.
3) Derive concentrations of concern (COC) for all identified ecological endpoints.
4) Evaluate the weight of the evidence of environmental hazard data.
5) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

#### 2.6.2.2 Human Health Hazards

EPA expects to consider and analyze human health hazards as follows:

1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).
2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for all identified human health hazard endpoints.
4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.
5) Evaluate the weight of the evidence of human health hazard data.
6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

### 2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook (U.S. EPA, 2000).* As defined in EPA's *Risk Characterization Policy*, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR) *(U.S. EPA, 2000)*. EPA will also present information in this section consistent with approaches described in the Risk Evaluation Framework Rule.

# REFERENCES


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# APPENDICES

# Appendix A REGULATORY HISTORY

## A.1 Federal Laws and Regulations

**Table_Apx A-1. Federal Laws and Regulations**

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| **EPA Regulations** | | |
| TSCA - Section 6(a) | Provides EPA with the authority to prohibit or limit the manufacture (including import), processing, distribution in commerce, use or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment. | Proposed rule under section 6 of TSCA to address the unreasonable risks presented by TCE use in vapor degreasing (82 FR 7432; January 19, 2017). |
| TSCA - Section 6(a) | Provides EPA with the authority to prohibit or limit the manufacture (including import), processing, distribution in commerce, use or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment | Proposed rule under section 6 of TSCA to address the unreasonable risks presented by TCE use in commercial and consumer aerosol degreasing and for spot cleaning at dry cleaning facilities (81 FR 91592; December 12, 2016). |
| TSCA - Section 6(b) | EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments. | TCE is on the initial list of chemicals to be evaluated for unreasonable risks under TSCA (81 FR 91927, December 19, 2016). |
| TSCA - Section 5(a) | Once EPA determines that a use of a chemical substance is a significant new use under TSCA section 5(a), persons are required to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use. | Significant New Use Rule (SNUR) (81 FR 20535; April 8, 2016). TCE is subject to reporting under the SNUR for manufacture (including import) or processing of TCE for use in a consumer product except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants and pepper spray. This SNUR ensures that EPA will have |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| | | the opportunity to review any new consumer uses of TCE and, if appropriate, take action to prohibit or limit those uses. |
| TSCA - Section 8(a) | The TSCA section 8(a) CDR rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States. | TCE manufacturing (including importing), processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011). |
| TSCA - Section 8(b) | EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed or imported in the United States. | TCE was on the initial TSCA Inventory and was therefore not subject to EPA's new chemicals review process (60 FR 16309, March 29, 1995). |
| TSCA - Section 8(e) | Manufacturers (including imports), processors and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. | 28 substantial risk notifications received for TCE (U.S. EPA, ChemView. Accessed April 13, 2017). |
| TSCA - Section 4 | Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures. | Seven studies received for TCE (U.S. EPA, ChemView. Accessed April 13, 2017). |
| EPCRA - Section 313 | Requires annual reporting from facilities in specific industry sectors that employ 10 or more full time equivalent employees and that manufacture, process, or otherwise use a TRI-listed chemical in quantities above threshold levels. | TCE is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987. |
| Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - Section 6 | FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. Pesticides may only be registered if, among other things, they do not cause "unreasonable | TCE is no longer used as an inert ingredient in pesticide products. |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| | adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either: (1) the pesticide, labeling, or other material does not comply with FIFRA or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment. | |
| CAA - Section 112(b) | Defines the original list of 189 HAPs. Under 112(c) of the CAA, EPA must identify and list source categories that emit HAPs and then set emission standards for those listed source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAPs by adding or deleting a substance. Since 1990, EPA has removed two pollutants from the original list, leaving 187 at present. | Lists TCE as a HAP (42 U.S.C. 7412(b)(1)). |
| CAA - Section 112(d) | Section 112(d) states that the EPA must establish a NESHAP for each category or subcategory of major sources and area sources of HAPs (listed pursuant to Section 112(c)). The standards must require the maximum degree of emission reduction that EPA determines to be achievable by each particular source category. Different criteria for maximum achievable control technology (MACT) apply for new and existing sources. Less stringent standards, known as generally available control technology (GACT) standards, are allowed at the Administrator's discretion for area sources. | On May 3, 2007, EPA promulgated NESHAPs regulating the emissions of a number of HAP solvents including for TCE for several industrial source categories, including halogenated solvent cleaning (72 FR 25138). |
| CWA – Sections 301(b), 304(b), 306, and 307(b) | Requires establishment of Effluent Limitations Guidelines and Standards for conventional, toxic, and non-conventional pollutants. For toxic | TCE is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such, is subject to effluent limitations. |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| | and non-conventional pollutants, EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology. Regulations apply to existing and new sources. | |
| CWA - Section 307(a) | Establishes a list of toxic pollutants or combination of pollutants under the to the CWA. The statute specifies a list of families of toxic pollutants also listed in 40 CFR 401.15. The "priority pollutants" specified by those families are listed in 40 CFR part 423, Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules, or on a case-by-case best professional judgement basis in NPDES permits. | |
| Safe Drinking Water Act (SDWA) - Section 1412 | Requires EPA to publish a non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs | EPA issued drinking water standards for TCE pursuant to section 1412 of the SDWA. EPA promulgated the NPDWR for TCE in 1987 with a MCLG of zero an enforceable MCL of 0.005 mg/L (52 FR 25690, July 8, 1987). |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| RCRA - Section 3001 | Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics. | TCE is included on the list of commercial chemical products, manufacturing chemical intermediates or off-specification commercial chemical products or manufacturing chemical intermediates that, when disposed (or when formulations containing any one of these as a sole active ingredient are disposed) unused, become hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Status: D040 at 0.5 mg/L; F001, F002; U228 |
| Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) - Section 102(a) | Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103.<br><br>Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold. | TCE is a hazardous substance with a reportable quantity pursuant to section 102(a) of CERCLA (40 CFR 302.4) and EPA is actively overseeing cleanup of sites contaminated with TCE pursuant to the National Contingency Plan (NCP) (40 CFR 751). |
| **Other Federal Regulations** | | |
| OccOSHA | Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions. | In 1971, OSHA issued occupational safety and health standards for TCE that included a Permissible Exposure Limit (PEL) of 100 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1000). |

