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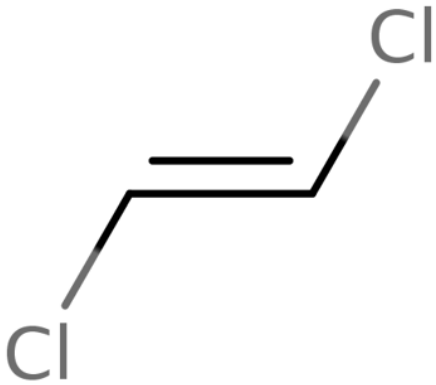
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Draft Scope of the Risk Evaluation for *trans*-1,2-Dichloroethylene

CASRN 156-60-5



April 2020

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Docket

Supporting information can be found in public docket: EPA-HQ-OPPT-2018-0465.

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ABBREVIATIONS AND ACRONYMS

ACGIH	American Conference of Governmental Industrial Hygienists
ACS	American Chemical Society
ADME	Absorption, Distribution, Metabolism, and Excretion
AIA	Aerospace Industries Association
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	Ambient Water Quality Criteria
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
BMF	Biomagnification factor
BOD	Biochemical Oxygen Demand
BP	Boiling Point
$BW^{3/4}$	Body Weight ¾ Extrapolation
CAA	Clean Air Act
CalEPA	California Environmental Protection Agency
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CDC	Centers for Diseases Control and Prevention
CDR	Chemical Data Reporting
CEHD	Chemical Exposure Health Data
CEM	Consumer Exposure Model
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFC-113	1,1,2-Trichloro-1,2,2-trifluoroethane
CFCs	Chlorofluorocarbons
CFR	Code of Federal Regulations
ChemSTEER	Chemical Screening Tool for Occupational Exposures and Releases
CHRIP	Chemical Risk Information Platform
COC	Concentration of Concern
CPCat	Chemical and Product Categories
CPDat	Consumer Product Database
CRC	Coordinating Research Council
CSCL	Chemical Substances Control Law
CWA	Clean Water Act
DCE	1,2-Dichloroethylene
DMR	Discharge Monitoring Report
EC	Engineering Control(s)
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
EPI	Estimation Programs Interface
ERG	Eastern Research Group
ESD	Emission Scenario Document
EU	European Union
FR	Federal Register
FYI	For your information
GDIT	General Dynamics Information Technology

GESTIS	Substance Database contains information for the safe handling of hazardous substances and other chemical substances at work
GS	Generic Scenario
HCFCs	Hydrochlorofluorocarbons
HERO	Health and Environmental Research Online
HFO	Hydrofluoroolefins
HHE	Health Hazard Evaluation
HMTA	Federal Hazardous Materials Transportation Act
HSDB	Hazardous Substances Data Bank
IBCs	Intermediate Bulk Containers
ICF	ICF is a global consulting services company
ICH	International Council for Harmonisation
IMAP	Inventory Multi-Tiered Assessment and Prioritisation (Australia)
IRIS	Integrated Risk Information System
ISHA	Industrial Safety and Health Act
IUPAC	International Union of Pure and Applied Chemistry
K_{OC}	Organic Carbon: Water Partition Coefficient
K_{OW}	Octanol: Water Partition Coefficient
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology
LC_{50}	50% Lethal Concentration
LC_x	Lethal Concentration
LOAELs	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
MACT	Maximum Achievable Control Technology
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MITI	Ministry of International Trade and Industry
MOA	Mode of Action
MP	Melting Point
MSW	Municipal Solid Waste
NEI	National Emissions Inventory
NEWMOA	Northeast Waste Management Officials' Association
NHANES	National Health and Nutrition Examination Survey
NICNAS	National Industrial Chemicals Notification and Assessment Scheme (Australia)
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NITE	National Institute of Technology and Evaluation
NLM	National Library of Medicine
NOAELs	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NPDES	National Pollutant Discharge Elimination System
NPDWR	National Primary Drinking Water Regulation
NPL	National Priorities List
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OEHHA	Office of Environmental Health Hazard Assessment (California)
OELs	Occupational Exposure Limits

ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
OTVDs	Open Top Vapor Degreasers
OW	EPA's Office of Water
P-chem	Physical-chemical
PBPK	Physiologically Based Pharmacokinetic
PBT	Persistent Bioaccumulation, and Toxic
PECO	Population, Exposure, Comparator, Outcome
PEL	Permissible Exposure Limit
PESS	Potentially Exposed or Susceptible Subpopulation
PODs	Points of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
QC	Quality Control
RCRA	Resource Conservation and Recovery Act
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (European Union)
REL	Recommended Exposure Limit
RIVM	Dutch National Institute for Public Health and the Environment
RQs	Risk Quotients
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
SNAP	Significant New Alternatives Policy
SRC	SRC Inc., formerly Syracuse Research Corporation
STORET	Storage and Retrieval for Water Quality Data; EPA's repository of water quality monitoring data
TBD	To be determined
TCCR	Transparent, Clear, Consistent and Reasonable
TDCE	*trans*-1,2-Dichloroethylene
TERA	Toxicology Excellence for Risk Assessment
TIAB	Title and Abstract
TK	Toxicokinetics
TLV	Threshold Limit Value
TMF	Trophic Magnification Factors
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TTO	Total Toxic Organics
TURA	Toxic Use Reduction Act
TWA	Time-weighted average
UCMR	Unregulated Contaminants Monitoring Rule
UIC	Underground Injection Control
USGS	United States Geological Survey
VP	Vapor Pressure
WHO	World Health Organization
WQX	Water Quality Exchange
WS	Water Solubility
WWT	Wastewater Treatment

EXECUTIVE SUMMARY

In December 2019, EPA designated *trans*-1,2-dichloroethylene (CASRN 156-60-5) as a high priority substance for risk evaluation following the prioritization process as required by section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations (40 CFR Part 702) (Docket ID: EPA-HQ-OPPT-2018-0465). The first step of the risk evaluation process is the development of the scope document and this document fulfills the TSCA regulatory requirement to issue a draft scope document as described in 40 CFR Part 702.41(c)(7). The draft scope for *trans*-1,2-dichloroethylene includes the following information: the conditions of use, potentially exposed or susceptible subpopulations (PESS) that EPA plans to consider in this risk evaluation, along with a description of the reasonably available information, hazards, exposures, conceptual models, analysis plan and science approaches, and plan for peer review for this chemical substance. EPA is providing a 45-day comment period on the draft scope. Comments received on this draft scope document will help inform development of the final scope document and the risk evaluation.

General Information. *trans*-1, 2-Dichloroethylene (CASRN 156-60-5) is a highly flammable, colorless liquid with a sharp, harsh odor. It is a synthetic chemical with no known natural sources, and it is used to produce solvents and in chemical mixtures. *trans*-1,2-Dichloroethylene is a highly water-soluble, volatile liquid. It is not expected to hydrolyze. Its Henry's law constant and vapor pressure indicate that it will tend to volatilize rather than persist in surface water or soil. *trans*-1,2-Dichloroethylene is not expected to persist in air due to reactions with photochemically produced hydroxyl radicals, nitrate radicals, and ozone. It is not readily biodegradable in aerobic aquatic environments and is expected to persist in anaerobic environments such as subsurface, groundwater, or enclosed pipes where volatilization is inhibited. It has low potential to bioaccumulate.

Reasonably Available Information. EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designation for *trans*-1, 2-dichloroethylene to inform the development of this draft scope document. To further develop this draft scope document, EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard) and the search and screening results to date are provided in Section 2.1. EPA is seeking public comment on this draft scope document and will consider additional information identified following publication of this draft scope document, as appropriate, in developing the final scope document. EPA is using the systematic review process described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a) to guide the process of searching for and screening reasonably available information, including information already in EPA's possession, for use and inclusion in the risk evaluation. EPA is applying these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS, and conditions of use that will help inform the risk evaluation for *trans*-1, 2-dichloroethylene.

Conditions of Use. EPA plans to evaluate manufacturing, including importing; processing; distribution in commerce; industrial, commercial and consumer uses; and disposal of *trans*-1, 2-dichloroethylene in the risk evaluation. *trans*-1, 2-dichloroethylene is manufactured within the U.S. as well as imported into the U.S. The chemical is processed as a reactant, incorporated into a formulation, mixture, or reaction products, and incorporated into articles. The identified processing activities also include the repackaging and recycling of *trans*-1, 2-dichloroethylene. Several industrial and commercial uses were identified that ranged from use as solvent for cleaning and degreasing to use as a component in a refrigerant blend. Only one consumer use was reported, for use in aerosol degreasers. EPA identified these conditions of use from information reported to EPA through Chemical Data Reporting (CDR) and Toxics Release

Inventory (TRI) reporting, published literature, and consultation with stakeholders both for uses currently in production and uses whose production may have ceased. Section 2.2.1 provides details about the conditions of use within the scope of the risk evaluation.

Conceptual Models. The conceptual models for *trans*-1, 2-dichloroethylene are presented in Section 2.6. Conceptual models are graphical depictions of the actual or predicted relationships of conditions of use, exposure pathways (e.g., media), exposure routes (e.g., inhalation, dermal, oral), hazards and receptors throughout the life cycle of the chemical substance - from manufacturing, processing, distribution in commerce, storage, or use, to release or disposal. EPA plans to focus the risk evaluation for *trans*-1,2-dichloroethylene on the following exposures, hazards and receptors, however, EPA also plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

- *Exposures (Pathways and Routes), Receptors and PESS.* EPA plans to analyze both human and environmental exposures resulting from the conditions of use of *trans*-1,2-dichloroethylene that EPA plans to consider in risk evaluation. Exposures for *trans*-1,2-dichloroethylene are discussed in Section 2.3. *trans*-1,2-Dichloroethylene is subject to reporting to TRI program and EPA anticipates using TRI information as reasonably available information to inform *trans*-1,2-dichloroethylene's environmental release assessment. For the 2018 reporting year, 18 facilities reported to EPA releases of *trans*-1,2-dichloroethylene to air and via land disposal. Additional information obtained through the results of systematic review searches will also inform expected exposures.

  EPA's plan as to environmental exposure pathways in the draft scope document considers whether and how other EPA-administered statutes and regulatory programs address the presence of *trans*-1,2-dichloroethylene in media pathways falling under the jurisdiction of those authorities. Section 2.6.3 discusses those pathways that may be addressed pursuant to other Federal laws. In Section 2.6.4, EPA presents the conceptual model describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of *trans*-1,2-dichloroethylene within the scope of the risk evaluation.

  Preliminarily, EPA plans to evaluate the following human and environmental exposure pathways, routes, receptors and PESS in the scope of the risk evaluation. However, EPA plans to consider comments received on this draft scope and other reasonably available information when finalizing this scope document, and to adjust the exposure pathways, exposure routes and hazards included in the scope document as needed.

