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Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro)

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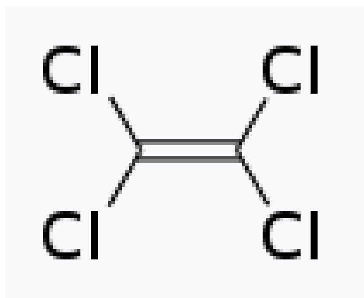

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ABBREVIATIONS

°C	Degrees Celsius
1-BP	1-Bromopropane
ACGIH	American Conference of Government Industrial Hygienists
AEGL	Acute Exposure Guideline Level
ATSDR	Agency for Toxic Substances and Disease Registries
atm	Atmosphere(s)
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL_4	Carbon Tetrachloride
CDC	Centers for Disease Control
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEPA	Canadian List of Toxic Substances
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFC	Chlorofluorocarbon
CHIRP	Chemical Risk Information Platform
cm^3	Cubic Centimeter(s)
COC	Concentration of Concern
CoRAP	Community Rolling Action Plan
cP	Centipoise
CPCat	Chemical and Product Categories
CPSC	Consumer Product Safety Commission
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DNAPL	Dense Non-Aqueous Phase Liquid
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 Documents
EU	European Union
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
FHSA	Federal Hazardous Substance Act
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
g	Gram(s)
GACT	Generally Available Control Technology
HAP	Hazardous Air Pollutant
HCFC	Hydrochlorofluorocarbon
HCl	Hydrochloric Acid
HFC	Hydrofluorocarbon
HSIA	Halogenated Solvents Industry Association
HPV	High Production Volume

Hr	Hour
IARC	International Agency for Research on Cancer
IDLH	Immediately Dangerous to Life and Health
i.p.	Intraperitoneal
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act
kg	Kilogram(s)
L	Liter(s)
lb	Pound(s)
Log K_{oc}	Logarithmic Organic Carbon:Water Partition Coefficient
Log K_{ow}	Logarithmic Octanol:Water Partition Coefficient
m^3	Cubic Meter(s)
MACT	Maximum Achievable Control Technology
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
mg	Milligram(s)
µg	Microgram(s)
mmHg	Millimeter(s) of Mercury
MOA	Mode of Action
MSDS	Material Safety Data Sheet
n	Number
NAAQS	National Ambient Air Quality Standards
NAC	National Advisory Committee
NAICS	North American Industry Classification System
NCEA	National Center for Environmental Assessment
NEI	National Emissions Inventory
NESHAP	National Emission Standards for Hazardous Air Pollutants
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIH	National Institutes of Health
NIOSH	National Institute of Occupational Safety and Health
NITE	National Institute of Technology and Evaluation
NPL	National Priorities List
NTP	National Toxicology Program
OAQPS	Office of Air Quality Planning and Standards
OCSPP	Office of Chemical Safety and Pollution Prevention
ODS	Ozone Depleting Substance
OECD	Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment
OEL	Occupational Exposure Limit
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBZ	Personal Breathing Zone
PCE	Perchloroethylene
PEL	Permissible Exposure Limit
PESS	Potentially Exposed Susceptible Subpopulation
POD	Point of Departure

POTW	Publicly Owned Treatment Works
ppb	Part(s) per Billion
PPE	Personal Protective Equipment
ppm	Part(s) per Million
PWS	Public Water System
RCRA	Resource Conservation and Recovery Act
SARA	Superfund Amendments and Reauthorization Act
SCHER	Scientific Committee on Health and Environmental Risks
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SIDS	Screening Information Data Set
SNAP	Significant New Alternatives Policy
STEL	Short-Term Exposure Limit
$t_{1/2}$	Half-life
TCCR	Transparent, Clear, Consistent, and Reasonable
TCE	Trichloroethylene
TLV	Threshold Limit Value
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TTO	Total Toxic Organics
TWA	Time-Weighted Average
U.S.	United States
VOC	Volatile Organic Compound
WHO	World Health Organization
Yr	Year(s)

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). Perchloroethylene 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. In June 2017, EPA published the Scope of the Risk Evaluation for perchloroethylene. As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for perchloroethylene. Comments received on this problem formulation document will inform development of the draft risk evaluation.

This problem formulation document refines the conditions of use, exposures and hazards presented in the scope of the risk evaluation for perchloroethylene and presents refined conceptual models and analysis plans that describe how EPA expects to evaluate the risk for perchloroethylene.

Perchloroethylene, also known as ethene, 1,1,2,2-tetrachloro, tetrachloroethylene and PCE, is a high production volume (HPV) solvent. Perchloroethylene is subject to a number of federal and state regulations and reporting requirements. For example, perchloroethylene has been a Toxics Release Inventory (TRI) reportable chemical under Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) since 1995. It is designated a Hazardous Air Pollutant (HAP) under the Clean Air Act (CAA), a hazardous waste under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) and a regulated drinking water contaminant under the Safe Drinking Water Act (SDWA).

Information on the domestic manufacture, processing and use of perchloroethylene is available to EPA through its Chemical Data Reporting (CDR) Rule, issued under TSCA. According to the 2016 CDR, more than 324 million pounds of perchloroethylene were manufactured (including imported) in the United States in 2015. According to the *Use and Market Profile for Tetrachloroethylene* (EPA-HQ-OPPT-2016-0732), perchloroethylene is primarily used to produce fluorinated compounds, such as hydrofluorocarbons (HFCs) and hydrochlorofluorocarbons (HCFCs) (65%) followed by dry cleaning (15%) and vapor degreasing solvents (10%). Other uses can be quite varied, including:

- Adhesives
- Degreasing
- Brake cleaner
- Laboratories
- Lubricants
- Mold cleaners, releases and protectants
- Oil refining

- Sealants
- Stainless steel polish
- Tire buffers and cleaners and
- Vandal mark removers.

This document presents the potential exposures that may result from the conditions of use of perchloroethylene. Exposures may occur to workers and occupational non-users (workers who do not directly handle the chemical but perform work in an area where the chemical is used), consumers and bystanders (non-product users that are incidentally exposed to the product) and the general population through inhalation, dermal and oral pathways. Workers and occupational non-users (ONU), who do not directly handle the chemical but perform work in an area where the chemical is used, may be exposed to perchloroethylene during a variety of conditions of use, such as manufacturing, processing and industrial and commercial uses, including uses in degreasing and adhesives. EPA expects that the highest exposures to perchloroethylene generally involve workers in industrial and commercial settings. Perchloroethylene can be found in numerous products and can, therefore, result in exposures to commercial and consumer users in indoor or outdoor environments. For perchloroethylene, EPA considers workers, occupational non-users, consumers, bystanders, and certain other groups of individuals who may experience greater exposures than the general population due to proximity to conditions of use to be potentially exposed or susceptible subpopulations. Exposures to the general population may occur from industrial and/or commercial uses; industrial releases to air, water or land; and other conditions of use. EPA will evaluate whether 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) that increase exposure and whether groups of individuals have heightened susceptibility, and should therefore be considered potentially exposed or susceptible subpopulations for purposes of the risk evaluation. EPA plans to further analyze inhalation exposures to vapors and mists for workers and occupational non-users and dermal exposures for skin contact with liquids in occluded situations for workers in the risk evaluation. For environmental release pathways, EPA plans to further analyze surface water exposure to aquatic vertebrates, invertebrates and aquatic plants and exposure to sediment-dwelling organisms.

Perchloroethylene has been the subject of several prior health hazard and risk assessments, including EPA’s Integrated Risk Information System (IRIS) Toxicological Review and a draft Agency for Toxic Substances and Disease Registry’s (ATSDR’s) Toxicological Profile. A number of targets of toxicity from exposures to perchloroethylene have been identified in animal and human studies for both oral and inhalation exposures. EPA plans to evaluate all potential hazards for perchloroethylene, using the primary literature identified in human health reviews and including any found in recent literature. Hazard endpoints identified in previous assessments include: acute toxicity, neurotoxicity, kidney toxicity, liver toxicity, developmental and reproductive toxicity and cancer. Support for an association with immune and blood effects was less well characterized. Perchloroethylene is also considered to be irritating.

The revised conceptual models presented in this problem formulation identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed or susceptible subpopulations; and hazards EPA expects to consider in the risk evaluation. The initial conceptual models provided in the scope document were revised during problem formulation based on evaluation of reasonably available information for physical and chemical properties, fate, exposures, hazards and conditions of use, and based upon consideration of other statutory and regulatory authorities. In each problem formulation document for the first 10 chemical substances, EPA also refined the activities, hazards and exposure pathways that will be included in and excluded from the risk evaluation.

EPA's overall objectives in the risk evaluation process are to conduct timely, relevant, high-quality, and scientifically credible risk evaluations within the statutory deadlines, and to evaluate the conditions of use that raise greatest potential for risk 82 FR 33726, 33728 (July 20, 2017).

1 INTRODUCTION

This document presents for comment the problem formulation of the risk evaluation to be conducted for perchloroethylene under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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, within 6 months after the initiation of a risk evaluation. The scope documents for all first 10 chemical substances were issued on June 22, 2017. The first 10 problem formulation documents are a refinement of what was presented in the first 10 scope documents. TSCA § 6(b)(4)(D) does not distinguish between scoping and problem formulation, and requires EPA to issue scope documents that include information about the chemical substance, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that the Administrator expects to consider in the risk evaluation. In the future, EPA expects scoping and problem formulation to be completed prior to the issuance of scope documents and intends to issue scope documents that include problem formulation.

As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for perchloroethylene. Comments received on this problem formulation document will inform development of the draft risk evaluation.

The Agency defines problem formulation as the analytical phase of the risk assessment in which "the purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined" (see Section 2.2 of the Framework for Human Health Risk Assessment to Inform Decision Making). The outcome of problem formulation is a conceptual model(s) and an analysis plan. The conceptual model describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed life stage(s) and population(s), and endpoint(s) that will be addressed in the risk evaluation (U.S. EPA, 2014e). The analysis plan follows the development of the conceptual model(s) and is intended to describe the approach for conducting the risk evaluation, including its design, methods and key inputs and intended outputs as described in the EPA Human Health Risk Assessment Framework (U.S. EPA, 2014e). The problem formulation documents refine the initial conceptual models and analysis plans that were provided in the scope documents.

First, EPA has removed from the risk evaluation any activities and exposure pathways that EPA has concluded do not warrant inclusion in the risk evaluation. For example, for some activities which were listed as "conditions of use" in the scope document, EPA has insufficient information following the further investigations during problem formulation to find they are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

Second, EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA) – and which EPA does not expect to include in the risk evaluation.

As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes.[1] EPA does not expect to include tany such excluded pathways as further explained below in the risk evaluation. The provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes.

Third, EPA identified any conditions of use, hazards, or exposure pathways which were included in the scope document and that EPA expects to include in the risk evaluation but which EPA does not expect to further analyze in the risk evaluation. EPA expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis and therefore expects to conduct no further analysis on those conditions of use, hazards or exposure pathways in order to focus the Agency's resources on more extensive or quantitative analyses. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations 82 FR 33726, 33734, 33739 (July 20, 2017).

EPA received comments on the published scope document for perchloroethylene and has considered the comments specific to perchloroethylene in this problem formulation document. EPA is soliciting public comment on this problem formulation document and when the draft risk evaluation is issued the Agency intends to respond to comments that are submitted. In its draft risk evaluation, EPA may revise the conclusions and approaches contained in this problem formulations, including the conditions of use and pathways covered and the conceptual models and analysis plans, based on comments received.

[1] As explained in the final rule for chemical risk evaluation procedures, "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, and consequently merit an unreasonable risk determination." [82 FR 33726, 33734, 33729 (July 20, 2017)]

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to perchloroethylene. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. EPA has evaluated and considered the impact of these existing laws and regulations (e.g., regulations on landfill disposal, design, and operations) in the problem formulation step to determine what, if any, further analysis might be necessary as part of the risk evaluation. Consideration of the nexus between these existing regulations and TSCA conditions of use may additionally be made as detailed/specific conditions of use and exposure scenarios are developed in conducting the analysis phase of the risk evaluation.

Federal Laws and Regulations

Perchloroethylene 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

Perchloroethylene 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

Perchloroethylene is subject to statutes or regulations in countries other than the United States. A summary of these laws and regulations 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. Table 1-1 shows the assessments that have been conducted. This table includes one additional document identified since the publication of the Scope document from the Office of Health and Environmental Assessment.

In addition to using this information, EPA intends to conduct a full review of the relevant data/information collected in the initial comprehensive search [see *Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0732)], using the literature search strategy [see *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document,* (EPA-HQ-OPPT-2016-0732)]. This will ensure that EPA considers data/information that has been made available since these assessments were conducted.

Table 1-1. Assessment History of Perchloroethylene

Authoring Organization	Assessment
EPA Assessments	
Integrated Risk Information System (IRIS)	Toxicological Review of Tetrachloroethylene (Perchloroethylene) (CAS No. 127-18-4) U.S. EPA (2012e)
Office of Air Quality Planning and Standards (OAQPS)	Perchloroethylene Dry Cleaners Refined Human Health Risk Characterization U.S. EPA (2005b)

Authoring Organization	Assessment
National Center for Environmental Assessment (NCEA)	Sources, Emission and Exposure for Trichloroethylene (TCE) and Related Chemicals U.S. EPA (2001c)
Office of Air Toxics	Tetrachloroethylene (Perchloroethylene); 127-18-4 U.S. EPA (2000b)
Office of Pesticides and Toxic Substances (now, Office of Chemical Safety and Pollution Prevention [OCSPP])	Occupational Exposure and Environmental Release Assessment of Tetrachloroethylene U.S. EPA (1985b)
Office of Health and Environmental Assessment	Final Health Effects Criteria Document for Tetrachloroethylene U.S. EPA (1985a)
Office of Water (OW)	Update of Human Health Ambient Water Quality Criteria: Tetrachloroethylene (Perchloroethylene) 127-18-4 U.S. EPA (2015b)
Office of Water (OW)	Ambient Water Quality Criteria for Tetrachloroethylene U.S. EPA (1980a)
Other U.S.-Based Organizations	
California Environmental Protection Agency, Office of Environmental Health Hazard Assessment (OEHHA), Air Toxics Hot Spots Program	Perchloroethylene Inhalation Cancer Unit Risk Factor Cal/EPA (2016)
Agency for Toxic Substances and Disease Registry (ATSDR)	Toxicological Profile for Tetrachloroethylene (PERC) (Draft) ATSDR (2014)
National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL Committee)	Tetrachloroethylene NAC/AEGL (2009)
California Environmental Protection Agency, OEHHA, Pesticide and Environmental Toxicology Section	Public Health Goal for Tetrachloroethylene in Drinking Water Cal/EPA (2001)
National Toxicology Program (NTP)	Toxicology and Carcinogenesis Studies of Tetrachloroethylene (Perchloroethylene); (CAS No. 127-18-4) in F344/N Rats and B6C3F1 Mice NTP (1986)
International	
International Agency for Research on Cancer (IARC)	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Tetrachloroethylene IARC (2014b)
European Union (EU), Scientific Committee on Health and Environmental Risks (SCHER)	SCHER, Scientific Opinion on the Risk Assessment Report on Tetrachloroethylene, Human Health Part, CAS No.: 127-18-4, 12 SCHER (2008)

Authoring Organization	Assessment
World Health Organization (WHO)	Concise International Chemical Assessment Document 68; Tetrachloroethylene WHO (2006)
EU, European Chemicals Bureau (ECB)	EU Risk Assessment Report; Tetrachloroethylene, Part 1 - environment (2005a)
National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Australia	Tetrachloroethylene; Priority Existing Chemical Assessment Report No. 15 NICNAS (2001)

1.3 Data and Information Collection

EPA/OPPT generally applies a systematic review process and workflow that includes: (1) data collection (2) data evaluation and (3) data integration of the scientific data used in risk evaluations 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 may occur during the process of risk evaluation. Additional information that may be considered and was not part of the initial comprehensive bibliographies will be documented in the Draft Risk Evaluation for perchloroethylene.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental and 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). For human health hazard, EPA/OPPT relied on the search strategies from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments, to identify relevant information published after the end date of the previous search to capture more recent literature. The *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0732) provides details about the data and information sources and search terms that were used in the literature 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 Perchloroethylene: Supplemental File for the TSCA Scope Document* (U.S. EPA, 2017d). 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 supplemental document: *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document* discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic* (U.S. EPA, 2017d).

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 supplemental document: *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document* and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review (U.S. EPA, 2017d).

Results of the initial search and categorization can be found in the supplemental document *Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0732) (U.S. EPA, 2017b). 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.

1.4 Data Screening During Problem Formulation

EPA/OPPT is in the process of completing the full text screening of the on-topic references identified in the *Perchloroethylene (CASRN: 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document* (U.S. EPA, 2017b). The screening process at the full-text level is described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a). Appendix F provides the inclusion and exclusion criteria applied at the full text screening. The eligibility criteria are guided by the analytical considerations in the revised conceptual models and analysis plan, as discussed in the problem formulation document. Thus, it is expected that the number of data/information sources entering evaluation is reduced to those that are relevant to address the technical approach and issues described in the analysis plan of this document.

Following the screening process, the quality of the included data/information sources will be assessed using the evaluation strategies that are described in *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018b).

2 PROBLEM FORMULATION

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 included in the scope document a life cycle diagram and conceptual models that describe the actual or potential relationships between perchloroethylene and human and ecological receptors. During the problem formulation, EPA revised the conceptual models based on further data gathering and analysis as presented in this problem formulation document. An updated 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 perchloroethylene.

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; EPA found no additional information during problem formulation that would change these values.

Table 2-1. Physical and Chemical Properties of Perchloroethylene

Property	Value[a]	References
Molecular formula	C_2Cl_4	
Molecular weight	165.833	
Physical form	Colorless liquid; ether-like, mildly sweet odor	Lewis (2007); NIOSH (2005); U.S. Coast Guard (1984)
Melting point	-22.3°C	Lide (2007)
Boiling point	121.3°C	Lide (2007)
Density	1.623 g/cm^3 at 20°C	Lide (2007)
Vapor pressure	18.5 mmHg at 25°C	Riddick et al. (1985)
Vapor density	5.7 (relative to air)	Browning (1965)
Water solubility	206 mg/L at 25°C	Horvath (1982)
Octanol:water partition coefficient (K_{ow})	3.40	Hansch et al. (1995)
Henry's Law constant	0.0177 atmm^3/mole	Gossett (1987)
Flash point	Not applicable	NFPA (2010)
Autoflammability	Not readily available	
Viscosity	0.839 cP @at 25°C	Hickman (2000)
Refractive index	1.4775	Lide (2007)
Dielectric constant	0 D	

[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

In the 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 Tetrachloroethylene*, EPA-HQ-OPPT-2016-0732). 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: Tetrachloroethylene (Perchloroethylene) and Use*, EPA-HQ-OPPT-2016-0732] 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 problem formulation document to the extent appropriate. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseeable activities associated with the subject chemical, based on reasonably available information.

2.2.2 Identification of Conditions of Use

To determine the current conditions of use of perchloroethylene and inversely, activities that do not qualify as conditions of use, EPA conducted extensive research and outreach. This included EPA's review of published literature and online databases including the most recent data available from EPA's Chemical Data Reporting program (CDR) and Safety Data Sheets (SDSs). EPA also conducted online research by reviewing company websites of potential manufacturers, importers, distributors, retailers, or other users of perchloroethylene and queried government and commercial trade databases. EPA also received comments on the Scope of the Risk Evaluation for perchloroethylene (EPA-HQ-OPPT-2016-0732) that were used to determine the conditions of use. In addition, EPA convened meetings with companies, industry groups, chemical users, states, environmental groups, and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. Those meetings included a February 14, 2017 public meeting with such entities (EPA-HQ-OPPT-2016-0732).

EPA has removed from the risk evaluation any activities that EPA concluded do not constitute conditions of use – for example because EPA has insufficient information to find certain activities are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." EPA has also identified any conditions of use that EPA does not expect to include in the risk evaluation. As explained in the final rule for Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, TSCA Section 6(b)(4)(D) requires EPA to identify "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider" in a risk evaluation, suggesting that EPA is not required to consider all conditions of use, and EPA may exclude certain activities that EPA has determined to be conditions of use on a case-by-case basis 82 FR 33736, 33729 (July 20, 2017). For example, EPA may exclude conditions of use that the Agency has sufficient basis to conclude would present only de minimus exposures or otherwise insignificant risks (such as use in a closed system that effectively precludes exposure or as an intermediate).

The activities that EPA no longer believes are conditions of use or were otherwise excluded during problem formulation are described in Section 2.2.2.1. The conditions of use included in the scope of the risk evaluation are summarized in Section 2.2.2.2.

2.2.2.1 Categories and Subcategories Determined Not to be Conditions of Use During Problem Formulation

For perchloroethylene, EPA has conducted public outreach and literature searches to collect information about perchloroethylene's conditions of use and has reviewed reasonably available information obtained or possessed by EPA concerning activities associated with perchloroethylene. Based on the foregoing research and outreach, EPA does not have reason to believe that any categories or subcategories identified in the perchloroethylene scope should be excluded from the scope of the risk evaluation. Therefore, no categories or subcategories of use for perchloroethylene will be excluded from the scope of the risk evaluation.

Table 2-2. Categories and Subcategories Determined Not to be Conditions of Use During Problem Formulation

Life Cycle Stage	Category [a]	Subcategory [b]	References
No categories or subcategories have been excluded from the risk evaluation.			

2.2.2.2 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

The uses of perchloroethylene include the production of fluorinated compounds, dry cleaning and vapor degreasing, as well as a number of smaller uses. Nearly 65% of the production volume of perchloroethylene is used as an intermediate in industrial gas manufacturing, more specifically to produce fluorinated compounds, such as hydrofluorocarbons (HFCs) and hydrochlorofluorocarbons (HCFCs) (NTP, 2014; ICIS, 2011). HFCs 134a and 125 are alternatives to chlorofluorocarbons (CFCs) and HCFCs, which are ozone depleting substances (ODSs), and the subject of a phase-out (https://www.epa.gov/ods-phaseout). HCFCs are transitional substances in the phase-out of ODSs (ICIS, 2011) (Public Comment, EPA-HQ-OPPT-2016-0732-0033). Previously, perchloroethylene was widely used to manufacture CFCs (esp. trichlorotrifluoroethane (CFC-113)) until production and importation of CFCs for most uses were phased out in the United States by regulations implementing the Montreal Protocol (40 CFR part 82). A relatively small amount of CFC-113 is still produced for exempted uses (teleconference with Honeywell, 2017; summary is available in the docket: EPA-HQ-OPPT-2016-0732).

The second largest use of perchloroethylene (~15%) is as a solvent in dry cleaning facilities (NTP, 2014). Perchloroethylene is non-flammable and effectively dissolves fats, greases, waxes and oils, without harming natural or human-made fibers. These properties enabled it to replace traditional petroleum solvents(ATSDR, 2014; Dow Chemical Co, 2008; Tirsell, 2000). The demand for perchloroethylene dry cleaning solvents has steadily declined as a result of the improved efficiency of dry cleaning equipment, increased chemical recycling and the popularity of wash-and-wear fabrics that eliminate the need for dry cleaning (ATSDR, 2014). Perchloroethylene is also used in dry cleaning detergent and dry cleaning sizing.

Approximately 60% of dry cleaning machines now use perchloroethylene as a solvent (DLI and NCA, 2017). In 1991, EPA estimated that 83% of all dry cleaning facilities used perchloroethylene as solvent (U.S. EPA, 1991). In 2008, the Halogenated Solvents Industry Association (HSIA) estimated that 70% of dry cleaners used perchloroethylene as dry cleaning solvent (EPA-HQ-OPPT-2016-0732-0027). Similarly, in 2011, King County, WA conducted a profile of the dry cleaning industry and found that 69% of respondents (105 of the 152 respondents) used perchloroethylene in their primary machine (Whittaker and Johanson, 2011). Hence, there appears to be a trend towards alternatives to perchloroethylene in dry cleaning. According to the dry cleaning industry, a majority of new perchloroethylene dry cleaning machines are sold in locations where local fire codes preclude the use of Class III combustible alternative solvents or where the nature of the dry cleaning operation requires the use of perchloroethylene (DLI and NCA, 2017).

The third most prevalent use of perchloroethylene (~10%) is as a vapor degreasing solvent (NTP, 2014). Perchloroethylene can be used to dissolve many organic compounds, select inorganic compounds and high-melting pitches and waxes making it ideal for cleaning contaminated metal parts and other fabricated materials (ATSDR, 2014). It is a very good solvent for greases, fats, waxes, oils, bitumen, tar and many natural and synthetic resins for use in chemical cleaning systems, degreasing light and heavy metals, degreasing pelts and leather (tanning), extraction of animal and vegetable fats and oils and textile dyeing (solvent for dye baths)(Stoye, 2000). Perchloroethylene is also used in cold cleaning, which is similar to vapor degreasing, except that cold cleaning does not require the solvent to be heated to its boiling point in order to clean a given component. Vapor degreasing and cold cleaning scenarios may include a range of open-top or closed systems, conveyorized/enclosed/inline systems, spray wands, dip containers and wipes.

Perchloroethylene has many other uses, which collectively constitute ~10% of the production volume. EPA's search of safety data sheets, government databases and other sources found over 375 products containing perchloroethylene. These uses include (but are not limited to):

- Adhesives
- Aerosol degreasing
- Brake cleaner
- Laboratories
- Lubricants
- Mold cleaners, releases and protectants
- Oil refining
- Sealants
- Stainless steel polish
- Tire buffers and cleaners
- Vandal mark removers

Many of these uses include consumer products, such as adhesives (arts and crafts, as well as light repairs), aerosol degreasing, brake cleaners, aerosol lubricants, sealants, sealants for gun ammunition, stone polish, stainless steel polish and wipe cleaners. The uses of perchloroethylene in consumer adhesives and brake cleaners are especially prevalent; EPA has found 16 consumer adhesive products and 14 consumer brake cleaners containing perchloroethylene [see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* and *Use and Market Profile for Tetrachloroethylene*, EPA-HQ-OPPT-2016-0732-0003].

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of conditions of use for perchloroethylene that EPA expects to consider in the risk evaluation. Using the 2016 CDR (U.S. EPA, 2016b), EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories. 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 certain relevant potential sources of release and human exposure associated with that life cycle stage.

Beyond the uses identified in the *Scope of the Risk Evaluation for Perchloroethylene*, EPA has received no additional information identifying additional current conditions of use for perchloroethylene from public comment and stakeholder meetings.

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

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 or intermediate	Intermediate in industrial gas manufacturing	U.S. EPA (2016b); Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0013; Public Comment, Public Comment, EPA-HQ-OPPT-2016-0732-DRAFT-0018; Public Comment, Public Comment, EPA-HQ-OPPT-2016-0732-0033
		Intermediate in basic organic chemical manufacturing	U.S. EPA (2016b); Market Profile, EPA-HQ-OPPT-2016-0732;
		Intermediate in petroleum refineries	U.S. EPA (2016b); Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0018
		Residual or byproduct	Public Comment, EPA-HQ-OPPT-2016-0732-0013
	Incorporated into formulation, mixture or reaction product	Cleaning and degreasing products	U.S. EPA (2016b); Public Comment, EPA-HQ-OPPT-2016-0732-0017
		Adhesive and sealant products	U.S. EPA (2016b)
		Paint and coating products	U.S. EPA (2016b)
		Other chemical products and preparations	U.S. EPA (2016b)
	Incorporated into articles	Plastic and rubber products	Use Document, EPA-HQ-OPPT-2016-0732-0003
	Repackaging	Solvent for cleaning or degreasing	U.S. EPA (2016b)
		Intermediate	U.S. EPA (2016b)
	Recycling	Recycling	U.S. EPA (2016b)
Distribution in commerce	Distribution	Distribution	Use Document, EPA-HQ-OPPT-2016-0732-0003

Life Cycle Stage	Category [a]	Subcategory [b]	References
Industrial use	Solvents (for cleaning or degreasing)	Solvents and/or Degreasers (cold, aerosol spray or vapor degreaser; not specified in comment)	Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0022; Public Comment, EPA-HQ-OPPT-2016-0732-0029
		Batch vapor degreaser (e.g., open-top, closed-loop)	U.S. EPA (1985b); Public Comment, EPA-HQ-OPPT-2016-0732-0015; Public Comment, EPA-HQ-OPPT-2016-0732-0027
		In-line vapor degreaser (e.g., conveyorized, web cleaner)	U.S. EPA (1985b); Public Comment, EPA-HQ-OPPT-2016-0732-0014
	Solvents (for cleaning or degreasing)	Cold cleaner	Market Profile, EPA-HQ-OPPT-2016-0732; ; Public Comment, EPA-HQ-OPPT-2016-0732-0017
		Aerosol spray degreaser/cleaner	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0017
		Dry cleaning solvent	Market Profile, EPA-HQ-OPPT-2016-0732; U.S. EPA (2006a)
		Spot cleaner	Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009
	Lubricants and greases	Lubricants and greases (e.g., penetrating lubricants, cutting tool coolants, aerosol lubricants)	U.S. EPA (2016b); Market Profile, ; Public Comment, EPA-HQ-OPPT-2016-0732-0027; Public Comment, EPA-HQ-OPPT-2016-0732-0029; Public Comment, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0027; Public

Life Cycle Stage	Category [a]	Subcategory [b]	References
			Comment, EPA-HQ-OPPT-2016-0732-0029
	Adhesive and sealant chemicals	Solvent-based adhesives and sealants	U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0015; Public Comment, EPA-HQ-OPPT-2016-0732-0022; Public Comment, EPA-HQ-OPPT-2016-0732-0027
	Paints and coatings including paint and coating removers	Solvent-based paints and coatings, including for chemical milling	U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0006; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0015; Public Comment, EPA-HQ-OPPT-2016-0732-0020; Public Comment, EPA-HQ-OPPT-2016-0732-0027; Public Comment,EPA-HQ-OPPT-2016-0732-0062
	Processing aids, not otherwise listed	Pesticide, fertilizer and other agricultural chemical manufacturing	U.S. EPA (2016b)
	Processing aids, specific to petroleum production	Catalyst regeneration in petrochemical manufacturing	U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Dow Chemical Co (2008); Public Comment, EPA-HQ-OPPT-2016-0732-0018; Public Comment, EPA-HQ-OPPT-2016-0732-0027

Life Cycle Stage	Category [a]	Subcategory [b]	References
	Other uses	Textile processing	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732
		Wood furniture manufacturing	Use Document, EPA-HQ-OPPT-2016-0732-0003
		Laboratory chemicals	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0015
		Foundry applications	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732
Commercial/consumer use	Cleaning and furniture care products	Cleaners and degreasers (other)	Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0017; Public Comment, EPA-HQ-OPPT-2016-0732-0022; EPA-HQ-OPPT-2016-0732-0023; Public Comment, EPA-HQ-OPPT-2016-0732-0027; Public Comment, EPA-HQ-OPPT-2016-0732-0029
		Dry cleaning solvent	Market Profile, EPA-HQ-OPPT-2016-0732; U.S. EPA (2006a); Public Comment, EPA-HQ-OPPT-2016-0732-0007; Public Comment, EPA-HQ-OPPT-2016-0732-0009
		Spot cleaner	Market Profile, EPA-HQ-OPPT-2016-0732; U.S. EPA (2006a); Public Comment, EPA-HQ-OPPT-2016-0732-0009
		Automotive care products (e.g., engine degreaser and brake cleaner)	U.S. EPA (2016b), Use Document, EPA-HQ-OPPT-2016-0732-0003; Market

Life Cycle Stage	Category [a]	Subcategory [b]	References
			Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0017; Public Comment, EPA-HQ-OPPT-2016-0732-0027
		Aerosol cleaner	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009
		Non-aerosol cleaner	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009
	Lubricants and greases	Lubricants and greases (e.g., penetrating lubricants, cutting tool coolants, aerosol lubricants)	U.S. EPA (2016b); Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0027; Public Comment, EPA-HQ-OPPT-2016-0732-0029
	Adhesives and sealant chemicals	Adhesives for arts and crafts	U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009
		Light repair adhesives	U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003
	Paints and coatings	Solvent-based paints and coatings	U.S. EPA (2016b); Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009; Public Comment, EPA-HQ-OPPT-2016-0732-0020; Public Comment, EPA-HQ-OPPT-2016-0732-0027
	Other uses	Carpet cleaning	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market

Life Cycle Stage	Category [a]	Subcategory [b]	References
			Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0009
		Laboratory chemicals	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732
		Metal (e.g., stainless steel) and stone polishes	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732
		Inks and ink removal products	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732
		Welding	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732;
		Photographic film	Use Document, EPA-HQ-OPPT-2016-0732-0003
		Mold cleaning, release and protectant products	Use Document, EPA-HQ-OPPT-2016-0732-0003; Market Profile, EPA-HQ-OPPT-2016-0732; Public Comment, EPA-HQ-OPPT-2016-0732-0017
Disposal	Disposal	Industrial pre-treatment	Use Document, EPA-HQ-OPPT-2016-0732-0003
		Industrial wastewater treatment	
		Publicly owned treatment works (POTW)	
		Underground injection	
		Municipal landfill	
		Hazardous landfill	
		Other land disposal	
		Municipal waste incinerator	
		Hazardous waste incinerator	
		Off-site waste transfer	
		Off-site waste transfer	

Life Cycle Stage	Category [a]	Subcategory [b]	References

[a] These categories of conditions of use appear in the initial life cycle diagram, reflect CDR codes and broadly represent conditions of use for perchloroethylene in industrial and/or commercial settings.
[b] These subcategories reflect more specific uses of perchloroethylene.