| Statutes/Regulations | Description of Authority/Regulation | Description of Regulation |
|---|---|---|
| | | While OSHA has established a PEL for TCE, OSHA has recognized 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. Section 6(a) of the OSH Act granted the Agency the authority to adopt existing Federal standards or national consensus standards as enforceable OSHA standards. For TCE, OSHA recommends the use of the NIOSH REL of 2 ppm (as a 60-minute ceiling) during the usage of TCE as an anesthetic agent and 25 ppm (as a 10-hour TWA) during all other exposures. |
| Atomic Energy Act | The Atomic Energy Act authorizes the Department of Energy to regulate the health and safety of its contractor employees | 10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for TCE is 50 ppm. |
| Federal Food, Drug, and Cosmetic Act (FFDCA) | Provides the FDA with authority to oversee the safety of food, drugs and cosmetics. | Tolerances are established for residues of TCE resulting from its use as a solvent in the manufacture of decaffeinated coffee and spice oleoresins (21 CFR 173.290). |

## A.2 State Laws and Regulations

**Table_Apx A-2. State Laws and Regulations**

| State Actions | Description of Action |
|---|---|
| California Code of Regulations (CCR), Title 17, Section 94509(a) | Lists standards for VOCs for consumer products sold, supplied, offered for sale or manufactured for use in California. As part of that regulation, use of consumer general purpose degreaser products that contain TCE are banned in California and safer substitutes are in use (17 CCR, Section 94509(a). |
| State Permissible Exposure Limits (PELs) | Most states have set PELs identical to the OSHA 100 ppm 8-hour TWA PEL. Nine states have PELs of 50 ppm. California's PEL of 25 ppm is the most stringent (CCR, Title 8, Table AC-1). |
| VOC regulations for consumer products | Many states regulate TCE as a VOC. These regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from state to state, and could include contact and aerosol adhesives, aerosols, electronic cleaners, footwear or leather care products and general degreasers, among other products. California (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Articles 1, 2, 3 and 4), Connecticut (R.C.S.A Sections 22a-174-40, 22a-174-41, and 22a-174-44), Delaware (Adm. Code Title 7, 1141), District of Columbia (Rules 20-720, 20-721, 20-735, 20-736, 20-737), Illinois (35 Adm Code 223), Indiana ( 326 IAC 8-15), Maine (Chapter 152 of the Maine Department of Environmental Protection Regulations), Maryland (COMAR 26.11.32.00 to 26.11.32.26), Michigan (R 336.1660 and R 336. 1661), New Hampshire (Env-A 4100) New Jersey (Title 7, Chapter 27, Subchapter 24), New York (6 CRR-NY III A 235), Rhode Island (Air Pollution Control Regulation No. 31) and Virginia (9VAC5 Chapter 45) all have VOC regulations or limits for consumer products. Some of these states also require emissions reporting. |
| Other | TCE is on California Proposition 65 List of chemicals known to cause cancer in 1988 or birth defects or other reproductive harm in 2014 (CCR Title 27, section 27001). TCE is on California's Safer Consumer Products Regulations Candidate List of chemicals that exhibit a hazard trait and are on an authoritative list (CCR Title 22, Chapter 55). |