  - *Occupational exposure pathways associated with industrial and commercial conditions of use:* For industrial and commercial uses of *trans*-1,2-dichloroethylene, EPA expects to analyze exposure to liquids for workers via the dermal route. In addition, EPA expects to analyze exposure to vapor and/or mist for workers and occupational non-users via the inhalation route.
  - *Consumer and bystander exposure pathways associated with consumer conditions of use:* EPA plans to evaluate the inhalation and dermal exposure to *trans*-1,2-dichloroethylene when consumers are handling cleaning and degreasing products.
  - *General population pathways:* EPA plans to evaluate exposure to *trans*-1,2-dichloroethylene via groundwater, and ambient air for the general population.
  - *Environmental exposures:* EPA plans to evaluate exposure to *trans*-1,2-dichloroethylene for aquatic and terrestrial receptors.

- *Receptors and PESS:* EPA plans to evaluate children, women of reproductive age (including, but not limited to, pregnant women), workers, and occupational non-users and consumers as receptors and PESS in the risk evaluation.

Hazards. Hazards for *trans*-1,2-dichloroethylene are discussed in Section 2.4. EPA completed preliminary reviews of information from peer-reviewed assessments and databases to identify potential environmental and human health hazards for *trans*-1,2-dichloroethylene as part of the prioritization process. EPA identified environmental hazard information during the prioritization process and information identified through systematic review methods and public comments may identify additional environmental hazards that warrant inclusion in the environmental hazard assessment in the risk evaluation. Environmental hazard effects were identified for aquatic and terrestrial organisms.

EPA will use systematic review methods to evaluate the epidemiological and toxicological literature for *trans*-1,2-dichloroethylene. Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-response assessment. EPA plans to evaluate all of the potential human health hazards for *trans*-1,2-dichloroethylene identified during prioritization. The broad health effect categories include immunological and irritation effects.

Analysis Plan. The analysis plan for *trans*-1,2-dichloroethylene is presented in Section 2.7. The analysis plan outlines the general science approaches that EPA plans to use for the various information streams (i.e., chemistry, fate, release and engineering, exposure, hazard) supporting the risk evaluation. The analysis plan is based on EPA's knowledge of *trans*-1,2-dichloroethylene to date which includes a partial, but ongoing, review of identified information as described in Section 2.1. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become reasonably available, EPA may update its analysis plan in the final scope document.

EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for *trans*-1,2-dichloroethylene, including the methods for assessing the quality of data and information and the approach for evidence synthesis and evidence integration supporting the exposure and hazard assessments. The details will be provided in a supplemental document that EPA anticipates releasing for public comment prior to the finalization of the scope document.

Peer Review. The draft risk evaluation for *trans*-1,2-dichloroethylene will be peer reviewed. Peer review will be conducted in accordance with relevant and applicable methods for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with section 26 of TSCA (See 40 CFR Part 702.45).

1 INTRODUCTION

This document presents for comment the draft scope of the risk evaluation to be conducted for *trans*-1,2-dichloroethylene 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) on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b) and 40 CFR Part 702, Subpart A require the Environmental Protection Agency (EPA) to designate chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at the time, and upon designating a chemical substance as a high-priority substance, initiate a risk evaluation on the substance. TSCA § 6(b)(4) directs EPA, in conducting risk evaluations for existing chemicals, 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.*"

TSCA § 6(b)(4)(D) and implementing regulations require that the 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. In addition, a draft scope is to be published pursuant to 40 CFR 702.41. In December 2019, EPA published a list of 20 chemical substances that have been designated high priority substances for risk evaluations (84 FR 71924), as required by TSCA § 6(b)(2)(B). *trans*-1,2-Dichloroethylene is one of the chemicals designated as a high priority substance for risk evaluation.

2 SCOPE OF THE EVALUATION

2.1 Reasonably Available Information

EPA conducted a comprehensive search for reasonably available information[1] to support the development of this draft scope document for *trans*-1,2-dichloroethylene. EPA leveraged the data and information sources already identified in the documents supporting the chemical substance's high-priority substance designations. In addition, EPA searched for additional data and information on physical and chemical properties, environmental fate, engineering, exposure, environmental and human health hazards that could be obtained from the following general categories of sources:

1. Gray literature, which is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases;
2. Databases containing publicly available, peer-reviewed literature; and
3. Data and information submitted under TSCA sections 4, 5, 8(e), and 8(d), as well as "for your information" (FYI) submissions.

Following the comprehensive search, EPA performed a title and abstract screening to identify information potentially relevant for the risk evaluation process. This step also classified the references into useful categories or tags to facilitate the sorting of information through the systematic review

[1] *Reasonably available information* means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14 (40 CFR 702.33).

process. The search and screening process was conducted based on EPA's general expectations for the planning, execution and assessment activities outlined in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018a). EPA will publish supplemental documentation on the systematic review methods supporting the *trans*-1,2-dichloroethylene risk evaluation to explain the literature and screening process presented in this document in the form of literature inventory trees. Please note that EPA focuses on the data collection phase (consisting of data search, data screening, and data extraction) during the preparation of the TSCA scope document, whereas the data evaluation and integration stages will occur during the development of the draft risk evaluation and thus are not part of the scoping activities described in this document.

The subsequent sections summarize the data collection activities completed to date for the general categories of sources and topic areas (or disciplines) using systematic review methods. EPA plans to seek public comments on the systematic review methods supporting the risk evaluation for *trans*-1,2-dichloroethylene upon publication of the supplemental documentation of those methods.

2.1.1 Search of Gray Literature

EPA surveyed the gray literature[2] and identified 123 search results relevant to EPA's risk assessment needs for *trans*-1,2-dichloroethylene. Appendix A lists the gray literature sources that yielded 123 discrete data or information sources relevant to *trans*-1,2-dichloroethylene. EPA further categorized the data and information into the various topic areas (or disciplines) supporting the risk evaluation (e.g., physical chemistry, environmental fate, ecological hazard, human health hazard, exposure, engineering) and the breakdown is shown in Figure 2-1. EPA is currently identifying additional reasonably available information (e.g., public comments), and the reported numbers in Figure 2-1 may change.

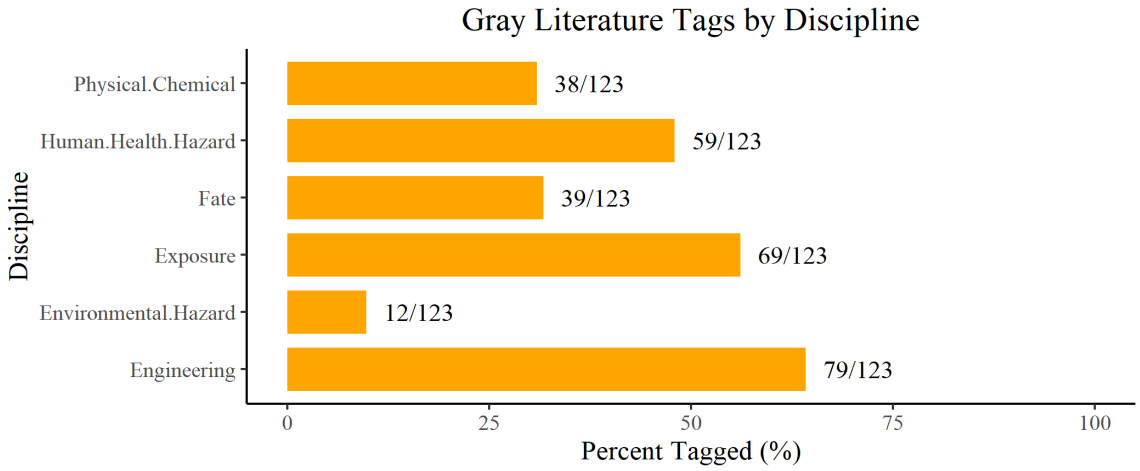

Figure 2-1. Gray Literature Tags by Discipline for *trans*-1,2-Dichloroethylene
The percentages across disciplines do not add up to 100%, as each source may provide data or information for various topic areas (or disciplines). TDCE = *trans*-1,2-dichloroethylene.

2.1.2 Search of Literature from Publicly Available Databases (Peer-reviewed Literature)

EPA is currently conducting a systematic review of the reasonably available literature. This includes performing a comprehensive search of the reasonably available peer review literature on physical-chemical properties, environmental fate and transport, engineering (environmental release and

[2] Gray literature is defined as the broad category of data/information sources not found in standard, peer-reviewed literature databases (e.g., PubMed and Web of Science). Gray literature includes data/information sources such as white papers, conference proceedings, technical reports, reference books, dissertations, information on various stakeholder websites, and other databases.

occupational exposure), exposure (environmental, general population and consumer) and environmental and human health hazards of *trans*-1,2-dichloroethylene. Eligibility criteria were applied in the form of PECO (population, exposure, comparator, outcome) statements. Included references met the PECO criteria, whereas excluded references did not meet the criteria (i.e., not relevant), and supplemental material was considered as potentially relevant. EPA plans to analyze the reasonably available information identified for each discipline during the development of the risk evaluation. The literature inventory trees depicting the number of references that were captured and those that were included, excluded, or tagged as supplemental material during the screening process for each discipline area are shown in Figure 2-2 through Figure 2-6. "TIAB" in these figures refer to "title and abstract" screening. Note that the sum of the numbers for the various sub-categories may be larger than the broader category because some studies may be included under multiple sub-categories. In other cases, the sum of the various sub-categories may be smaller than the main category because some studies may not be depicted in the sub-categories if their relevance to the risk evaluation was unclear.