2.2.2.3 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-1 depicts the conditions of use that are considered within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, distribution, use (industrial, commercial, consumer, where distinguishable) and disposal. Additions or changes to conditions of use based on additional information gathered or analyzed during problem formulation were described in Sections 2.2.2.1 and 2.2.2.2. 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.

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, 2016a).

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 (U.S. EPA, 2016b), when the volume was not claimed confidential business information (CBI).

The 2016 CDR reporting data for perchloroethylene are provided in Table 2-4 from EPA's CDR database (U.S. EPA, 2016b). This information has not changed from that provided in the scope document.

Table 2-4. Production Volume of Perchloroethylene in CDR Reporting Period (2012 to 2015) [a]

Reporting Year	2012	2013	2014	2015
Total Aggregate Production Volume (lbs)	387,623,401	391,403,540	355,305,850	324,240,744

[a] The CDR data for the 2016 reporting period is available via ChemView (https://java.epa.gov/chemview) (U.S. EPA, 2016b). The CDR data presented in the problem formulation is more specific than currently available in ChemView.

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR (U.S. EPA, 2016b) and included in the life cycle diagram (Figure 2-1) are summarized below. 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, distribution, 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 2016)* (U.S. EPA, 2016b).

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 (U.S. EPA, 2016a)). This category includes a wide variety of uses, including, but not limited to, the use of perchloroethylene as a commercial dry cleaning solvent, in spot cleaning formulations, in automotive care products such as brake cleaners and engine degreasers, and other aerosol and non-aerosol type cleaners.

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 textile (U.S. EPA, 2016a). This category includes the use of perchloroethylene in vapor degreasing, cold cleaning, in industrial and commercial aerosol degreasing products and in industrial dry cleaning applications, including spot cleaning.

The "**Lubricants and Greases**" category encompasses chemical substances contained in products used to reduce friction, heat generation and wear between solid surfaces (U.S. EPA, 2016a). This category covers a variety of lubricants and greases that contain perchloroethylene including, but not limited to, penetrating lubricants, cutting tool coolants, aerosol lubricants, red greases, white lithium greases, silicone-based lubricants and chain and cable lubricants.

The "**Adhesives and Sealants**" category encompasses chemical substances contained in adhesive and sealant products used to fasten or bond other materials together (U.S. EPA, 2016a). EPA anticipates that the primary subcategory will be the use of perchloroethylene in solvent-based adhesives and sealants. This category covers industrial, commercial and consumer uses of adhesives and sealants.

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 (U.S. EPA, 2016a; OECD, 2009c). Coating may provide protection to surfaces from a variety of effects such as corrosion and UV degradation; may be purely decorative; or provide other functions (OECD, 2009c). EPA anticipates that the primary subcategory will be the use of perchloroethylene in solvent-based coatings. This category covers industrial, commercial and consumer uses of paints and coatings.

The "**Processing aids for agricultural product manufacturing**" category encompasses a variety of chemical substances that are used to improve the processing characteristics or operation of process equipment or to alter or buffer the pH of the substance (U.S. EPA, 2016a). Processing aids do not become a part of the final reaction product and are not intended to affect the function of the product (U.S. EPA, 2016a). Based on the 2016 CDR, EPA anticipates the primary subcategory will be the use in pesticide, fertilizer or other agricultural product manufacturing; however, the exact use in this subcategory has yet to be identified be EPA. Examples of processing aids include buffers, dehumidifiers, dehydrating agents, sequestering agents and chelators (U.S. EPA, 2016a).

The "**Processing aid for petrochemical manufacturing**" category is similar to the "Processing aid for agricultural product manufacturing" category except the chemicals are used specifically during the production of oil, gas and other similar products (U.S. EPA, 2016a). Based on the U.S. EPA (2016a) and a Dow Chemical Company Product Safety Assessment (Dow Chemical Co, 2008), EPA anticipates the primary subcategory will be the use of perchloroethylene for catalyst regeneration in petrochemical manufacturing.

Figure 2-1 depicts the life cycle diagram for perchloroethylene from manufacture to the point of disposal. Activities related to distribution (e.g., loading, unloading) will be considered throughout the perchloroethylene life cycle, rather than using a single distribution scenario.

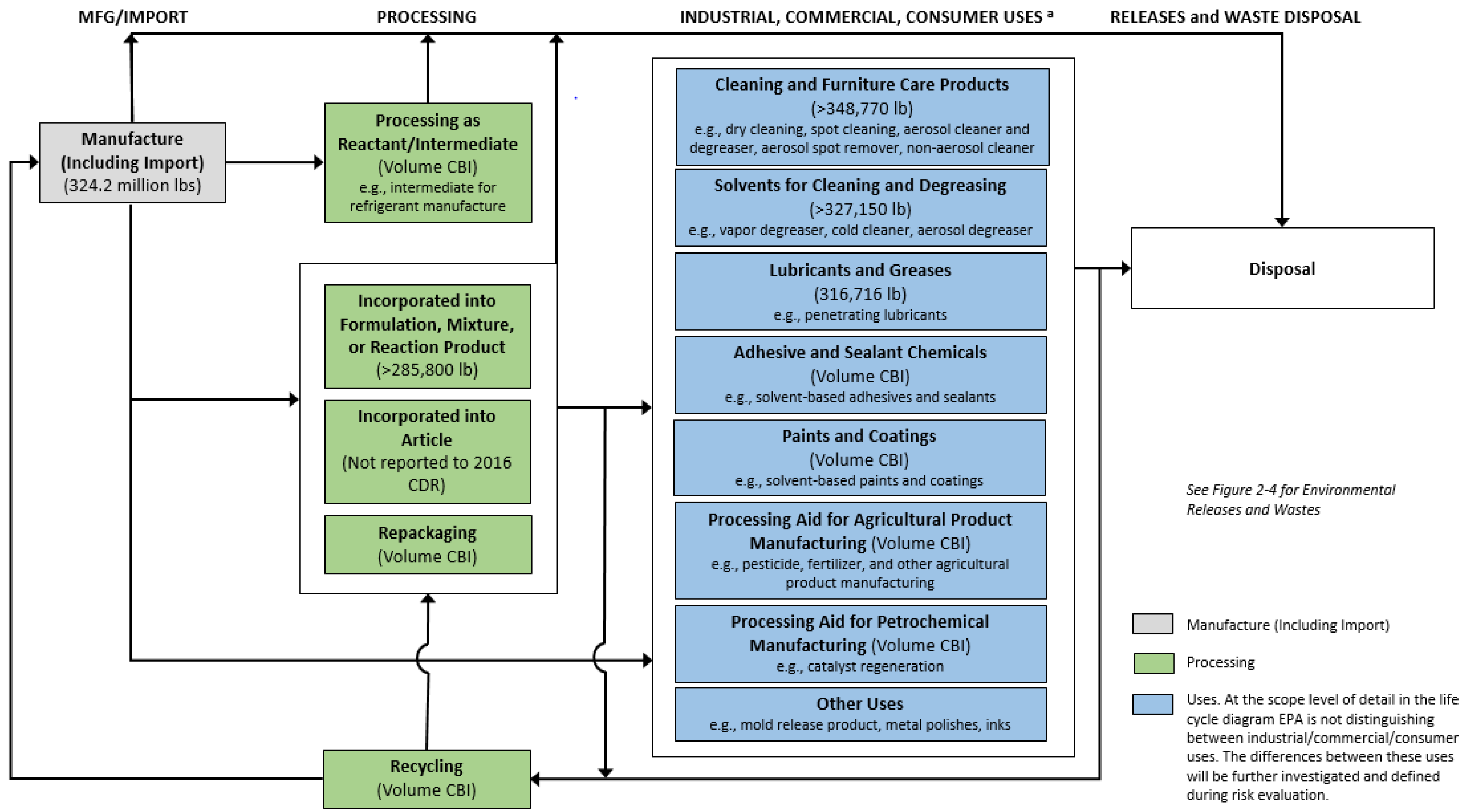

Figure 2-1. Perchloroethylene Life Cycle Diagram

The 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, where distinguishable), distribution and disposal. The production volumes shown are for reporting year 2015 from the 2016 CDR reporting period (U.S. EPA, 2016b). Activities related to distribution (e.g., loading, unloading) will be considered throughout the perchloroethylene life cycle, rather than using a single distribution scenario.

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

2.3 Exposures

For TSCA exposure assessments, post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of perchloroethylene 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 to perchloroethylene.

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 2-5 provides environmental fate data that EPA identified and considered in developing the scoping and problem formulation for perchloroethylene.

Fate data including volatilization during wastewater treatment, volatilization from lakes and rivers, biodegradation rates, and organic carbon:water partition coefficient (log K_{OC}) were used when considering changes to the conceptual models. Model results and basic principles were used to support the fate data used in problem formulation while the literature review is currently underway through the systematic review process.

The environmental fate and transport of perchloroethylene has been assessed by WHO (2006); (ECB, 2005a). This section was prepared, in part, based on these reviews, supplemented by information from EPI Suite™ (U.S. EPA, 2012b) modules.

Based on its vapor pressure and Henry's Law constant, perchloroethylene will tend to partition from water to air and, to a lesser extent, soil to air. The persistence of perchloroethylene is highly dependent on specific environmental and microbial conditions (WHO, 2006; ECB, 2005a). In the vapor phase, perchloroethylene can be slowly transformed by reaction with hydroxyl and other radicals with half-lives of months or greater, and long-range transport may occur. In water, perchloroethylene is generally stable. Aqueous photolysis has not been observed and is not expected to be a significant degradation process. Hydrolysis, if it occurs, is expected to be slow with a half-life of greater than months to years.

Chemicals that enter wastewater treatment plants (WWTP) may be incorporated into sludge if they are not rapidly degraded or transferred into the vapor phase. Sorption to organic and inorganic solids will result in the chemical being settled out during coagulation and flocculation. EPI Suite™ (U.S. EPA, 2012b) modules were used to predict volatilization of perchloroethylene from wastewater treatment plants, lakes, and rivers and to confirm the data showing slow biodegradation. The EPI Suite™ module that estimates chemical removal in sewage treatment plants ("STP" module) was run using default settings to evaluate the potential for perchloroethylene to volatilize to air or adsorb to sludge during wastewater treatment. The STP module estimates that about 80% of perchloroethylene in wastewater will be removed by volatilization. Based on measured log K_{oc} = 1.6-2.7 perchloroethylene is not expected to sorb to a large extent but may also be settled out by entrainment and incorporation into flocs. During sludge processing perchloroethylene will tend to be transferred to air during dewatering and volume reduction processes. When biosolids (processed sludge) are land applied perchloroethylene will be transferred to air during spraying and over time by volatilization from solids and liquid phases.

Perchloroethylene in surface waters can be expected to volatilize into the atmosphere. However, perchloroethylene is denser than water and only slightly soluble in water. In soil and aquifers, it will tend to remain in the aqueous phase and be transported to ground water. Anaerobic biodegradation is expected to be a significant degradation mechanism in soil and ground water.

The EPI Suite™ module that estimates volatilization from lakes and rivers ("Volatilization" module) was run using default settings to evaluate the volatilization half-life of perchloroethylene in surface water. The parameters required for volatilization (evaporation) rate of an organic chemical from the water body to air are water depth, wind, and current velocity of the river or lake. The volatilization module estimates that the half-life of perchloroethylene in a model river will be 0.05 days and the half-life in a model lake will be 5 days.

In ground water, perchloroethylene may be present as a dense non-aqueous phase liquid (DNAPL), which, because it is denser than water, means that it will form a separate phase, often at the base of an aquifer. The half-life degradation rate in ground water is estimated to be between one to two years, based on aqueous aerobic biodegradation (Howard, 1991) but may be considerably longer under certain conditions.

Table 2-5. Environmental Fate Characteristics of Perchloroethylene

Property or Endpoint	Value [a]	References
Direct photodegradation	3 years (atmosphere)	ECB (2005a)
Indirect photodegradation	96 days (atmosphere)	ECB (2005a)
Hydrolysis half-life	Months-years	ECB (2005a)
Biodegradation	No degradation (aerobic in mixed and pure culture, modified shake flask, river die-away study, sewage inoculated). <1 day to weeks (anaerobic, based on multiple studies).	ECB (2005a)
Bioconcentration factor (BCF)	40 and 49 (fish) 312 and 101 (marine algae)	ECB (2005a)
Bioaccumulation factor (BAF)	46 (estimated)	U.S. EPA (2012b); ECB (2005a)
Organic carbon:water partition coefficient (log K_{oc})	1.62.7 2.9 (estimated)	U.S. EPA (2012b); ECB (2005a)
[a] Measured unless otherwise noted.		

The EPI Suite™ module that predicts biodegradation rates ("BIOWIN" module) was run using default settings to estimate biodegradation rates of perchloroethylene in soil and sediment. Mixed results were obtained: four of the models built into the BIOWIN module (BIOWIN 1, 2, 5 and 6) estimate that perchloroethylene will not rapidly biodegrade in aerobic environments, while two (BIOWIN 3 and 4) estimate that perchloroethylene will rapidly biodegrade in aerobic environments. These results support the biodegradation data presented in the perchloroethylene Scope Document (U.S. EPA, 2017c), which indicated that in soil and sediment, aerobic and anaerobic degradation can occur but is generally slow. Several microbial species have been identified that are capable of degrading perchloroethylene under certain conditions but overall biodegradation in these environments is expected to be slow with half-life of months or greater. The model that estimates anaerobic biodegradation (BIOWIN 7) predicts that perchloroethylene will degrade more rapidly under anaerobic conditions.

With BCFs and BAFs ranging from 40 to 100, ECB (2005a),WHO (2006) and ECB (2005a) indicate that there is limited potential for perchloroethylene to bioaccumulate in plants and animals.

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 considered 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, perchloroethylene is a TRI-reportable substance effective January 1, 1987. During problem formulation, EPA further analyzed the TRI data and examined the definitions of elements in the TRI data to determine the level of confidence that a release would result from certain types of disposal to land (e.g., RCRA Subtitle C hazardous landfill and Class I underground Injection wells) and incineration. EPA also examined how perchloroethylene is treated at industrial facilities.

Table 2-6 provides production-related waste managed data (also referred to as waste managed) for perchloroethylene reported by industrial facilities to the TRI program for 2015. Table 2-7 provides more detailed information on the quantities released to air or water or disposed of on land.

Table 2-6. Summary of Perchloroethylene TRI Production-Related Waste Managed in 2015 (lbs)

Number of Facilities	Recycling	Energy Recovery	Treatment	Releases [a, b, c]	Total Production Related Waste
27	46,406,761	2,341,981	15,132,768	1,177,484	65,058,994

Data source: 2015 TRI Data [updated March 2017 (U.S. EPA, 2017f)].
[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, 27 facilities reported a total of 65 million pounds of perchloroethylene waste managed. Of this total, roughly 46 million pounds were recycled, 2.3 million pounds were recovered for energy, 15 million pounds were treated and 1.18 million pounds were released into the environment.

Release quantities in Table 2-7 are more representative of actual releases during the year. Production-related waste managed shown in Table 2-6 excludes any quantities reported as catastrophic or one-time releases (TRI Section 8 data), while release quantities shown in Table 2-7 include both production-related and non-routine quantities (TRI Section 5 and 6 data). Table 2-6 counts all release quantities reported to TRI while Table 2-7 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 disposal. 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, 2017e).

Table 2-7. Summary of Perchloroethylene 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		435,558	279,073		272	78,121	414		
Totals	27	714,631		10,393	78,807			373,653	1,177,484

Data source: 2015 TRI Data [updated March 2017) (U.S. EPA, 2017e))].
[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 2-6 excludes any quantities reported as catastrophic or one-time releases (TRI Section 8 data), release quantities shown in Table 2-7 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, 2017e).

Table 2-8 provides an additional representation of TRI data including the volume of perchloroethylene sent to each release, disposal, and waste treatment method.

Table 2-8. Summary of 2015 TRI Releases for Perchloroethylene (CASRN 127-18-4)

Waste Type	Conceptual Model Release Category	TRI Category	Volume from TRI (lbs)	Number of Reporting Sites from TRI	% of Total Production Related Waste Managed
Wastewater or Liquid Wastes	Industrial Pre-Treatment (indirect discharge)	POTW	857	15	<0.001%
	Industrial WWT (indirect discharge)	Off-site WWT (non-POTW)	9,187	5	<0.001%
	Industrial WWT (direct discharge)	Water	349	19	<0.001%
	Underground Injection	Class I Underground Injection	271	6	<0.001%
Solid Wastes and Liquid Wastes	Hazardous and Municipal Waste Landfill	RCRA Subtitle C Landfill	78,120	20	0.12%
		Other Landfills, Land Treatment, and Disposal	413	19	<0.001%
	Hazardous and Municipal Waste Incinerators, Recycling and Other Treatment	Off-site Incineration	1,098,035	65	1.7%
		Energy Recovery	2,341,981	44	3.6%
		Other Treatment and Management Methods	269,529	19	0.41%
		Transfers to Waste Broker	138,052	16	0.21%
		Recycling	46,406,761	51	71.3%
		Unspecified Treatment Methods[2]	14,000,805	44	21.5%
Emissions to Air	Emissions to Air	Fugitive Air[1]	279,073	152	0.43%
		Stack Air[1]	435,558	119	0.70%
Total Production Related Waste Managed			65,067,293	219	
Total One-Time Release Waste			31,082	6	<0.001%
Total Waste Managed			65,098,375	219	

[2] Because sites such as treatment, storage, and disposal facilities (TSDFs) are required to report to TRI, the total volumes for these categories may include volumes reported as transferred to off-site treatment, such as off-site incineration.

Releases to Air
TRI data in Table 2-8 show air as a primary medium of environmental release. These releases include both fugitive air emissions and point source (stack) air emissions. Fugitive air emissions (totaling 279,073 pounds from 2015 TRI data) are emissions that do not occur through a confined air stream, which may include equipment leaks, releases from building ventilation systems, and evaporative losses from surface impoundments and spills. Point source (stack) air emissions (totaling 435,558 pounds from TRI reporting year 2015 data) are releases to air that occur through confined air streams, such as stacks, ducts or pipes.

Releases to Water
In the 2015 TRI, 349 lbs of perchloroethylene were reported as directly released to surface water discharge, 857 lbs were sent to POTWs, and 9,187 lbs were sent to off-site non-POTW wastewater treatment.

Releases to Land
As shown in Table 2-8, TRI reports approximately 78,000 pounds transferred to RCRA Subtitle C landfills. EPA will not further analyze releases to hazardous waste landfills because these types of landfill mitigate exposure to the wastes. TRI also reports approximately 414 pounds transferred to other land disposal methods. As discussed in Section 2.3.5.3, perchloroethylene will not appreciably bind to sediment, soil or biosolids.

Incineration
During problem formulation, EPA reviewed air emissions from on-site incineration and energy recovery. Air emissions resulting from these operations are already included in the TRI reports and will be used in the analysis of air releases.

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 perchloroethylene:

Environment
Perchloroethylene has been found in air, soil, surface water, salt water, drinking water, aquatic organisms and terrestrial organisms (WHO, 2006). Historic industrial, commercial and military use of perchloroethylene, including unregulated or improper disposal of perchloroethylene wastes, has resulted in location-specific soil and ground water contamination. Perchloroethylene is a common ground water contaminant at hazardous waste sites in the U.S. (ATSDR, 2014) and a common drinking water contaminant (U.S. EPA, 2016b). EPA will analyze manufacturing, processing, distribution, use, disposal and recycling to identify and characterize current sources of release and contamination.

Urban and industrial areas are prone to higher perchloroethylene air concentrations than rural areas due to the concentration of sources (ATSDR, 2014; U.S. EPA, 2012e; WHO, 2006). EPA air monitoring data from 2013 reported detection of perchloroethylene in 77% of ambient air samples, with 58% of detects above the method detection limit (U.S. EPA, 2015a)(Table 4.1). Indoor air concentrations of perchloroethylene tend to be greater than concentrations in outdoor air (ATSDR, 2014; U.S. EPA, 2012e).

Perchloroethylene is a common contaminant in municipal drinking water supplies and ground water, with some of the highest measured concentrations in ground water occurring near perchloroethylene contaminated sites (for some examples, see (ATSDR, 2014; WHO, 2006) and references therein). EPA and the USGS National Water Quality Assessment Program (Cycle 1, 1992-2001) reported perchloroethylene contamination in U.S. surface water and ground water in 19.6% of samples (n=5,911) and at 13.2% of sites (n=4,295), with detection in surface water occurring more frequently than in ground water (U.S. EPA, 2009). EPA's Second Six-Year Review Contaminant Occurrence Data reported occurrence of monitored chemicals in U.S. drinking water supplies from 1998 to 2005. The Second Six-Year Review data showed perchloroethylene occurrence in 2.5% of roughly 50,000 public water systems, with thirty-six states reporting drinking water systems with at least one detection above the maximum contaminant level (MCL: 5 µg/L) (U.S. EPA, 2009).

Air

Urban and industrial areas are prone to higher perchloroethylene air concentrations than rural areas due to the concentration of sources (ATSDR, 2014; U.S. EPA, 2012e; WHO, 2006). Monitoring data (measured) from EPA's Air Quality System (AQS) and the open literature, as well as modeled estimates based on the National Air Toxics Assessment (NATA) and TRI emissions data suggest that perchloroethylene (tetrachloroethylene) is present in ambient air. The 2011 NATA analysis indicates perchloroethylene concentrations range from non-detect to 5.07 µg/m^3, with a mean 0.1 µg/m^3. EPA air monitoring data from 2013 reported detection of perchloroethylene in 77% of ambient air samples, with 58% of detects above the method detection limit (U.S. EPA, 2015a) (Table 4.1). The EPA Report on the Environment (U.S. EPA, 2017a) evaluated perchloroethylene concentrations from ambient air monitoring data, 2003-2013, and demonstrated that the annual average perchloroethylene air concentration is decreasing over time, from 0.429 µg/m^3 to 0.115 µg/m^3 (https://cfpub.epa.gov/roe/index.cfm).

Indoor air concentrations of perchloroethylene tend to be greater than concentrations in outdoor air (ATSDR, 2014; U.S. EPA, 2012e). In a multi-city study that evaluated the relationship between indoor and outdoor air pollutant concentrations, perchloroethylene was measured in 44.3% of 555 homes in three US cities (Weisel et al., 2005). In this study, the median concentration was 0.56 µg/m^3 and the 99th percentile was 20.9 µg/m^3. The median indoor air level of perchloroethylene in about 400 Dutch homes was 4 µg/m^3, while maximum levels varied between 49 and 205 µg/m^3. Levels can be much higher in buildings housing dry cleaning facilities. For example, sampling (over 100 samples) of air in six residential apartments in two buildings where dry cleaning was carried out on the ground floor revealed tetrachloroethene concentrations ranging from 50 to 6100 µg/m^3, with means ranging from 358 to 2408 µg/m^3 (ECB, 2005a).

Surface Water

Discharge Monitoring data (measured) were reported in EPA's Discharge Monitoring Report (DMR) Pollutant Loading Tool (https://cfpub.epa.gov/dmr/ez_search.cfm). The tool uses discharge monitoring report (DMR) data from ICIS-NPDES to calculate pollutant discharge amounts. This tool includes the top facility discharges for 2017. This information was used as a screening tool to evaluate some preliminary drinking concentrations. Using this tool an average concentration from the top discharger (total of 70 samples) would be 0.019 mg/L (19 ug/L) and the average maximum concentration for discharge would be 0.05 mg/L (50 ug/L). Note that this would only report the discharge to stream based on permits and would not report the actual stream concentrations. Reporting discharge would likely overestimate the actual stream concentrations.

A search was done through the European IPCheM database which is a single access point for locating and retrieving chemical surface water monitoring data collections (https://ec.europa.eu/jrc/en/event/conference/ipchem). Using this tool, an average concentration from the top dischargers (total of 20 samples) in surface water was 0.0058 mg/L (5.8 ug/L) and the average of the maximum concentration for 20 dischargers would be 0.0089 mg/L (8.9 ug/L) with >1000 samples collected indicating that ICIS-NPDES discharges would result in an overestimate to actual stream concentrations.

According to WHO (2006), perchloroethylene has been measured in surface (river) waters in Germany, Finland, the Netherlands, Italy, France, Switzerland, the United Kingdom, and the USA. Concentrations ranged from 0.01 to 168 µg/l, with levels typically below 5 µg/l.

Groundwater

Although groundwater can be higher than concentrations in surface water, this could reflect the fact that groundwater measurements tend to be taken where a problem (e.g. a spill) is thought to exist. Groundwater levels are usually below 10 µg/l, but concentrations as high as 1300 µg/l have been reported for a legacy contaminated site. Historic industrial, commercial, and military use of perchloroethylene, including unregulated or improper disposal of perchloroethylene wastes are considered legacy uses, but have resulted in location-specific soil and groundwater contamination (ECB, 2005a).

Sediment

Perchloroethylene is not likely to be in the sediment based on its physical and chemical properties. Nevertheless, perchloroethylene has been measured in sediment samples at 1–50 µg/kg wet weight in Germany and at <5 µg/kg wet weight in the USA (WHO, 2006). A search was done through the European IPCheM database. Using this tool, an average sediment concentration (from only 12 samples collected) was <15 µg/kg.

Soil

According to ECB (2005a), volatilization of perchloroethylene from dry soil is likely to be rapid due to its high vapor pressure and low adsorption to soil.

Biota

The EU Risk Assessment Report (ECB, 2005a) summarized data on measured levels of perchloroethylene in biota, including algae, invertebrates, fish and terrestrial plants. Nearly all reported concentrations are from locations in the EU and are below ~25 µg/kg.

Biomonitoring

Perchloroethylene has been measured in biomonitoring samples of U.S. populations. A subset of National Health and Nutrition Examination Survey (NHANES) data (1999-2000) reported in Lin et al. (2008) show the presence of perchloroethylene in 77% of human blood samples from non-smoking U.S. adults. Updated biomonitoring data reported by the Centers for Disease Control (CDC), sampled between 2001 and 2008, show a possible decline in the prevalence of perchloroethylene in U.S. population human blood samples, however limits of detection differ between the two data sets, complicating direct comparison. The CDC data show a decreasing concentration trend over the timeframe of data collection (CDC, 2017).

2.3.4 Environmental Exposures

The manufacturing, processing, use and disposal of perchloroethylene can result in releases to the environment. In this section, EPA presents exposures to aquatic and terrestrial organisms.

Aquatic Environmental Exposures

EPA identified and reviewed national scale monitoring data to support this problem formulation. EPA and the USGS National Water Quality Assessment Program (Cycle 1, 1992-2001) reported perchloroethylene contamination in U.S. surface water and ground water in 19.6% of samples (n=5,911) and at 13.2% of sites (n=4,295), with detection in surface water occurring more frequently than in ground water (U.S. EPA, 2009). More recently measured, national-scale monitoring data was from EPA's STOrage and RETreival (STORET) and National Water Information System (NWIS). Based on STORET query for perchloroethylene for the past ten years, perchloroethylene is detected in surface water in the United States. The data showed a detection rate (above quantification limit and/or above reporting limit) of approximately 15% for surface water, with detections ranging from 0.02 µg/L to 26.7 µg/L.

Terrestrial Environmental Exposures

Terrestrial species populations living near industrial and commercial facilities using perchloroethylene may be exposed via multiple routes such as ingestion of surface waters and inhalation of outdoor air. As described in Section 2.3.3, perchloroethylene is present and measurable through monitoring in a variety of environmental media including ambient and indoor air, surface water and ground water.

2.3.5 Human Exposures

In this section EPA presents occupational, consumer exposures and general population exposures. Subpopulations, including potentially exposed and susceptible subpopulations, within these exposure categories are also presented.

2.3.5.1 Occupational Exposures

Exposure pathways and exposure routes are listed below for worker activities under the various conditions of use (industrial or commercial) described in Section 2.2. In addition, exposures to occupational non-users (ONU) who do not directly handle the chemical but perform work in an area where the chemical is present are listed. Engineering controls and/or personal protective equipment may impact occupational exposure levels.

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

- Unloading and transferring perchloroethylene to and from storage containers to process vessels;
- Handling, transporting and disposing of waste containing perchloroethylene;
- Using perchloroethylene in process equipment (e.g., vapor degreasing machine);
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations or products containing perchloroethylene for quality control;
- Repackaging chemicals, formulations or products containing perchloroethylene;
- Applying formulations and products containing perchloroethylene onto substrates (e.g., spray applying coatings or adhesives containing perchloroethylene);
- Use in dry cleaning processes; and
- Performing other work activities in or near areas where perchloroethylene is used.

During problem formulation, EPA further analyzed the expected physical form, associated exposure route, and exposure pathway for each condition of use.

Key Data

Key data that inform occupational exposure assessment 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 Occupational Safety and Health Information System (OIS) at https://ois.osha.gov/portal/server.pt Appendix B includes a summary of perchloroethylene personal monitoring air samples obtained from OSHA inspections conducted between 2011 and 2016. 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/. HHE will be considered during risk evaluation.

Inhalation

Based on these occupational exposure scenarios, inhalation exposure to vapor is expected. EPA anticipates this is the most important perchloroethylene exposure pathway for workers and occupational nonusers based on the high volatility of perchloroethylene. Based on the potential for spray application of some products containing perchloroethylene exposures to mists are also expected for workers and ONU and will be incorporated into the occupational inhalation exposure estimates.