## A.3 International Laws and Regulations

**Table_Apx A-3. Regulatory Actions by Other Governments and Tribes**

| Country/ Organization | Requirements and Restrictions |
|---|---|
| Canada | TCE is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). TCE is also regulated for use and sale for solvent degreasing under *Solvent Degreasing Regulations (SOR/2003-283)* (*Canada Gazette*, Part II on August 13, 2003). The purpose of the regulation is to reduce releases of TCE into the environment from solvent degreasing facilities using more than 1000 kilograms of TCE per year. The regulation includes a market intervention by establishing tradable allowances for the use of TCE in solvent degreasing operations that exceed the 1000 kilograms threshold per year. |
| European Union | In 2011, TCE was added to Annex XIV (Authorisation list) of regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). Entities that would like to use TCE needed to apply for authorization by October 2014, and those entities without an authorization must stop using TCE by April 2016. The European Chemicals Agency (ECHA) received 19 applications for authorization from entities interested in using TCE beyond April 2016.<br>TCE is classified as a carcinogen category 1B, and was added to the EU REACH restriction of substances classified as carcinogen category 1A or 1B under the EU Classification and Labeling regulation (among other characteristics) in 2009. The restriction bans the placing on the market or use of TCE as substance, as constituent of other substances, or, in mixtures for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than 0.1 % w/w (Regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)).<br>Previous regulations, such as the Solvent Emissions Directive (Directive 1999/13/EC) introduced stringent emission controls of TCE. |

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|---|---|
| Australia | In 2000, TCE was assessed (National Industrial Chemicals Notification and Assessment Scheme, NICNAS, 2016, *Trichloroethylene*. Accessed April, 18 2017). |
| Japan Chemical Substances Control Law | TCE is regulated in Japan under the following legislation:<br>• Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL)<br>• Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof<br>• Industrial Safety and Health Act (ISHA)<br>• Air Pollution Control Law<br>• Water Pollution Control Law<br>• Soil Contamination Countermeasures Act<br>• Law for the Control of Household Products Containing Harmful Substances<br><br>(National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHIRP), Accessed April 18, 2017). |
| Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Japan, Latvia, New Zealand, People's Republic of China, Poland, Singapore, South Korea, Spain, Sweden, Switzerland, United Kingdom | Occupational exposure limits for TCE (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017). |

# Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for TCE.

## B.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities for consideration.

### B.1.1 Manufacture (including Import)

#### B.1.1.1 Domestic Manufacture

TCE was previously produced through chlorination of acetylene to 1,1,2,2-tetrachloroethane, then dehydrochlorination to TCE in an aqueous base or by thermal cracking (Snedecor et al., 2004). Due to rising costs of acetylene, this process has largely been phased-out (ATSDR, 2014; Snedecor et al., 2004). Currently, most TCE is manufactured via chlorination or oxychlorination of ethylene, dichloroethane or ethylene dichloride (EDC) (ATSDR, 2014; Snedecor et al., 2004).

- Chlorination - The chlorination process involves a catalytic reaction of chlorine and ethylene, dichloroethane or EDC to form TCE and perchloroethylene (PCE) as co-products and hydrochloric acid (HCl) as a byproduct (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985). Typical catalysts include potassium chloride, aluminum chloride, Fuller's earth, graphite, activated carbon and activated charcoal (Snedecor et al., 2004).
- Oxychlorination - The oxychlorination process involves the reaction of either chlorine or HCl and oxygen with ethylene, dichloroethane or EDC in the presence of a catalyst to produce TCE and PCE as co-products (ATSDR, 2014; Snedecor et al., 2004) . The process usually occurs in a fluidized-bed reactor (Snedecor et al., 2004). Common catalysts are mixtures of potassium and cupric chlorides (Snedecor et al., 2004).

In either process the product ratio of TCE to PCE products are controlled by adjusting the reactant rations (Snedecor et al., 2004).