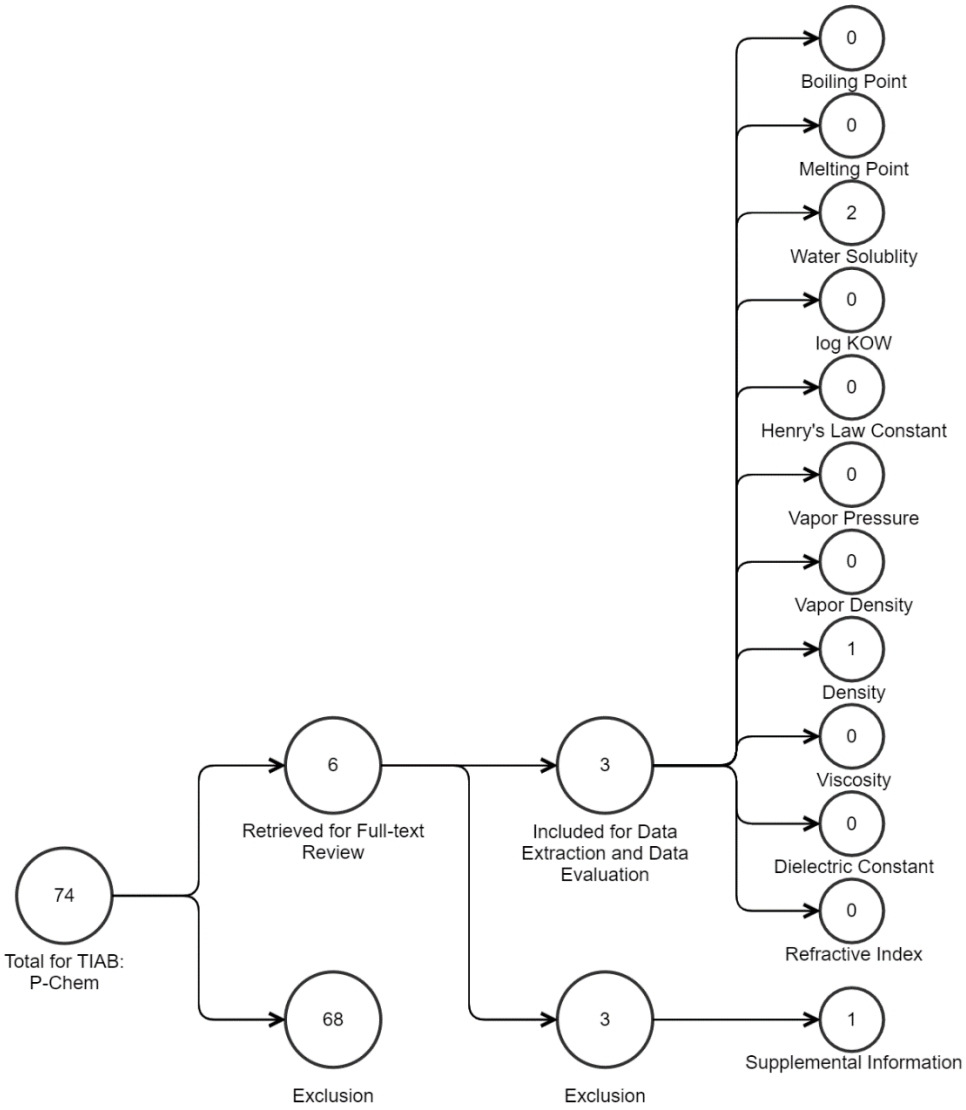

Figure 2-2. Peer-Reviewed Literature - Physical-Chemical Properties Search Results for *trans*-1,2-Dichloroethylene

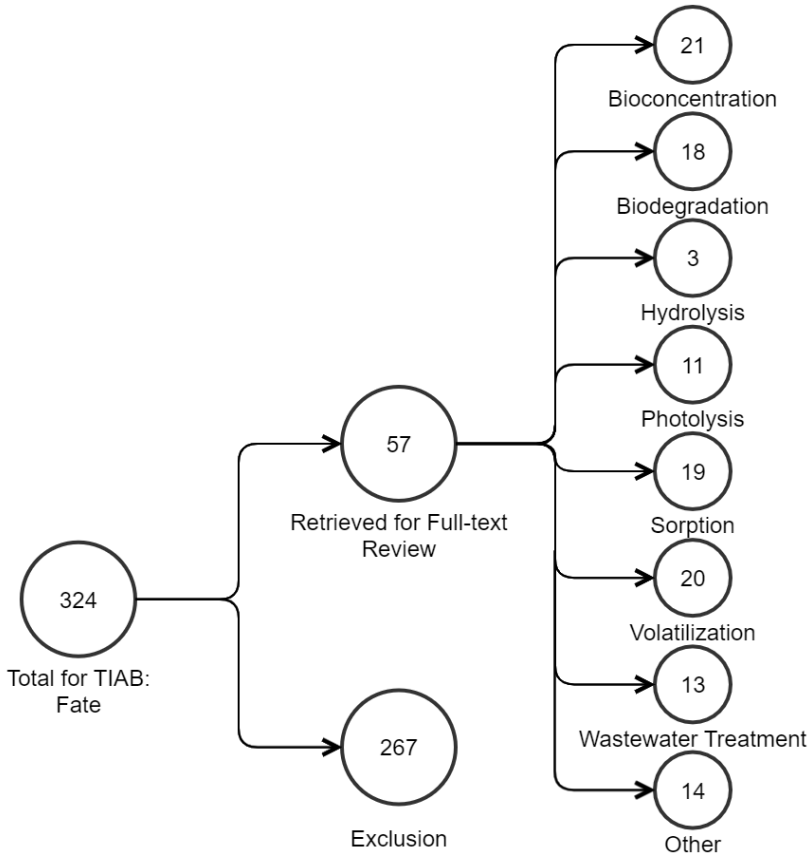

Figure 2-3. Peer-Reviewed Literature - Fate and Transport Search Results for *trans*-1,2-Dichloroethylene

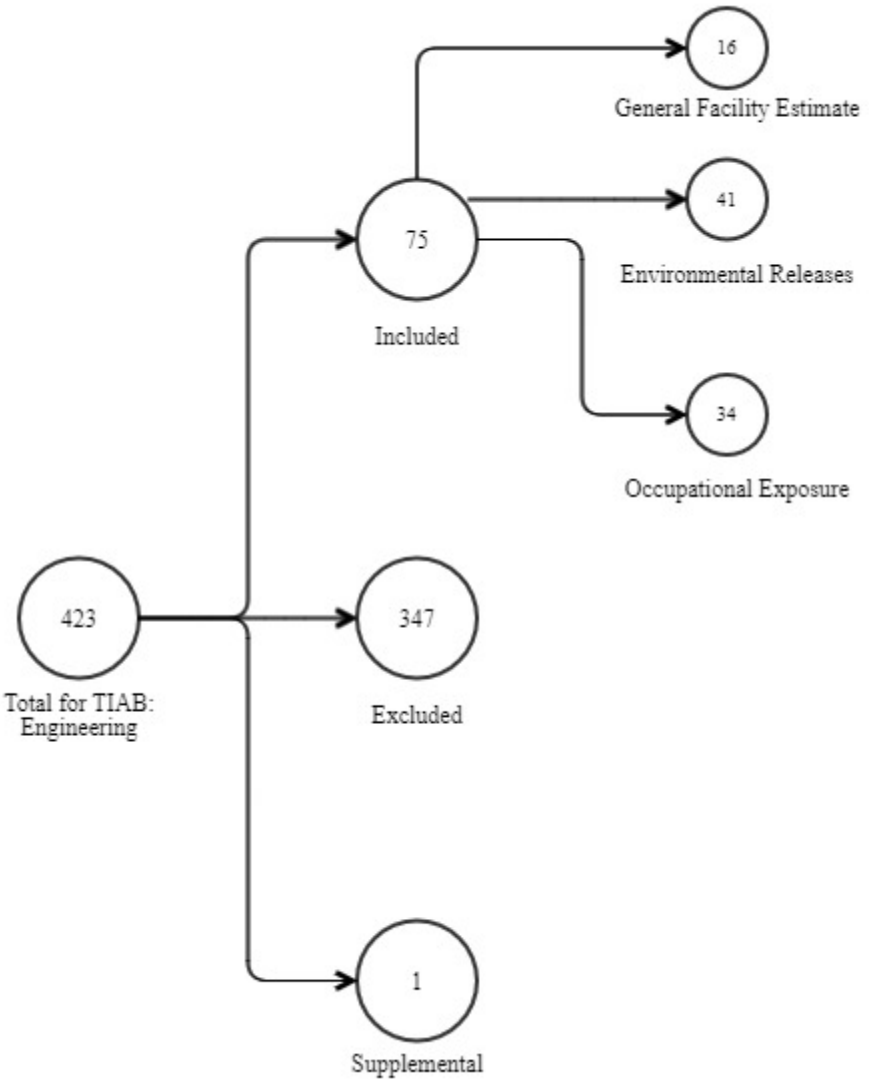

Figure 2-4. Peer-Reviewed Literature - Engineering Search Results for *trans*-1,2-Dichloroethylene

Figure 2-5. Peer-Reviewed Literature - Exposure Search Results for *trans*-1,2-Dichloroethylene

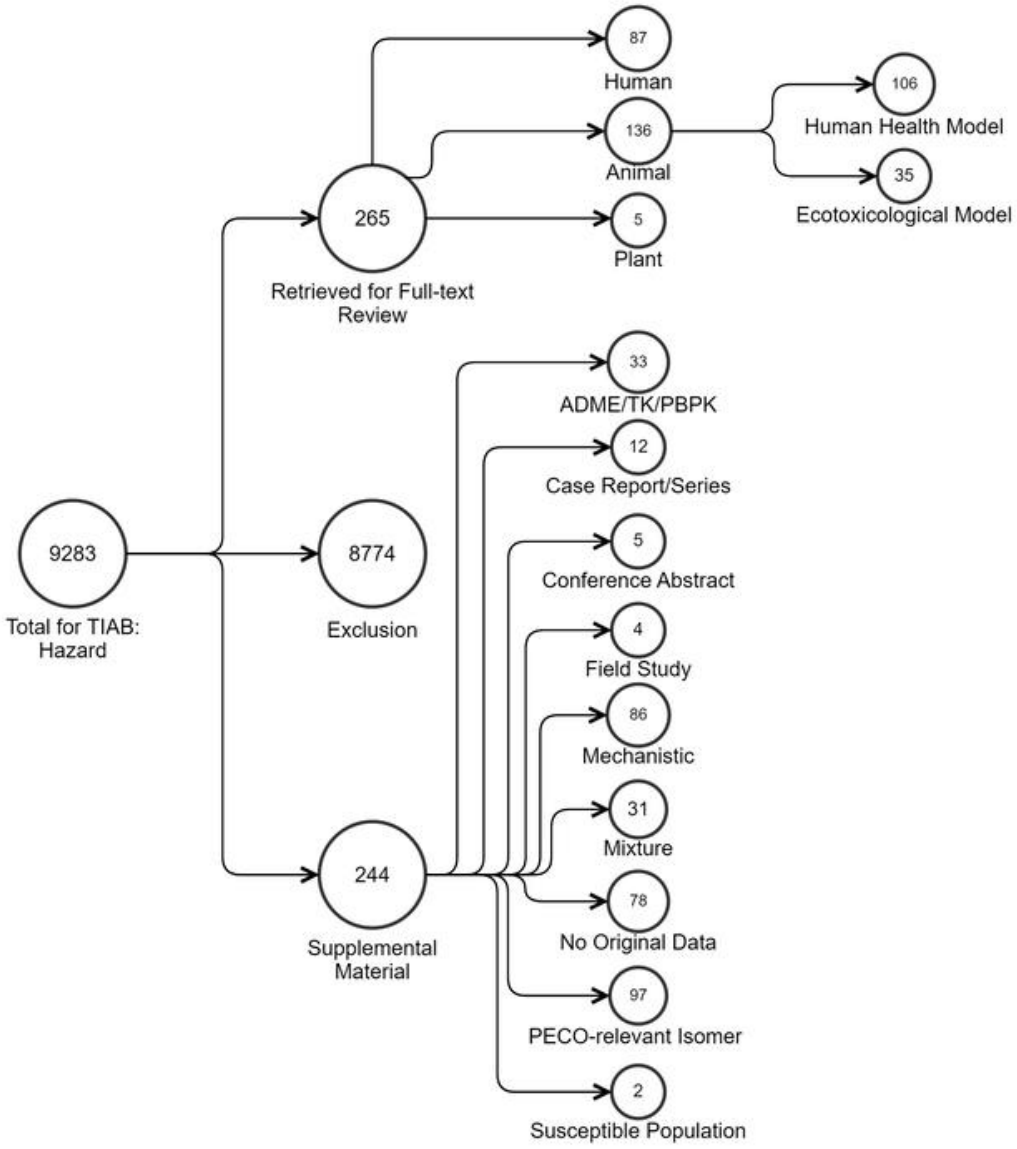

Figure 2-6. Peer-Reviewed Literature - Hazard Search Results for *trans*-1,2-Dichloroethylene

2.1.3 Search of TSCA Submissions

Table 2-1 presents the results of screening the titles of data sources and reports submitted to EPA under various sections of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA screened a total of 63 submissions using inclusion/exclusion criteria specific to individual disciplines. EPA identified 60 submissions that met the inclusion criteria in these statements and identified 2 submissions with supplemental data. EPA excluded one submission because the report was identified as an environmental impact statement for proposed equipment.