The United States has several regulatory and non-regulatory exposure limits for perchloroethylene: An OSHA Permissible Exposure Limit (PEL) of 100 ppm (685 mg/m^3), the ceiling is 200 ppm and the peak for a single time period up to 5 minutes for any 3 hours is 300 ppm, based on central nervous system effects, eye and skin irritation and liver and kidney damage.(OSHA, 1997) and an American Conference of Government Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 25 ppm 8-hour TWA (ACGIH, 2001). A NIOSH Recommended Exposure Limit (REL) has not been established, but California has set its PEL at 25 ppm (170 mg/m^3) as a time weighted average, 100 ppm (685 mg/m^3) as a short term exposure limit (STEL) and 300 ppm as a ceiling.
The influence of these exposure limits on occupational exposures will be considered in the occupational exposure assessment. Also, the National Institute for Occupational Safety and Health (NIOSH) indicates that perchloroethylene has an immediately dangerous to life and health (IDLH) value of 150 ppm based on effects that might occur from a 20-30-minute exposure, and NIOSH provides a notation that perchloroethylene is a potential occupational carcinogen (NIOSH, 1994a).

Dermal

Based on the conditions of use, EPA expects dermal exposures for workers who have skin contact with liquids and vapors. Occupational non-users are not directly handling perchloroethylene; therefore, skin contact with liquid perchloroethylene is not expected for occupational non-users but skin contact with vapors is expected for occupational nonusers.

2.3.5.2 Consumer Exposures

Perchloroethylene can be found in consumer and/or commercial products that are readily available for public purchase at common retailers (EPA-HQ-OPPT-2016-0732-0003, Sections 3 and 4 and Table 2-3) and can therefore result in exposures to consumers and bystanders (non-product users that are incidentally exposed to the product). The magnitude of exposure will depend upon the concentration of perchloroethylene products, use patterns (including frequency, duration, amount of product used, room of use) and application methods. Several consumer products need to be analyzed including solvents for cleaning and degreasing, lubricants and greases, adhesives and sealant chemicals, paints and coatings, cleaning and furniture care products, and other uses such as mold release products, metal polishes and inks. Application activities include using aerosol and non-aerosol spraying, wiping, and painting. Other activities include mixing, pouring, and placing various types of liquids, slurries and pastes. Information regarding use patterns and application methods will be needed to build exposure scenarios. Any products which are spray applied are likely to result in some level of inhalation exposure to the consumer user and bystander in the room of use. Products used in the liquid form are also likely to result in some level of inhalation exposure to the consumer given the high vapor pressure of perchloroethylene. Consumer exposures are expected to be acute in nature, however, there may be a subset of consumers who use products on a frequent or regular basis resulting in sub-chronic or chronic exposures.

Although perchloroethylene is a liquid at room temperature, it has a high vapor pressure and tends to volatilize to air. It should be noted that the nature of the consumer solvent (whether the solvent has a high vapor pressure) and the overall percentage of perchloroethylene in the mixture may either increase or decrease the evaporation rates. Consumer products formulated with a high vapor pressure solvent and have high weight fraction of perchloroethylene will vaporize at a faster rate. The nature of the solvent and weight fraction will influence the exposure pathway.

Inhalation

EPA expects that inhalation exposure to vapor will be the primary route of exposure for consumer users of perchloroethylene containing products. The magnitude of exposure will depend upon the concentration of perchloroethylene in products, use patterns (including frequency, duration, amount of product used, room of use) and application methods. Several product types and scenarios will be analyzed including spray adhesives, spray degreasers (engine cleaning and electronics cleaning), and aerosol spot removers. Information regarding use patterns and application methods will be needed to build exposure scenarios for other products identified during scoping (e.g., liquid cleaners, adhesive accelerants, building and construction materials, cutting oils). Any products which are spray applied are likely to result in some level of inhalation exposure to the consumer user and also to a bystander in the room of use. Products used in the liquid form are also likely to result in some level of inhalation exposure to the consumer given the high vapor pressure of perchloroethylene. Consumer exposures are expected to be acute in nature, however, there may be a subset of consumers who use products on a frequent or regular basis resulting in sub-chronic or chronic exposures.

Exposures routes for consumers using perchloroethylene-containing products primarily include direct inhalation of vapors, mists and aerosols (e.g., aerosols from spray applications), indirect inhalation exposures after application and dermal exposure to products. Bystanders may be exposed through inhalation of vapors and mists that deposit in the upper respiratory tract; EPA assumes mists will be absorbed via inhalation.

Dermal

There is the potential for dermal exposures to perchloroethylene in consumer uses. Exposure to perchloroethylene may also occur via dermal contact with dry-cleaned fabrics or other articles treated with products containing perchloroethylene (U.S. EPA, 2012e). Perchloroethylene is absorbed dermally, and potential exposures will depend on exposure characteristics such as skin surface area, product volume and exposure duration. The potential for dermal absorption is limited based on high vapor pressure, and perchloroethylene is expected to volatilize quickly from surfaces (see Section 2.5.2). However, the nature of the product or article containing perchloroethylene, chemical loading, other components present in product mixtures and the weight fraction of perchloroethylene in the product will affect dermal absorption.

Oral

Consumers may be exposed to perchloroethylene via transfer of chemical from hand to mouth. However, this exposure pathway is expected to be limited by a combination of dermal absorption and volatilization of perchloroethylene from skin. Due to the expected very low magnitude of accidental hand to mouth exposure, EPA does not plan to further assess this pathway.

Exposures from Disposal

EPA does not expect exposure to consumers from disposal of consumer products. It is anticipated that most products will be disposed of in original containers, particularly those products that are purchased as aerosol cans.

2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of perchloroethylene could result in potential pathways for oral, dermal or inhalation exposure to the general population.

Inhalation

General population inhalation exposure to perchloroethylene in air may result from industrial manufacturing and processing plant fugitive and stack emissions. Perchloroethylene volatilizes from contaminated soil and shallow ground water, possibly resulting in elevated outdoor inhalation exposure. Through a process known as vapor intrusion, volatilized perchloroethylene may also infiltrate residential and commercial buildings through cracks in floors, crawl spaces, pipe fittings and toilet and sewer junctions, leading to elevated indoor concentrations of perchloroethylene and greater inhalation exposure (ATSDR, 2014; U.S. EPA, 2012f). In addition, inhalation exposures to perchloroethylene may occur due to volatilization of perchloroethylene from contaminated water (municipal or well water) during showering and bathing (U.S. EPA, 2012e).

Families of workers with occupational perchloroethylene exposure are exposed secondarily by perchloroethylene volatilization from workers clothing, and from exhaled breath, as un-metabolized perchloroethylene is exhaled on the breath as the primary excretion mechanism in humans (ATSDR, 2014; U.S. EPA, 2012e).

Indoor emissions, from the use of perchloroethylene containing products and articles (e.g., degreasers; recently dry-cleaned clothing), may also be sources of perchloroethylene in indoor air (ATSDR, 2014; U.S. EPA, 2012e).

Oral

The general population may ingest perchloroethylene via contaminated drinking water, ground water and/or surface water (ATSDR, 2014; U.S. EPA, 2012e). Perchloroethylene enters water supplies through industrial and commercial wastewater and liquid waste streams, sewage sludge land application, wet deposition (rain) and leaching from contaminated soils (U.S. EPA, 2009). Oral ingestion pathways may include exposure to contaminated drinking water or breast milk, or incidental ingestion of contaminated water while swimming or bathing. Infants and young children may also be exposed to perchloroethylene via mouthing of treated products and articles (e.g., spot treatment of carpets; dry cleaned blanket).

The EU Risk Assessment Report (ECB, 2005a) indicates that perchloroethylene may be present in fish, although EPA does not anticipate fish ingestion to be a significant general population exposure pathway, as perchloroethylene has a low bioaccumulation potential in aquatic organisms (BCF 40 50`, Kow < 3)(WHO, 2006).

Dermal

General population dermal exposure to perchloroethylene is possible from showering, bathing and swimming in contaminated water (U.S. EPA, 2012e). Perchloroethylene is absorbed dermally, and potential exposures will depend on exposure characteristics such as skin surface area, exposure media concentration and exposure duration. The potential for dermal absorption is limited based on high vapor pressure, and perchloroethylene is expected to volatilize quickly from surfaces (see Section 2.5.2). However, the nature of the environmental media containing perchloroethylene and chemical loading will affect dermal absorption.

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2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires the determination of whether a chemical substance presents an 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." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

As part of the Problem Formulation, EPA identified potentially exposed and susceptible subpopulations for further analysis during the development and refinement of the life cycle, conceptual models, exposure scenarios, and analysis plan. 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.

EPA identifies the following as potentially exposed or susceptible subpopulations that EPA plans to analyze in the risk evaluation due to their *greater exposure*:

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. Perchloroethylene has been identified 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 identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution or use sites).

Perchloroethylene is lipophilic, and accumulates in fatty fluids and tissues in the human body. Subpopulations that may have higher body fat composition, and may be more highly exposed include pubescent and adult women, including women of child-bearing age. The EPA IRIS Assessment for perchloroethylene (U.S. EPA, 2012e) also identified the developing fetus as potentially exposed, as well as infants consuming breastmilk, particularly for mothers with occupational exposure to perchloroethylene or exposure due to proximity to industrial or commercial sources (U.S. EPA, 2012e). Infants fed by formula may also experience increased perchloroethylene exposure if perchloroethylene is present in drinking water supplies (U.S. EPA, 2012e).

In developing exposure scenarios, EPA will analyze available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or lifestage 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, 2006b).

The behavior of children may put them in closer contact with some sources of perchloroethylene, such as carpet cleaners. Children may be exposed via inhalation as bystanders, during consumer use in the home. Children tend to consume more water and food per body weight relative to adults, and have greater skin surface area and skin permeability than adults, relative to weight, which can result in proportionally higher ingestion and dermal exposures. Children's exposure to perchloroethylene via ingestion of contaminated food is likely to be low. Perchloroethylene has low bioaccumulation potential and, if present, would have low concentrations in fish or seafood. The half-life of perchloroethylene in soil is short, and is unlikely to be found in food crops. Perchloroethylene has been measured in fatty foods (butter, oils and meats) when stored in proximity to indoor perchloroethylene sources (U.S. EPA, 2012d). Drinking water could be a significant source of perchloroethylene ingestion exposure for children, who drink roughly four times as much water as adults (U.S. EPA, 2011).

EPA will continue to analyze available data to ascertain whether some human receptor groups may be exposed via pathways that may be distinct to a particular subpopulation or lifestage (e.g., children's crawling, mouthing or hand-to-mouth behaviors).

In summary, in the risk evaluation for perchloroethylene, EPA expects to analyze the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use, and other groups of individuals within the general population who may experience greater exposure. EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

2.4 Hazards

For scoping, EPA conducted comprehensive searches for data on hazards of perchloroethylene, as described in the supplemental document: *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental File for the TSCA Scope Document*. Based on initial screening, EPA expects to analyze the hazards of perchloroethylene identified in this problem formulation 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 will be analyzed for every exposure scenario.

2.4.1 Environmental Hazards

EPA identified the following existing sources of environmental hazard data for perchloroethylene: European Chemicals Bureau (ECB) EU Risk Assessment Report Tetrachloroethylene, Part 1 - environment (ECB, 2005a) and World Health Organization (WHO) Concise International Chemical Assessment Document 68; Tetrachloroethylene WHO (WHO, 2006). Only the *on-topic* references listed in the Ecological Hazard Literature Search Results were considered as potentially relevant data/information sources for the risk evaluation. Inclusion criteria were used to screen the results of the ECOTOX literature search (as explained in the *Strategy for Conducting Literature Searches for Perchloroethylene: Supplemental Document to the TSCA Scope Document, CASRN:127-18-4*. Data from the screened literature are summarized below (Table 2-9) as ranges (min-max). EPA expects to review these data/information sources during risk evaluation using the data quality review evaluation metrics and the rating criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018a).

Toxicity to Aquatic Organisms
The acute 96-hour LC50 values for fish range from 4 mg/L for Flagfish (*Jordanella floridae*) to 28.1 mg/L for Indian Silverside (*Menidia berylina*). With aquatic invertebrates, the LC/EC50 values ranged from 2.85 – 30.8 mg/L. For algal toxicity 72/96-hr EC50 values were 3.64 – 500 mg/L based on biomass and abundance (Table 2-9).

Chronic aquatic toxicity data for perchloroethylene are available. Chronic toxicity to fish values range from 0.5- 1.4 mg/L. A 28-day Daphnia magna study reported NOEC value of 0.505 mg/L based on reproduction using measured concentrations. Another 28-day Opossum Shrimp (*Americanmysis bahia*) study reported NOEC value of 0.370 mg/L. For the most conservative chronic toxicity values were reported as algal 72-h NOEC= 0.01 – 0.02 mg/L and LOEC= 0.02– 0.05 mg/L. Based on these NOEC and LOEC, the chronic toxicity values are calculated as 0. 0.014 – 0.032 mg/L (Table 2-9).

Toxicity to Soil/Sediment and Terrestrial Organisms
An earthworm (*Eisenia foetida*) toxicity study of perchloroethylene has been tested using OECD Guideline No. 207. The 14-day LC50 was 100–320 mg/kg, the 28-day NOEC (based upon cocoons) was ≤18 mg/kg, and the 28-day NOEC (based upon appearance) was 18–32 mg/kg. Another perchloroethylene study using the carabid beetle (*Poecilus cupreus*) was conducted. No mortality or behavioral changes were observed in this study (Table 2-9).

For terrestrial plants, a 21-day study of lettuce (*Lactuca sativa*) showed EC50 of 12 mg/L based on biomass. Another study looked at the effects on the early developmental stage of lettuce (*Avena sativa*), germinated plants, the 16-day EC50 (growth) was 861 mg/kg based on the converted standard organic matter content.

Table 2-9: Ecological Hazard Characterization of Perchloroethylene

Duration	Test organism	Endpoint	Hazard value*	Units	Effect Endpoint	References
Aquatic Organisms						
Acute	Fish	LC_{50}	4 – 28.1	mg/L	Mortality	Smith (1991); Horne (1983)
	Aquatic invertebrates	LC/EC_{50}	2.85 – 30.8	mg/L	Immobilization	Hollister (1968); Call (1983) as cited in WHO (2006)
	Algae	EC_{50}	3.64 - 500	mg/L	Biomass/ Abundance	Brack (1994) as cited in ECB (2005); U.S. EPA (1980a) as cited in WHO (2006)
	Amphibians	EC_{50}	2.5 -20.0	mg/L	Mortality	McDaniel (2004)
	Acute COC	0.80 mg/L				
Chronic	Fish	ChV	0.5-1.4	mg/L	Growth	Ahmad (1984); Smith (1991) as cited in ECB (2005)
	Aquatic invertebrates	ChV	0.37 – 1.11 (NOEC)	mg/L	Mortality/ Reproduction	Hollister (1968); Richter et al. (1983) as cited in ECB (2005); Call (1983) as cited in WHO (2006)
	Algae	NOEC LOEC ChV	0.01-0.02 0.02-0.05 0.014-0.032	mg/L	Abundance	Labra (2010);
	Chronic COC	0.001 mg/L				
Terrestrial Organisms						
Acute	Terrestrial invertebrates	LC_{50}	100 - 320	mg/Kg	Cocoons appearance	(Vonk et al., 1986) as cited in WHO (2006)
	Terrestrial plants	EC_{50}	861	mg/Kg	Growth	(Bauer and Dietze, 1992) as cited in WHO (2006)
Chronic	Terrestrial plants	EC_{50}	12	mg/L	Biomass	Hulzebos, 1993

*** Values in the tables are presented as reported by the study authors**

Concentrations of Concern

The screening-level acute and chronic concentrations of concern (COCs) for perchloroethylene were derived based on the lowest or most toxic ecological toxicity values (e.g., L/EC50). The information below describes how the acute and chronic COC's were calculated for environmental toxicity of perchloroethylene using assessment factors.

The application of assessment factors is based on established EPA/OPPT methods (U.S. EPA, 2013, 2012c) and were used in this hazard assessment to calculate lower bound effect levels (referred to as the concentration of concern; COC) that would likely encompass more sensitive species not specifically represented by the available experimental data. Also, assessment factors are included in the COC calculation to account for differences in inter- and intra-species variability, as well as laboratory-to-field variability. It should be noted that these assessment factors are dependent upon the availability of datasets that can be used to characterize relative sensitivities across multiple species within a given taxa or species group, but are often standardized in risk assessments conducted under TSCA, due to limited data availability.

The concentrations of concern for each endpoint were derived based on the ecological hazard data for perchloroethylene. The information below describes how the acute and chronic COCs were calculated for aquatic toxicity.

The acute COC is derived by dividing acute aquatic invertebrates LC50 of 2.85 mg/L (the lowest acute value in the dataset) by an assessment factor (AF) of 5:

- Lowest value for aquatic invertebrates LC50 (2.85 mg/L) / AF of 5 = 0.57 mg/L or 570 µg/L.

The acute COC of 570 µg/L, derived from experimental aquatic invertebrate's endpoint, is used as a conservative hazard level in this problem formulation for perchloroethylene.

The chronic COC was determined based on the lowest chronic toxicity value divided by an assessment factor of 10.

- Lowest chronic value for 72-h algal ChV = 0.014 mg/L / 10 = 0.0014 mg/L or 1.4 µg/L.

The chronic COC of 1.4 µg/L, derived from experimental algae endpoint, is used as the lower bound hazard level in this problem formulation for perchloroethylene.

2.4.2 Human Health Hazards

Perchloroethylene has an existing EPA IRIS Assessment U.S. EPA (2012e) and a draft ATSDR Toxicological Profile (ATSDR, 2014); hence, many of the hazards of perchloroethylene have been previously compiled. EPA expects to use these previous analyses as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analysis. The relevant studies will be evaluated using the data quality criteria in the *Application of Systematic Review in TSCA Risk Evaluations* document. 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 perchloroethylene (*Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document*). EPA expects to consider potential human health hazards associated with perchloroethylene. Based on reasonably available information, the following sections describe the potential hazards associated with perchloroethylene.

2.4.2.1 Non-Cancer Hazards

The EPA IRIS Assessment on perchloroethylene (U.S. EPA, 2012e) evaluated the following non-cancer hazards that may be associated with perchloroethylene exposures: the central nervous system (neurotoxicity), kidney, liver and development and reproduction. In general, neurological effects were found to be associated with lower perchloroethylene inhalation exposures. According to the EPA IRIS Assessment (U.S. EPA, 2012e), support for an association with immune and blood effects were less well characterized. In their draft Toxicological Profile for perchloroethylene, ATSDR (2014) identified similar hazard concerns. The National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL, 2009) also identified irritation as a hazard concern.

Acute Toxicity

Data from acute exposure studies in animals and human incidents indicate that short term exposure to perchloroethylene may cause irritation and neurotoxicity and can impair cognitive function in humans (U.S. EPA, 2012e). An Acute Exposure Guidance Limit (AEGL) values, established by the National Advisory Committee for Acute Exposure Guideline Levels for Hazardous Substances (NAC/AEGL, 2009), has been developed based on irritation to humans (AEGL-1), ataxia in rodents (AEGL-2), and lethality in mice (AEGL-3) (NAC/AEGL, 2009).

Neurotoxicity

Evidence in humans and animals show that chronic exposure to perchloroethylene can cause neurotoxicity, resulting in decrements in color vision, visuospatial memory and possibly other aspects of cognition and neuropsychological function (U.S. EPA, 2012e). Neurotoxic effects have been characterized in human controlled exposure, occupational exposure and residential studies, as well as in experimental animal studies, providing evidence of an association between perchloroethylene exposure and neurological deficits (U.S. EPA, 2012e). The EPA IRIS assessment for perchloroethylene (U.S. EPA, 2012e) further notes that the nervous system is an expected target with oral perchloroethylene exposures because perchloroethylene and metabolites produced from inhalation exposures will also reach the target tissue via oral exposure.

Kidney Toxicity

Evidence for kidney toxicity in humans is based on studies of kidney biomarkers, which provide information on nephron integrity and tubule damage. Epidemiologic studies support an association between perchloroethylene and chronic kidney disease (U.S. EPA, 2012e). Animal evidence supports an association between perchloroethylene exposure and chronic kidney disease. Adverse effects on the kidney (e.g., kidney-to-body weight ratios, hyaline droplet formation, glomerular "nephrosis," karyomegaly (enlarged nuclei), cast formation, and other lesions or indicators of renal toxicity) have been observed in studies of rodents exposed to high concentrations of perchloroethylene by inhalation, oral and intraperitoneal (i.p.) injection of perchloroethylene metabolites (U.S. EPA, 2012e).

Liver Toxicity

Liver toxicity (i.e., necrosis, vacuolation, etc) has been reported in multiple animal species by inhalation and oral exposures to perchloroethylene, with the mouse typically being more sensitive than the rat (U.S. EPA, 2012e). The liver effects are characterized by increased liver weight, necrosis, inflammatory cell infiltration, triglyceride increases proliferation, cytoplasmic vacuolation (fatty changes), pigment in cells, oval cell hyperplasia and regenerative cellular foci. The EPA IRIS Assessment for perchloroethylene (U.S. EPA, 2012e) found suggestive evidence that perchloroethylene is a liver toxicant in humans.

Reproductive/Developmental Toxicity

The EPA IRIS Assessment for perchloroethylene (U.S. EPA, 2012e) evaluated the developmental and reproductive toxicity of perchloroethylene in humans and animals. Studies of tetrachloroethylene exposure in humans have evaluated several reproductive outcomes including effects on menstrual disorders, semen quality, fertility, time to pregnancy, and risk of adverse pregnancy outcomes including spontaneous abortion, low birth weight or gestational age, birth anomalies, and stillbirth (U.S. EPA, 2012e). Data from animal studies identified various manifestations of developmental toxicity including, increased mortality and decreased body weight in the offspring of rodents exposed via inhalation.

Irritation
U.S. EPA (2012e) and ATSDR (2014) indicate perchloroethylene is irritating. Irritation data for perchloroethylene have also been reviewed outside the EPA IRIS Assessment. Controlled exposures in humans and case reports have identified eye and nose irritation (NAC/AEGL, 2009).

2.4.2.2 Genotoxicity and Cancer Hazards

Epidemiologic data provide evidence associating perchloroethylene with several cancer types, including non-Hodgkin lymphoma, multiple myeloma and bladder cancer, with more limited evidence for esophageal, kidney, lung, cervical and breast cancer (U.S. EPA, 2012e). Perchloroethylene is generally considered to be non-genotoxic, however several metabolites exhibit mutagenic and/or genotoxic properties and may contribute to potential genotoxic mode of action (MOA) (U.S. EPA, 2012e). In 2012, EPA released the outcome of the weight-of-evidence cancer assessment, which described the weight-of-evidence judgment of the likelihood that perchloroethylene is a human carcinogen, and quantitative estimates of risk from oral and inhalation exposure (U.S. EPA, 2012e). Following U.S. EPA (2005a) Guidelines for Carcinogen Risk Assessment, EPA concluded that perchloroethylene is "likely to be carcinogenic in humans by all routes of exposure" (U.S. EPA, 2012e).

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 analyze available data to ascertain whether some human receptor groups may show greater susceptibility to the chemical's hazards due to intrinsic factors. EPA plans to analyze the susceptibility factors identified in the EPA IRIS assessment for perchloroethylene U.S. EPA (2012e) and ATSDR (2014) evaluations. These assessments both identified the following subpopulations as possibly more susceptible to adverse effects associated with perchloroethylene exposures: early and later lifestages and groups defined by health and nutrition status, gender, race/ethnicity, genetics and multiple exposures and cumulative risk. However U.S. EPA (2012e) also determined that the available data was insufficient to allow for a quantitative assessment of the impact of susceptibility on risk.

The California Office of Environmental Health Hazard Assessment OEHHA (2016) derived an inhalation cancer unit risk factor for perchloroethylene based on the same physiologically based pharmacokinetic (PBPK) model (Chiu and Ginsberg, 2011) used in the EPA IRIS assessment (U.S. EPA, 2012e). The model included both oxidative metabolism and glutathione conjugation metabolism; the latter varies greatly within the human population, with some variation representing sensitive subpopulations (Spearow et al., 2017; OEHHA, 2016). EPA will consider this information during the risk evaluation phase.

2.5 Conceptual Models

EPA risk assessment guidance (U.S. EPA, 2014d), defines Problem Formulation as the part of the risk assessment framework that identifies the major factors to be considered in the assessment. It draws from the regulatory, decision-making and policy context of the assessment and informs the assessment's technical approach.

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. The initial conceptual models describing the scope of the assessment for perchloroethylene, have been refined during problem formulation. The changes to the conceptual models in this problem formulation are described along with the rationales.

In this section EPA outlines those pathways that will be included and further analyzed in the TSCA risk evaluation; will be included but will not be further analyzed in risk evaluation; and will not be included in the TSCA risk evaluation and the underlying rationale for these decisions.

EPA determined as part of problem formulation that it is not necessary to conduct further analysis on certain exposure pathways that were identified in the perchloroethylene scope document and that remain in the risk evaluation. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without extensive or quantitative risk evaluations. 82 FR 33726, 33734, 33739 (July 20, 2017).

As part of this problem formulation, EPA also identified exposure pathways under regulatory programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist, i.e., the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA). OPPT worked closely with the offices within EPA that administer and implement the regulatory programs under these statutes. In some cases, EPA has determined that chemicals present in various media pathways (i.e., air, water, land) fall under the jurisdiction of existing regulatory programs and associated analytical processes carried out under other EPA-administered statutes and have been assessed and effectively managed under those programs. EPA believes that the TSCA risk evaluation should generally focus on those exposure pathways associated with TSCA conditions of use that are not adequately assessed and effectively managed under the regulatory regimes discussed above because these pathways are likely to represent the greatest areas of risk concern. As a result, EPA does not expect to include in the risk evaluation certain exposure pathways identified in the perchloroethylene scope document.

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

The revised conceptual model (Figure 2-2) describes the pathways of exposure from industrial and commercial activities and uses of perchloroethylene that EPA expects to include in the risk evaluation. There are exposures to workers and/or occupational non-users via inhalation routes and/or exposures to workers via dermal routes for all conditions of use identified in this problem formulation. In addition to the pathways illustrated in the figure, EPA will evaluate activities resulting in exposures associated with distribution in commerce (e.g. loading, unloading) throughout the various lifecycle stages and conditions of use (e.g. manufacturing, processing, industrial use, commercial use, disposal) rather than a single distribution scenario.

Inhalation

Inhalation exposures for workers are regulated by OSHA's occupational safety and health standards for perchloroethylene which include a PEL of 100 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.134). EPA expects that for workers and occupational non-users exposure via inhalation will be the most significant route of exposure for most exposure scenarios. EPA expects to further analyze inhalation exposures to vapors and mists for workers and occupational non-users in the risk evaluation.

Dermal

There is the potential for dermal exposures to perchloroethylene in many worker scenarios. Where workers may be exposed to perchloroethylene, the OSHA standard requires that workers are protected from contact (e.g. gloves) (29 CFR 1910.132). Dermal exposures would be concurrent with inhalation exposures and the overall contribution of dermal exposure to the total exposure is expected to be small however there may be exceptions for occluded scenarios. Occupational non-users are not directly handling perchloroethylene; therefore, skin contact with liquid perchloroethylene is not expected for occupational non-users and EPA does not expect to further analyze this pathway in the risk evaluation. EPA expects to further analyze dermal exposures for skin contact with liquids.

The parameters determining the absorption of perchloroethylene vapor are based on the concentration of the vapor, the duration of exposure and absorption. As described by ATSDR, a human study comparing absorption of perchloroethylene vapor via the dermal and inhalation routes (*i.e.*, exposure to vapor with and without respiratory protection) found that absorption via the dermal route is only 1% of the combined dermal and inhalation routes (ATSDR, 2014). Therefore, EPA will not further analyze worker or occupational non-user exposure via vapor-to-dermal contact, because the contribution to overall exposure will be orders of magnitude lower than direct inhalation of vapors.

Waste Handling, Treatment and Disposal

Figure 2-2 shows that waste handling, treatment and disposal is expected to lead to the same pathways as other industrial and commercial activities and uses. The path leading from the “Waste Handling, Treatment and Disposal” box to the “Hazards Potentially Associated with Acute and/or Chronic Exposures See Section 2.4.2” box was re-routed to accurately reflect the expected exposure pathways, routes, and receptors associated with these conditions of use of perchloroethylene.

For each condition of use identified in Table 2-3, a determination was made as to whether or not each unique combination of exposure pathway, route, and receptor will be further analyzed in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix C and Appendix E.

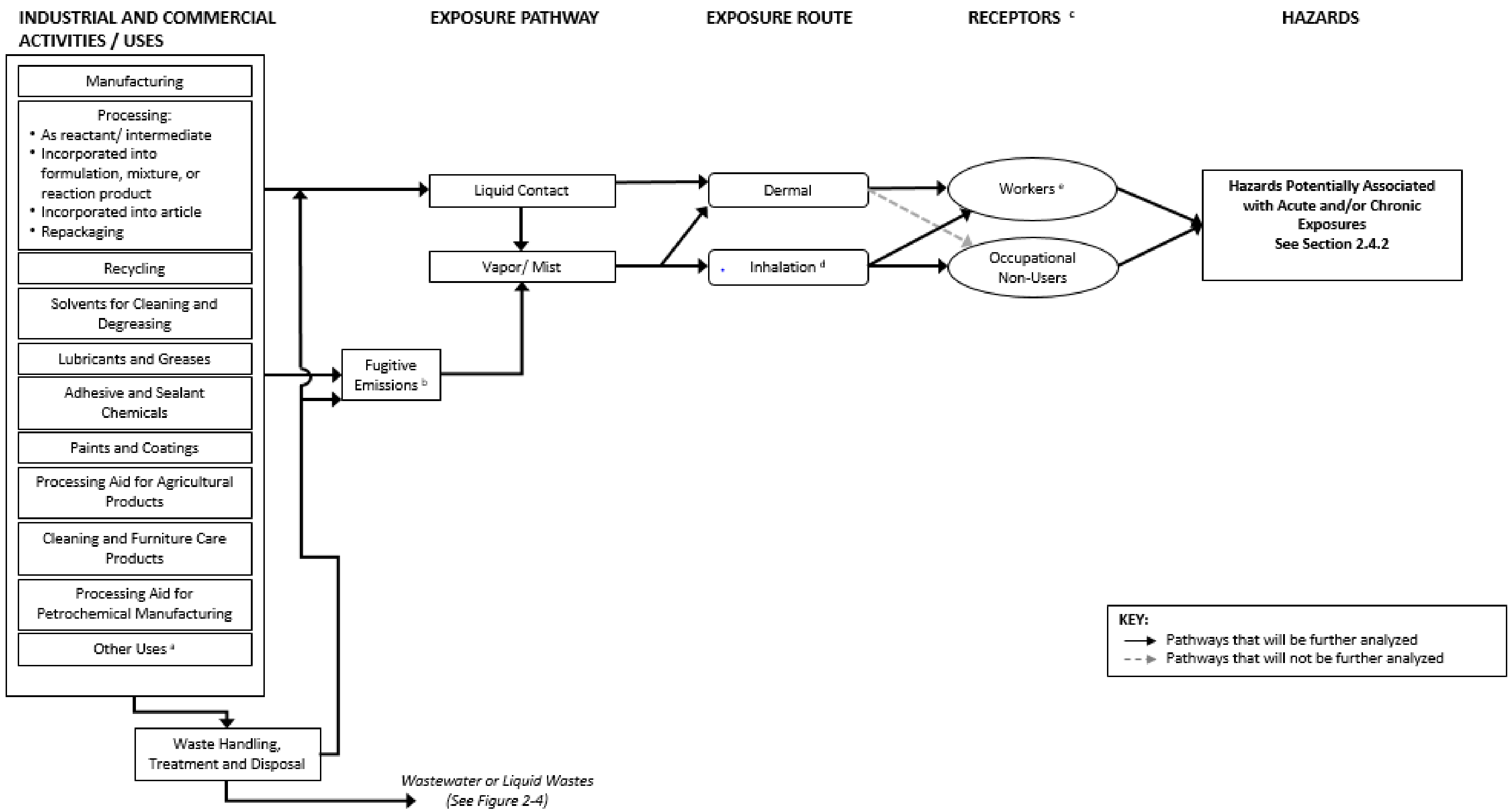

Figure 2-2. Perchloroethylene Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

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

[a] Some products are used in both commercial and consumer applications such adhesives and sealants. Additional uses of perchloroethylene are included in Table 2-3.