#### B.1.1.2 Import

EPA has also not identified specific activities related to the import of TCE. EPA expects imported chemicals are stored in warehouses prior to distribution for further processing and use. In some cases, the chemicals may be repackaged into differently sized containers, depending on customer demand, and quality control (QC) samples may be taken for analyses.

According to Snedecor et al. (2004), TCE is typically shipped by truck or rail car or in 55-gallon drums. TCE may be stored in mild steel tanks equipped with vents and vent dryers to prevent water accumulation Snedecor et al. (2004).

### B.1.2 Processing and Distribution

#### B.1.2.1 Processing as a Reactant/ Intermediate

Processing as a reactant or intermediate is the use of TCE as a feedstock in the production of another chemical product via a chemical reaction in which TCE is consumed to form the product. TCE is used a s a feedstock in the production of HFCs alternatives to CFCs, specifically the HFC-134a alternative to CFC-12 (ATSDR, 2014; Elsheikh et al., 2005; Snedecor et al., 2004). The production of HFC-134a from TCE can be carried out in one of two processes (Elsheikh et al., 2005). In the first process, TCE is fluorinated in either a gas- or liquid-phase reaction with hydrofluoric acid using a Lewis acid catalyst to produce the hydrochlorofluorocarbon, HCFC-133a, which is then subsequently fluorinated to produce HFC-134a by reaction with hydrofluoric acid using a catalyst (Elsheikh et al., 2005; Smart and Fernandez, 2000). The second process involves fluorination of TCE using a chromium-based catalyst to form HCFC-133a as the major product and HFC-134a as the minor product (Elsheikh et al., 2005). The HFC-134a is then separated out using distillation and the HCFC-133a is recycled back through the reactor (Elsheikh et al., 2005).

#### B.1.2.2 Incorporating into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. The uses of TCE that may require incorporation into a formulation include adhesives, sealants, coatings and lubricants. TCE-specific formulation processes were not identified; however, several Emission Scenario Documents (ESDs) published by the OECD have been identified that provide general process descriptions for these types of products. The formulation of coatings typically involves dispersion, milling, finishing and filling into final packages (OECD, 2009b). Adhesive formulation involves mixing together volatile and non-volatile chemical components in sealed, unsealed or heated processes (OECD, 2009a). Sealed processes are most common for adhesive formulation because many adhesives are designed to set or react when exposed to ambient conditions (OECD, 2009a). Lubricant formulation typically involves the blending of two or more components, including liquid and solid additives, together in a blending vessel (OECD, 2004).

#### B.1.2.3 Repackaging

EPA has not identified specific information for the repackaging of TCE. EPA expects repackaging sites receive the chemical in bulk containers and transfer the chemical from the bulk container into another smaller container in preparation for distribution in commerce.

#### B.1.2.4 Recycling

TRI data from 2015 indicate that some sites ship TCE for off-site recycling. EPA did not identify TCE-specific information for recycling; however, a general description of waste solvent recovery processes was identified. Waste solvents are generated when the solvent stream becomes contaminated with suspended and dissolved solids, organics, water or other substance (U.S. EPA, 1980). Waste solvents can be restored to a condition that permits reuse via solvent reclamation/recycling (U.S. EPA, 1980). The recovery process involves an initial vapor recovery (e.g., condensation, adsorption and absorption) or mechanical separation (e.g., decanting, filtering, draining, setline and centrifuging) step followed by distillation, purification and final packaging (U.S. EPA, 1980).

### B.1.3 Uses

EPA assessed inhalation risks from TCE in vapor and aerosol degreasing, spot cleaning at dry cleaning facilities and arts and craft uses (U.S. EPA, 2014b) and also completed four supplemental analyses as identified in Table 1-1. Based on these analyses, EPA published two proposed rules to address the unreasonable risks presented by TCE use in vapor degreasing and in commercial and consumer aerosol degreasing and for spot cleaning at dry cleaning facilities (82 FR 7432, January 19, 2017; 81 FR 91592, December 16, 2016). Scenarios already assessed in the 2014 risk assessment will not be re-evaluated in the risk evaluation to which this scope applies.

#### B.1.3.1 Solvent for Cleaning or Degreasing

***Vapor Degreasing***

The process information for vapor degreasing systems is not provided in this scope document. This scenario was previously assessed in the 2014 risk assessment (U.S. EPA, 2014b) and will not be re-evaluated in the risk evaluation to which this scope applies.