EPA plans to conduct additional deduplication at later stages of the systematic review process (e.g., full text screening), when more information regarding the reports is available.

Table 2-1. Results of Title Screening of Submissions to EPA under Various Sections of TSCA [a]

Discipline	Included	Supplemental [b]
Physicochemical Properties	0	0
Environmental Fate and Transport	3	0
Environmental and General Population Exposure	57	0
Occupational Exposure/Release Information	3	0
Environmental Hazard	0	0
Human Health Hazard	1	2

[a] Individual submissions may be relevant to multiple disciplines.
[b] Included submissions may contain supplemental data for other disciplines, which will be identified at full-text review.

2.2 Conditions of Use

As described in the *Proposed Designation of trans-1,2-dichloroethylene (CASRN 156-60-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA assembled information from the CDR and TRI programs to determine conditions of use or significant changes in conditions of use of the chemical substance. EPA also consulted a variety of other sources to identify uses of *trans*-1,2-dichloroethylene, including: published literature, company websites, and government and commercial trade databases and publications. To identify formulated products containing *trans*-1,2-dichloroethylene, EPA searched for safety data sheets (SDS) using internet searches, EPA Chemical and Product Categories (CPCat) data, and other resources in which SDSs could be found. SDSs were cross-checked with company websites to make sure that each product SDS was current. In addition, EPA incorporated communications with companies, industry groups, environmental organizations, and public comments to supplement the use information.

EPA identified and described the categories and subcategories of conditions of use that EPA plans to include in the scope of the risk evaluation (Section 2.2.1; Table 2-2). The conditions of use that EPA plans to include in the scope are those reflected in the life cycle diagrams and conceptual models.

After gathering reasonably available information related to the manufacture, processing, distribution in commerce, use, and disposal of *trans*-1,2-dichloroethylene, EPA identified those categories or subcategories of use activities for *trans*-1,2-dichloroethylene the Agency determined not to be conditions of use or will otherwise be excluded during scoping. These categories and subcategories are described in Section 2.2.2.

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

Table 2-2 lists the conditions of use that EPA plans to include in the scope of the risk evaluation. EPA is looking for more information to confirm the reports of *trans*-1,2-dichloroethylene used for inspection penetrant and pipe repair that are not currently included as conditions of use.

Table 2-2. Conditions of Use Included in the Scope of the Risk Evaluation

Life-Cycle Stage	Category	Subcategory	Reference
Manufacturing	Domestic manufacture/Import	Domestic Manufacture	U.S. EPA (2019)

Life-Cycle Stage	Category	Subcategory	Reference
Manufacturing	Import	Import	U.S. EPA (2019)
Processing	Processing as a reactant	Plating agents and surface treating agents	U.S. EPA (2019)
Processing	Processing as a reactant	Intermediate in chemical product and preparation manufacturing	Dreher (2014); Axiall (2016)
Processing	Processing – incorporation into formulation, mixture or reaction product	Solvents (for cleaning or degreasing)	U.S. EPA (2019)
Processing	Processing – incorporation into formulation, mixture or reaction product	Solvents (which become part of product formulation or mixture)	U.S. EPA (2019)
Processing	Processing – incorporation into formulation, mixture or reaction product	Adhesives and sealant chemicals	Wilsonart (2017)
Processing	Processing – incorporation into formulation, mixture or reaction product	Foam blowing additive	Axiall (2016)
Processing	Processing – incorporation into formulation, mixture or reaction product	Carrier solvent in adhesives, coatings, inks, lubricants, and silicones.	EPA-HQ-OPPT-2018-0465-0009
Processing	Incorporation into articles	Propellant and blowing agent in plastics product manufacturing; flexible polyurethane foam manufacturing	U.S. EPA (2019)
Processing	Repackaging	Repackaging	U.S. EPA (2019)
Processing	Recycling	Recycling	U.S. EPA (2019)
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Industrial/commercial use	Solvents (for cleaning or degreasing)	Vapor degreaser	EPA-HQ-OPPT-2018-0465-0006
Industrial/commercial use	Solvents (for cleaning or degreasing)	Aerosol spray cleaner/degreaser	EPA-HQ-OPPT-2018-0465-0003; EPA-HQ-OPPT-2018-0465-0006; EPA-HQ-

Life-Cycle Stage	Category	Subcategory	Reference
			OPPT-2018-0465-0009
Industrial/commercial use	Solvents (for cleaning or degreasing)	Flux remover (liquid and aerosol)[3]	ACL Staticide (2016)
Commercial use	Solvents (for cleaning or degreasing)	Refrigerant flush	Ace (2015)
Industrial/commercial use	Cleaning and furnishing care products	Spot cleaner; stain remover	U.S. EPA (2019)
Industrial/commercial use	Functional fluids (open systems)	Smoothing fluid in additive manufacturing	Microcare (2018)
Industrial/commercial use	Anti-adhesive agent	Mold release	EPA-HQ-OPPT-2018-0465-0006
Industrial/commercial use	Solvents (which become part of product formulation or mixture)	Urethane coatings	Miller-Stephenson (2016 a,b)
Industrial/commercial use	Lubricants and greases	Liquid and spray lubricants and greases, and penetrating lubricants	EPA-HQ-OPPT-2018-0465-0006
Industrial/commercial use	Adhesives and sealants	Solvent-based adhesives and sealants; adhesive accelerant	Wilsonart (2017); Permabond (2018).
Industrial/commercial use	Functional fluids (closed systems)	Refrigerant	U.S. EPA (2016)
Industrial/commercial use	Functional fluids (closed systems)	Pharmaceutical and medicine manufacturing	Dreher (2014); ICH (2016)
Industrial/commercial use	Processing aids	Extraction solvent for thermoplastics	Dreher (2014)
Commercial use	Propellants and blowing agents	Polyurethane foam building insulation	Demilec (2017a); Demilec (2017b); Covestro LLC. (2016)
Industrial/commercial use	Other uses	Laboratory chemicals	Thermo Fisher Scientific (2018)
Consumer use	Solvents (for cleaning or degreasing)	Aerosol degreaser	CRC Industries Inc. (2017)
Consumer use	Propellants and blowing agents	Polyurethane foam building insulation	Demilec (2017a); Demilec (2017b); Covestro LLC. (2016)

[3] Flux removal can be done by vapor degreasing, which is listed above separately as a COU.

Life-Cycle Stage	Category	Subcategory	Reference
Consumer use	Cleaning and furnishing care products	Spot cleaner; stain remover	Albatross USA Inc (2020)
Consumer use	Adhesives and sealants	Solvent-based; adhesive accelerant	Permabond (2018).
Disposal	Disposal	Disposal	

- Life Cycle Stage Use Definitions (40 CFR § 711.3)
  - "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.

2.2.2 Activities Excluded from the Scope of 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 may exclude certain activities that it determines to be conditions of use on a case-by-case basis. (82 FR 33736, 33729; July 20, 2017). As a result, EPA does not plan to include in this scope or in the risk evaluation activities that the Agency has concluded do not constitute conditions of use.

No conditions of use were excluded for *trans*-1,2-dichloroethylene.

2.2.3 Production Volume

As reported to EPA during the 2016 CDR reporting period and described here as a range to protect production volumes that were claimed as confidential business information (CBI), total production volume of *trans*-1,2-dichloroethylene in 2015 was between 1 million and 10 million pounds (U.S. EPA 2017). EPA also uses pre-2015 CDR production volume information, as detailed in the *Proposed Designation of trans-1,2-dichloroethylene (CASRN 156-60-5) as a High-Priority Substance for Risk Evaluation*(U.S. EPA, 2019a) and will include future production volume information as it becomes available to support the exposure assessment.

2.2.4 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-7 depicts the conditions of use that EPA plans to consider in the risk evaluation for the various life cycle stages. This section provides a brief overview of the industrial, commercial, and consumer use categories included in the life cycle diagram. Appendix E contains more detailed descriptions (e.g., process descriptions, worker activities) for each manufacturing, processing, distribution in commerce, use, and disposal category based on preliminary information.

The information in the life cycle diagram is grouped according to the CDR processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses). The production volume of *trans*-1,2-dichloroethylene in 2015 is included in the lifecycle diagram, as reported to EPA during the 2016 CDR reporting period, as a range between 1 million and 10 million pounds (U.S. EPA, 2019b).