[b] 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.

[c] Receptors include potentially exposed or susceptible subpopulations.

[d] Exposure may occur through mists that deposit in the upper respiratory tract however, based on physical chemical properties, mists of perchloroethylene will likely be rapidly absorbed in the respiratory tract or evaporate and will be considered as an inhalation exposure.

[e] 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 Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

The revised conceptual model (Figure 2-3) illustrates the pathways of exposure from consumer uses of perchloroethylene that EPA expects to include in the risk evaluation. It should be noted that some consumers may purchase and use products primarily intended for commercial use.

Inhalation

EPA expects inhalation to be the primary route of exposure and plans to further analyze inhalation exposures to perchloroethylene vapor and mist for consumers and bystanders.

Dermal

There is potential for dermal exposures to perchloroethylene from consumer uses. Dermal exposure may occur via direct liquid contact during use. Direct contact with liquid perchloroethylene would be concurrent with inhalation exposures and dermal exposures to consumers in occluded and non-occluded scenarios are expected. Bystanders will not have direct dermal contact with liquid perchloroethylene. EPA expects to further analyze direct dermal contact with liquid perchloroethylene for consumers.

Consumers and bystanders can have skin contact with perchloroethylene vapor concurrently with inhalation exposures. Similar to workers (see Section 2.5.1) the parameters determining the absorption of perchloroethylene vapor are based on the concentration of the vapor, the duration of exposure and absorption. The concentration of the vapor and the duration of exposure are the same for concurrent dermal and inhalation exposures. Therefore, the differences between dermal and inhalation exposures depend on the absorption. As described by ATSDR, a human study comparing absorption of perchloroethylene vapor via the dermal and inhalation routes (*i.e.*, exposure to vapor with and without respiratory protection) found that absorption via the dermal route is only 1% of the combined dermal and inhalation routes (ATSDR, 2014). Therefore, EPA will not further analyze consumer or bystander exposure via vapor-to-dermal contact, because the contribution to overall exposure will be orders of magnitude lower than direct inhalation of vapors.

Oral

Consumers may be exposed to perchloroethylene via transfer of chemical from hand to mouth. This exposure pathway will be limited by a combination of dermal absorption and volatilization; therefore, this pathway will not be further evaluated.

Furthermore, based on available toxicological data, EPA does not expect that considering separate oral routes of exposure for mists or for incidental ingestion would have significantly different toxicity, rather mists will be included as part of consumer inhalation exposures and skin contact will be included as part of consumer dermal exposures. Bystanders are not directly handling perchloroethylene; therefore, inhalation exposure to mists and incidental ingestion via contact with perchloroethylene are not expected for bystanders. EPA plans no further analysis of this pathway for consumers or bystanders.

Disposal

EPA does not expect to further analyze exposure to consumers from disposal of consumer products. It is anticipated that most products will be disposed of in original containers, particularly those products that are purchased as aerosol cans.

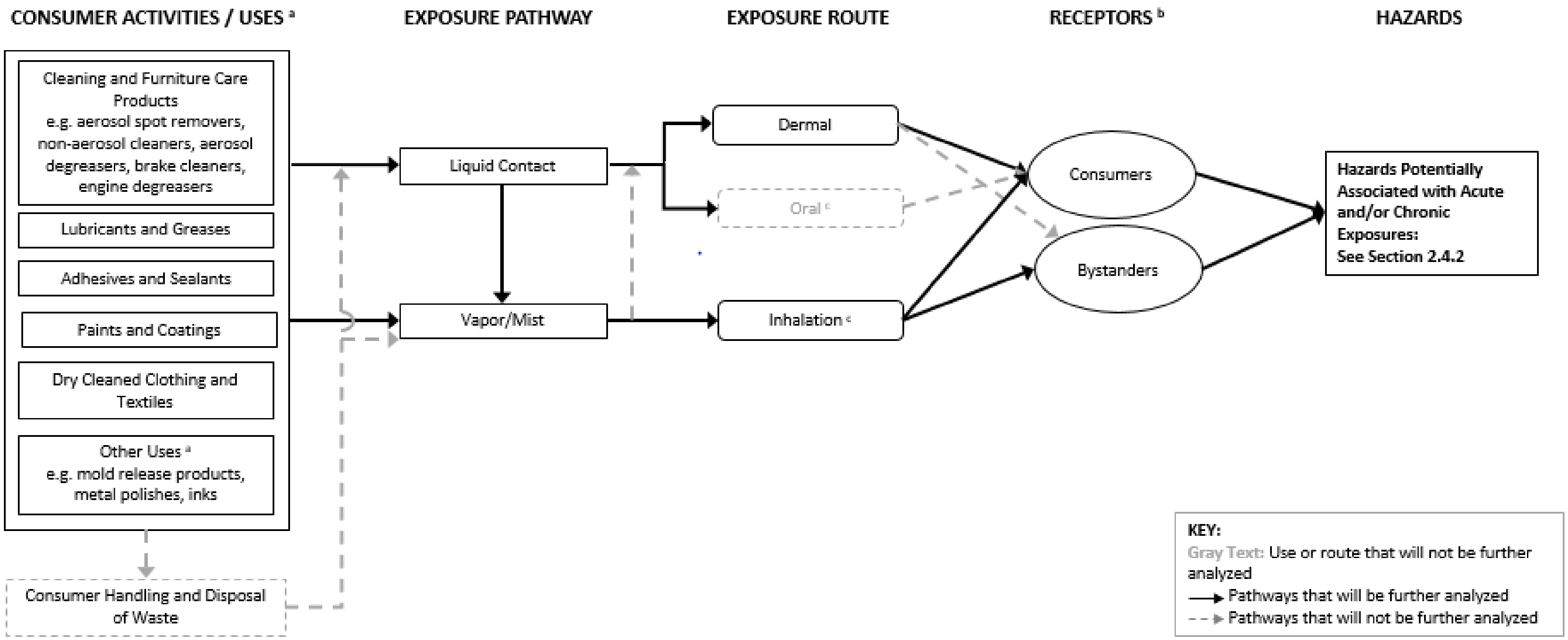

Figure 2-3. Perchloroethylene Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

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

[a] Some products are used in both commercial and consumer applications. Additional uses of perchloroethylene are included in Table 2.3.

[b] Receptors include potentially exposed or susceptible subpopulations

[c] .Consumers may be exposed to perchloroethylene via transfer of chemical from hand to mouth. This exposure pathway will be limited by a combination of dermal absorption and volatilization; therefore, this pathway will not be further evaluated.

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

The revised conceptual model (Figure 2-4) illustrates the expected exposure pathways to human (i.e., general population) and ecological receptors (i.e., aquatic and terrestrial) from environmental releases and waste streams associated with industrial and commercial activities for perchloroethylene that EPA expects to include in the risk evaluation. The pathways that EPA expects to include and analyze further in the risk evaluation is described in Section 2.5.3.1 and shown in the conceptual model Figure 2-4. The pathways that EPA does not expect to include in the risk evaluation s are described in Section 2.5.3.2.

2.5.3.1 Pathways That EPA Expects to Include and Further Analyze in the Risk Evaluation

EPA plans to analyze aquatic organisms exposed via contaminated surface water.

There are no national recommended water quality criteria for the protection of aquatic life for perchloroethylene and as a result EPA does not believe that perchloroethylene exposure to aquatic organisms in surface water has been adequately assessed or effectively managed under other EPA statutory authorities (see Section 2.5.3.2). EPA identified and reviewed national scale monitoring data to support this problem formulation. EPA and the USGS National Water Quality Assessment Program (Cycle 1, 1992-2001) reported perchloroethylene contamination in U.S. surface water and ground water in 19.6% of samples (n=5,911) and at 13.2% of sites (n=4,295), with detection in surface water occurring more frequently than in ground water (U.S. EPA, 2009). More recently measured, national-scale monitoring data was from EPA's STOrage and RETreival (STORET) and National Water Information System (NWIS). Based on STORET query for perchloroethylene for the past ten years, perchloroethylene is detected in surface water in the United States. The data showed a detection rate (above quantification limit and/or above reporting limit) of approximately 15% for surface water, with detections ranging from 0.02 µg/L to 26.7 µg/L. As summarized in Section 2.4.1 perchloroethylene showed hazard at concentrations as low as 14 µg/L for aquatic plants. The chronic COC value of 1 µg/L is not sufficiently below the range of monitored concentrations to eliminate risk concerns. Therefore, EPA plans to evaluate risks to aquatic organisms from exposures to perchloroethylene in surface waters.

2.5.3.2 Pathways That EPA Does Not Expect to Include in the Risk Evaluation

Exposures to receptors may occur from industrial and/or commercial uses, industrial releases to air, water or land; and other conditions of use. As described in section 2.5, pathways under other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist will not be included in the risk evaluation. These pathways are described below.

Ambient Air Pathway

The Clean Air Act (CAA) contains a list of hazardous air pollutants (HAP) and provides EPA with the authority to add to that list pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects. For stationary source categories emitting HAP, the CAA requires issuance of technology-based standards and, if necessary, additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment. The CAA thereby provides EPA with comprehensive authority to regulate emissions to ambient air of any hazardous air pollutant.

Perchloroethylene is a HAP. EPA has issued a number of technology-based standards for source categories that emit perchloroethylene to ambient air and, as appropriate, has reviewed, or is in the process of reviewing remaining risks. Because stationary source releases of perchloroethylene to ambient air are adequately assessed and any risks effectively managed when under the jurisdiction of the CAA, EPA does not plan to evaluate emission pathways to ambient air from commercial and industrial stationary sources or associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation.

Drinking Water Pathway
EPA has regular analytical processes to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under the Safe Drinking Water Act (SDWA). Under SDWA, EPA must also review and revise "as appropriate" existing drinking water regulations every 6 years.

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) for perchloroethylene under the Safe Drinking Water Act. EPA has set an enforceable Maximum Contaminant Level (MCL) as close as feasible to a health based, non-enforceable Maximum Contaminant Level Goal (MCLG). Feasibility refers to both the ability to treat water to meet the MCL and the ability to monitor water quality at the MCL, SDWA Section 1412(b)(4)(D), and public water systems are required to monitor for the regulated chemical based on a standardized monitoring schedule to ensure compliance with the (MCL).

Hence, because the drinking water exposure pathway for perchloroethylene is currently addressed in the SDWA regulatory analytical process for public water systems, EPA does not plan to include this pathway in the risk evaluation for perchloroethylene under TSCA. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together providing understanding and analysis of the SDWA regulatory analytical processes and to exchange information related to toxicity and occurrence data on chemicals undergoing risk evaluation under TSCA.

Ambient Water Pathways
EPA develops recommended water quality criteria under section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA develops and publishes water quality criteria based on priorities of states and others that reflect the latest scientific knowledge. A subset of these chemicals are identified as "priority pollutants" (103 human health and 27 aquatic life). The CWA requires states adopt numeric criteria for priority pollutants for which EPA has published recommended criteria under section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with designated uses adopted the state. When states adopt criteria that EPA approves as part of state's regulatory water quality standards, exposure is considered when state permit writers determine if permit limits are needed and at what level for a specific discharger of a pollutant to ensure protection of the designated uses of the receiving water. Once states adopt criteria as water quality standards, the CWA requires National Pollutant Discharge Elimination System (NPDES) discharge permits include effluent limits as stringent as necessary to meet standards. CWA section 301(b)(1)(C). This is the process used under the CWA to address risk to human health and aquatic life from exposure to a pollutant in ambient waters.

EPA has identified perchloroethylene as a priority pollutant and EPA has developed recommended water quality criteria for protection of human health for perchloroethylene which are available for adoption into state water quality standards for the protection of human health and are available for use by NPDES permitting authorities in deriving effluent limits to meet state narrative criteria. As such, EPA does not expect to include this pathway in the risk evaluation under TSCA. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together providing understanding and analysis of the CWA water quality criteria development process and to exchange information related to toxicity of chemicals undergoing risk evaluation under TSCA. EPA may update its CWA section 304(a) water quality criteria for perchloroethylene in the future under the CWA.

EPA has not developed CWA section 304(a) recommended water quality criteria for the protection of aquatic life for perchloroethylene, so there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. As a result, this pathway will undergo aquatic life risk evaluation under TSCA (see Section 2.4.1). EPA may publish CWA section 304(a) aquatic life criteria for perchloroethylene in the future if it is identified as a priority under the CWA.

Biosolids Pathways

CWA Section 405(d) requires EPA to 1) promulgate regulations that establish numeric criteria and management practices that are adequate to protect public health and the environment from any reasonably anticipated adverse effects of toxic pollutants during the use or disposal of sewage sludge, and 2) review such regulations at least every two years to identify additional toxic pollutants that occur in biosolids (i.e., "Biennial Reviews") and regulate those pollutants if sufficient scientific evidence shows they may be present in sewage sludge in concentrations which may adversely affect public health or the environment. EPA also periodically conducts surveys to determine what may be present in sewage sludge. EPA has conducted four sewage sludge surveys and identified compounds that occur in biosolids in seven Biennial Reviews. EPA has regulated 10 chemicals in biosolids under CWA 405(d).

EPA has identified perchloroethylene in biosolids biennial reviews. The purpose of such reviews is to identify additional toxic pollutants in biosolids. EPA can potentially regulate those pollutants under CWA 405(d), based on a subsequent assessment of risk. EPA's Office of Water is currently developing modeling tools in order to conduct risk assessments for chemicals in biosolids. Because the biosolids pathway for perchloroethylene is currently being addressed in the CWA regulatory analytical process, this pathway will not be further analyzed in the risk evaluation for perchloroethylene under TSCA. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together to discuss significant data gaps and exchange information related to exposure and toxicity of this chemical as OW conducts the risk assessment under the CWA.

Disposal Pathways

Perchloroethylene is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the F, K and U lists. The general RCRA standard in Section RCRA 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "necessary to protect human health and the environment," RCRA 3004(a). The regulatory criteria for identifying "characteristic" hazardous wastes and for "listing" a waste as hazardous also relate solely to the potential risks to human health or the environment. 40 C.F.R. §§ 261.11, 261.21-261.24. RCRA statutory criteria for identifying hazardous wastes require EPA to "tak[e] 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." Subtitle C control cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act (CAA) hazardous waste combustion MACT) or injected into UIC Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

EPA does not expect to include emissions to ambient air from municipal and industrial waste incineration and energy recovery units in the risk evaluation, as they are regulated under section 129 of the Clean Air Act. CAA section 129 also requires EPA to review and, if necessary, add provisions to ensure the standards adequately protect public health and the environment. Thus, combustion by-products from incineration treatment of perchloroethylene wastes (the majority of the 1.1 million lbs identified as treated in Tables 2-6 – 2-8) would be subject to these regulations, as would perchloroethylene burned for energy recovery (2.3 million lbs).

EPA does not expect to include on-site releases to land that go to underground injection in its risk evaluation. TRI reporting in 2016 indicated 272 pounds released to underground injection to a Class I well and no releases to underground injection wells of Classes II-VI. Environmental disposal of perchloroethylene injected into Class I well types managed and prevented from further environmental release by RCRA and SDWA regulations. Therefore, disposal of perchloroethylene via underground injection is not likely to result in environmental and general population exposures.

EPA does not expect to include on-site releases to land from RCRA Subtitle C hazardous waste landfills or exposures of the general population (including susceptible populations) or terrestrial species from such releases in the TSCA evaluation. Based on 2015 reporting to TRI, the majority of the land disposals occur in Subtitle C landfills (78,120 lbs). Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general population exposure to perchloroethylene in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

EPA does not expect to include on-site releases to land from RCRA Subtitle D municipal solid waste landfills or exposures of the general population (including susceptible populations) or terrestrial species from such releases in the TSCA evaluation. While permitted and managed by the individual states, municipal solid waste (MSW) landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements, and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lbs per month). Bulk liquids may not be disposed in Subtitle C landfills.

EPA does not expect to include on-site releases to land from industrial non-hazardous waste and construction/demolition waste landfills in the perchloroethylene risk evaluation. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring and corrective action and a prohibition on open dumping and disposal of bulk liquids. States may also establish additional requirements such as for liners, post-closure and financial assurance, but are not required to do so. Therefore, EPA does not expect to include this pathway in the risk evaluation.

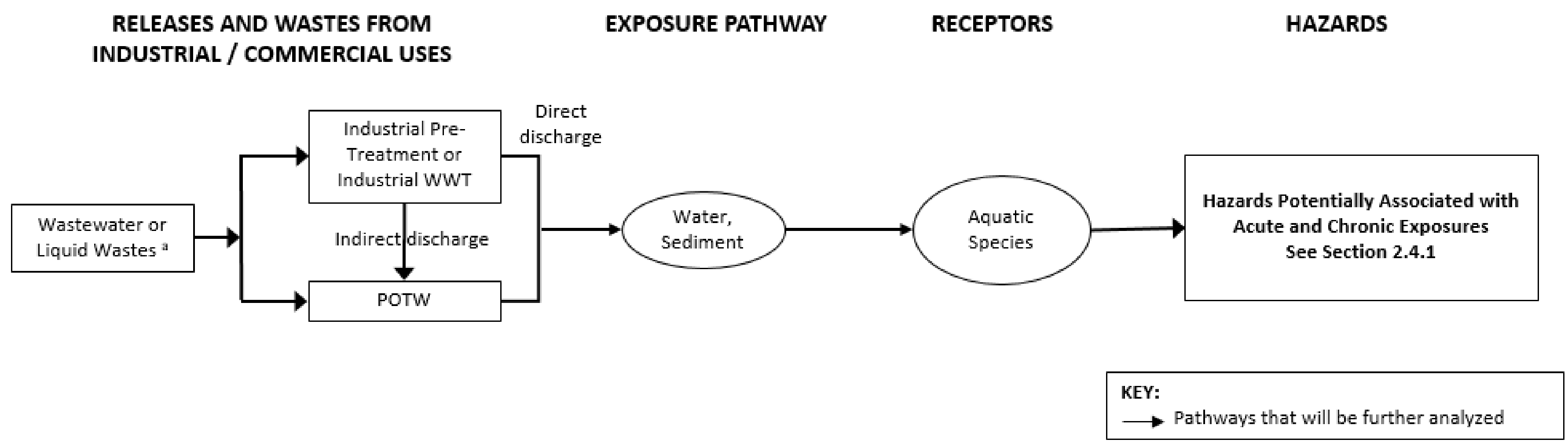

Figure 2-4. Perchloroethylene Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of perchloroethylene that will be analyzed.
[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).

2.6 Analysis Plan

The analysis plan presented in the problem formulation elaborates on the initial analysis plan that was published in the *Scope of the Risk Evaluation for Perchloroethylene (*U.S. EPA, 2017c*)*.

The analysis plan outlined here is based on the conditions of use for perchloroethylene, as described in Section 2.2 of this problem formulation. EPA is implementing systematic review approaches to identify, select, assess, integrate and summarize the findings of studies supporting the TSCA risk evaluation. The analytical approaches and considerations in the analysis plan are used to frame the scope of the systematic review activities for this assessment. The supplemental document, *Application of Systematic Review in TSCA Risk Evaluations,* provides additional information about criteria and methods that have been and will be applied to the first 10 chemical risk evaluations.

While EPA has conducted a comprehensive search for reasonably available data, as described in the Scope of the Risk Evaluation for Perchloroethylene (U.S. EPA, 2017c), 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 during risk evaluation. EPA will continue to consider new information submitted by the public.

During risk evaluation, EPA will rely on the comprehensive literature results [*Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0732)] or supplemental literature searches to address specific questions. Further, EPA may consider any relevant confidential business information (CBI) in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. The analysis plan is based on EPA's knowledge of perchloroethylene to date, which includes partial, but not complete review of identified literature. If additional data or approaches become available, EPA may refine its analysis plan based on this information.

2.6.1 Exposure

Based on their physical-chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment chemical substances are more likely to be present in some media and less likely to be present in others. Media-specific levels will vary based on the chemical substance of interest. For most chemical substances level(s) can be characterized through a combination of available monitoring data and modeling approaches.

2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to relevant 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. EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is shown in Appendix B-1. EPA will continue to review potentially relevant data sources identified in Table Apx B-3.1 in Appendix B during risk evaluation.

   EPA plans to review the following key data sources in Table 2-10 for additional information on activities resulting in environmental releases. The evaluation strategy for engineering and occupational data sources discussed in the *Application of Systematic Review in TSCA Risk Evaluations* describes how data, information, and studies will be reviewed.

Table 2-10. Potential Sources of Environmental Release Data

U.S. EPA TRI Data (Reporting Year 2016 only)
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
EU Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Specific Environmental Release Categories (SpERC) factsheets
Discharge Monitoring Report (DMR) surface water discharge data for perchloroethylene from NPDES-permitted facilities

2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI program). EPA has reviewed key release data sources including the Toxics Release Inventory (TRI), and the data from this source is summarized in Section 2.3.2 above and also in Appendix B. EPA will continue to review relevant data sources as identified in Table Apx B-3.2 in Appendix B during risk evaluation. EPA will match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA will attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and chemical and physical properties. Data for solvents that are used in the same types of applications may be considered as surrogate data for perchloroethylene. As with perchloroethylene, trichloroethylene is used in paints and coatings, in adhesives and sealants, and as solvents for cleaning and degreasing. EPA will evaluate the use of data for solvents such as trichloroethylene as surrogates to fill data gaps where uses of perchloroethylene and other solvents align. If surrogate data are used, EPA normally converts air concentrations using the ratio of the vapor pressures of the two chemicals. EPA will review literature sources identified and if surrogate data are found, EPA will match these data to applicable conditions of use for potentially filling data gaps.

4) Understand and consider regulatory limits that may inform estimation of environmental releases. EPA has identified information from various EPA statutes (including, for example, regulatory limits, reporting thresholds or disposal requirements) that may be relevant to release estimation. Some of the information has informed revision of the conceptual models during problem formulation. EPA will further consider relevant regulatory requirements in estimating releases during risk evaluation.

5) Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases. Potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) have been identified that correspond to some conditions of use. For example, the ESD on Industrial Use of Adhesives for Substrate Bonding, the ESD on the Coating Industry (Paints, Lacquers and Varnishes), and the GS on the Use of Vapor Degreasers are some of the ESDs and GSs that EPA may use to assess potential releases. EPA will need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify ESDs or GSs corresponding to several conditions of use, including use of perchloroethylene as

an intermediate, recycling of perchloroethylene, use of perchloroethylene as an industrial processing aid, and use of perchloroethylene in commercial carpet cleaning. EPA will perform additional targeted research to understand those conditions of use which may inform identification of release scenarios. EPA may also need to perform targeted research for applicable models and associated parameters that EPA may use to estimate releases for certain conditions of use. If ESDs and GSs are not available, other methods may be considered. Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including the application of default assumptions such as standard loss fractions associated with drum cleaning (3%) or single process vessel cleanout (1%).

6) Map or group each condition(s) of use to a release assessment scenario. EPA has identified release scenarios and mapped them to some conditions of use. For example, some scenario groupings include Contractor Adhesive Removal and Industrial In-line Vapor Degreasing. EPA grouped similar conditions of use (based on factors including process equipment and handling, release sources and usage rates of perchloroethylene and formulations containing perchloroethylene, or professional judgment) into scenario groupings but may further refine these groupings as additional information becomes available during risk evaluation.
   EPA was not able to identify release scenarios corresponding to several conditions of use due to a lack of general knowledge of those conditions of use. EPA will perform additional targeted research to understand those uses which may inform identification of release scenarios.
7) Complete the weight of the evidence of environmental release data.
   EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental release data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

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.

   Key environmental fate characteristics were included in assessments conducted by the EPA Integrated Risk Information System (U.S. EPA, 2012d), EPA Office of Water (U.S. EPA, 2015b), US Agency for Toxic Substances and Disease Registry (ATSDR, 2014) and European Chemicals Bureau (ECB, 2005b). These information sources will be used as a starting point for the environmental fate assessment. Other sources that will be consulted include those that are identified through the systematic review process. Studies will be evaluated using the evaluation strategies laid out in *Application of Systematic Review in TSCA Risk Evaluations*.

   If measured values resulting from sufficiently high-quality studies are not available (to be determined through the systematic review process), chemical properties will be estimated using

EPI Suite, SPARC, and other chemical parameter estimation models. Estimated fate properties will be reviewed for applicability and quality.

2) Using measured environmental fate data and/or environmental fate modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to environmental receptors.

   Measured fate data including volatilization from water, sorption to organic matter in soil and sediments, aqueous and atmospheric photolysis rates, and aerobic and anaerobic biodegradation rates, along with physical-chemical properties and models such as the EPI Suite™ STP model (which estimates removal in wastewater treatment due to adsorption to sludge and volatilization to air) and volatility model (which estimates half-life from volatilization from a model river and model lake), will be used to characterize the movement of perchloroethylene within and among environmental media and the persistence of perchloroethylene in media.

3) Evaluate the weight of the evidence of environmental fate data.
   EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental fate data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.3 Environmental Exposures

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

1) Refine and finalize exposure scenarios for environmental receptors by considering unique combinations of sources (use descriptors), exposure pathways, exposure settings, populations exposed, and exposure routes. For perchloroethylene, exposure scenarios for environmental receptors include exposures from surface water.

2) Review reasonably available environmental and biological monitoring data for environmental exposure to surface water. EPA will rely on databases (see examples below) and literature obtained during systematic review to include ranges and trends of chemical in surface water, including any trends seen in concentrations and spatial trends.
   - STORET and NWIS (USGS/EPS): https://www.epa.gov/waterdata/storage-and-retrieval-and-water-quality-exchange#portal
   - OPPT monitoring database

3) 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 that estimate surface water (e.g. E-FAST) will be evaluated and considered alongside available surface water data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations generally consider the following inputs: direct release into surface water and transport (partitioning within media) and characteristics of the environment (river flow, volume of pond, meteorological data).

4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. For example, site/location, time period, and conditions under which monitored data were collected will be evaluated to determine relevance and applicability to wider scenario development. Any studies which relate levels of perchloroethylene in the environment or biota with specific sources or groups of sources will be evaluated.

5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates. EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental exposure data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence. Refer to the supplemental document, Application of Systematic Review in TSCA Risk Evaluations, for more information on the general process for data integration.

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. EPA expects to review exposure data including workplace monitoring data collected by government agencies such as the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Health (NIOSH), and monitoring data found in published literature. These workplace monitoring data include personal exposure monitoring data (direct exposures) and area monitoring data (indirect exposures).

   EPA has reviewed available monitoring data collected by OSHA and NIOSH and will match these data to applicable conditions of use. EPA has also identified additional data sources that may contain relevant monitoring data for the various conditions of use. EPA will review these sources (identified in Table 2-11 and in Table Apx-B-3.3) and extract relevant data for consideration and analysis during risk evaluation.

   OSHA has established a permissible exposure limit (PEL) of 100 ppm 8-hour time-weighted average (TWA). The American Conference of Government Industrial Hygienists (ACGIH) has established a Threshold Limit Value (TLV) of 25 ppm 8-hour TWA. Also, NIOSH has established an immediately dangerous to life or health (IDLH) value of 150 ppm. EPA will consider the influence of these regulatory limits and recommended exposure guidelines on occupational exposures in the occupational exposure assessment.

   Table 2-11. Potential Sources of Occupational Exposure Data

2014 Draft ATSDR Toxicological Profile for Perchloroethylene
U.S. OSHA Chemical Exposure Health Data (CEHD) program data
U.S. NIOSH Health Hazard Evaluation (HHE) Program reports
1985 EPA Occupational Exposure and Release Assessment for Tetrachloroethylene

2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to perchloroethylene. EPA will review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps. For several conditions of use (e.g., vapor degreasing, cold cleaning, coating applications, adhesive applications), EPA believes trichloroethylene and other

similar solvents that share the same conditions of use may serve as surrogate for perchloroethylene.

3) For conditions of use where data is limited or not available, review existing exposure models that may be applicable in estimating exposure levels. EPA has identified potentially relevant OECD ESDs and EPA GS corresponding to some conditions of use. For example, the ESD on Industrial Use of Adhesives for Substrate Bonding, the ESD on Metalworking Fluids, and the GS for Textile Finishing are some of the ESDs and GS's that EPA may use to estimate occupational exposures. EPA will need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify ESDs or GS's corresponding to several conditions of use, including use of perchloroethylene as an intermediate, recycling of perchloroethylene, use as an industrial processing aid, and commercial carpet cleaning. EPA will perform additional targeted research to understand those conditions of use, which may inform identification of exposure scenarios. EPA may also need to perform targeted research to identify applicable models that EPA may use to estimate exposures for certain conditions of use.

   EPA was not able to identify release scenarios corresponding to several conditions of use. EPA may conduct industry outreach efforts or perform supplemental, targeted literature searches to better understand the process steps involved in that condition of use before occupational exposure assessment can be made. EPA will perform additional targeted research to understand those conditions of use, which may inform identification of exposure scenarios. EPA will consider exposure models in the Chemical Screening Tool For Exposure and Environmental Releases (ChemSTEER) Tool that are routinely used for assessing new chemicals. EPA may also need to perform targeted research to identify other applicable models that EPA could use to estimate exposures for certain conditions of use.

4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. This step will be performed after Steps #2 and #3 above. Based on information developed from Step #2 and Step #3, EPA will evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios). EPA may utilize existing, peer-reviewed exposure models developed by EPA/OPPT, other government agencies, or available in the scientific literature, or EPA may elect to develop additional models to assess specific condition(s) of use. Inhalation exposure models may be simple box models or two-zone (near-field/far-field) models. In two-zone models, the near-field exposure represents potential inhalation exposures to workers, and the far-field exposure represents potential inhalation exposures to occupational non-users.

   As part of the 2014 risk assessment (RA) and subsequent Section 6 rulemaking for TCE and the 2016 draft RA for 1-BP, EPA developed models to assess inhalation exposures to workers and occupational non-users during the use of these chemicals in dry cleaning, spot cleaning, vapor degreasing, cold cleaning, and aerosol degreasing. During risk evaluation, EPA will evaluate the applicability of these models to perchloroethylene, and adapt and refine these models as necessary for evaluating exposure to perchloroethylene in these scenarios.

   EPA will consider the effect of evaporation when evaluating options for dermal exposure assessment. In addition, EPA will consider the impact of occluded exposure or repeated dermal contacts. EPA anticipates that existing EPA/OPPT dermal exposure models would not be suitable for quantifying dermal exposure to semi-volatile chemicals such as perchloroethylene.