***Conveyorized Vapor Degreasers***

Conveyorized vapor degreasing systems are solvent cleaning machines that use an automated parts handling system, typically a conveyor, to automatically provide a continuous supply of parts to be cleaned. Conveyorized degreasing systems are usually fully enclosed except for the conveyor inlet and outlet portals. Conveyorized degreasers are likely used in similar shop types as batch vapor degreasers except for repair shops, where the number of parts being cleaned is likely not large enough to warrant the use of a conveyorized system. There are seven major types of conveyorized degreasers: monorail degreasers, cross-rod degreasers, vibra degreasers, ferris wheel degreasers, belt degreasers, strip degreasers and circuit board degreasers (U.S. EPA, 1977).

***Cold Cleaners***

TCE can also be used as a solvent in cold cleaners, which are non-boiling solvent degreasing units. Cold cleaning operations include spraying, brushing, flushing and immersion; the use process and worker activities associated with cold cleaning have been previously described in EPA's TCE Risk Assessment (U.S. EPA, 2014a).

***Aerosol Spray Degreasers and Cleaners***

EPA assessed inhalation risks from TCE in vapor and aerosol degreasing, spot cleaning at dry cleaning facilities and arts and craft uses (U.S. EPA, 2014a) and also completed four supplemental analyses as identified in Table 1-1. Based on these analyses, EPA published two proposed rules to address the unreasonable risks presented by TCE use in vapor degreasing and in commercial and consumer aerosol degreasing and for spot cleaning at dry cleaning facilities (82 FR 7432, January 19, 2017; 81 FR 91592, December 16, 2016). Scenarios already assessed in the 2014 risk assessment (U.S. EPA, 2014a) will not be re-evaluated in the risk evaluation to which this scope applies.

***Non-Aerosol Degreasing and Cleaning***

TCE can also be used as a solvent in non-aerosol degreasing and cleaning products. Non-aerosol cleaning products typically involve dabbing or soaking a rag with cleaning solution and then using the rag to wipe down surfaces or parts to remove contamination (U.S. EPA, 2014a). The cleaning solvent is usually applied in excess and allowed to air-dry (U.S. EPA, 2014a). Parts may be cleaned in place or removed from the service item for more thorough cleaning (U.S. EPA, 2014a).

### B.1.3.2 Lubricants and Greases

The Use Document for TCE [EPA-HQ-OPPT-2016-0737-0003 (U.S. EPA, 2017a)] identified TCE in penetrating lubricants and tap and die fluids. EPA has not identified process information specific to tap and die fluids; however, the OECD ESD on Use of Metalworking Fluids provides a general process description for metalworking fluids. Metalworking fluids are unloaded, either diluted with water and transferred to the trough or directly transferred to the trough without dilution (OECD, 2011). The fluid is then pumped from the trough and applied to the metal parts, as needed, during shaping (OECD, 2011). Parts are then allowed to drip dry and the fluids are collected and treated with other process fluids (OECD, 2011). Parts may be rinsed down or wiped and then cleaned via alkaline cleaning or degreasing prior to the final finishing operations (OECD, 2011). Any metalworking fluid residue remaining on the part is removed during the cleaning or degreasing operation (OECD, 2011).

EPA has not identified process-specific information regarding the use of TCE in penetrating lubricants. More information on this use will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

### B.1.3.3 Adhesive and Sealants

Based on products identified in EPA's Use Document, EPA-HQ-OPPT-2016-0737-0003, TCE may be used in adhesive and sealants for industrial, commercial and consumer applications. EPA did not identify TCE-specific information for adhesive and sealant use; however, the OECD ESD for Use of Adhesives provides general process descriptions and worker activities for industrial adhesive uses. Liquid adhesives are unloaded from containers into the coating reservoir, applied to a flat or three-dimensional substrate and the substrates are then joined and allowed to cure (OECD, 2013). The majority of adhesive applications include spray, roll, curtain, syringe or bead application (OECD, 2013). For solvent-based adhesives, the volatile solvent (in this case TCE) evaporates during the curing stage (OECD, 2013).

EPA's Use Document, EPA-HQ-OPPT-2016-0737-0003 indicates that adhesives and sealants containing TCE may be used in both commercial and consumer applications. EPA did not identify process information for commercial and consumer use of adhesives and sealants; EPA anticipates that the application methods for commercial and consumer uses may include spray, brush, syringe, eyedropper, roller and bead applications.

### B.1.3.4 Cleaning and Furniture Care Products

EPA interprets this reported commercial/consumer use category in CDR "Cleaning and Furniture Care Products" to include the use of TCE in spot cleaning and carpet cleaning applications. This use includes both professional spot cleaning (dry cleaning) and carpet cleaning activities as well as use in consumer purchased spot cleaning and carpet cleaning products.