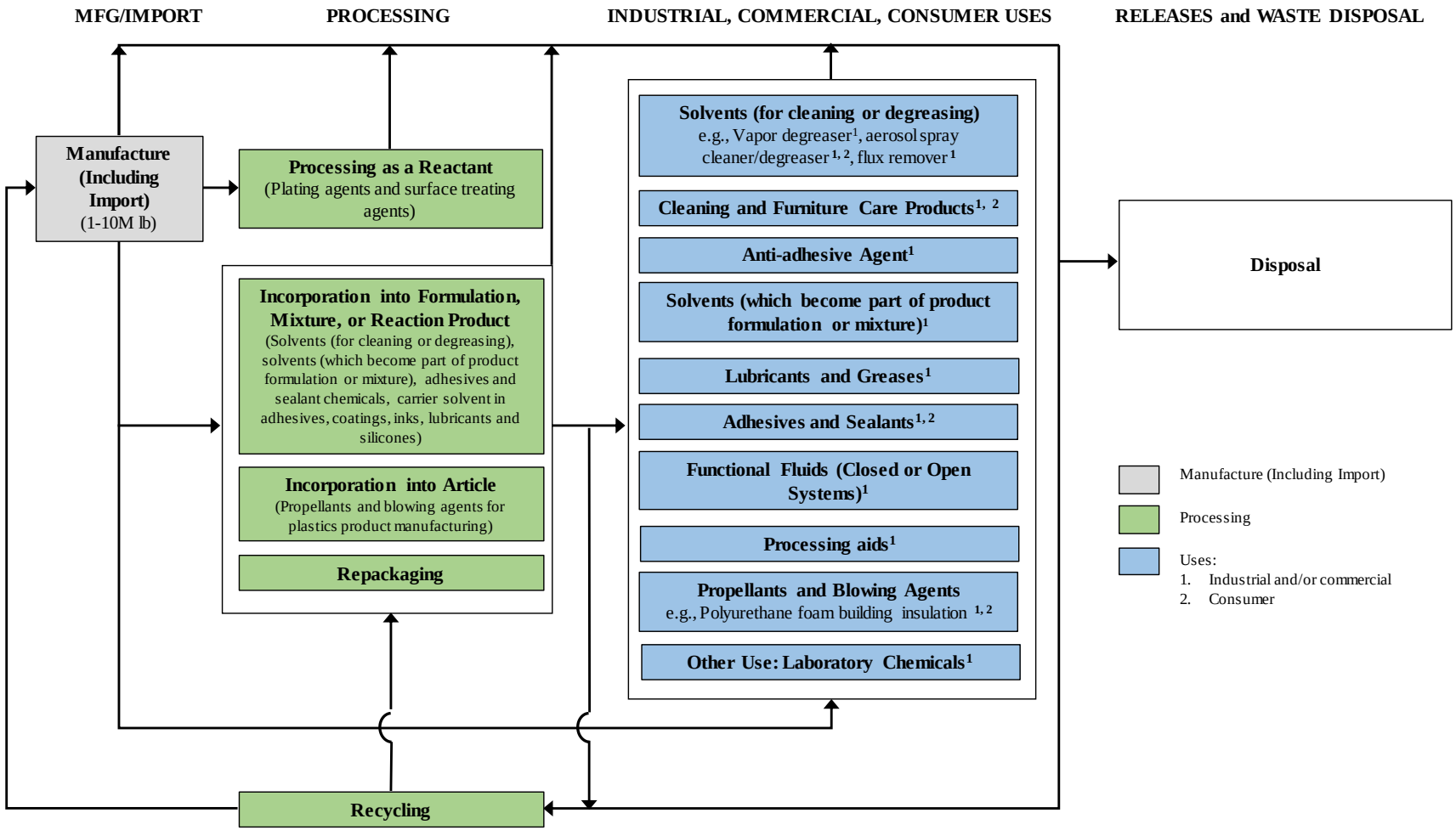

Figure 2-7. *trans*-1,2-Dichloroethylene Life Cycle Diagram

Volume is not depicted in the life cycle diagram for processing and industrial, commercial, and consumer uses as specific production volume is claimed confidential business information (CBI) or withheld pursuant to TSCA §14. There may be additional activities and uses not shown in the diagram that are claimed CBI.

2.3 Exposures

For TSCA exposure assessments, EPA plans to analyze exposures and releases to the environment resulting from the conditions of use within the scope of the risk evaluation for *trans*-1,2-dichloroethylene. Release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations, and environmental receptors. EPA plans to take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to *trans*-1,2-dichloroethylene.

2.3.1 Physical and Chemical Properties

Consideration of physical and chemical properties are essential for a thorough understanding or prediction of environmental fate (i.e., transport and transformation) and the eventual environmental concentrations. They can also inform the hazard assessment. EPA plans to use the physical and chemical properties described in the *Proposed Designation of trans-1,2-Dichloroethylene (CASRN 156-60-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA (2019)) to support the development of the risk evaluation for *trans*-1,2-dichloroethylene. The values for the physical and chemical properties(Appendix B) may be updated as EPA identifies additional information through systematic review methods.

2.3.2 Environmental Fate and Transport

Understanding of environmental fate and transport processes assists in the determination of the specific exposure pathways and potential human and environmental receptors that need to be assessed in the risk evaluation for *trans*-1,2-dichloroethylene. EPA plans to use the environmental fate characteristics described in the *Proposed Designation of trans-1,2-Dichloroethylene (CASRN 156-60-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA (2019)) to support the development of the risk evaluation for *trans*-1,2-dichloroethylene. The values for the environmental fate properties (Appendix C) may be updated as EPA identifies additional information through systematic review methods.

2.3.3 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses) are a 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 plans to consider in evaluating exposure are data reported to the TRI program. EPA's TRI database contains information on chemical waste management activities that are disclosed by industrial and federal facilities, including quantities released into the environment (i.e., to air, water, and land), treated, burned for energy recovery, recycled, or transferred off-site to other facilities for these purposes.

Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313, 1,2-dichloroethylene (CASRN 540-59-0) is a TRI-reportable substance effective as of January 01, 1987 (40 CFR 372.65). For TRI reporting[4], facilities in covered sectors in the United States are required to disclose releases and other waste management quantities of 1,2-dichloroethylene as CASRN 540-59-0 if they manufacture (including import) or process more than 25,000 pounds or otherwise use more than 10,000 pounds of the chemical in a given year by July 1 of the following year.

[4] For TRI reporting criteria see https://www.epa.gov/toxics-release-inventory-tri-program/basics-tri-reporting

Facilities reporting 1,2-dichloroethylene releases and waste management quantities are not required to differentiate between the *cis*- and *trans*- isomers; as such there is no way to differentiate between the isomers from reported TRI data. However, since the relative percentages of commercial forms of 1,2-dichloroethylene tend to be 60% *cis*- isomer:40% *trans*-isomer, one can roughly estimate the specific quantities of each isomer that comprise mass quantities reported to TRI for 1,2-dichloroethylene.

Table 2-3 provides production-related waste management data for 1,2-dichloroethylene (two isomers or mixture of two) reported by facilities to EPA for reporting year 2018.[5] As shown in the table, 18 facilities reported a total of nearly 10 million pounds of 1,2-dichloroethylene waste managed. Nearly 90% of the total production-related waste quantities reported for the chemical was treated. Compared to the other waste management quantities reported, very little of 1,2-dichloroethylene (less than 0.13%) was disposed of or otherwise released to the environment during 2018.

Table 2-3. Summary of 1,2-Dichloroethylene Production-Related Waste Managed in 2018

Year	Number of Facilities	Recycled (lbs)	Recovered for Energy (lbs)	Treated (lbs)	Released (lbs) [a,b,c]	Total Production Related Waste (lbs)
2018	18	421,620	590,821	8,934,334	12,611	9,959,385

Data source: U.S. EPA, 2018a (Updated November 2019)
[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.

Table 2-4 provides a summary of the quantities of 1,2-dichloroethylene released or disposed of to the environment during 2018.[5] There were zero pounds reported as released to water via surface water discharges, and a total of 9,477 pounds released to air, mostly as fugitive emissions. Very little of 1,2-dichloroethylene was disposed of to land. The 3,102 pounds classified as "other releases" were sent off site to waste brokers for disposal, accounting for roughly ¼ of total releases.

Table 2-4. Summary of Releases of 1,2-Dichloroethylene to the Environment During 2018

	Number of Facilities	Air Releases		Water Releases (lbs)	Land Disposal			Other Releases (lbs)[a]	Total Releases (lbs) [b, c]
		Stack Air Releases (lbs)	Fugitive Air Releases (lbs)		Class I Under-ground Injection (lbs)	RCRA Subtitle C Landfills (lbs)	All other Land Disposal (lbs)[a]		
Totals	18	1,806	7,671	0	4	3	24	3,102	12,611
		9,477			31				

Data source: U.S. EPA, 2018a (Updated November 2019)
[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 2-3 excludes any quantities reported as catastrophic or one-time releases (TRI Form R, section 8 data), release quantities shown in Table 2-4

[5] Reporting year 2018 is the most recent TRI data available. Data presented in Table 2-3 were queried using TRI Explorer and uses the 2018 National Analysis data set (released to the public in November 2019). This dataset includes revisions for the years 1988 to 2018 processed by EPA.

include both production-related and non-production-related quantities for 2018. In the case of 1,2-dichloroethylene the total release quantities shown in the two tables are the same, but for other TRI chemicals they may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017d).

EPA plans to review these data in conducting the exposure assessment component of the risk evaluation for *trans*-1,2-dichloroethylene.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of *trans*-1,2-dichloroethylene can result in releases to the environment and exposure to aquatic and terrestrial receptors (biota). Environmental exposures to biota are informed by releases into the environment, overall persistence, degradation, and bioaccumulation, and partitioning across different media. Concentrations of chemical substances in biota provide evidence of exposure. EPA plans to review available environmental exposure data in biota in the risk evaluation. Monitoring data were identified in the EPA's data search for *trans*-1,2-dichloroethylene and can be used in the exposure assessment. 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.

EPA plans to review available environmental monitoring data in the risk evaluation. USGS's Monitoring Data – National Water Quality Monitoring Council has identified *trans*-1,2-dichloroethylene in air, ground water, sediment, soil, surface water and biota (e.g., fish tissue concentrations) (USGS 1991a-g). In the United States, the California Environmental Protection Agency (CalEPA) has measured *trans*-1,2-dichloroethylene in surface water at levels of 0.43–1,307 ppb and in groundwater at levels of 0.25–500,000 ppb (CalEPA 2006). A source of *trans*-1,2-dichloroethylene is anaerobic biodegradation of chlorinated solvents, and these are present at detectable levels in landfill gases (ATSDR 1996). Disposal and leaching of chlorinated solvent waste may lead to levels of trans-1,2-dichloroethylene in soil and sediment via the migration of trans-1,2-dichloroethylene from groundwater.

2.3.5 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2.1. In addition, EPA plans to analyze exposure to occupational non-users, i.e., workers who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also plans to consider the effect(s) that engineering controls (EC) and/or personal protective equipment (PPE) have on occupational exposure levels as part of the draft risk evaluation.