5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios. EPA will review potentially relevant data sources on engineering controls and personal protective equipment as identified in Table_Apx B-3.4 in the Appendix and to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA will assess worker exposure pre- and post-implementation of engineering controls, using available information on available control technologies and control effectiveness. For example, EPA may assess worker exposure in industrial use scenarios before and after implementation of local exhaust ventilation.

6) Map or group each condition of use to occupational exposure assessment scenario(s). EPA has identified exposure scenarios and mapped them to some (or most) conditions of use. EPA was not able to identify occupational exposure scenarios corresponding to several conditions of use due generally to a lack of understanding of those conditions of use (e.g., use of perchloroethylene metal and stone polishes). EPA will perform targeted research to understand those uses which may inform identification of occupational exposure scenarios. EPA grouped similar conditions of use (based on factors including process equipment and handling, usage rates of perchloroethylene and formulations containing perchloroethylene, exposure/release sources) into scenario groupings but may further refine these groupings as additional information is identified during risk evaluation.

7) Evaluate the weight of the evidence of occupational exposure data. EPA will rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence. Refer to the *Application of Systematic Review in TSCA Risk Evaluations* document for more information on the general process for data integration.

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) Refine and finalize exposure scenarios for consumers by mapping sources of exposure (i.e., consumer products), exposure pathways, exposure settings, exposure routes, and populations exposed. Considerations for constructing exposure scenarios for consumers:
    - Reasonably available data on consumer products or products available for consumer use including the weight fraction of perchloroethylene in products;
    - Information characterizing the use patterns of consumer products containing perchloroethylene including the following: intended or likely consumer activity, method of application (e.g., spray-applied, brush-applied, dip), formulation type, amount of product used, frequency and duration of individual use events, and room or setting of use;
    - The associated route of exposure for consumers; and
    - Populations who may be exposed to products as users or bystanders in the home, including potentially exposed and susceptible subpopulations such as children or women

of child bearing age and subsets of consumers who may use commercially-available products or those who may use products more frequently than typical consumers.

During consumer exposure modeling, these factors determine the resulting exposure route and magnitude. For example, while the product with the highest weight fraction in a given consumer product scenario could be run early on to indicate preliminary levels of exposure, that product may not actually result in the highest potential exposure due to having a lower frequency of use.

2) Evaluate the potential and magnitude of exposure routes based on available data. perchloroethylene, inhalation of vapor is expected to result in higher exposure to consumers and bystanders in the home compared to dermal absorption through direct contact due to fate and exposure properties. The data sources associated with these respective pathways have not been comprehensively evaluated, therefore quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet possible.

3) Review and use existing indoor exposure models that may be applicable in estimating inhalation and dermal exposure. For example, the Consumer Exposure Model (CEM version 2.0) and the Multi-Chamber Concentration and Exposure Model (MCCEM) to estimate and evaluate indoor exposures to perchloroethylene in consumer and commercial products.

4) Review reasonably available empirical 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 each other and with indoor air and product use monitoring data for perchloroethylene.

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. Based on hazard concerns, certain subpopulations such as pregnant women may be included for any consumer use scenarios, as a user or bystander. For a small subset of uses (e.g. craft glues and adhesives) children may be users of perchloroethylene containing products. For other uses of perchloroethylene containing products children and/or infants would generally not considered "users", but may be assessed as bystanders of consumer uses in the home. Other subpopulations may be subject to greater exposure, such as DIY users or those in the business of arts and crafts. Considerations will include:
    - Age-specific differences (exposure factors and activity patterns) for populations defined in the exposure scenarios. Exposure factors and activities patterns will be sourced from EPA's 2011 Exposure Factors Handbook.
    - Characteristics of the user of the consumer product and the bystander in the room, including for example, women of child bearing age and children.
    - Subpopulations that may have greater exposure due to magnitude, frequency or duration of exposure.

7) Evaluate the weight of evidence of consumer exposure estimates based on different approaches. EPA will rely on the weight of the scientific evidence when evaluating and integrating consumer exposure data. The data integration strategy will be designed to be fit-for-purpose in which EPA

will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence. Refer to the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* for more information on the general process for data evaluation. Map or group each condition of use to consumer exposure assessment scenario(s). Refine and finalize exposure scenarios for consumers by mapping sources of exposure (i.e., consumer products), exposure pathways, exposure settings, exposure routes, and populations exposed. Considerations for constructing exposure scenarios for consumers:

2.6.1.6 General Population

EPA does not expect to consider and analyze general population exposures in the risk evaluation for perchloroethylene EPA has determined that the existing regulatory programs and associated analytical processes have addressed or are in the process of addressing potential risks of perchloroethylene that may be present in various media pathways (e.g., air, water, land) for the general population. For these cases, EPA believes that the TSCA risk evaluation should focus not on those exposure pathways, but rather on exposure pathways associated with TSCA uses that are not subject to those regulatory processes.

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA will conduct an environmental hazard assessment of perchloroethylene 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).

   Environmental hazard data will be evaluated using the ecological toxicity data quality criteria outlined in the Application of Systematic Review in TSCA Risk Evaluations document. The study evaluation results will be documented in the risk evaluation phase and data from suitable studies will be extracted and integrated in the risk evaluation process.

   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. Suitable environmental hazard data will be reviewed for acute and chronic endpoints for mortality and other effects (e.g. growth, immobility, reproduction, etc.). EPA will evaluate the character of the concentration-response relationship (i.e. positive, negative or no response) as part of the review.
   Sufficient environmental hazard studies are available to assess the hazards of environmental concentrations of perchloroethylene to aquatic species.

2) Derive aquatic concentrations of concern (COC) for acute and, where possible, chronic endpoints. The aquatic environmental hazard studies may be used to derive acute and chronic concentrations of concern (COC) for mortality, behavioral, developmental and reproductive or other endpoints determined to be detrimental to environmental populations. Depending on the robustness of the evaluated data for a particular organism (e.g. aquatic invertebrates), environmental hazard values (e.g. ECx/LCx/NOEC/LOEC, etc.) may be derived and used to further understand the hazard characteristics of perchloroethylene to aquatic species.

3) Evaluate the weight of the evidence of environmental hazard data. EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental hazard data. The data integration strategy will be designed to be fit-for-purpose. EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence. Refer to the supplemental document, Application of Systematic Review in TSCA Risk Evaluations, for more information on the general process for data integration.

4) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments. EPA believes there is sufficient information to evaluate the potential risks to aquatic organisms from exposures to perchloroethylene in ground water and surface water.

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 as needed (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).

   For the perchloroethylene risk evaluation, EPA will evaluate information in the IRIS assessment and human health studies using OPPT's structured process described in the document, *Application of Systematic Review in TSCA Risk Evaluations*. Human and animal data will be identified and included as described in the inclusion and exclusion criteria in Appendix F. EPA expects to prioritize the evaluation of mechanistic evidence. Specifically, EPA does not plan to evaluate mechanistic studies unless needed to clarify questions about associations between perchloroethylene and health effects and its relevance to humans. The *Applications of Systematic Review* document describes the process of how studies will be evaluated using specific data evaluation criteria and a predetermined approach. Study results will be extracted and presented in evidence tables by hazard endpoint. EPA expects to evaluate relevant studies identified in the Integrated Risk Information System (IRIS) *Toxicological Review of Tetrachloroethylene* (U.S. EPA, 2012e). In addition, EPA intends to review studies published after the acute reference values were published (e.g. AEGLs) from January 1, 2010 to March 2, 2017 that were captured in the comprehensive literature search conducted by the Agency for perchloroethylene (see *Perchloroethylene (CASRN 127-18-4) Bibliography: Supplemental File for the TSCA Scope Document*) using the approaches described in *Application of Systematic Review in TSCA Risk Evaluations*. To more fully understand circumstances related to deaths by individuals using perchloroethylene, EPA/OPPT will review case reports, case series and ecological studies related to deaths and effects that may imminently lead to death (respiratory distress). EPA/OPPT will not be evaluating case reports and series or ecological studies for endpoints that appear to be less severe endpoints (e.g., nausea).

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. Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to perchloroethylene hazard(s).

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.

   Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the data quality criteria described in *Application of Systematic Review in TSCA Risk Evaluations*. Data quality evaluation will be performed on relevant studies identified in the IRIS assessment (U.S. EPA, 2012e), and assessments of the effects of acute exposures in the (NAC/AEGL). Data quality evaluation will also be performed on studies that were identified in the comprehensive literature search and that met the inclusion criteria for full-text screening (see *Application of Systematic Review in TSCA Risk Evaluations*. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (oral, inhalation) and by cancer and noncancer endpoints.

   Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011, 1994). Dose-response analyses performed to support the IRIS oral and inhalation reference dose determinations and for the cancer unit risk and slope factor (U.S. EPA, 2012e) may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints or additional hazard endpoints would not alter the analysis.

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.

   Hazard data will be evaluated to determine the type of dose-response modeling that is applicable, if the dose-response modeling requires updating. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with the EPA *Benchmark Dose Technical Guidance Document*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified.

   EPA will evaluate whether the available PBPK and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD, or for extrapolation of the POD to appropriate exposure durations for the risk evaluation.

5) 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.

   EPA believes there are sufficient data to conduct dose-response analysis with benchmark dose modeling or NOAELs or LOAELs for both inhalation and oral routes of exposure.

   A route-to-route extrapolation from the inhalation and oral toxicity studies is needed to assess systemic risks from dermal exposures. Without an adequate PBPK model, the approaches described in the EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* could be applied. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure.

6) Evaluate the weight of the evidence of human health hazard data. EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence. Refer to the S*ystematic Review Approaches and Methods Applied to TSCA Risk Evaluations* document for more information on the general process for data evaluation.

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, 2000a). 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, 2000a). EPA will also present information in this section consistent with approaches described in the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act Risk Evaluation Framework Rule (82 FR 33726). For instance, in the risk characterization summary, EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. EPA will also be guided by EPA's Information Quality Guidelines (U.S. EPA, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA will also identify: (1) Each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) each appropriate upper-bound or lower bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

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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		
Toxics Substances Control Act (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.	Perchloroethylene is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
Toxics Substances Control Act (TSCA) – Section 8(a)	The TSCA Section 8(a) Chemical Data Reporting (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.	Perchloroethylene manufacturing (including importing), processing, and use information is reported under the Chemical Data Reporting (CDR) rule (76 FR 50816, August 16, 2011).
Toxics Substances Control Act (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.	Perchloroethylene was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process (76 FR 50816, August 16, 2011).
Toxics Substances Control Act (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.	Eleven risk reports received for perchloroethylene (1978-2010) (US EPA, ChemView. Accessed April 13, 2017).
Toxics Substances Control Act (TSCA) – Section 4	Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Nine chemical data submissions from test rules received for perchloroethylene (1978-1980) (US EPA, ChemView. Accessed April 13, 2017).
Emergency Planning and Community Right-to-Know Act (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	Perchloroethylene is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	TRI-listed chemical in quantities above threshold levels.	
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - Sections 3 and 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 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.	EPA removed perchloroethylene and other chemical substances from its list of pesticide product inert ingredients used in pesticide products (63 FR 34384, June 24, 1998).
Clean Air Act (CAA) – Section 112(b)	Defines the original list of 189 hazardous air pollutants (HAP). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAP 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 HAP by adding or deleting a substance. Since 1990 EPA has removed two pollutants from the original list leaving 187 at present.	Lists perchloroethylene as a Hazardous Air Pollutant (42 U.S. Code § 7412), and is considered an "urban air toxic" (CAA Section 112(k)).
Clean Air Act (CAA) – Section 112(d)	Section 112(d) states that the EPA must establish national emission standards for HAP (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 the 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	There are a number of source-specific CAA, Section 112, NESHAPs for perchloroethylene, including: Dry cleaners (73 FR 39871, July 11, 2008) Organic liquids distribution (non-gasoline) (69 FR 5038, February 3, 2004) Off-site waste and recovery operations (64 FR 38950, July 20, 1999) Rubber Tire Manufacturing (67 FR 45588, July 9, 2002)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	standards, known as generally available control technology (GACT) standards, are allowed at the Administrator's discretion for area sources.	Wood furniture manufacturing (60 FR 62930, December 7, 1995) Synthetic organic chemical manufacturing (59 FR 19402, April 22,1994) Chemical Manufacturing Area Source Categories (74 FR 56008, October 29, 2009) Publicly Owned Treatment Works (64 FR 57572, October 26, 1999) Site Remediation includes perchloroethylene (68 FR 58172, October 8, 2003)
Clean Air Act (CAA) – Section 112(d) and 112(f)	Risk and technology review (RTR) of section 112(d) MACT standards. Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to section 112(d) MACT standards, and to determine if additional standards are needed to reduce remaining risks. Section 112(d)(6) requires EPA to review and revise the MACT standards, as necessary, taking into account developments in practices, processes and control technologies."	EPA has promulgated a number of RTR NESHAP (e.g., the RTR NESHAP for Perchloroethylene Dry Cleaning (71 FR 42724; July 27, 2006) and the RTR NESHAP for Halogenated Solvent Cleaning (72 FR 25138; May 3, 2007) and will do so, as required, for the remaining source categories with NESHAP
Clean Air Act (CAA) – Section 183(e)	Section 183(e) requires EPA to list the categories of consumer and commercial products that account for at least 80 percent of all VOC emissions in areas that violate the National Ambient Air Quality Standards (NAAQS) for ozone and to issue standards for these categories that require "best available controls." In lieu of regulations, EPA may issue control techniques guidelines if the guidelines are determined to be substantially as effective as regulations.	Perchloroethylene is listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). Perchloroethylene has a reactivity factor of 0.04g O3/g VOC.
Clean Air Act (CAA) – Section 612	Under Section 612 of the Clean Air Act (CAA), EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ozone depleting substances within a comparative risk framework. EPA publishes lists of acceptable and unacceptable alternatives. A determination that an	Under the SNAP program, EPA listed perchloroethylene as an acceptable substitute in cleaning solvent for metal cleaning, electronics cleaning and precision cleaning (59 FR 13044, March 18, 1994). Perchloroethylene is cited as an alternative to methyl chloroform and CFC-113 for metals,

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	alternative is unacceptable or acceptable only with conditions, is made through rulemaking.	electronics and precision cleaning. Perchloroethylene was also noted to have no ozone depletion potential and cited as a VOC-exempt solvent and acceptable ozone-depleting substance substitute (72 FR 30142, May 30, 2007).
Clean Water Act (CWA) – Section 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 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.	Perchloroethylene is designated as a toxic pollutant under section 307(a)(1) of CWA and as such is subject to effluent limitations. Also under section 304, perchloroethylene is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)).
Clean Water Act (CWA) 304(a)	Section 304(a)(1) of the Clean Water Act (CWA) requires EPA to develop and publish, and from time to time revise, recommended criteria for the protection of water quality that accurately reflect the latest scientific knowledge. Water quality criteria developed under section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects.	
Clean Water Act (CWA) – Section 307(a)	Establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 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 (Sections 301(b), 304(b), 307(b), 306), or on a case-by-case best professional judgement basis in NPDES permits (Section 402(a)(1)(B)).	

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
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 judgment 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	Perchloroethylene is subject to National Primary Drinking Water Regulations (NPDWR) under SDWA with a MCLG of zero and an enforceable maximum contaminant level (MCL) of 0.005 mg/L (40 CFR 141.61). On January 11, 2017, EPA announced a review of the eight existing NPDWRs (82 FR 3518). Perchloroethylene is one of the eight NPDWRs. EPA requested comment on the eight NPDWRs identified as candidates for revision.
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Section 102(a) and 103	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. 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.	Perchloroethylene is a hazardous substance under CERCLA. Releases of perchloroethylene in excess of 100 pounds must be reported (40 CFR 302.4).
Resource Conservation and Recovery Act (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	Perchloroethylene is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: D039 at 0.7 mg/L; F001, F002; U210.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	In 2013, EPA modified its hazardous waste management regulations to conditionally exclude solvent-contaminated wipes that have been cleaned and reused from the definition of solid waste under RCRA (78 FR 46447, July 31, 2013).
Superfund Amendments and Reauthorization Act (SARA) –	Requires the Agency to revise the hazardous ranking system and update the National Priorities List of hazardous waste sites, increases state and citizen involvement in the superfund program and provides new enforcement authorities and settlement tools.	Perchloroethylene is listed on SARA, an amendment to CERCLA and the CERCLA Priority List of Hazardous Substances. This list includes substances most commonly found at facilities on the CERCLA National Priorities List (NPL) that have been deemed to pose the greatest threat to public health.
Other Federal Regulations		
Federal Hazardous Substance Act (FHSA)	Allows the Consumer Product Safety Commission (CPSC) to (1) require precautionary labeling on the immediate container of hazardous household products or (2) to ban certain products that are so dangerous or the nature of the hazard is such that required labeling is not adequate to protect consumers.	Under the Federal Hazardous Substance Act, section 1500.83(a)(31), visual novelty devices containing perchloroethylene are regulated by CPSC.
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the U.S. FDA (Food and Drug Administration) with authority to oversee the safety of food, drugs and cosmetics.	The FDA regulates perchloroethylene in bottled water. The maximum permissible level of perchloroethylene in bottled water is 0.005 mg/L (21 CFR 165.110).
Occupational Safety and Health Act (OSH Act)	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. Under the Act, the Occupational Safety and Health Administration can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure	In 1970, OSHA issued occupational safety and health standards for perchloroethylene 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
	monitoring, engineering and administrative control measures and respiratory protection.	
Atomic Energy Act Department of Energy (DOE)	The Atomic Energy Act authorizes DOE 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 perchloroethylene is 25 ppm (8hr Time Weighted Average) and 100 ppm Short Term Exposure Limit(STEL).

A.2 State Laws and Regulations

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State actions	
State Permissible Exposure Limits	California has a workplace PEL of 25 ppm (California, OEHHA, 1988)
State Right-to-Know Acts	Massachusetts (454 CMR 21.00), New Jersey (42 N.J.R 1709(a)), Pennsylvania (Chapter 323, Hazardous Substance List), Rhode Island (RI Gen. Laws Sec. 28-21-1et seq).
Volatile Organic Compound (VOC) Regulations for Consumer Products	Many states regulate perchloroethylene 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, 20737), 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	There are several state level NESHAPs for dry cleaning and restrictions or phase outs of perchloroethylene (e.g. California, Maine, Massachusetts). Numerous states list perchloroethylene on a list of chemical substances of high concern to children (e.g. Oregon, Vermont, Washington). Under the California Proposition 65 list

State Actions	Description of Action
	(California OEHHA), perchloroethylene is known to the state of California to cause cancer.

A.3 International Laws and Regulations

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

Country/Organization	Requirements and Restrictions
Canada	Perchloroethylene is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). The use and sale of perchloroethylene in the dry cleaning industry is regulated under *Use in Dry Cleaning and Reporting Requirements Regulations (Canada Gazette*, Part II on March 12, 2003. Perchloroethylene 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 perchloroethylene into the environment from solvent degreasing facilities using more than 1,000 kilograms of perchloroethylene per year. The regulation includes a market intervention by establishing tradable allowances for the use of perchloroethylene in solvent degreasing operations that exceed the 1,000 kilograms threshold per year.
European Union	Perchloroethylene was evaluated under the 2013 Community Rolling Action Plan (CoRAP). The conclusion was no additional regulatory action was required (European Chemicals Agency (ECHA) database. Accessed April, 18 2017).
Australia	In 2011, a preliminary assessment of perchloroethylene was conducted (National Industrial Chemicals Notification and Assessment Scheme, NICNAS, 2016, Tetrachloroethylene. Accessed April, 18 2017).
Japan	Perchloroethylene is regulated in Japan under the following legislation: • Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) • Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof • Industrial Safety and Health Act (ISHA) • Air Pollution Control Law • Water Pollution Control Law • Soil Contamination Countermeasures Act • Law for the Control of Household Products Containing Harmful Substances (National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHIRP). Accessed April 18, 2017)
Australia, Austria, Belgium, Canada, Denmark, European Union, Finland, France,	Occupational exposure limits for perchloroethylene (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017).

Country/Organization	Requirements and Restrictions
Germany, Hungary, Ireland, Israel, Japan, Latvia, New Zealand, People's Republic of China, Poland, Singapore, South Korea, Spain, Sweden, Switzerland, United Kingdom	
Basel Convention	Halogenated organic solvents (Y41) are listed as a category of waste under the Basel Convention – Annex I. Although the United States is not currently a party to the Basel Convention, this treaty still affects U.S. importers and exporters.
OECD Control of Transboundary Movements of Wastes Destined for Recovery Operations	Halogenated organic solvents (A3150) are listed as a category of waste subject to The Amber Control Procedure under Council Decision C (2001) 107/Final.

Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

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

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. EPA will consider this information in combination with available monitoring data and estimation methods and models, as appropriate, to quantify occupational exposure and releases for the various conditions of use in the risk evaluation.

B.1.1 Manufacture (Including Import)

B.1.1.1 Domestic Manufacture

Perchloroethylene was previously produced through chlorination of acetylene to tetrachloroethane, then dehydrochlorination to trichloroethylene (TCE), followed by chlorination of TCE to pentachloroethane and finally dehydrochlorination to perchloroethylene (Snedecor et al., 2004). The last U.S. plant using the acetylene process was shut down in 1978 (Snedecor et al., 2004). Currently, most perchloroethylene is manufactured using one of three methods: chlorination of ethylene dichloride (EDC); chlorination of hydrocarbons containing one to three carbons (C1 to C3) or their partially chlorinated derivatives; or oxychlorination of two-carbon (C2) chlorinated hydrocarbons (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985b).

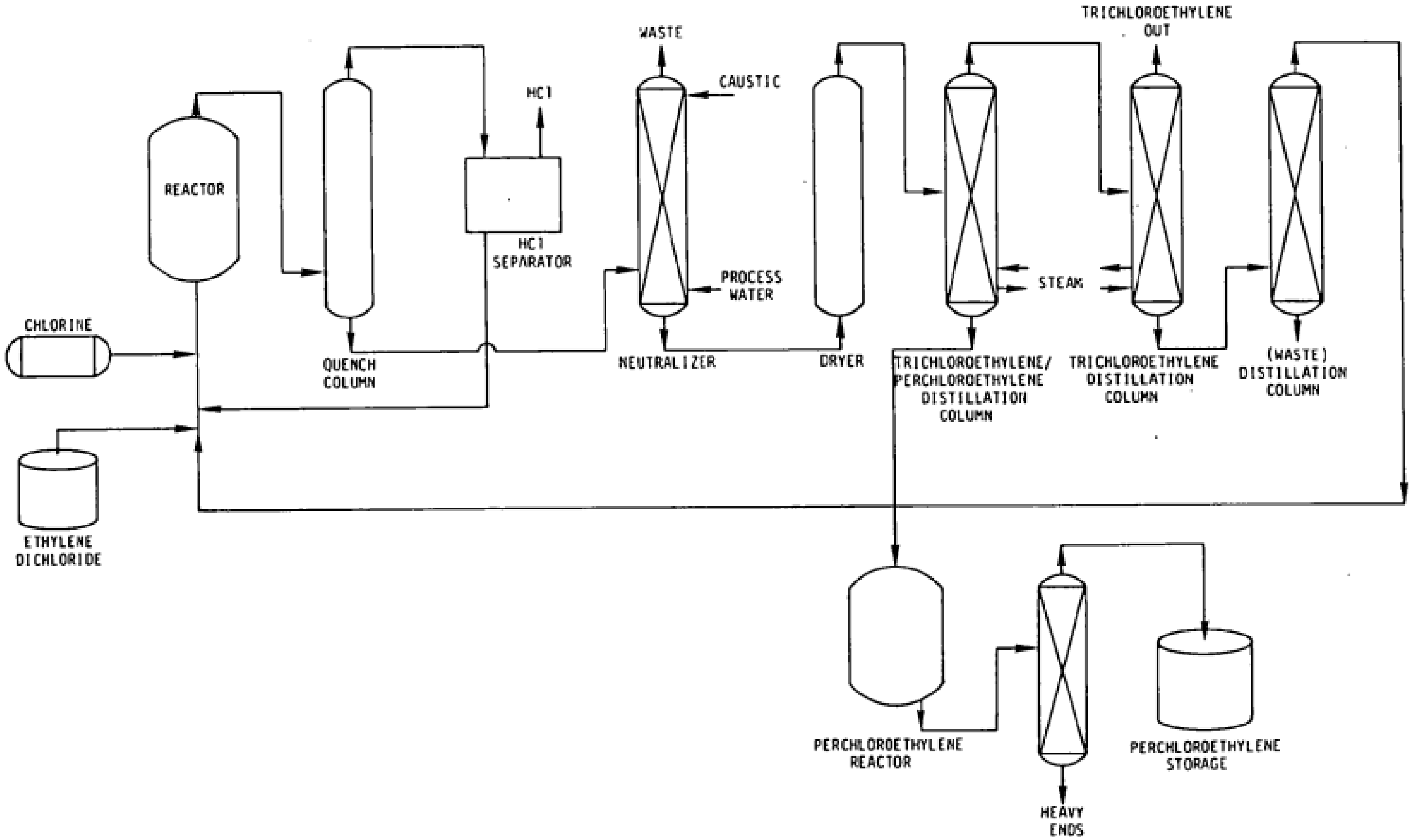
Chlorination of EDC **–** The chlorination of EDC involves a non-catalytic reaction of chlorine and EDC or other C2 chlorinated hydrocarbons to form perchloroethylene and TCE as co-products and hydrochloric acid (HCl) as a byproduct (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985b). Following reaction, the product undergoes quenching, HCl separation, neutralization, drying and distillation (U.S. EPA, 1985b). This process is advantageous at facilities that have a feedstock source of mixed C2 chlorinated hydrocarbons from other processes and an outlet for the HCl byproduct (Snedecor et al., 2004). Figure_Apx B-1 illustrates a typical process diagram of the production of perchloroethylene via EDC chlorination (U.S. EPA, 1985b).

Chlorination of C1-C3 hydrocarbons **–** The chlorination of C1-C3 hydrocarbons involves the reaction of chlorine with a hydrocarbon such as methane, ethane, propane, propylene or their chlorinated derivatives, at high temperatures (550–700°C), with or without a catalyst, to form perchloroethylene and carbon tetrachloride (CCl_4) as co-products and HCl as a byproduct (ATSDR, 2014; Snedecor et al., 2004; U.S. EPA, 1985b). This process is advantageous because mixed chlorinated hydrocarbon wastes from other processes can be used as a feedstock (ATSDR, 2014; (Snedecor et al., 2004)). Due to phase-out of CFC-11 and CFC-12 and most CCl_4 uses, most facilities using this method maximize the production of perchloroethylene and minimize or eliminate the production of CCl_4 (Snedecor et al., 2004). Figure_Apx B-2 illustrates a typical process diagram of the production of perchloroethylene via C1-C3 hydrocarbon chlorination (U.S. EPA, 1985b).

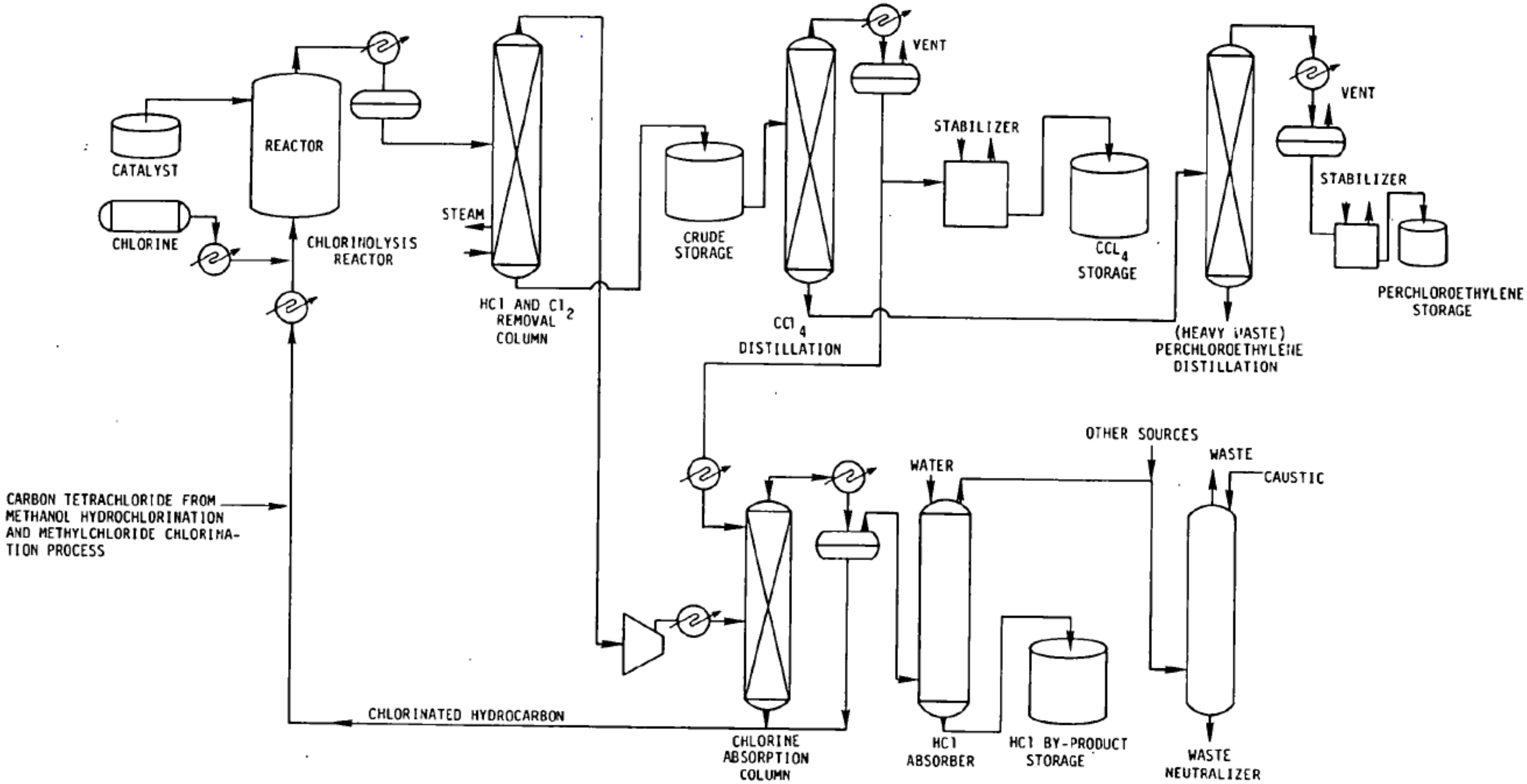
Oxychlorination of C2 chlorinated hydrocarbons **–** The oxychlorination of C2 chlorinated hydrocarbons involves the reaction of either chlorine or HCl and oxygen with EDC in the presence of a catalyst to produce perchloroethylene and TCE as co-products (ATSDR, 2014; Snedecor et al., 2004). Following reaction, the product undergoes HCl separation, drying, distillation, neutralization with ammonia and a final drying step (U.S. EPA, 1985b). The advantage of this process is that no byproduct

HCl is produced and can be combined with other processes as a net HCl consumer (ATSDR, 2014; Snedecor et al., 2004). Figure_Apx B-3 illustrates a typical process diagram of the production of perchloroethylene via oxychlorination of C2 hydrocarbons (U.S. EPA, 1985b).