### B.1.3.5 Paints and Coatings

Based on products identified in EPA's Use Document, EPA-HQ-OPPT-2016-0737-0003, TCE may be used in various paints and coatings for industrial, commercial and consumer applications. EPA did not identify TCE specific information for paints and coating use; however, several OECD ESDs and EPA generic scenarios provide general process descriptions and worker activities for industrial and commercial uses. Typical coating applications include manual application with roller or brush, air spray systems, airless and air-assisted airless spray systems, electrostatic spray systems, electrodeposition/electrocoating and autodeposition, dip coating, curtain coating systems, roll coating

systems and supercritical carbon dioxide systems (OECD, 2009b). After application, solvent-based coatings typically undergo a drying stage in which the solvent evaporates from the coating (OECD, 2009b).

#### B.1.3.6 Other Uses

Based on products identified in EPA's Use Document, EPA-HQ-OPPT-2016-0737-0003, a variety of other uses may exist for TCE, including use in hoof polish, pepper spray and as a toner aide. It is unclear at this time the total volume of TCE used in any of these applications. EPA has not identified any information to further refine the use of TCE in these products at this time; more information on these uses will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

### B.1.4 Disposal

Federal regulations prevent land disposal of various chlorinated solvents (including TCE) (ATSDR, 2014). The recommended disposal method is mixing with a combustible fuel followed by incineration (ATSDR, 2014). In incineration, complete combustion is necessary to prevent phosgene or other toxic byproduct formation (ATSDR, 2014).

## B.2 Occupational Exposure Data

EPA presents below an example of occupational exposure-related information from the preliminary data gathering. EPA will consider this information and data in combination with other data and methods for use in the risk evaluation.

Table_Apx B-1 summarizes the industry sectors with TCE OSHA CEHD data (OSHA, 2017).

**Table_Apx B-1. Summary of Industry Sectors with TCE Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2003 and 2017**

| NAICS Code | NAICS Description |
|---|---|
| 236220 | Commercial and institutional building construction |
| 313312 | Bleaching textile products, apparel and fabrics (except broadwoven) |
| 313320 | Fabric coating mills |
| 314999 | All other miscellaneous textile product mills |
| 325212 | Synthetic rubber manufacturing |
| 325520 | Adhesive manufacturing |
| 326150 | Urethane and other foam product (except polystyrene) manufacturing |
| 326199 | All other plastics product manufacturing |
| 326211 | Tire manufacturing (except retreading) |
| 326299 | All other rubber product manufacturing |
| 331210 | Iron and steel pipe and tube manufacturing from purchased steel |
| 331491 | Nonferrous metal (except copper and aluminum) rolling, drawing and extruding |
| 331512 | Steel investment foundries |
| 331528 | Beryllium castings (except die-castings), unfinished manufacturing |

| NAICS Code | NAICS Description |
|---|---|
| 332116 | Metal stampings (except automotive, cans, cooking, closures, crowns), unfinished, manufacturing |
| 332439 | Other metal container manufacturing |
| 332710 | Machine shops |
| 332721 | Precision turned product manufacturing |
| 332722 | Bolt, nut, screw, rivet and washer manufacturing |
| 332811 | Metal heat treating |
| 332813 | Electroplating, plating, polishing, anodizing and coloring |
| 332991 | Ball and roller bearing manufacturing |
| 332994 | Small arms, ordnance and ordnance accessories manufacturing |
| 332996 | Fabricated pipe and pipe fitting manufacturing |
| 332999 | All other miscellaneous fabricated metal product manufacturing |
| 333111 | Farm machinery and equipment manufacturing |
| 333513 | Arbor presses, metalworking, manufacturing |
| 334412 | Bare printed circuit board manufacturing |
| 334419 | Other electronic component manufacturing |
| 334513 | Instruments and related products manufacturing for measuring, displaying and controlling industrial process variables |
| 335311 | Power, distribution and specialty transformer manufacturing |
| 336370 | Motor vehicle metal stamping |
| 339114 | Dental equipment and supplies manufacturing |
| 339950 | Sign manufacturing |
| 339991 | Industrial machinery and equipment merchant wholesalers |
| 423830 | Plastics materials and basic forms and shapes merchant wholesalers |
| 424610 | Dry cleaning and laundry services (except coin-operated) |
| 812320 | Industrial launderers |
| 926150 | Space research and technology |
| 927110 | Industrial machinery and equipment merchant wholesalers |