Worker activities associated with conditions of use within the scope of the risk evaluation for *trans*-1,2-dichloroethylene will be analyzed, including but not limited to:

- Unloading and transferring *trans*-1,2-dichloroethylene to and from storage containers to process vessels;
- Handling, transporting and disposing of waste containing *trans*-1,2-dichloroethylene;
- Cleaning and maintaining equipment;
- Sampling chemicals, formulations or products containing *trans*-1,2-dichloroethylene for quality control;
- Repackaging chemicals, formulations or products containing *trans*-1,2-dichloroethylene.

trans-1,2-Dichloroethylene has a vapor pressure of 331 mmHg at 25°C (see Appendix B), hence, inhalation exposure is a significant route of exposure for workers and occupational non-users (ONUs) in

occupational exposure scenarios where *trans*-1,2-dichloroethylene is used and handled in open systems or where there is potential for mist generation. The extent of exposure could vary from facility to facility depending on many factors including but not limited to EC, type of facility, and facility design. *trans*-1,2-Dichloroethylene has an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL)[6] of 200 ppm or 790 mg/m^3 over an 8-hour workday, time weighted average (TWA). This chemical also has a National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL)[7] of 200 ppm (790 mg/m^3) TWA. The American Conference of Governmental Industrial Hygienists (ACGIH) sets the Threshold Limit Value (TLV) at 200 ppm TWA.

EPA plans to analyze worker exposure to liquids via the dermal route. EPA does not plan to analyze dermal exposure for occupational non-users because they do not directly handle *trans*-1,2-dichloroethylene. EPA generally does not evaluate occupational exposures through the oral route because oral exposure is typically incidental in nature.

EPA generally does not evaluate occupational exposures through the oral route. Workers may inadvertently transfer chemicals from their hands to their mouths, ingest inhaled particles that deposit in the upper respiratory tract or consume contaminated food. The frequency and significance of this exposure route are dependent on several factors including the p-chem properties of the substance during expected worker activities, workers' awareness of the chemical hazards, the visibility of the chemicals on the hands while working, workplace practices, and personal hygiene that is difficult to predict (Cherrie et al., 2006). However, EPA will consider oral exposure on a case-by-case basis.

2.3.6 Consumer Exposures

No conditions of use information for *trans*-1,2-dichloroethylene was found in the 2012 or 2016 CDR. One material safety data sheet indicated that *trans*-1,2-dichloroethylene is solvents for cleaning and or degreasing, particularly as an aerosol degreaser (CRC Industries Inc. (2017)). Additional conditions of use include cleaning and furnishing care products such as spot cleaners and stain removers, as well as adhesives and sealants which may be solvent-based or adhesive accelerants (Albatross USA Inc (2020), Permabond (2018)). Off-gassing of *trans*-1,2-dichloroethylene from polyurethane foam and building insulation is a potential source of exposure to *trans*-1,2-dichloroethylene. In addition, the Consumer Product Database (CPDat) indicated that *trans*-1,2-dichloroethylene in used as a consumer product in in cleaners, propellants, and solvents.

Consumers using or disposing of aerosol degreasing products, cleaning and furnishing care products, or adhesives and sealants, may be exposed to *trans*-1,2-dichloroethylene through direct liquid contact which may lead to a dermal exposure. In addition, due to its high volatility at room temperature *trans*-1,2-dichloroethylene may expose consumers via a vapor pathway which may lead to inhalation exposure. Bystanders present during the consumer use or disposal of solvents used for cleaning and or degreasing, cleaning and furnishing care products, adhesives and sealants, or polyurethane foam building insulation, may also be exposed to *trans*-1,2-dichloroethylene via vapors leading to inhalation exposures. The vapor to inhalation exposure route is particularly noteworthy for *trans*-1,2-dichloroethylene as known products are supplied as aerosols.

2.3.7 General Population Exposures

Releases of *trans*-1,2-dichloroethylene from certain conditions of use, such as manufacturing, disposal, or waste treatment activities, may result in general population exposures via drinking water ingestion,

[6] OSHA, 2009. Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs). https://www.osha.gov/dsg/annotated-pels/tablez-1.html
[7] NIOSH, 2005. NIOSH Pocket Guide to Chemical Hazards. https://www.cdc.gov/niosh/npg/npgdcas.html

dermal contact, and inhalation from air releases. The general population that lives in urban areas may be exposed to low levels (0.013-0.076 ppb) of *trans*-1,2-dichloroethylene via air (ATSDR 1996). In addition, the general population may also be exposed to low levels of *trans*-1,2-dichloroethylene in U.S. drinking water supplies. Community systems that rely on groundwater supplies may have a higher possibility of exposure to *trans*-1,2-dichloroethylene (ATSDR 1996). There is a lack of available data to quantify general population exposure to *trans*-1,2-dichloroethylene by oral and dermal routes (ATSDR 2016, CalEPA 2006).

The OECD monitoring database has identified human biomonitoring data for *trans*-1,2-dichloroethylene (OECD 2018). However, blood concentrations of *trans*-1,2-dichloroethylene were below the limit of detection in 2,754 individuals who participated in the National Health and Nutrition Examination Survey (NHANES) 2011-2012 subsample of the U.S. population (CDC, 2018)

2.4 Hazards (Effects)

2.4.1 Environmental Hazards

As described in the *Proposed Designation of trans-1,2-Dichloroethylene (CASRN 156-60-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential environmental hazards for *trans*-1,2-dichloroethylene. EPA is in the process of identifying additional reasonably available information through systematic review methods and public comments that may inform potential environmental hazards associated with *trans*-1,2-dichloroethylene exposure.

2.4.2 Human Health Hazards

As described in the *Proposed Designation of trans-1,2-Dichloroethylene (CASRN 156-60-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA 2019a), EPA considered reasonably available information from peer-reviewed assessments and databases to identify potential human health hazards for *trans*-1,2-dichloroethylene. EPA plans to evaluate all of the potential human health hazards for *trans*-1,2-dichloroethylene identified during prioritization. The health effect categories screened for during prioritization included acute toxicity, irritation/corrosion, dermal sensitization, respiratory sensitization, genetic toxicity, repeated dose toxicity, reproductive toxicity, developmental toxicity, immunotoxicity, neurotoxicity, carcinogenicity, epidemiological or biomonitoring studies and absorption, distribution, metabolism, and excretion (ADME). EPA is in the process of identifying additional reasonably available information through systematic review methods and public input, which may update the list of potential human health hazards under the scope of the risk evaluation. If necessary, EPA plans to update the list of potential hazards in the final scope document of the *trans*-1,2-dichloroethylene risk evaluation.

2.5 Potentially Exposed or Susceptible Subpopulations

TSCA requires the EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." 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 for 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).

During the Prioritization process, EPA identified the following potentially exposed or susceptible subpopulations based on CDR information and studies reporting developmental and reproductive effects: women of reproductive age (e.g., pregnant women per TSCA statute), workers and consumers (U.S. EPA 2019). EPA plans to evaluate these potentially exposed or susceptible subpopulations in the risk evaluation.

In developing exposure scenarios, EPA plans to 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 life stage 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, 2006a). Likewise, EPA plans to evaluate available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.6 Conceptual Models

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of *trans*-1,2-dichloroethylene. Pathways and routes of exposure associated with workers and occupational non-users are described in Section 2.6.1, and pathways and routes of exposure associated with consumers are described in Section 2.6.2. Pathways and routes of exposure associated with environmental releases and wastes, including those pathways that may be addressed pursuant to other Federal laws are discussed and depicted the conceptual model shown in Section 2.6.3. Pathways and routes of exposure associated with environmental releases and wastes, excluding those pathways that may be addressed pursuant to other Federal laws, are presented in the conceptual model shown in Section 2.6.4.

2.6.1 Conceptual Model for Industrial and Commercial Activities and Uses

Figure 2-8 illustrates the conceptual model for the pathways of exposure from industrial and commercial activities and uses of *trans*-1,2-dichloroethylene that EPA plans to include in the risk evaluation. There is potential for exposures to workers and/or occupational non-users via inhalation routes and exposures to workers via dermal routes. It is expected that inhalation exposure to vapors is the most likely exposure route. In addition, workers at waste management facilities may be exposed via inhalation or dermal routes from wastewater treatment, incineration or via other disposal methods. EPA plans to 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, and disposal) rather than a single distribution scenario. For each condition of use identified in Table 2-2, an initial determination was made as to whether or not each 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 F.

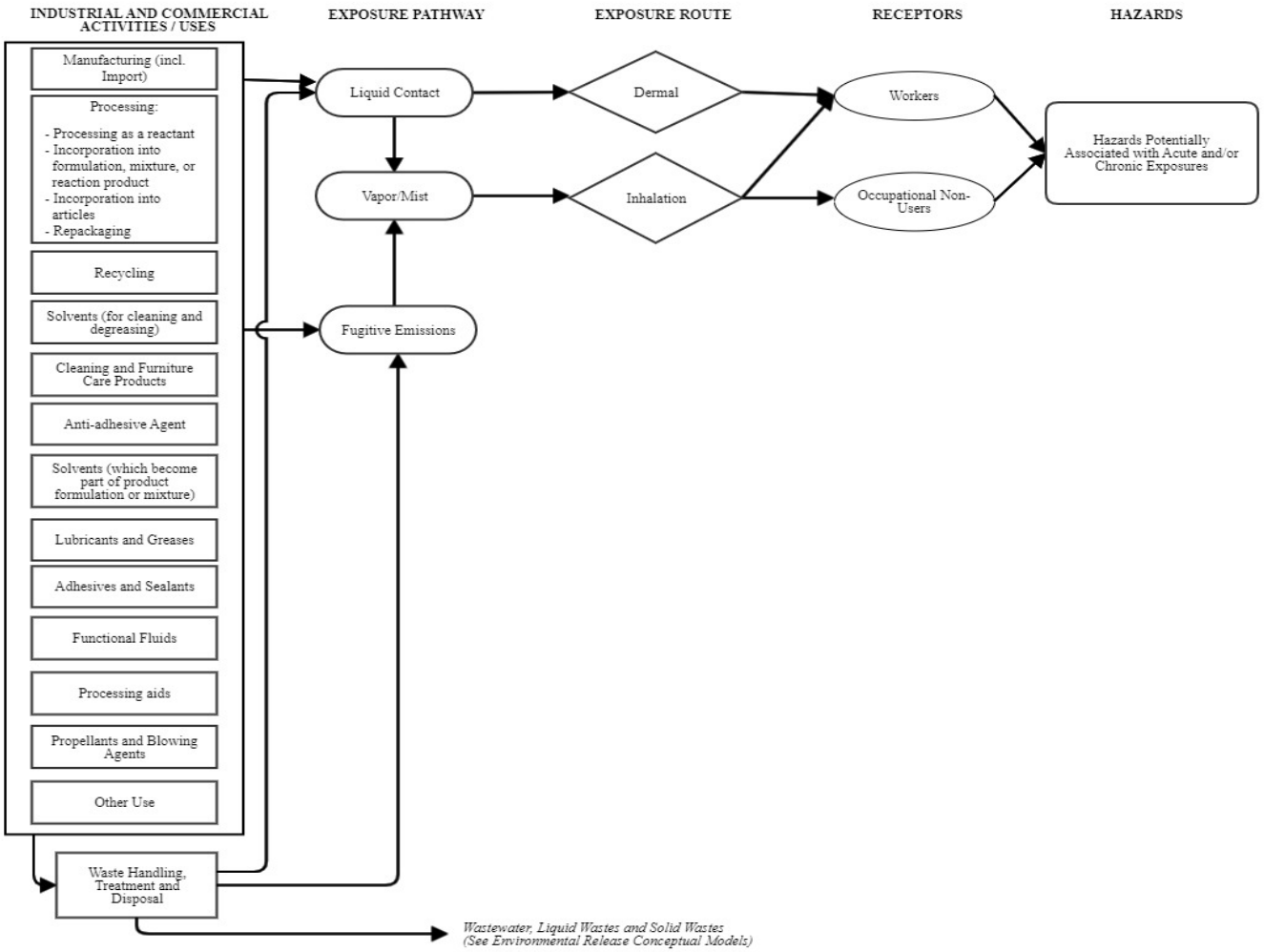

Figure 2-8. *trans*-1,2-Dichloroethylene Occupational Exposure Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of *trans*-1,2-dichloroethylene.