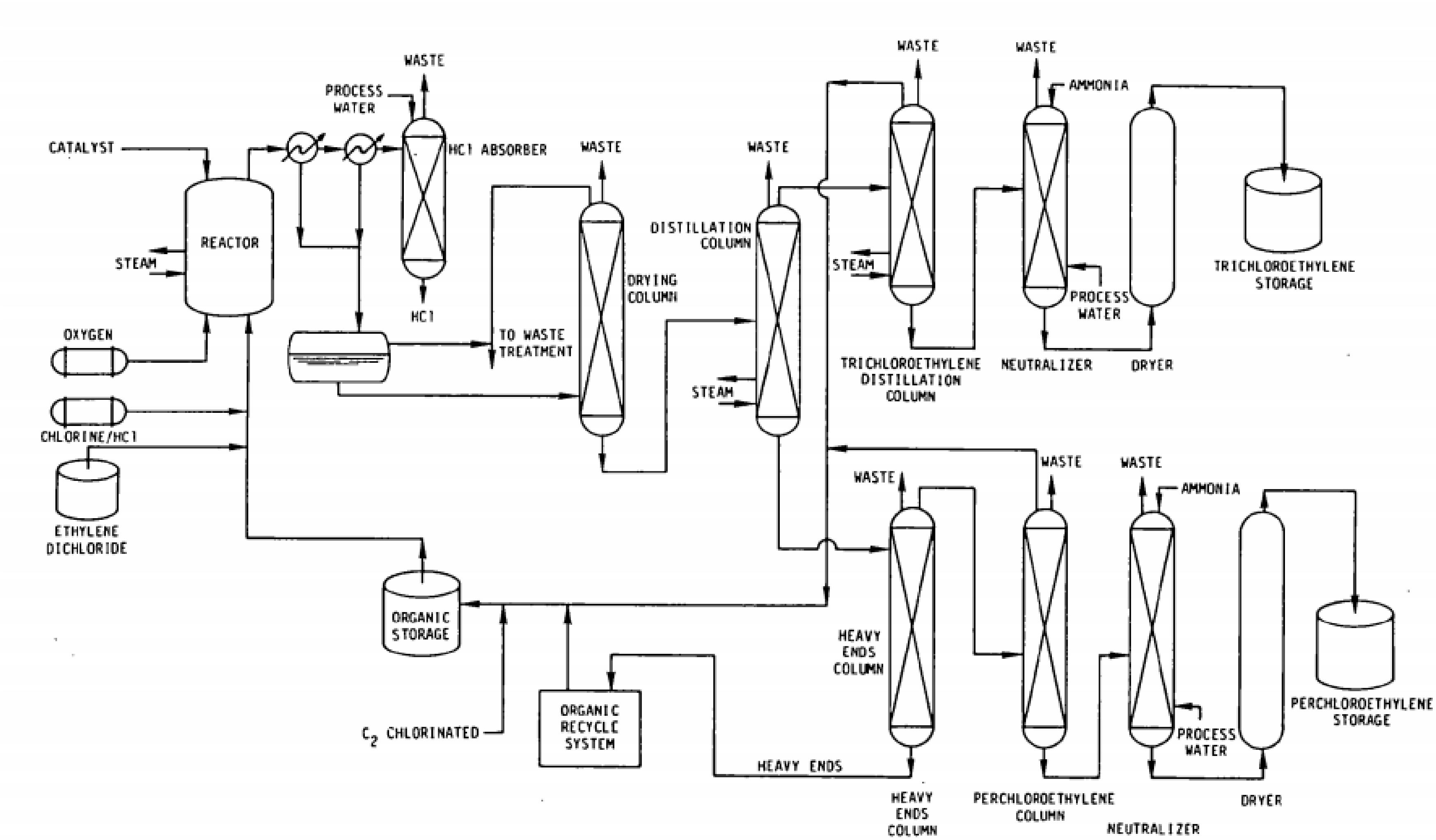
In all three processes the product ratio of perchloroethylene to TCE/CCl_4 products are controlled by adjusting the reactant ratios (Snedecor et al., 2004).



Figure_Apx B-1. Process Flow Diagram for the Manufacture of Perchloroethylene via Chlorination of EDC (EPA, 1985)



Figure_Apx B-2. Process Flow Diagram for the Manufacture of Perchloroethylene via Chlorination of Hydrocarbons (EPA, 1985)



Figure_Apx B-3. Process Flow Diagram for the Manufacture of Perchloroethylene via Oxychlorination of C2 Chlorinated Hydrocarbons (EPA, 1985)

B.1.1.2 Import

According to Snedecor et al. (2004), perchloroethylene may be shipped by barge, tank car, tank truck or 55-gallon steel drums. Perchloroethylene may be stored in steel tanks that are dry, free of rust and equipped with a chemical vent dryer and controlled evaporation vent (Snedecor et al., 2004).

B.1.2 Processing and Distribution

Based on the reported industrial processing operations in the 2016 CDR, perchloroethylene may be incorporated into a variety of formulations, products and articles, or used industrially as a chemical intermediate (U.S. EPA, 2016b). Some industrial or commercial products may also be repackaged into appropriately-sized containers to meet specific customer demands (U.S. EPA, 2016b).

B.1.2.1 Reactant or Intermediate

Processing as a reactant or intermediate is the use of perchloroethylene as a feedstock in the production of another chemical product via a chemical reaction in which perchloroethylene is consumed to form the product. In the past, perchloroethylene was used as feedstock (with chlorine) for the manufacture of one- and two-carbon (C1 and C2) CFCs (Smart and Fernandez, 2000). However, due to discovery that CFCs contribute to stratospheric ozone depletion, the use of CFCs was phased-out by the year 2000 to comply with the Montreal Protocol (Smart and Fernandez, 2000). Since the phase-out of CFCs, perchloroethylene has been used to manufacture the CFC alternatives, HCFCs, specifically the HCFC-123 alternative to CFC-11 (Smart and Fernandez, 2000). Perchloroethylene is also used as a feedstock in the production of trichloroacetyl chloride (Smart and Fernandez, 2000).

HCFC-123 is produced by fluorination of perchloroethylene with liquid or gaseous hydrofluoric acid (HF). The manufacture of HCFC is more complex than the manufacture of CFCs due to potential byproduct formation or catalyst inactivation caused by the extra hydrogen atom in the HCFCs (Smart and Fernandez, 2000). Therefore, the process involved in the manufacture of HCFCs requires additional reaction and distillation steps as compared to the CFC manufacturing process (Smart and Fernandez, 2000).

Perchloroethylene is also used by Honeywell International Inc. in the manufacture of HFC-125 (R-125), HCFC-124 (R-124), and CFC-113 (R-113) (Honeywell, 2017). In 2016, Honeywell used approximately 65 million pounds of perchloroethylene to manufacture R-125 and R-124 and approximately 20 million pounds to manufacture R-113 (Honeywell, 2017). The majority of the R-113 is used as an intermediate for manufacture of chlorotrifluoroethylene (CTFE) monomer; however, a small portion is used in exempted applications vital to U.S. security (Honeywell, 2017). Perchloroethylene is received at the Honeywell facilities in railcars and trucks and is transferred into storage vessels with a pump and vapor balance (Honeywell, 2017). Some perchloroethylene is lost when disconnecting the hose; however, the storage tank is pressurized so there are no point emissions or breathing losses (Honeywell, 2017). The primary emission of perchloroethylene at Honeywell facilities are from fugitive emissions. The facilities utilize a fugitive emissions monitoring program and leak detection program to reduce fugitive emissions (Honeywell, 2017).

Honeywell representatives indicated that the R-125/R-124 processes achieve a once through perchloroethylene conversion of 95% and the remaining 5% is recovered and recycled back into the process (Honeywell, 2017). For the R-113 process, the once through conversion rate is 99% and the remaining 1% is recovered and recycled back into the process (Honeywell, 2017). The ultimate conversion from both processes is 100%. Honeywell indicated they do not detect any perchloroethylene in their products (Honeywell, 2017).

Perchloroethylene is also used in catalyst regeneration at petroleum refineries (Dow Chemical Co., 2008; Public Comment, EPA-HQ-OPPT-2016-0732-0018). Perchloroethylene is consumed in the catalyst regeneration process; therefore, EPA considers this use as a reactant/intermediate. According to public comments from the American Fuel and Petrochemical Manufacturers (AFPM) (Public Comment, EPA-HQ-OPPT-2016-0732-0018), perchloroethylene is used in both the reforming and isomerization processes at refineries. In the reforming process, perchloroethylene is added directly to a regenerator in a Continuous Catalytic Regeneration reforming unit, and in the isomerization process, perchloroethylene is added to the hydrocarbon feed (Public Comment, EPA-HQ-OPPT-2016-0732-0018). In both processes, perchloroethylene provides chlorine ions to regenerate the catalysts and is consumed in the process (Public Comment, EPA-HQ-OPPT-2016-0732-0018).

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 perchloroethylene that may require incorporation into a formulation include adhesives, sealants, coatings, inks, lubricants and plastic and rubber manufacturing. Perchloroethylene specific formulation processes were not identified; however, several ESDs published by the OECD and Generic Scenarios published by EPA have been identified that provide general process descriptions for these types of products.

The formulation of coatings and inks typically involves dispersion, milling, finishing and filling into final packages (OECD, 2009c; U.S. EPA, 2001b). 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, 2004a). In plastics and rubber manufacturing the formulation step usually involves the compounding of the polymer resin with additives and other raw materials to form a masterbatch in either open or closed blending processes (U.S. EPA, 2014b; OECD, 2009b). After compounding, the resin is fed to an extruder where is it converted into pellets, sheets, films or pipes (U.S. EPA, 2014b).

B.1.2.3 Incorporating into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) that is distributed for industrial, trade or consumer use. The use of perchloroethylene in plastic and rubber manufacturing and the use in textile processing (as a finishing agent) are the only uses that would incorporate perchloroethylene into an article. Perchloroethylene may also be used in the plastics and rubber product manufacturing as a degreasing solvent (NIOSH, 1994b). For descriptions of degreaser uses see Appendix B.1.3.2.

Plastics and Rubber Product Manufacturing

In plastic manufacturing, the final plastic article is produced in a conversion process that forms the compounded plastic into the finished products (U.S. EPA, 2014c; OECD, 2009b). The converting process is different depending on whether the plastic is a thermoplastic or a thermosetting material (OECD, 2009b). Thermoplastics converting involves the melting of the plastic material, forming it into a new shape and then cooling it (U.S. EPA, 2014c; OECD, 2009b). The converting of thermoplastics may involve extrusion, injection molding, blow molding, rotational molding or thermoforming (U.S. EPA, 2014c; OECD, 2009b).

Conversion of thermosetting materials involves using heat and pressure to promote curing, typically through cross-linking (OECD, 2009b). The primary conversion process for thermosetting materials is compression molding; however, fiber reinforced thermosetting plastics are converted using hand layup, spray molding and filament winding (OECD, 2009b). After the forming process, finishing operations such as filing, grinding, sanding, polishing, painting, bonding, coating and engraving are performed to complete the process (U.S. EPA, 2014c).

Textile Processing

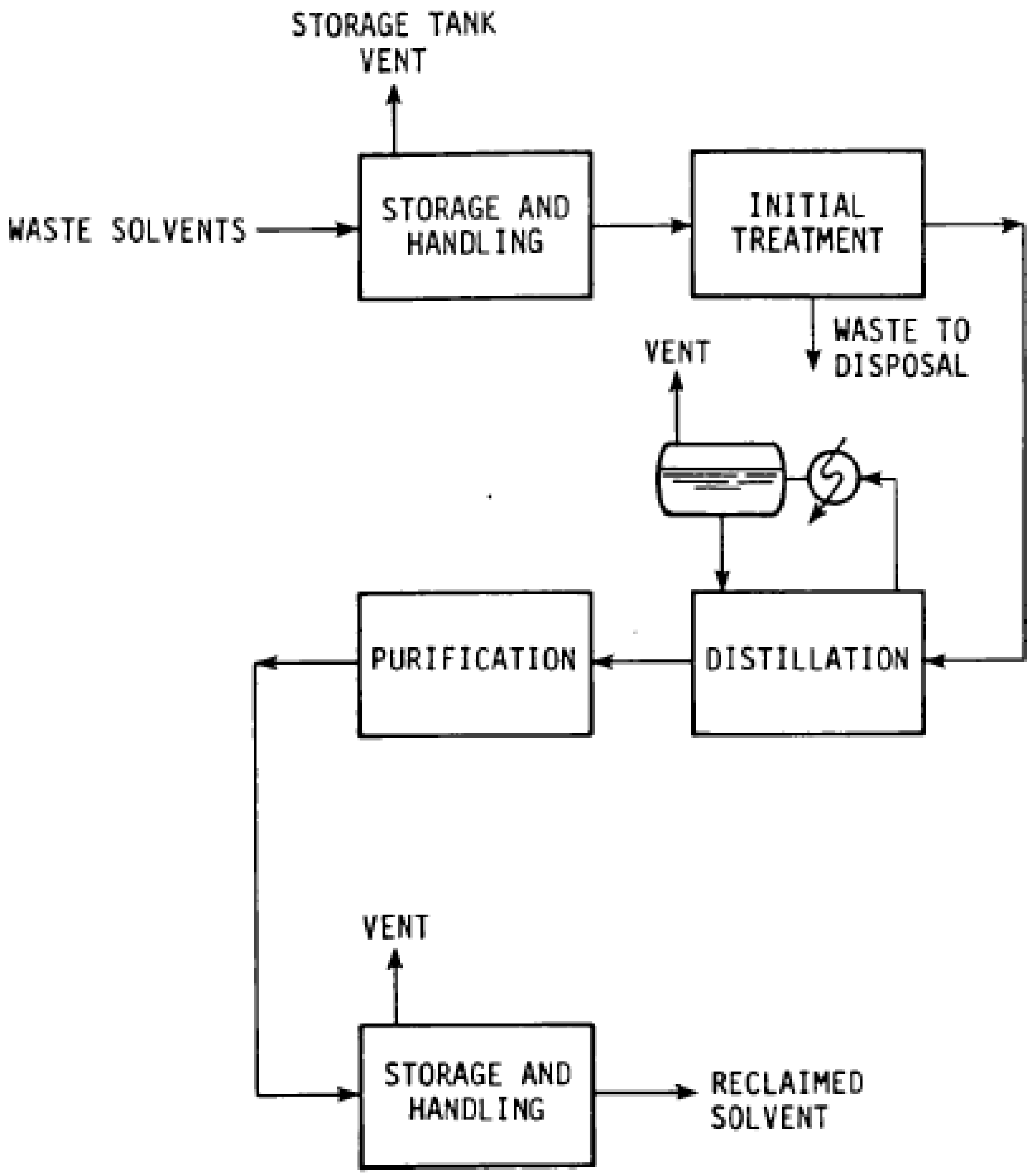
In textile processing, the purpose of the finishing stage is to impart special qualities to the textile (i.e. article). Perchloroethylene may be used as a water and stain repellant or as a fabric protector during textile finishing [cite market report]. Finishes may include mechanical treatments (e.g., calendaring and napping) or chemical treatments (e.g. stiffening, softening, water and soil repellents, antimicrobials, and fire retardants) (OECD, 2004b). The finishing process occurs after the textile is pre-treated and/or dyed/printed (OECD, 2004b). Chemical finishes are applied from aqueous solution/dispersions using the pad/dry/cure process (OECD, 2004b). In this process, the fabric is immersed in the aqueous finishing solution and then squeezed between metal rolls to remove excess solution and evenly distribute the finishing agent (OECD, 2004b). The fabric is then passed over a series of heated metal rolls for drying and cured using an oven (OECD, 2004b).

B.1.2.4 Repackaging

Typical 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.1.2.5 Recycling

Waste perchloroethylene solvent is generated when it becomes contaminated with suspended and dissolved solids, organics, water or other substance (U.S. EPA, 1980c). Waste solvents can be restored to a condition that permits reuse via solvent reclamation/recycling (U.S. EPA, 1985a, 1980c). Waste perchloroethylene is shopped to a solvent recovery site where it is piped or manually loaded into process equipment (U.S. EPA, 1985a). The waste solvent then undergoes a 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, 1985a, 1980c). Figure_Apx B-4 illustrates a typical perchloroethylene solvent recovery process flow diagram (U.S. EPA, 1985a).



Figure_Apx B-4. Process Flow Diagram of Perchloroethylene Solvent Recovery (U.S. EPA, 1985b)

B.1.3 Uses

In this document, EPA has grouped uses based on CDR categories, and identified examples within these categories as subcategories of use. Note that some subcategories of use may be grouped under multiple CDR categories. The differences between these uses will be further investigated and defined later during risk evaluation.

B.1.3.1 Cleaning and Furniture Care Products

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. Products designed to clean wood floors or other substrates which contain perchloroethylene are used in industrial or commercial settings and are primarily formulated as liquids.

Dry Cleaning Solvent and Spot Cleaner

Perchloroethylene can be used as a solvent in dry cleaning machines and is found in products used to spot clean garments. Spot cleaning products can be applied to the garment either before or after the garment is dry cleaned. The process and worker activities associated with commercial dry cleaning and spot cleaning have been previously described in EPA's 1-Bromopropane (1-BP) Draft Risk Assessment (U.S. EPA, 2016c). Note: The 1-BP risk assessment focuses on use at commercial dry cleaning facilities; however, according to EPA's *Economic Impact Analysis of the Final Perchloroethylene Dry Cleaning Residual Risk Standard* (U.S. EPA, 2006a), there are seven industrial dry cleaners that use perchloroethylene. Industrial dry cleaners clean heavily stained articles such as work gloves, uniforms, mechanics' overalls, mops and shop rags (U.S. EPA, 2006a). The general worker activities at industrial dry cleaners are not expected to significantly differ from activities at commercial dry cleaners.

Non-Aerosol Degreasers and Cleaners

Perchloroethylene 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).

Aerosol Spray Degreasers and Cleaners

Aerosol degreasing is a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts. Products containing perchloroethylene may be used in aerosol degreasing applications such as brake cleaning, engine degreasing and metal product cleaning. This use has been previously described in EPA's 1-BP Draft Risk Assessment (U.S. EPA, 2016c). Aerosol degreasing may occur at either industrial facilities or at commercial repair shops to remove contaminants on items being serviced. Aerosol degreasing products may also be purchased and used by consumers for various applications.

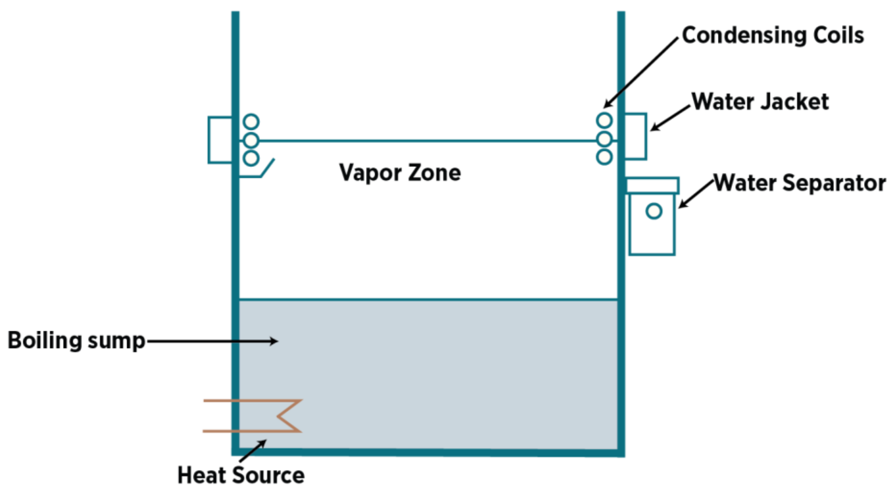
B.1.3.2 Solvents for Cleaning and Degreasing

EPA has gathered information on different types of cleaning and degreasing systems from recent TCE risk assessment (U.S. EPA, 2014e) and risk management activities (FR 81(242): 91592-91624. December 16, 2016, and FR 82(12): 7432-7461. January 19, 2017) and 1-BP risk assessment (U.S. EPA, 2016c) activities. Provided below are descriptions of five cleaning and degreasing uses of perchloroethylene.

Vapor Degreasers
Vapor degreasing is a process used to remove dirt, grease and surface contaminants in a variety of metal cleaning industries. Vapor degreasing may take place in batches or as part of an in-line (i.e., continuous) system. Vapor degreasing equipment can generally be categorized into one of three degreaser types described below:

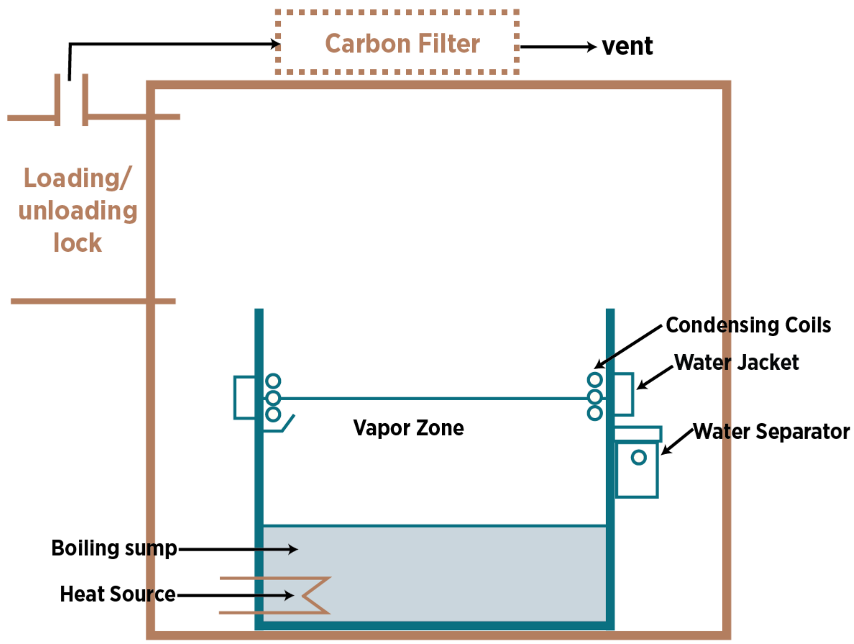
Batch vapor degreasers: In batch machines, each load (parts or baskets of parts) is loaded into the machine after the previous load is completed. Individual organizations, regulations and academic studies have classified batch vapor degreasers differently. For the purposes of the scope document, EPA categories the batch vapor degreasers into five types: open top vapor degreasers (OTVDs); OTVDs with enclosures; closed-loop degreasing systems (airtight); airless degreasing systems (vacuum drying); and airless vacuum-to-vacuum degreasing systems.

- Open top vapor degreasers (OTVD) – In OTVDs, a vapor cleaning zone is created by heating the liquid solvent in the OTVD causing it to volatilize. Workers manually load or unload fabricated parts directly into or out of the vapor cleaning zone. The tank usually has chillers along the side of the tank to prevent losses of the solvent to the air. However, these chillers are not able to eliminate emissions, and throughout the degreasing process significant air emissions of the solvent can occur. These air emissions can cause issues with both worker health and safety as well as environmental issues. Additionally, the cost of replacing solvent lost to emissions can be expensive (NEWMOA, 2001). Figure_Apx B-5 illustrates a standard OTVD.



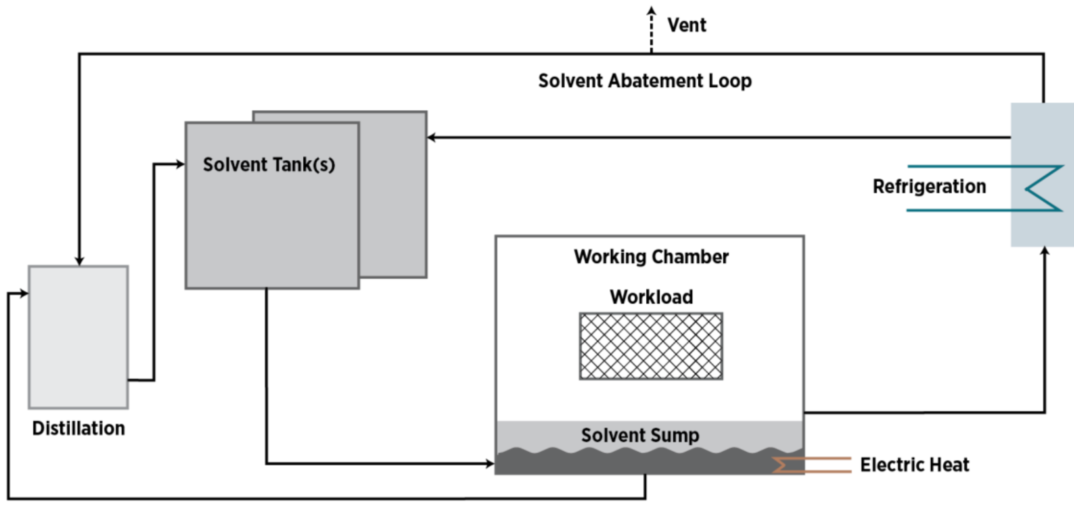
Figure_Apx B-5. Open Top Vapor Degreaser

- OTVD with enclosure – OTVDs with enclosures operate the same as standard OTVDs except that the OTVD is enclosed on all sides during degreasing. The enclosure is opened and closed to add or remove parts to/from the machine, and solvent is exposed to the air when the cover is open. Enclosed OTVDs may be vented directly to the atmosphere or first vented to an external carbon filter and then to the atmosphere (U.S. EPA; ICF Consulting, 2004; U.S. EPA). Figure_Apx B-6 illustrates an OTVD with an enclosure. The dotted lines in Figure_Apx B-6 represent the optional carbon filter that may or may not be used with an enclosed OTVD.



Figure_Apx B-6. Open Top Vapor Degreaser with Enclosure

- Closed-loop degreasing system (Airtight) – In closed-loop degreasers, parts are placed into a basket, which is then placed into an airtight work chamber. The door is closed and solvent vapors are sprayed onto the parts. Solvent can also be introduced to the parts as a liquid spray or liquid immersion. When cleaning is complete, vapors are exhausted from the chamber and circulated over a cooling coil where the vapors are condensed and recovered. The parts are dried by forced hot air. Air is circulated through the chamber and residual solvent vapors are captured by carbon adsorption. The door is opened when the residual solvent vapor concentration has reached a specified level (Kanegsberg and Kanegsberg, 2011). Figure_Apx B-7 illustrates a standard closed-loop vapor degreasing system.



Figure_Apx B-7. Closed-loop/Vacuum Vapor Degreaser

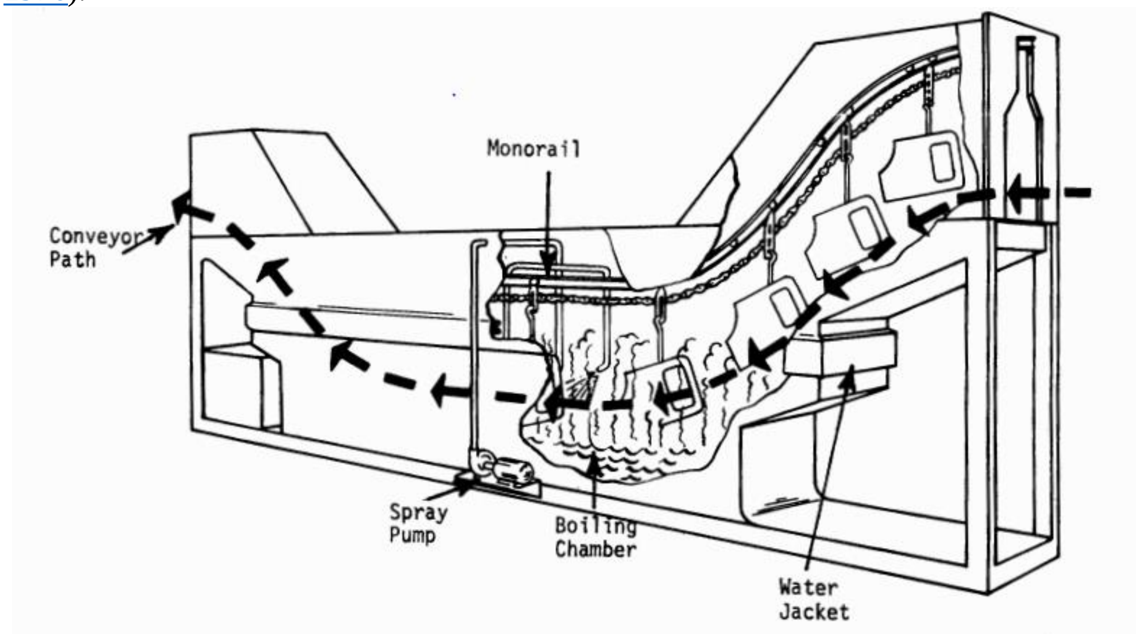
- Airless degreasing system (vacuum drying) – Airless degreasing systems are also sealed, closed-loop systems, but remove air at some point of the degreasing process. Removing air typically takes the form of drawing vacuum, but could also include purging air with nitrogen at some point of the process (in contrast to drawing vacuum, a nitrogen purge operates at a slightly positive pressure). In airless degreasing systems with vacuum drying only, the cleaning stage works similarly as with the airtight closed-loop degreaser. However, a vacuum is generated during the drying stage, typically below 5 torr (5 mmHg). The vacuum dries the parts and a vapor recovery system captures the vapors (Kanegsberg and Kanegsberg, 2011; NEWMOA, 2001; U.S. EPA, 2001a).

- Airless vacuum-to-vacuum degreasing system – Airless vacuum-to-vacuum degreasers are true "airless" systems because the entire cycle is operated under vacuum. Typically, parts are placed into the chamber, the chamber sealed, and then vacuum drawn within the chamber. The typical solvent cleaning process is a hot solvent vapor spray. The introduction of vapors in the vacuum chamber raises the pressure in the chamber. The parts are dried by again drawing vacuum in the chamber. Solvent vapors are recovered through compression and cooling. An air purge then purges residual vapors over an optional carbon adsorber and through a vent. Air is then introduced in the chamber to return the chamber to atmospheric pressure before the chamber is opened (Durkee, 2014; NEWMOA, 2001).

The general design of vacuum vapor degreasers and airless vacuum degreasers is similar as illustrated in Figure_Apx B-7 for closed-loop systems except that the work chamber is under vacuum during various stages of the cleaning process.