2.6.2 Conceptual Model for Consumer Activities and Uses

The conceptual model in Figure 2-9 presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of *trans*-1,2-dichloroethylene. EPA expects inhalation to be the primary route of exposure and plans to analyze inhalation exposures to *trans*-1,2-dichloroethylene vapor for consumers and bystanders. Aerosol application of solvents for cleaning and degreasing, cleaning and furnishing care products, and adhesives and sealants may result in an inhalation of mist for consumers and bystanders. Off-gassing of *trans*-1,2-dichloroethylene from polyurethane foam insulation may also result in inhalation exposures to consumers and bystanders. There is potential for dermal exposures to *trans*-1,2-dichloroethylene via direct contact with liquid during consumer uses. Bystanders are not expected to have direct dermal contact to *trans*-1,2-dichloroethylene. EPA plans to analyze direct dermal contact with liquid *trans*-1,2-dichloroethylene for consumers using cleaning and furnishing care products, solvents for cleaning and degreasing, and adhesives and sealants. The supporting rationale for consumer pathways that are in scope for *trans*-1,2-dichloroethylene are included in Appendix G.

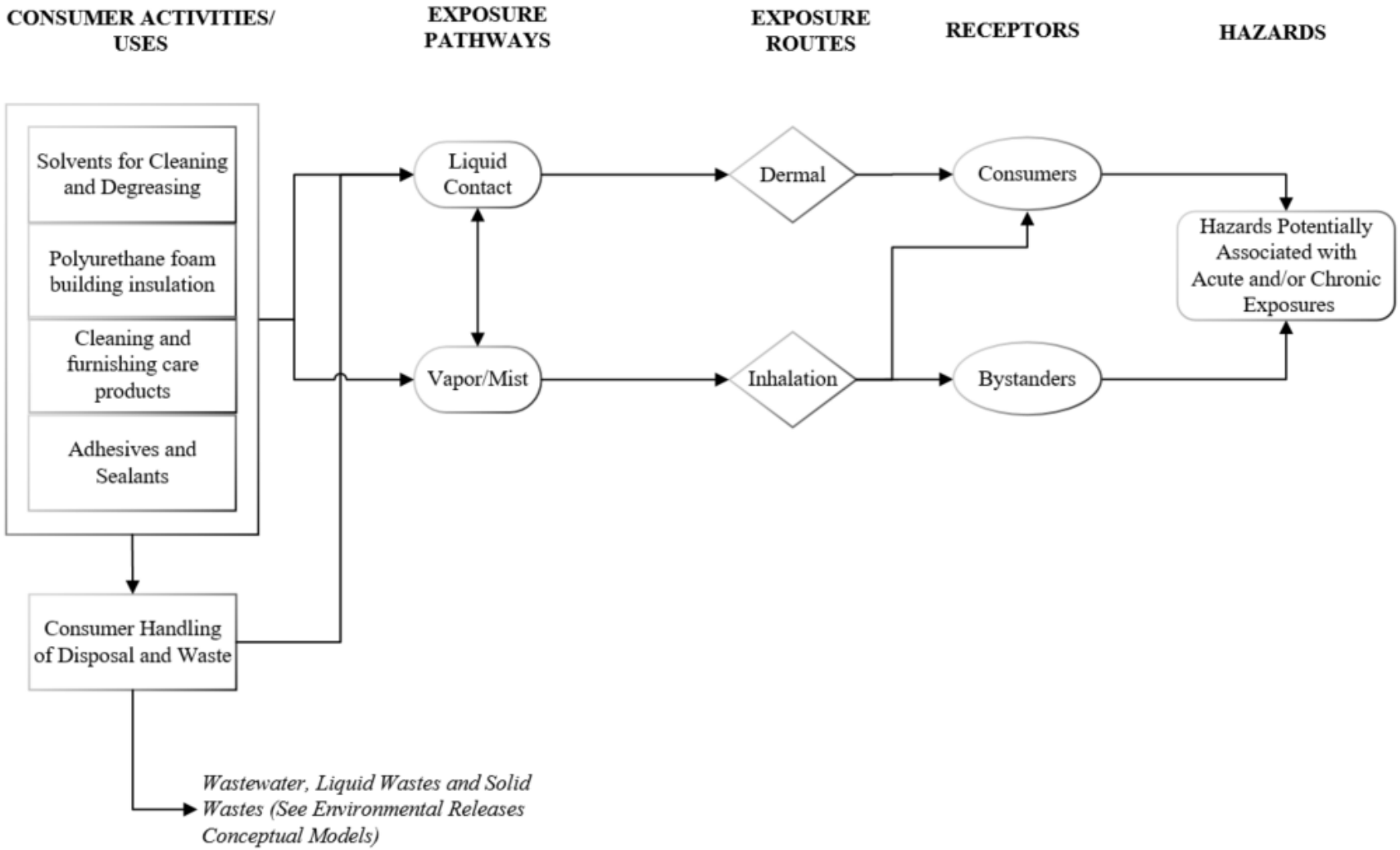

Figure 2-9. *trans*-1,2-Dichloroethylene Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of *trans*-1,2-dichloroethylene.

Note:

a) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.6.3 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards (Regulatory Overlay)

In this section, EPA presents the conceptual models describing the identified exposures (pathways and routes), receptors and hazards associated with the conditions of use of *trans*-1,2-dichloroethylenewithin the scope of the risk evaluation. It also discusses those pathways that may be addressed pursuant to other Federal laws.

In complying with TSCA, EPA plans to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, maximize scientific and analytical efforts, and meet the statutory deadline for completing risk evaluations. OPPT is working closely with the offices within EPA that administer and implement the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA), to identify how those statutes and any associated regulatory programs address the presence of *trans*-1,2-dichloroethylene in exposure pathways falling under the jurisdiction of these EPA statutes.

The conceptual model in Figure 2-10 presents the potential exposure pathways, exposure routes and hazards to human and environmental receptors from releases and waste streams associated with industrial and commercial uses of *trans*-1,2- dichloroethylene. This figure includes overlays, labeled and shaded to depict the regulatory programs (*e.g.*, CAA, SDWA, CWA, RCRA) and associated pathways that EPA considered in developing this conceptual model for the draft scope document. The pathways are further described in Section 2.6.3.1 through Section 2.6.3.3.

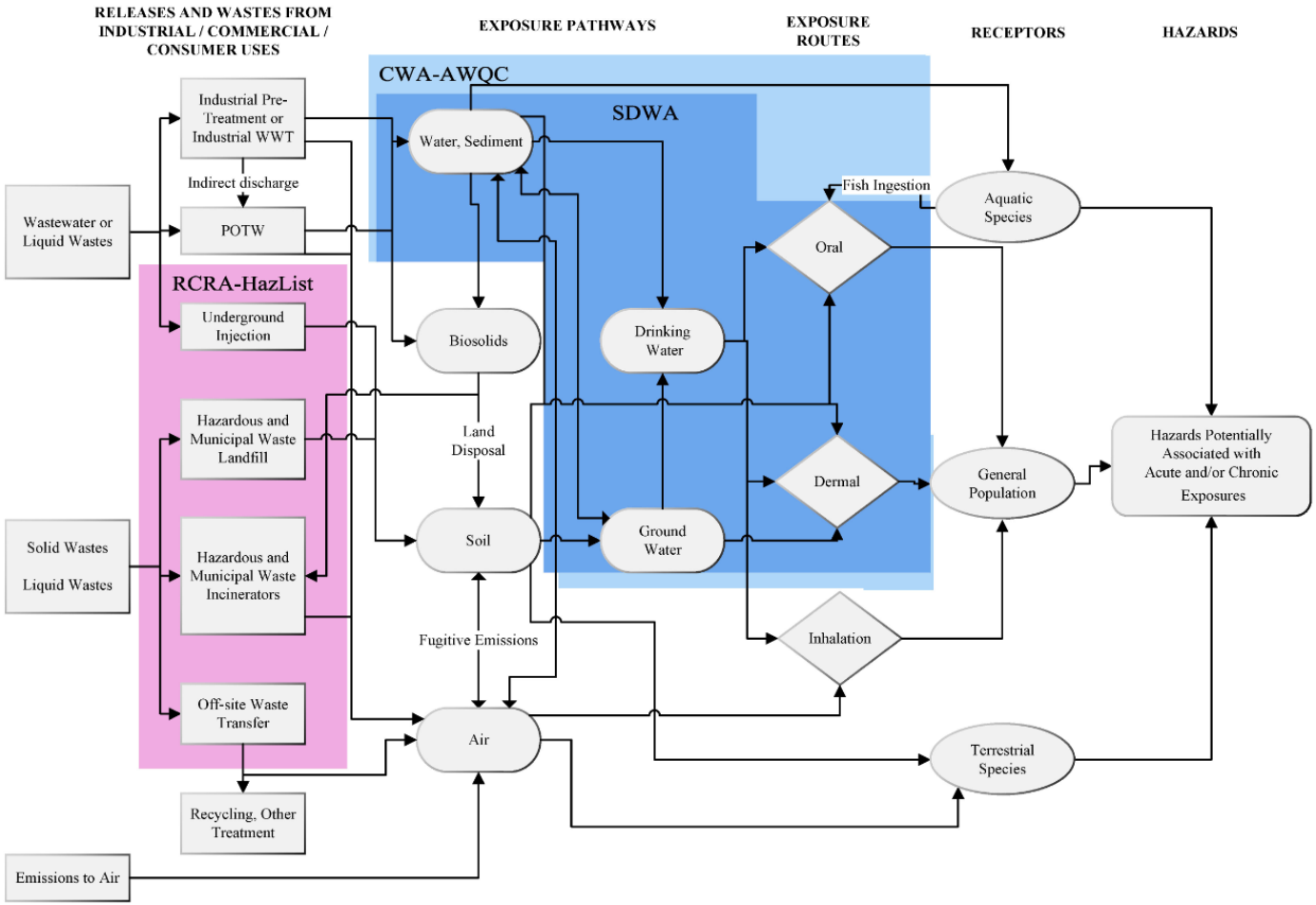

Figure 2-10. *trans*-1,2-Dichloroethylene Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards (Regulatory Overlay)

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of *trans*-1,2-dichloroethylene including the environmental statutes covering those pathways. Notes:

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 Publicly Owned Treatment Works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW. Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water. Inhalation from drinking water may occur via showering

b) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.6.3.1 Drinking Water Pathway

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) under the Safe Drinking Water Act for *trans*-1,2- Dichloroethylene. 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. The MCL for *trans*-1,2- Dichloroethylene in water is 100 ppb.