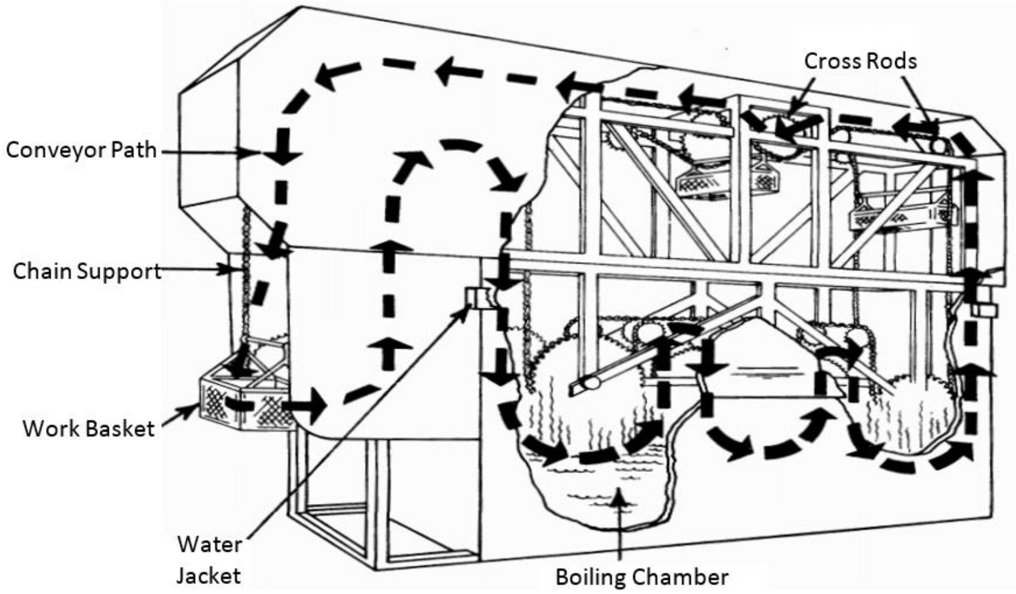
Conveyorized vapor degreasers: In conveyorized systems, an automated parts handling system, typically a conveyor, continuously loads parts into and through the vapor degreasing equipment and the subsequent drying steps. Conveyorized degreasing systems are usually fully enclosed except for the conveyor inlet and outlet portals. Conveyorized degreasers are likely used in shops where there are a large number of parts being cleaned. 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).

- Monorail Degreasers – Monorail degreasing systems are typically used when parts are already being transported throughout the manufacturing areas by a conveyor (U.S. EPA, 1976). They use a straight-line conveyor to transport parts into and out of the cleaning zone. The parts may enter one side and exit and the other or may make a 180° turn and exit through a tunnel parallel to the entrance (U.S. EPA, 1976). Figure_Apx B-8 illustrates a typical monorail degreaser (U.S. EPA, 1976).



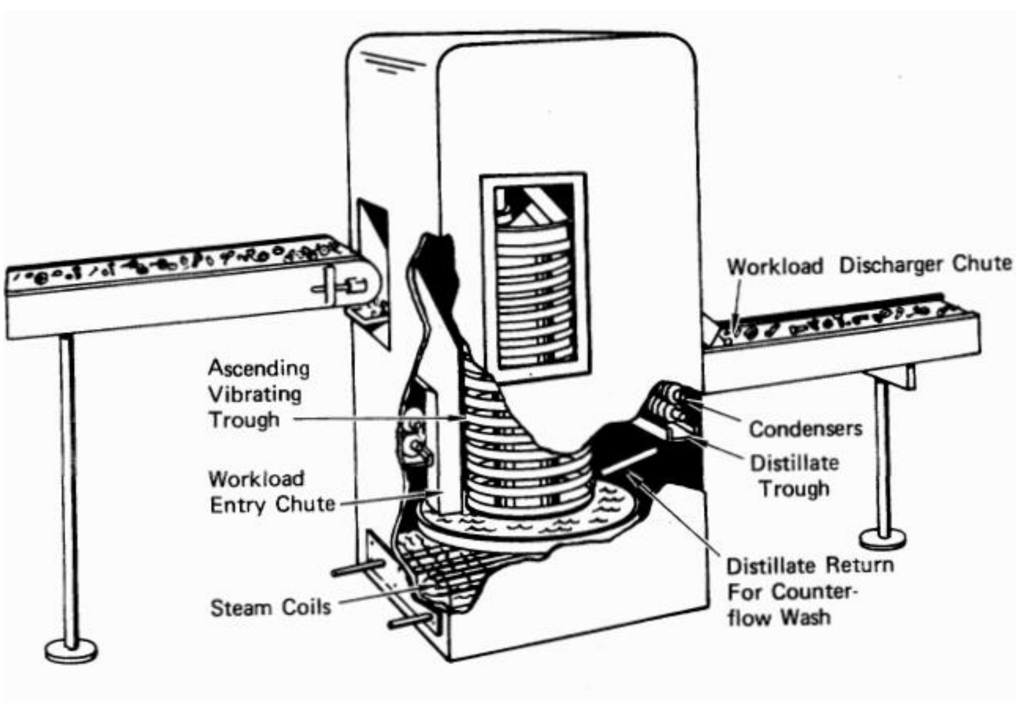
Figure_Apx B-8. Monorail Conveyorized Vapor Degreasing System (EPA, 1977a)

- Cross-rod Degreasers – Cross-rod degreasing systems utilize two parallel chains connected by a rod that support the parts throughout the cleaning process. The parts are usually loaded into perforated baskets or cylinders and then transported through the machine by the chain support system. The baskets and cylinders are typically manually loaded and unloaded (U.S. EPA, 1976). Cylinders are used for small parts or parts that need enhanced solvent drainage because of crevices and cavities. The cylinders allow the parts to be tumbled during cleaning and drying and thus increase cleaning and drying efficiency. Figure_Apx B-9 illustrates a typical cross-rod degreaser (U.S. EPA, 1976).



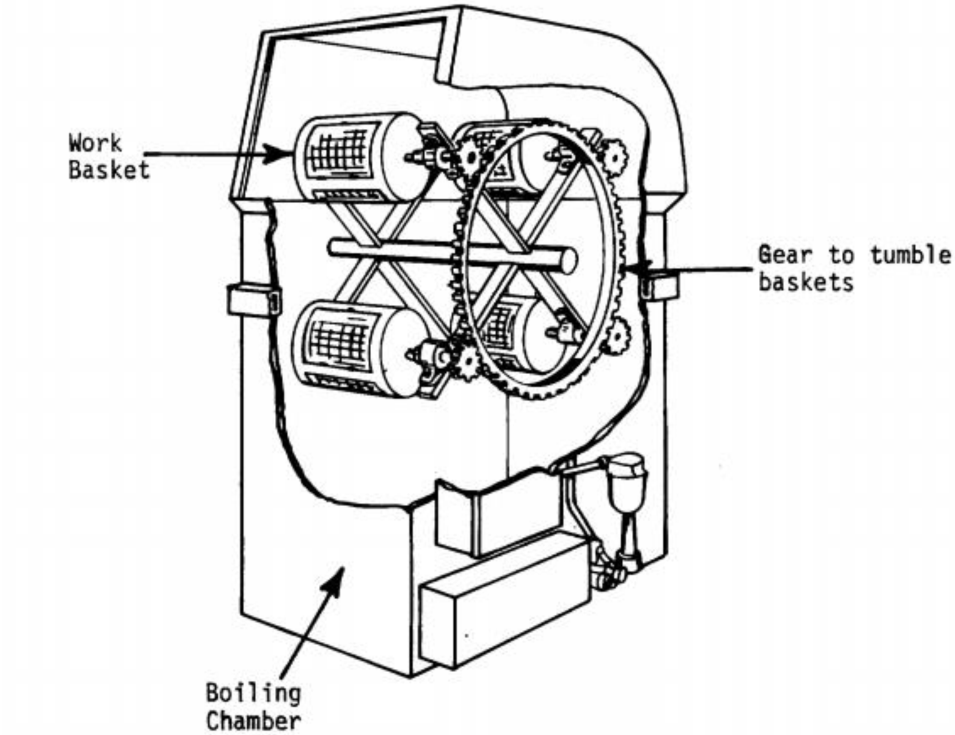
Figure_Apx B-9. Cross-Rod Conveyorized Vapor Degreasing System (EPA, 1977a)

- Vibra Degreasers – In vibra degreasing systems, parts are fed by conveyor through a chute that leads to a pan flooded with solvent in the cleaning zone. The pan and the connected spiral elevator are continuously vibrated throughout the process causing the parts to move from the pan and up a spiral elevator to the exit chute. As the parts travel up the elevator, the solvent condenses and the parts are dried before exiting the machine (U.S. EPA, 1976). Figure_Apx B-10 illustrates a typical vibra degreaser (U.S. EPA, 1976).



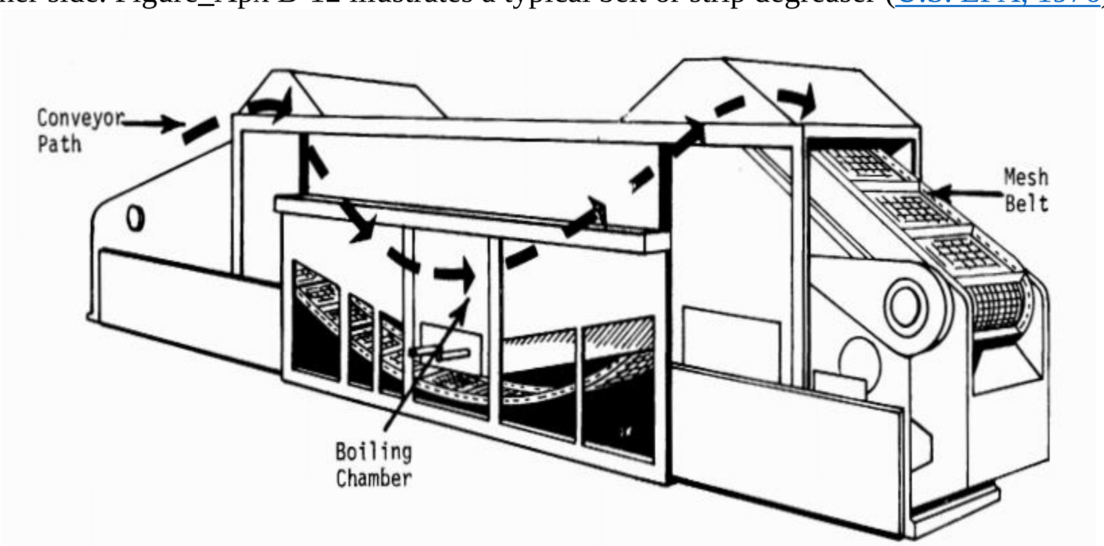
Figure_Apx B-10. Vibra Conveyorized Vapor Degreasing System (U.S. EPA, 1977)

- Ferris wheel degreasers – Ferris wheel degreasing systems are generally the smallest of all the conveyorized degreasers (U.S. EPA, 1976). In these systems, parts are manually loaded into perforated baskets or cylinders and then rotated vertically through the cleaning zone and back out. Figure_Apx B-11 illustrates a typical ferris wheel degreaser (U.S. EPA, 1976).



Figure_Apx B-11. Ferris Wheel Conveyorized Vapor Degreasing System (EPA, 1977a)

- Belt degreasers – Belt degreasing systems (similar to strip degreasers; see next bullet) are used when simple and rapid loading and unloading of parts is desired (U.S. EPA, 1976). Parts are loaded onto a mesh conveyor belt that transports them through the cleaning zone and out the other side. Figure_Apx B-12 illustrates a typical belt or strip degreaser (U.S. EPA, 1976).

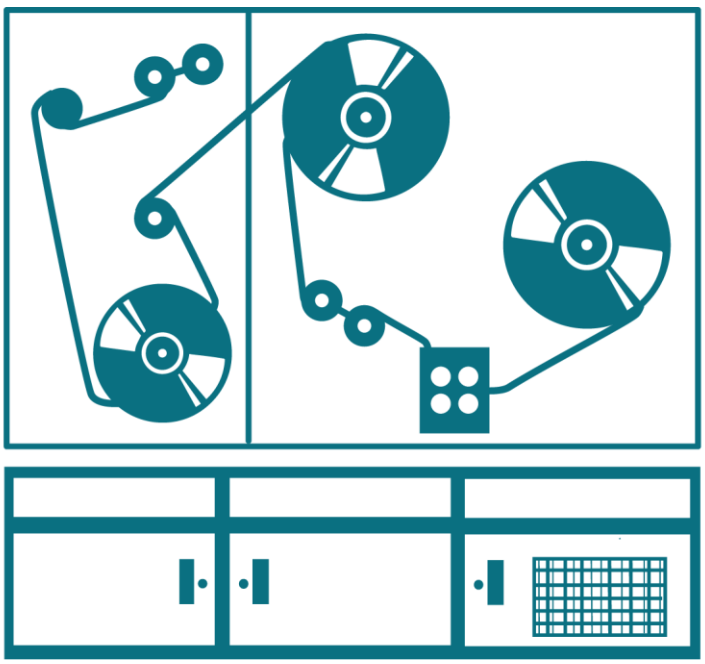


Figure_Apx B-12. Belt/Strip Conveyorized Vapor Degreasing System (U.S. EPA, 1977)

- Strip degreasers – Strip degreasing systems operate similar to belt degreasers except that the belt itself is being cleaned rather than parts being loaded onto the belt for cleaning. Figure_Apx B-12 illustrates a typical belt or strip degreaser (U.S. EPA, 1976).

- Circuit board cleaners – Circuit board degreasers use any of the conveyorized designs. However, in circuit board degreasing, parts are cleaned in three different steps due to the manufacturing processes involved in circuit board production (U.S. EPA, 1976).

Continuous web vapor degreasers: Continuous web cleaning machines are a subset of conveyorized degreasers but differ in that they are specifically designed for cleaning parts that are coiled or on spools such as films, wires and metal strips (Kanegsberg and Kanegsberg, 2011; U.S. EPA, 2006b). In continuous web degreasers, parts are uncoiled and loaded onto rollers that transport the parts through the cleaning and drying zones at speeds greater than 11 feet per minute (U.S. EPA, 2006b). The parts are then recoiled or cut after exiting the cleaning machine (Kanegsberg and Kanegsberg, 2011; U.S. EPA, 2006b). Figure_Apx B-13 illustrates a typical continuous web cleaning machine.



Figure_Apx B-13. Continuous Web Vapor Degreasing System

Cold Cleaners

Perchloroethylene 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. In a typical batch-loaded, maintenance cold cleaner, dirty parts are cleaned manually by spraying and then soaking in the tank. After cleaning, the parts are either suspended over the tank to drain or are placed on an external rack that routes the drained solvent back into the cleaner. Batch manufacturing cold cleaners could vary widely, but have two basic equipment designs: the simple spray sink and the dip tank. The dip tank design typically provides better cleaning through immersion, and often involves an immersion tank equipped with agitation (U.S. EPA, 1981). Emissions from batch cold cleaning machines typically result from (1) evaporation of the solvent from the solvent-to-air interface, (2) "carry out" of excess solvent on cleaned parts and (3) evaporative losses of the solvent during filling and draining of the machine (U.S. EPA, 2006b).

Non-Aerosol Degreasers and Cleaners
Perchloroethylene 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).

Aerosol Spray Degreasers and Cleaners
Aerosol degreasing is a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts. Products containing perchloroethylene may be used in aerosol degreasing applications such as brake cleaning, engine degreasing and metal product cleaning. This use has been previously described in EPA's 1-BP Draft Risk Assessment(U.S. EPA, 2016c). Aerosol degreasing may occur at either industrial facilities or at commercial repair shops to remove contaminants on items being serviced. Aerosol degreasing products may also be purchased and used by consumers for various applications.

B.1.3.3 Lubricant and Greases

In the 2016 CDR (U.S. EPA, 2016b), two companies reported commercial use of perchloroethylene in lubricants and greases. The *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* [EPA-HQ-OPPT-2016-0732-0003] identified perchloroethylene in penetrating lubricants, cutting oils, aerosol lubricants, red greases, white lithium greases, silicone lubricants and greases and chain and cable lubricants. Most of the products identified by EPA are applied by either aerosol or non-aerosol spray applications.

B.1.3.4 Adhesives and Sealants

Based on products identified in *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* [EPA-HQ-OPPT-2016-0732-0003] and 2016 CDR reporting, perchloroethylene may be used in adhesive and sealants for industrial, commercial and consumer applications (U.S. EPA, 2016b). The OECD ESD for Use of Adhesives (OECD, 2013) 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 perchloroethylene) evaporates during the curing stage (OECD, 2013). Worker activities include unloading activities, container and equipment cleaning activities and manual applications of adhesive (OECD, 2013). Based on EPA's knowledge of the industry, overlap in process descriptions, worker activities and application methods are expected for sealant products.

EPA's *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* (EPA-HQ-OPPT-2016-0732-0003) states that the use of perchloroethylene in consumer adhesives is especially prevalent with uses in arts and crafts and light repairs. EPA has also identified several sealants and adhesives that contain perchloroethylene and are marketed for commercial uses, such as construction applications. Based on EPA's knowledge of the industry, the likely application methods for commercial and consumer uses include spray, brush, syringe, eyedropper, roller and bead applications.

B.1.3.5 Paints and Coatings

Based on products identified in *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* (EPA-HQ-OPPT-2016-0732-0003)] and 2016 CDR reporting (U.S. EPA, 2016b), perchloroethylene may be used in various paints and coatings for industrial, commercial and consumer applications. 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, 2009c). After application, solvent-based coatings typically undergo a drying stage in which the solvent evaporates from the coating (OECD, 2009c).

B.1.3.6 Processing Aid for Pesticide, Fertilizer and Other Agricultural Manufacturing

In the 2016 CDR (U.S. EPA, 2016b), two sites owned by Olin Corporation reported use of perchloroethylene as a "processing aid, not otherwise listed" for use in the "pesticide, fertilizer, and other agricultural chemical manufacturing" industry.

B.1.3.7 Processing Aid, Specific to Petroleum Production

In the 2016 CDR (U.S. EPA, 2016b), two sites owned by Olin Corporation reported use of perchloroethylene as a "processing aid, specific to petroleum production" for use in the "Petrochemical Manufacturing" industry. A Dow Product Safety Assessment (Dow Chemical Co, 2008) for perchloroethylene describes a use at oil refineries for catalyst regeneration. However, a public comment from AFPM (Public Comment, EPA-HQ-OPPT-2016-0732-0018) indicates that perchloroethylene is consumed in the catalyst regeneration process and therefore would be considered an "intermediate" (see Appendix B.1.2.1 for description). It is unclear if this CDR reporting code is related to the use in catalyst regeneration or another processing aid use.

B.1.3.8 Other Uses

Other Industrial Uses

Based on products identified in *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* (EPA-HQ-OPPT-2016-0732-0003) , a variety of other industrial uses may exist for perchloroethylene, including textile processing, laboratory applications, foundry applications and wood furniture manufacturing. It is unclear at this time the total volume of perchloroethylene used in any of these applications. More information on these uses will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

Other Commercial/Consumer Uses

Based on products identified in EPA's *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Tetrachloroethylene (Perchloroethylene)* (EPA-HQ-OPPT-2016-0732-0003) , a variety of other commercial and consumer uses may exist for perchloroethylene including carpet cleaning; laboratory applications; metal and stone polishes; inks and ink removal products; welding applications; photographic film applications; mold cleaning, release and protectant products. Similar to the "Other" industrial uses, more information on these uses will be gathered through expanded literature searches in subsequent phases of the risk evaluation process.

B.1.4 Disposal

Perchloroethylene is listed as a hazardous waste under RCRA and federal regulations prevent land disposal of various chlorinated solvents that may contain perchloroethylene (ATSDR, 2014).

Perchloroethylene may be disposed of by absorption in vermiculite, dry sand, earth or other similar material and then buried in a secured sanitary landfill or incineration (HSDB, 2012). In incineration, complete combustion is necessary to prevent phosgene formation and acid scrubbers must be used to remove any haloacids produced (ATSDR, 2014). Perchloroethylene may also be discharged to waterways if proper permits are held (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 personal monitoring OSHA CEHD data by NAICS code (OSHA, 2017a) and Table_Apx B-2 summarizes NIOSH HHE data.

Table_Apx B-1. Summary of Perchloroethylene Personal Monitoring Air Samples Obtained from OSHA Inspections Conducted Between 2011 and 2016

Release/Exposure Scenario	NAICS	NAICS Description	8-hr TWA Concentration (ppm)[a]					STEL, Peak, or Ceiling Concentration (ppm)				
			Number of Data Points	Minimum	Maximum	Average	Number of Zero Values[b]	Number of Data Points	Minimum	Maximum	Average	Number of Zero Values[b]
Unknown, company inspected is an excavation contractor, possibly from contact with soil contaminated with perchloroethylene	236220	Commercial and Institutional Building Construction	2	0	0	0	2	2	0	0	0	2
Unknown, likely impurity in refrigerant	238220	Plumbing, Heating, and Air-Conditioning Contractors	1	5.2			0	No Data Available				
Textile pre-treatment or textile finishing	313310	Textile and Fabric Finishing Mills	1	0			1	1	0			1
Textile pre-treatment or textile finishing	313312	Textile and Fabric Finishing (except Broadwoven Fabric) Mills[c]	1	0			1	1	0			1
Other uses (ink and ink removal products), wipe cleaning, or aerosol degreasing	323113	Commercial Screen Printing	1	0			1	1	0			1
Plastics converting (possibly as a degreaser/cleaner, mold release agent, or paint/coating)	326199	All Other Plastics Product Manufacturing	2	0.2	0.3	0.2	0	1	0.9			0
Vapor degreasing or cold cleaning	331512	Steel Investment Foundries	3	0.02	0.03	0.02	0	No Data Available				
Vapor degreasing or cold cleaning	332439	Other Metal Container Manufacturing	2	0.03	0.03	0.03	0	No Data Available				
Vapor degreasing or cold cleaning	332991	Ball and Roller Bearing Manufacturing	3	0	0	0	3	3	0	0	0	3
Vapor degreasing or cold cleaning	332996	Fabricated Pipe and Pipe Fitting Manufacturing	3	0	0	0	3	3	0	0	0	3

<table>
<tr><th rowspan="2">Release/Exposure Scenario</th><th rowspan="2">NAICS</th><th rowspan="2">NAICS Description</th><th colspan="5">8-hr TWA Concentration (ppm)[a]</th><th colspan="5">STEL, Peak, or Ceiling Concentration (ppm)</th></tr>
<tr><th>Number of Data Points</th><th>Minimum</th><th>Maximum</th><th>Average</th><th>Number of Zero Values[b]</th><th>Number of Data Points</th><th>Minimum</th><th>Maximum</th><th>Average</th><th>Number of Zero Values[b]</th></tr>
<tr><td>Vapor degreasing or cold cleaning</td><td>334511</td><td>Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing</td><td>1</td><td colspan="3">0.3</td><td>0</td><td>1</td><td colspan="3">0.3</td><td>0</td></tr>
<tr><td>Vapor degreasing or cold cleaning</td><td>335999</td><td>All Other Miscellaneous Electrical Equipment and Component Manufacturing</td><td>1</td><td colspan="3">2.1</td><td>0</td><td>1</td><td colspan="3">19</td><td>0</td></tr>
<tr><td>Unknown, likely impurity in refrigerant</td><td>445110</td><td>Supermarkets and Other Grocery (except Convenience) Stores</td><td>2</td><td>0</td><td>0</td><td>0</td><td>2</td><td>2</td><td>0</td><td>0</td><td>0</td><td>2</td></tr>
<tr><td>Industrial and commercial dry cleaning</td><td>448110</td><td>Men's Clothing Stores</td><td>1</td><td colspan="3">7.8</td><td>0</td><td>1</td><td colspan="3">8.6</td><td>0</td></tr>
<tr><td>Commercial auto repair/servicing</td><td>485410</td><td>School and Employee Bus Transportation</td><td>1</td><td colspan="3">63</td><td>0</td><td>1</td><td colspan="3">100</td><td>0</td></tr>
<tr><td>Commercial auto repair/servicing</td><td>811198</td><td>All Other Automotive Repair and Maintenance</td><td>1</td><td colspan="3">110</td><td>0</td><td>1</td><td colspan="3">120</td><td>0</td></tr>
<tr><td>Industrial and commercial dry cleaning</td><td>812310</td><td>Coin-Operated Laundries and Drycleaners</td><td>1</td><td colspan="3">2.3</td><td>0</td><td>1</td><td colspan="3">9.1</td><td>0</td></tr>
<tr><td>Industrial and commercial dry cleaning</td><td>812320</td><td>Drycleaning and Laundry Services (except Coin-Operated)</td><td>30</td><td>0.1</td><td>390</td><td>27.8</td><td>0</td><td>22</td><td>0.5</td><td>480</td><td>55.4</td><td>0</td></tr>
<tr><td>Unknown – this seems to be for OSHA inspectors which could have been collected during site inspections</td><td>926150</td><td>Regulation, Licensing, and Inspection of Miscellaneous Commercial Sectors</td><td>6</td><td>0</td><td>7.2</td><td>1.4</td><td>3</td><td>6</td><td>0</td><td>7.2</td><td>1.6</td><td>3</td></tr>
<tr><td>Vapor degreasing, cold cleaning, aerosol degreasing, wipe cleaning or other uses (laboratory chemical)</td><td>927110</td><td>Space Research and Technology</td><td>1</td><td colspan="3">0</td><td>1</td><td>1</td><td colspan="3">0</td><td>1</td></tr>
</table>

[a] Assumes all TWA data are 8-hr TWA.
[b] For facilities where all samples are measured as zero, it is unclear if perchloroethylene is present at the facility. For facilities where the samples are zero and other samples are greater than zero, the zero values likely represent non-detects.
[c] This is a 2007 NAICS code, the corresponding 2012 and 2017 NAICS code is 313310 for "Textile and Fabric Finishing Mills."
Note: The data set also includes samples for a facility classified using the 2012/2017 NAICS code as a separate line item. All data for both NAICS codes were zero values.

Table_Apx B-2. Summary of Monitoring Data from NIOSH Health Hazard Evaluations Conducted since 1990

Data Source	Report Number	Exposure/Release Scenario	Facility Description	Number of Exposure Samples	Minimum of Exposure Values (ppm)	Maximum of Exposure Values (ppm)	Comments
NIOSH, 1992	HETA 91-351-2252	Industrial and commercial dry cleaning	Office co-located with a dry cleaner	0	No exposure data provided.		
NIOSH, 1994	HETA 91-377-2383	Plastics converting (as a degreaser)	Molded rubber parts manufacturer	PBZ: 15 Area: 2	PBZ: ND Area: 0.76	PBZ: 5.3 Area: 1.2	PBZ: Full-shift TWA Area: 2-hr Measurement
NIOSH, 1999	HETA 98-0249-2773	Industrial and commercial dry cleaning	Dry cleaning facility in a hotel	PBZ: 5 Area: 2	PBZ: 0.17 Area: 5.6	PBZ: 5.8 Area: 7.4	All full-shift measurements. Study also took "real-time" peak measurements ranging from 377 to >2,000 ppm.
NIOSH, 2008	HETA 07-0055-3073	Commercial auto repair/ servicing	School bus maintenance shop	0	No exposure data provided.		

ND – Non-detect

B.3 References related to Risk Evaluation – Environmental Release and Occupational Exposure

Table_Apx B-3. Potentially Relevant Data Sources for Process Description Related Information for Perchloroethylene[3]

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[3] The data sources identified are based on preliminary results to date of the full-text screening step of the Systematic Review process. Further screening and quality control are on-going.

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Burkhart, J. E.,Jennison, E. A. (1994). Health hazard evaluation report no. HETA 92-0297-2396, Exxon Chemical Company, Pottsville Film Plant, Polyethylene Film Department, Mar-Lin, Pennsyvlania #journal#, #volume#(#issue#), #Pages#	Burkhart and Jennison (1994)
McCleery, R. E.,Nemhauser, J. B.,Martinez, K. F. (2002). Health hazard evaluation report no. HETA 200-0124-2875, Tenneco Automotive, Milan, Ohio #journal#, #volume#(#issue#), #Pages#	McCleery et al. (2002)

Apol, A. G. (1981). Health hazard evaluation report no. HETA 81-105-831, Labels West, Inc., Redmond, Washington #journal#, #volume#(#issue#), #Pages#	Apol (1981)
Marlow, D. A. (1996). Health hazard evaluation report no. HETA 94-0405-2551, Metropolitan St. Louis Sewer District, Lemay Wastewater Treatment Plant, St. Louis, Missouri #journal#, #volume#(#issue#), #Pages#	Marlow (1996)
Sussell, A.,Singal, M.,Lerner, P. J. (1993). Health hazard evaluation report no. HETA 90-226-2281, Alaska Airlines, Seattle, Washington #journal#, #volume#(#issue#), #Pages#	Sussell et al. (1993)
White, G. L.,Schwartz, E. (1979). Health hazard evaluation report no. HEE 79-41-594, Stout Sportswear, Queens Long Island City, New York #journal#, #volume#(#issue#), #Pages#	White and Schwartz (1979)
Burr, G. A.,Todd, W. (1986). Health hazard evaluation report no. HETA 86-005-1679, Dutch Girl Cleaners, Springdale, Ohio #journal#, #volume#(#issue#), #Pages#	Burr and Todd (1986)
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Iarc, (1999). IARC Monographs on the evaluation of carcinogenic risks to humans: Trichloroethylene, tetrachloroethylene, and some other chlorinated agents #journal#, 106(#issue#), #Pages#	IARC (2014a)
Fda, (1977). Evaluation of production cleaning processes for electronic medical devices: Part II, cleaning solvents #journal#, #volume#(#issue#), #Pages#	FDA (1977)
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Osha, (2017). Guidance and information for: Reducing worker exposure to perchloroethylene (perc) in dry cleaning #journal#, #volume#(#issue#), #Pages#	OSHA (2017b)
Osha, (2004). Guidance and information for: Reducing worker exposure to perchloroethylene (perc) in dry cleaning #journal#, #volume#(#issue#), #Pages#	OSHA (2004)
The Massachusetts Toxics Use Reduction Institute, University of Massachusetts Lowell (2006). Five chemicals alternatives assessment study #journal#, #volume#(#issue#), #Pages#	The Massachusetts Toxics Use Reduction Institute (2006)
U.S, E. P. A. (1998). Design for the environment: Garment and textile care program #journal#, #volume#(#issue#), #Pages#	U.S. EPA (1998b)

Empe, Inc Consulting Engineers (1986). Hazardous waste management study: Dry cleaners #journal#, #volume#(#issue#), #Pages#	EMPE (1986)
Nc, Denr (2001). Alternatives to the predominant dry cleaning processes #journal#, #volume#(#issue#), #Pages#	NC DENR (2001)
European Chlorinated Solvents, Association (2016). Guidance on storage and handling of chlorinated solvents #journal#, #volume#(#issue#), #Pages#	European Chlorinated Solvents Association (ECSA) (2016)
U.S, E. P. A.,I. C. F. Consulting (2004). The U.S. solvent cleaning industry and the transition to non ozone depleting substances #journal#, #volume#(#issue#), #Pages#	U.S. EPA; ICF Consulting (2004)
Hsia, (2008). Chlorinated solvents - The key to surface cleaning performance #journal#, #volume#(#issue#), #Pages#	HSIA (2008)
Atsdr, (2014). Toxicological profile for tetrachloroethylene #journal#, #volume#(#issue#), #Pages#	ATSDR (2014)
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Erm, (2017). Life cycle assessment of used oil management #journal#, #volume#(#issue#), #Pages#	ERM (2017)
Japanese Ministry of, Environment (2004). Manual for PRTR release estimation models: 1. Examples of calculation in typical processes #journal#, #volume#(#issue#), #Pages#	Japanese Ministry of Environment (2004a)

Table_Apx B-4. Potentially Relevant Data Sources for Estimated or Measured Release Data for Perchloroethylene[4]

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U.S, E. P. A. (2001). Sources, emission and exposure for trichloroethylene (TCE) and related chemicals #journal#, GRA and I(#issue#), 138	U.S. EPA (2001c)
Garetano, G.,Gochfeld, M. (2000). Factors influencing tetrachloroethylene concentrations in residences above dry-cleaning establishments Archives of Environmental Health, 55(1), 59-68	Garetano and Gochfeld (2000)
Schreiber, J. S.,House, S.,Prohonic, E.,Smead, G.,Hudson, C.,Styk, M.,Lauber, J. (1993). An investigation of indoor air contamination in residences above dry cleaners Risk Analysis, 13(3), 335-344	Schreiber et al. (1993)
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Gilbert, D.,Goyer, M.,Lyman, W.,Magil, G.,Walker, P.,Wallace, D.,Wechsler, A.,Yee, J. (1982). An exposure and risk assessment for tetrachloroethylene #journal#, #volume#(#issue#), #Pages#	Gilbert et al. (1982)
Tsai, W. enT (2012). An Analysis of Reducing Perchloroethylene Emissions in the Urban Environment: A Case Study of Taiwan CLEAN - Soil, Air, Water, 40(2), 123-126	Tsai (2012)

[4] The data sources identified are based on preliminary results to date of the full-text screening step of the Systematic Review process. Further screening and quality control are on-going.

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U.S, E. P. A. (1995). EPA office of compliance sector notebook project. Profile of the dry cleaning industry #journal#, #volume#(#issue#), #Pages#	U.S. EPA (1995a)
Oecd, (2009). Emission scenario document on adhesive formulation #journal#, #volume#(#issue#), #Pages#	OECD (2009a)
Oecd, (2013). Emission scenario document on the industrial use of adhesives for substrate bonding #journal#, #volume#(#issue#), #Pages#	OECD (2013)
U.S, E. P. A. (1995). Guidance document for the halogenated solvent cleaner NESHAP #journal#, #volume#(#issue#), #Pages#	U.S. EPA (1995b)
Oecd, (2015). Emission scenario documents on coating industry (paints, lacquers and varnishes) #journal#, #volume#(#issue#), #Pages#	OECD (2009c)
(1978). Control of volatile organic emissions from perchloroethylene dry cleaning systems #journal#, #volume#(#issue#), #Pages#	1978)
U.S, E. P. A. (1980). Compilation of Air Pollutant Emission Factors Chapter 4.7: Waste Solvent Reclamation #journal#, #volume#(#issue#), #Pages#	U.S. EPA (1980b)
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U.S, E. P. A. (1998). Cleaner technologies substitutes assessment for professional fabricare processes: Summary #journal#, #volume#(#issue#), #Pages#	U.S. EPA (1998a)
ToxNet Hazardous Substances Data, Bank (2017). HSDB: Tetrachloroethylene #journal#, #volume#(#issue#), #Pages#	ToxNet Hazardous Substances Data Bank (2017)
Atsdr, (2011). Case studies in environmental medicine: tetrachloroethylene toxicity #journal#, #volume#(#issue#), #Pages#	ATSDR (2011)
The Massachusetts Toxics Use Reduction Institute, University of Massachusetts Lowell (2006). Five chemicals alternatives assessment study #journal#, #volume#(#issue#), #Pages#	The Massachusetts Toxics Use Reduction Institute (2006)
Empe, Inc Consulting Engineers (1986). Hazardous waste management study: Dry cleaners #journal#, #volume#(#issue#), #Pages#	EMPE (1986)
Nc, Denr (2001). Alternatives to the predominant dry cleaning processes #journal#, #volume#(#issue#), #Pages#	NC DENR (2001)

European Chlorinated Solvents, Association (2016). Guidance on storage and handling of chlorinated solvents #journal#, #volume#(#issue#), #Pages#	European Chlorinated Solvents Association (ECSA) (2016)
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Chemistry Industry Association of, Canada (2017). All substances emissions for 2012 and projections for 2015 #journal#, #volume#(#issue#), #Pages#	Chemistry Industry Association of Canada (2017b)
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Japanese Ministry of, Environment (2004). Manual for PRTR release estimation models: 1. Examples of calculation in typical processes #journal#, #volume#(#issue#), #Pages#	Japanese Ministry of Environment (2004a)

Table_Apx B-5. Potentially Relevant Data Sources for Personal Exposure Monitoring and Area Monitoring Data for Perchloroethylene[5]

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[5] The data sources identified are based on preliminary results to date of the full-text screening step of the Systematic Review process. Further screening and quality control are on-going.

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Mutti, A.,Smargiassi, A. (1998). Selective vulnerability of dopaminergic systems to industrial chemicals: risk assessment of related neuroendocrine changes Toxicology and Industrial Health, 14(1-2), 311-323	Mutti and Smargiassi (1998)
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U.S, E. P. A. (2001). Sources, emission and exposure for trichloroethylene (TCE) and related chemicals #journal#, GRA and I(#issue#), 138	U.S. EPA (2001c)
van Wijngaarden, E.,Hertz-Picciotto, I. (2004). A simple approach to performing quantitative cancer risk assessment using published results from occupational epidemiology studies Science of the Total Environment, 332(1-3), 81-87	van Wijngaarden and Hertz-Picciotto (2004)
Ohtsuki, T.,Sato, K.,Koizumi, A.,Kumai, M.,Ikeda, M. (1983). Limited capacity of humans to metabolize tetrachloroethylene International Archives of Occupational and Environmental Health, 51(4), 381-390	Ohtsuki et al. (1983)
Ludwig, H. R.,Meister, M. V.,Roberts, D. R.,Cox, C. (1983). Worker exposure to perchloroethylene in the commercial dry cleaning industry American Industrial Hygiene Association Journal, 44(8), 600-605	Ludwig et al. (1983)
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Ruhe, R. L. (1982). Health hazard evaluation report no. HETA 82-040-119, Synthes Ltd. (USA), Monument, Colorado #journal#, #volume#(#issue#), #Pages#	Ruhe (1982)
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Appendix C SUPPORTING TABLE FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES CONCEPTUAL MODEL

Table_Apx C-1. Industrial and Commercial Activities and Uses Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
Manufacture	Domestic Manufacture	Domestic Manufacture	Manufacture of perchloroethylene via chlorination of ethylene dichloride, chlorination of C1-C3 hydrocarbons, oxychlorination of C2 chlorinated hydrocarbons, and as a byproduct	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. Number of exposed workers may be high per CDR (2 submissions reported 100-500 workers each).
				Vapor	Inhalation	Workers	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during manufacturing.
Manufacture	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. Exposure will only occur in the event the imported material is repackaged.
				Vapor	Inhalation	Workers	Yes	Exposure expected only in the event the imported material is repackaged into different sized containers. Exposure frequency may be low.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
				Vapor	Inhalation	ONU	Yes	Exposure expected only in the event the imported material is repackaged into different sized containers. Exposure frequency may be low.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during import.
Processing	Processing as a reactant	Intermediate in industrial gas manufacturing; all other basic inorganic chemical manufacturing; all other basic organic chemical manufacturing; and petroleum refining	Manufacture of HCFCs, HFCs, CFCs, trichloroacetyl chloride, HCl, muriatic acid, and refinery reformer and isomerization catalyst regeneration	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, the number of workers may be high per CDR (1 submission reporting 10-25 workers, 2 submissions reporting 100-500 workers, and 5 submissions reporting NKRA).
				Vapor	Inhalation	Workers	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed. However, potential for exposure may be low in scenarios where perchloroethylene is consumed as a chemical intermediate.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed. However, potential for exposure may be low in scenarios where perchloroethylene is consumed as a chemical intermediate.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during processing as an intermediate.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
Processing	Incorporated into formulation, mixture or reaction product	Solvent for cleaning or degreasing; adhesive and sealant chemicals; paint and coating products; and other chemical products and preparations	Formulation of aerosol and non-aerosol products	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, the number of workers may be high per CDR (1 submission reporting <10 workers, 1 submission reporting 10-25 workers, 1 submission reporting 25-50 workers, 2 submissions reporting 50-100 workers, 2 submissions reporting 100-500 workers, and 3 submissions reporting NKRA).
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected at processing sites that formulate products containing perchloroethylene. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected at processing sites that formulate products containing perchloroethylene. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during processing/formulation operations.
Processing	Incorporated into articles	Plastics and rubber products manufacturing; and textile processing	Plastics converting; and textile finishing	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected at processing sites that incorporate perchloroethylene into articles. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected at processing sites that incorporate perchloroethylene into articles. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during processing operations.
Processing	Repackaging	Solvent for cleaning or degreasing; and intermediate	Repackaging into large and small containers	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. Exposure frequency may be low.
				Vapor	Inhalation	Workers	Yes	Exposure frequency may be low.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Exposure frequency may be low.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during repackaging.
Processing	Recycling	Recycling	Recycling of process solvents containing perchloroethyl ene	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. EPA expects significant volume of perchloroethylene to be sent to off-site recycling (~67% of reported releases/transfers in TRI were reported as transfers to off-site recycling).
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected at recycling sites. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed. EPA expects significant volume of perchloroethylene to be sent to off-site recycling (~67% of reported releases/transfers in TRI were reported as transfers to off-site recycling).

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected at recycling sites. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed. EPA expects significant volume of perchloroethylene to be sent to off-site recycling (~67% of reported releases/transfers in TRI were reported as transfers to off-site recycling).
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during recycling.
Distribution in commerce	Distribution	Distribution	Distribution of bulk shipment of perchloroethylene; and distribution of formulated products	Liquid Contact, Vapor	Dermal/ Inhalation	Workers, ONU	No	Exposure will only occur in the event of spills.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
Industrial use	Solvents (for cleaning or degreasing)	Batch vapor degreaser (e.g., open-top, closed-loop); and In-line vapor degreaser (e.g., conveyorized, web cleaner)	Open top vapor degreasing (OTVD); OTVD with enclosures; Conveyorized vapor degreasing; Cross-rod and ferris wheel vapor degreasing; Web vapor degreasing; Airtight closed-loop degreasing system; Airless vacuum-to-vacuum degreasing system; Airless vacuum drying degreasing system	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact or dermal immersion may occur, especially while cleaning and maintaining degreasing equipment.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected for vapor degreasing activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected for vapor degreasing activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during degreasing operations.
Industrial use	Solvents (for cleaning or degreasing)	Cold cleaner	Cold cleaning - maintenance (manual spray; spray sink; dip tank)	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact or dermal immersion may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected for cold cleaning activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected for cold cleaning activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	EPA will further evaluate to determine if mist generation is applicable.
Industrial use	Processing aids	Pesticide, fertilizer and other agricultural chemical manufacturing; and petrochemical manufacturing	Industrial processing aid	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. Additionally, EPA will need additional information to fully understand the use of perchloroethylene in this scenario to determine potential for dermal exposure.
				Vapor	Inhalation	Workers	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed. However, EPA will need additional information to fully understand the use of perchloroethylene in this scenario to determine potential for inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed. However, EPA will need additional information to fully understand the use of perchloroethylene in this scenario to determine potential for inhalation exposure.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during use of industrial processing aid.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
Industrial use	Other uses	Textile processing; wood furniture manufacturing; laboratory chemicals; and foundry applications	See Table XX for specific scenario corresponding to the condition of use.	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur for some miscellaneous conditions of use.
				Vapor	Inhalation	Workers	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	EPA will further analyze to determine if mist generation is applicable to specific conditions of use in this scenario.
Industrial / commercial / consumer use	Solvents (for cleaning or degreasing)	Aerosol spray degreaser/ cleaner	Aerosol use in degreasing/ cleaning	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected for aerosol degreasing activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected for aerosol degreasing activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analylzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	Mist generation expected for aerosol applications.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
Industrial / commercial / consumer use	Solvents (for cleaning or degreasing); and cleaning and furniture care products	Dry cleaning solvent; and spot cleaner	Industrial and commercial dry cleaning	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected for dry cleaning activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected for dry cleaning activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	Mist generation expected for spot cleaning.
				Indoor vapor	Dermal	Co-located population	No	Exposure via dermal and oral routes may be unlikely.
				Indoor vapor	Oral	Co-located population	No	Exposure via dermal and oral routes may be unlikely.
				Indoor vapor	Inhalation	Co-located population	No	EPA expects persons living in residences co-located with dry cleaners to be exposed to vapor. Exposure will occur primarily via the inhalation route. However, the NESHAP for the use of perchloroethylene in Dry Cleaners required the phase-out of perchloroethylene in co-located buildings by 2020.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
Industrial / commercial / consumer use	Lubricants and greases	Lubricants and greases (e.g., penetrating lubricants, cutting tool coolants, aerosol lubricants)	Aerosol application of lubricants to substrates	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected for application of aerosol lubricants. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected for application of aerosol lubricants. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	Mist generation expected for aerosol applications.
Industrial / commercial / consumer use	Lubricants and greases	Metalworking lubricants (cutting fluids)	Use of metalworking fluids (cutting fluids)	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected for use of metalworking fluids. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected for use of metalworking fluids. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	Mist generation expected from use of metalworking fluids.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
Industrial / commercial / consumer use	Adhesives and sealants	Solvent-based adhesives and sealants; and light repair adhesives	Spray adhesive application; and other adhesive and sealant applications (e.g. roll)	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected from adhesive applications. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected from adhesive applications. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	Mist generation expected for spray and roll applications. EPA will further analyze to determine if mist generation is applicable for each adhesive/sealant product.
Industrial / commercial / consumer use	Paints and coatings including paint and coating removers	Solvent-based paints and coatings	Spray coating application; and other paint and coating applications (e.g. roll)	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected from coating applications. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected from coating applications. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	Mist generation expected for spray and roll applications. EPA will further analyze to determine if mist generation is applicable for each paint/coating product.
Commercial / consumer use	Cleaning and furniture care products	Automotive care products (e.g., engine degreaser and brake cleaner)	Commercial auto repair/ servicing	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected for aerosol degreasing activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected for aerosol degreasing activities. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	Mist generation expected for aerosol applications.
Commercial / consumer use	Cleaning and furniture care products	Non-aerosol cleaner	Wipe cleaning	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected from wipe cleaning. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected from wipe cleaning. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further anallyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected during wipe cleaning.
Commercial / consumer use	Cleaning and furniture care products	Carpet cleaner	Commercial carpet spotting and stain removers	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur.
				Vapor	Inhalation	Workers	Yes	Inhalation exposure is expected from carpet cleaning. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	Inhalation exposure is expected from carpet cleaning. perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be furtheranalyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	EPA will further analyze to determine if mist generation is applicable.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / no Further Evaluation
Commercial / consumer use	Other uses	Laboratory chemicals; metal and stone polishes; inks and ink removal products; welding; photographic film; and mold cleaning, release and protectant products	See Table XX for specific scenario corresponding to the condition of use.	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. However, repeat contact may occur may occur for some miscellaneous conditions of use.
				Vapor	Inhalation	Workers	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	Yes	EPA will further analyze to determine if mist generation is applicable to specific conditions of use in this scenario.
Disposal	Waste Handling, Treatment and Disposal	Disposal of perchloroethylene wastes	Worker handling of wastes	Liquid Contact	Dermal	Workers	Yes	Contact time with skin is expected to be <10 min due to volatilization. Frequency of exposure and the potential for dermal immersion needs to be further analyzed.
				Vapor	Inhalation	Workers	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
				Vapor	Inhalation	ONU	Yes	perchloroethylene is semi-volatile (VP = 18.5 mmHg) at room temperature, inhalation pathway should be further analyzed.
				Mist	Dermal/ Inhalation	Workers, ONU	No	Mist generation not expected from waste handling.

Appendix D SUPPORTING TABLE FOR CONSUMER ACTIVITIES AND USES CONCEPTUAL MODEL

Table_Apx D-1. Consumer Activities and Uses Conceptual Model Supporting Table

Categories of Conditions of Use for Consumer Activities	Exposure Pathway	Exposure Pathway	Receptor	Rationale for Inclusion
Cleaning and Furniture Care Products; Lubricants and Greases; Adhesives and Sealants; Paints and Coatings; Dry Cleaned Clothing and Textiles; Other Uses	Liquid Contact	Dermal	Consumer	Perchloroethylene is found in consumer products, dermal contact to perchloroethylene containing liquids will be further analyzed for consumer exposure
	Vapor/Mist (Includes Liquid Contact)	Inhalation (includes Oral)	Consumer, Bystanders	Perchloroethylene is found in consumer products and may volatilize, depending on product formulation and percent composition. Inhalation exposure to perchloroethylene containing liquids will be further analyzed for consumers and bystanders

ONU = Occupational Non-User

Appendix E SUPPORTING TABLE FOR ENVIRONMENTAL RELEASES AND WASTES CONCEPTUAL MODEL

Table_Apx E-1. Environmental Releases and Wastes Conceptual Model Supporting Table

Life Cycle Stage	Release Category	Release/ Exposure Scenario	Exposure Pathway/ Media	Exposure Routes	Receptor/ Population	Proposed for Further Risk Evaluation	Rationale for Further Evaluation/ no Further
Manufacture and Import; Processing as Reactant/ Intermediate; Incorporation into Formulation; Mixture or Reaction Product; Incorporation into Article; Use of Product of Article; Repackaging; Recycling	Wastewater or Liquid Wastes	Industrial Pre-Treatment and Industrial WWT and/or Municipal WWT	Water, Sediment	Water	Aquatic Species	Yes	Perchloroethylene toxicity to aquatic and sediment dwelling aquatic species is expected to be low-moderate; perchloroethylene has low bioaccumulation potential, and conservative estimates for surface water and sediment concentrations due to current TSCA uses were below identified COCs

Appendix F INCLUSION AND EXCLUSION CRITERIA FOR FULL TEXT SCREENING

Appendix F contains the eligibility criteria for various data streams informing the TSCA risk evaluation: environmental fate; engineering and occupational exposure; exposure to consumers; and human health hazard. The criteria are applied to the *on-topic* references that were identified following title and abstract screening of the comprehensive search results published on June 22, 2017.

Systematic reviews typically describe the study eligibility criteria in the form of PECO statements or a modified framework. PECO stands for Population, Exposure, Comparator and Outcome and the approach is used to formulate explicit and detailed criteria about those characteristics in the publication that should be present in order to be eligible for inclusion in the review. EPA/OPPT adopted the PECO approach to guide the inclusion/exclusion decisions during full text screening.

Inclusion and exclusion criteria were also used during the title and abstract screening, and documentation about the criteria can be found in the *Strategy for Conducting Literature Searches* document published in June 2017 along with each of the TSCA Scope documents. The list of *on-topic* references resulting from the title and abstract screening is undergoing full text screening using the criteria in the PECO statements. The overall objective of the screening process is to select the most relevant evidence for the TSCA risk evaluation. As a general rule, EPA is excluding non-English data/information sources and will translate on a case by case basis.

The inclusion and exclusion criteria for ecotoxicological data have been documented in the ECOTOX SOPs. The criteria can be found at https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4) and in the *Strategy for Conducting Literature Searches* document published along with each of the TSCA Scope documents.

Since full text screening commenced right after the publication of the TSCA Scope document, the criteria were set to be broad to capture relevant information that would support the initial risk evaluation. Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the revised risk evaluation.

These refinements will include changes to the inclusion and exclusion criteria discussed in this appendix to better support the revised risk evaluation and will likely reduce the number of data/information sources that will undergo evaluation.

F.1 Inclusion Criteria for Data Sources Reporting Environmental Fate Data

EPA/OPPT developed a generic PESO statement to guide the full text screening of environmental fate data sources. PESO stands for Pathways and Processes, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the PESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental fate assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PESO statement.

EPA describes the expected exposure pathways to human receptors from consumer uses of perchloroethylene that EPA plans to include in the risk evaluation in Section 2.5.2. EPA expects that the primary route of exposure for consumers will be via inhalation. There may also be dermal exposure. Environmental fate data will not be used to further assess these exposure pathways as they are expected to occur in the indoor environment.

During problem formulation, exposure pathways to human and ecological receptors from environmental releases and waste stream associated with industrial and commercial activities will not be further analyzed in risk evaluation. For a description of the rationale behind this conclusion, see Section 2.5.3.2. In the absence of exposure pathways for further analysis, environmental fate data will not be further evaluated. Therefore, PESO statements describing fate endpoints, associated processes, media and exposure pathways that were considered in the development of the environmental fate assessment for perchloroethylene will not be presented.

F.2 Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

EPA/OPPT developed a generic RESO statement to guide the full text screening of engineering and occupational exposure literature(Table Apx F-3). RESO stands for Receptors, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the RESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria specified in the RESO statement will be eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure assessments, while those that do not meet these criteria will be excluded.

The RESO statement should be used along with the engineering and occupational exposure data needs table (Table_Apx F-3) when screening the literature.

Since full text screening commenced right after the publication of the TSCA Scope document, the criteria for engineering and occupational exposure data were set to be broad to capture relevant information that would support the risk evaluation. Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the revised risk evaluation.

Table_Apx F-1. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

RESO Element	**Evidence**
Receptors	• **Humans:** Workers, including occupational non-users • **Environment:** Aquatic ecological receptors (release estimates input to Exposure) Please refer to the conceptual models for more information about the ecological and human receptors included in the TSCA risk evaluation.

Exposure	• Worker exposure to and occupational environmental releases of the chemical substance of interest
	  o Dermal and inhalation exposure routes (as indicated in the conceptual model)
	  o Surface water (as indicated in the conceptual model)
	
	Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.

Setting or Scenario	• Any occupational setting or scenario resulting in worker exposure and environmental releases (includes all manufacturing, processing, use, disposal indicated in Table A-3.
Outcomes	• Quantitative estimates* of worker exposures and of environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*

* Metrics (e.g., mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering, Release, and Occupational Exposure Data Needs (Table 2) provides a list of related and relevant general information.

TSCA=Toxic Substances Control Act

Table_Apx F-2. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments

Objective Determined during Scoping	Type of Data
General Engineering Assessment (may apply for either or both Occupational Exposures and / or Environmental Releases)	1. Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (e.g., each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. [Tags: Life cycle description, Life cycle diagram] [a] 2. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. [Tags: Production volume, Import volume, Use volume, Percent PV] [a] 3. Description of processes, equipment, unit operations, and material flows and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). [Tags: Process description, Process material flow rate, Annual operating days, Annual batches, Weight fractions (for each of above, manufacture, import, processing, use)] [a] 4. Basic chemical properties relevant for assessing exposures and releases, e.g., molecular weight, normal boiling point, melting point, physical forms, and room temperature vapor pressure. [Tags: Molecular weight, Boiling point, Melting point, Physical form, Vapor pressure, Water solubility] [a] 5. Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. [Tags: Numbers of sites (manufacture, import, processing, use), Site locations] [a]
Occupational Exposures	6. Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. [Tags: Worker activities (manufacture, import, processing, use)] [a] 7. Potential routes of exposure (e.g., inhalation, dermal). [Tags: Routes of exposure (manufacture, import, processing, use)] [a] 8. Physical form of the chemical(s) of interest for each exposure route (e.g., liquid, vapor, mist) and activity. [Tags: Physical form during worker activities (manufacture, import, processing, use)] [a] 9. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). [Tags: PBZ measurements (manufacture, import, processing, use)] [a] 10. Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). [Tags: Area measurements (manufacture, import, processing, use)] [a] 11. For solids, bulk and dust particle size characterization data. [Tags: PSD measurements (manufacture, import, processing, use)] [a] 12. Dermal exposure data. [Tags: Dermal measurements (manufacture, import, processing, use)] 13. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). [Tags: Worker exposure modeling data needs (manufacture, import, processing, use)] [a] 14. Exposure duration (hr/day). [Tags: Worker exposure durations (manufacture, import, processing, use)] [a] 15. Exposure frequency (days/yr). [Tags: Worker exposure frequencies (manufacture, import, processing, use)] [a] 16. Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. [Tags: Numbers of workers exposed (manufacture, import, processing, use)] [a] 17. Personal protective equipment (PPE) types employed by the industries within scope. [Tags: Worker PPE (manufacture, import, processing, use)] [a] 18. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of

Objective Determined during Scoping	Type of Data
	exposure reductions. [Tags: Engineering controls (manufacture, import, processing, use), Engineering control effectiveness data] [a]
Environmental Releases	19. Description of relvant sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. [Tags: Release sources (manufacture, import, processing, use)] [a] 20. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each relevant environmental media (air, water, land) and treatment and disposal methods (POTW, incineration, landfill), including releases per site and aggregated over all sites (annual release rates, daily release rates) [Tags: Release rates (manufacture, import, processing, use)] [a] 21. Release or emission factors. [Tags: Emission factors (manufacture, import, processing, use)] [a] 22. Number of release days per year. [Tags: Release frequencies (manufacture, import, processing, use)] [a] 23. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). [Tags: Release modeling data needs (manufacture, import, processing, use)] [a] 24. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions. [Tags: Treatment/ emission controls (manufacture, import, processing, use), Treatment/ emission controls removal/ effectiveness data] [a]

Notes:

[a] These are the tags included in the full text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.

Abbreviations:

hr=Hour
kg=Kilogram(s)
lb=Pound(s)
yr=Year
PV=Particle volume
PBZ=
POTW=Publicly owned treatment works
PPE=Personal projection equipment
PSD=Particle size distribution
TWA=Time-weighted average

F.3 Inclusion Criteria for Data Sources Reporting Exposure Data on Consumers and Ecological Receptors

EPA/OPPT developed PECO statements to guide the full text screening of exposure data/information for human (i.e., consumers, potentially exposed or susceptible subpopulations) and ecological receptors. Subsequent versions of the PECO statements may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PECO statement are eligible for inclusion, considered for evaluation, and possibly included in the exposure assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PECO statement. The perchloroethylene-specific PECO is provided in Table_Apx F-5.

Since full text screening commenced right after the publication of the TSCA Scope document, the criteria for exposure data were set to be broad to capture relevant information that would support the risk evaluation. Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the risk evaluation.

Table_Apx F-3. Inclusion Criteria for the Data Sources Reporting Perchloroethylene Exposure Data on Consumers and Ecological Receptors

PECO Element	Evidence
Population	**Human:** Consumers; bystanders in the home; children; infants; pregnant women; lactating women.
	Ecological: Aquatic species.
Exposure	**Expected Primary Exposure Sources, Pathways, Routes:** • Sources: Industrial and commercial activities involving non-closed systems producing releases to surface water; consumer uses in the home producing releases to air and dermal contact • Pathways: indoor air, direct contact and surface water. • Routes of Exposure: Inhalation via indoor air (consumer and bystander populations) and incidental ingestion of aerosols and mists; dermal exposure via direct contact with consumer products containing perchloroethylene
Comparator (Scenario)	**Human:** Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
	Ecological: Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
Outcomes for Exposure Concentration or Dose	**Human:** Acute, subchronic, and/or chronic external dose estimates (mg/kg/day); acute, subchronic, and/or chronic air and water concentration estimates (mg/m^3 or mg/L). Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered.
	Ecological: A wide range of ecological receptors will be considered (range depending on available ecotoxicity data).

Abbreviations:
Kg=Kilogram(s)
Mg=Milligram(s)
M^3=Cubic meter
L=Liter(s)

F.4 Inclusion Criteria for Data Sources Reporting Ecological Hazards

Table_Apx F-4. Ecological Hazard PECO (Populations, Exposures, Comparators, Outcomes) Statement for Perchloroethylene

PECO Element	Evidence
Population	Tests of the single chemical (*i.e.*, PERC) on live, whole, taxonomically verifiable organisms, (including gametes, embryos, or plant or fungal sections capable of forming whole, new organisms) and *in vitro* systems.
Exposure	**Chemical:** Tests using single, verifiable chemical, administered through an acceptable route. Must also be used in relevant environmental exposure studies, as determined by usual toxicology standards.
	Concentration: Study must specify the amount of chemical the organisms were exposed to, either as a concentration in the environment when administered via environmental media (e.g. air, soil, water, or sediment), or as a dosage when introduced directly into or on the organism via oral (e.g. diet or gavage), topical or injection routes.
	Duration: Study must specify the duration from the time of initial exposure to the time of measurement. May be imprecise, as in "less than 6 months," "one growing season," or "from 3 to 5 weeks."
Comparator	Study must have controls or reference locations.
Outcome	Measurable/observable biological effect(s) (e.g. mortality, behavioral, population, biochemical, cellular, physiological, growth, reproduction, etc.) of an acceptable organism to a chemical.

F.5 Inclusion Criteria for Data Sources Reporting Human Health Hazards

EPA/OPPT developed a perchloroethylene-specific PECO statement (Table _Apx F-7) to guide the full text screening of the human health hazard literature. Subsequent versions of the PECOs may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the criteria specified in the PECO statement will be eligible for inclusion, considered for evaluation, and possibly included in the human health hazard assessment, while those that do not meet these criteria will be excluded according to the exclusion criteria.

In general, the PECO statements were based on (1) information accompanying the TSCA Scope document, and (2) preliminary review of the health effects literature from authoritative sources cited in the TSCA Scope documents. When applicable, these authoritative sources (e.g., IRIS assessments, EPA/OPPT's Work Plan Problem Formulations or risk assessments) will serve as starting points to identify PECO-relevant studies.

Table_Apx F-5. Inclusion and Exclusion Criteria for Data Sources Reporting Human Health Hazards Related to Perchloroethylene (PERC)[a]

PECO Element	Evidence Stream	Papers/Features Included	Papers/Features Excluded
Population [b]	*Human*	• Any population • All lifestages • All study designs, includes: ○ Controlled exposure, cohort, case-control, cross-sectional, case-crossover, ecological, case studies and case series	
	Animal	• All non-human whole-organism mammalian species • All lifestages	• Non-mammalian species
Exposure	*Human*	• Exposure based on administered dose or concentration of perchloroethylene, biomonitoring data (e.g., urine, blood or other specimens), environmental or occupational-setting monitoring data (e.g., air, water levels), job title or residence • Any metabolites of interest as identified in biomonitoring studies • Exposure identified as ***or presumed to be*** from oral, dermal, inhalation routes • Any number of exposure groups • Quantitative, semi-quantitative or qualitative estimates of exposure • Exposures to multiple chemicals/mixtures only if perchloroethylene or related metabolites were independently measured and analyzed	• Route of exposure ***not*** by inhalation, oral or dermal type (e.g., intraperitoneal, injection) • Multiple chemical/mixture exposures with no independent measurement of or exposure to perchloroethylene (or related metabolite)
	Animal	• A minimum of 2 quantitative dose or concentration levels of perchloroethylene plus a negative control group [a] • Acute, subchronic, chronic exposure from oral, dermal, inhalation routes • Exposure to perchloroethylene only (no chemical mixtures)	• Only 1 quantitative dose or concentration level in addition to the control [a] • Route of exposure ***not*** by inhalation, oral or dermal type (e.g., intraperitoneal, injection) • No duration of exposure stated • Exposure to perchloroethylene in a chemical mixture
Comparator	*Human*	• Any or no comparison	
	Animal	• Negative controls that are vehicle-only treatment and/or no treatment	• Negative controls ***other than*** vehicle-only treatment or no treatment
Outcome	*Human and Animal*	• Endpoints described in the perchloroethylene scope document [c]: ○ Acute toxicity ○ Neurotoxicity ○ Liver toxicity ○ Reproductive/developmental toxicity ○ Irritation ○ Cancer • Other endpoints [d]	
General Considerations		**Papers/Features Included**	**Papers/Features Excluded**
		• Written in English [e]	• Not written in English [e]

PECO Element	Evidence Stream	Papers/Features Included	Papers/Features Excluded
		• Reports a primary source or meta-analysis [a] • Full-text available • Reports both perchloroethylene exposure ***and*** a health outcome	• Reports secondary source (e.g., review papers) [a] • No full-text available (e.g., only a study description/abstract, out-of-print text) • Reports a perchloroethylene-related exposure ***or*** a health outcome, but not both (e.g. incidence, prevalence report)