The drinking water exposure pathway for *trans*-1,2-dichloroethylene is currently addressed in the SDWA regulatory analytical process for public water systems. 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.

2.6.3.2 Ambient Water Pathway

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 has developed recommended water quality criteria for protection of human health for *trans*-1,2- Dichloroethylene which are available for possible adoption into state water quality standards and are available for possible use by NPDES permitting authorities in deriving effluent limits to meet state narrative criteria. As such, EPA's OW and OPPT 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 *trans*-1,2-dichloroethylene in the future under the CWA.

EPA has developed CWA section 304(a) recommended human health criteria for 122 chemicals and aquatic life criteria for 47 chemicals. A subset of these chemicals is identified as "priority pollutants" (103 human health and 27 aquatic life), including o-dichlorobenzene. For pollutants with recommended human health criteria, EPA regulations require that state criteria contain sufficient parameters and constituents to protect designated uses. Once states adopt criteria as water quality standards, the CWA requires that 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 permit issuance process accounts for risk in accordance with the applicable ambient water exposure pathway (human health or aquatic life as applicable) for the designated water use and, therefore, can the risk from the pathway can be considered assessed and managed.

EPA has not developed CWA section 304(a) recommended water quality criteria for the protection of aquatic life for *trans*-1,2-dichloroethylene, 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. EPA may publish CWA section 304(a) aquatic life criteria for *trans*-1,2-dichloroethylene in the future if it is identified as a priority under the CWA.

2.6.3.3 Disposal and Soil Pathways

Trans-1,2- Dichloroethylene is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33) as a listed waste on the U079, F024, F025 lists. The general 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 CFR §§ 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 controls 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 Maximum Achievable Control Technology (MACT)) or injected into Underground Injection Control (UIC) Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

Emissions to ambient air from municipal and industrial waste incineration and energy recovery units that form combustion by-products from incineration treatment of *trans*-1,2-dichloroethylene wastes may be subject to regulations, as would trans-1,2-dichloroethylene burned for energy recovery.

TRI reporting in 2018 indicated 4 pounds released to underground injection to Class I wells. Environmental disposal of *trans*-1,2-dichloroethylene injected into Class I hazardous waste well types fall under the jurisdiction of RCRA and SDWA and disposal of *trans*-1,2-dichloroethylene via underground injection is not likely to result in environmental and general population exposures.

EPA has identified releases to land that go to RCRA Subtitle C hazardous waste landfills. Based on 2018 reporting, TRI land disposal includes Subtitle C landfills (3 pounds) with an additional amount transferred to "other landfills" both on-site and off-site (24 pounds reported in 2018). 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 in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

trans-1,2-Dichloroethylene is present in commercial and consumer products that may be disposed of in landfills, such as Municipal Solid Waste (MSW) landfills. On-site releases RCRA Subtitle D municipal solid waste landfills leading to exposures of the general population (including susceptible populations) or terrestrial species from such releases are expected to be minimal based on current TRI releases (i.e., 24 lb in 2018) for *trans*-1,2-dichloroethylene. 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 lb per month). Bulk liquids, such as free solvent, may not be disposed of at MSW landfills.

On-site releases to land from industrial non-hazardous and construction/demolition waste landfills may occur for *trans*-1,2-dichloroethylene. Industrial non-hazardous and construction/demolition waste landfills are primarily regulated under authorized 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.

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

As described in Section 2.6.3, some pathways in the conceptual models are covered under the jurisdiction of other environmental statutes administered by EPA. The conceptual model depicted in Figure 2-11 presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of *trans*-1,2-dichloroethylene that EPA plans to consider in the risk evaluation. The exposure pathways, exposure routes and hazards presented in this conceptual model are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of *trans*-1,2-dichloroethylene in exposure pathways falling under the jurisdiction of these EPA statutes.

The diagram shown in Figure 2-11 includes releases from industrial, commercial and/or consumer uses to water/sediment; biosolids and soil, via direct and indirect discharges to water, that may lead to exposure to aquatic and terrestrial receptors, and to the general population and terrestrial species from emissions to air. The supporting basis for environmental pathways considered for *trans*-1,2-dichloroethylene are included in Appendix H.

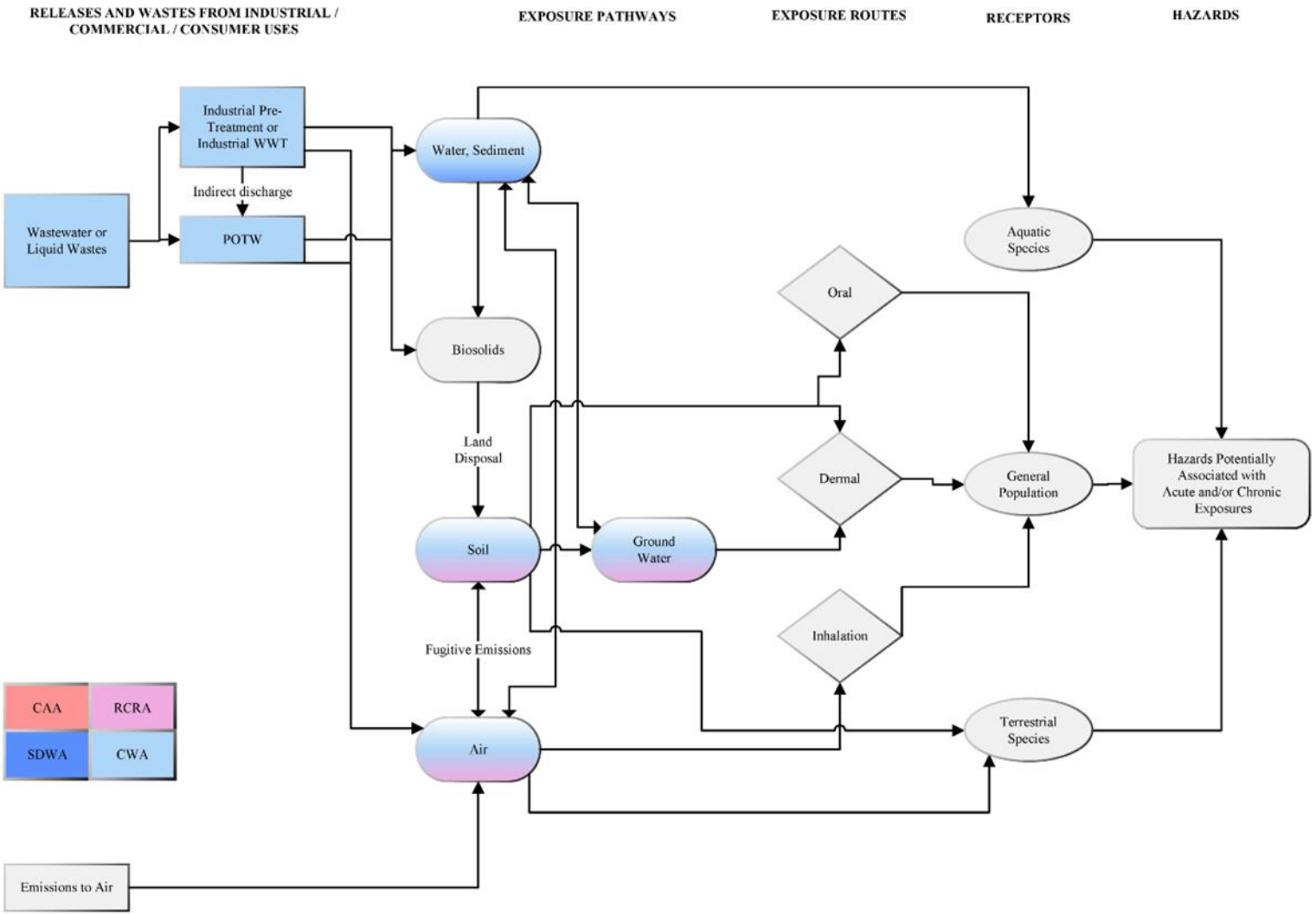

Figure 2-11. *trans*-1,2-Dichloroethylene Conceptual Model for Environmental Releases and Wastes: Environmental and General Population Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from releases and wastes from industrial, commercial, and consumer uses of *trans*-1,2-dichloroethylene that EPA plans to consider in the risk evaluation. Notes:

a) Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW.

b) Receptors include potentially exposed or susceptible subpopulations (see Section 2.5).

2.7 Analysis Plan

The analysis plan is based on EPA's knowledge of *trans*-1,2-dichloroethylene to date which includes a partial, but not complete review of identified information as described in Section 2.1. EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for further evaluating conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during risk evaluation. Further, EPA may consider any relevant CBI in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. EPA plans to continue to consider new information submitted by the public. Should additional data or approaches become available, EPA may update its analysis plan in the final scope document. As discussed in the *Application of Systematic Review in TSCA Risk Evaluations* document [EPA Document #740-P1-8001], targeted supplemental searches during the analysis phase may be necessary to identify additional information (e.g., commercial mixtures) for the risk evaluation of *trans*-1,2-dichloroethylene.

2.7.1 Physical and Chemical Properties and Environmental Fate

EPA plans to analyze the physical and chemical (physical-chemical) properties and environmental fate and transport of *trans*-1,2-dichloroethylene as follows:

1) **Review reasonably available measured or estimated physical-chemical properties and environmental fate endpoint data collected using systematic review procedures and, where available, environmental assessments conducted by other regulatory agencies.**
   EPA plans to review data and information collected through the systematic review methods and public comments about the physical-chemical properties (Appendix B) and fate endpoints (Appendix C) listed in the *Proposed Designation of trans-1,2-Dichloroethylene (CASRN 156-60-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019). All sources cited in EPA's analysis will be evaluated according to the procedures described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Where the systematic review process fails to identify experimentally measured chemical property values of sufficiently high quality, these values will be estimated using chemical parameter estimation models as appropriate. Model-estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of physical-chemical properties and environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.**
   Measured data and, where necessary, model predictions of physical-chemical properties and environmental fate endpoints will be used to characterize the persistence and movement of *trans*-1,2-dichloroethylene within and across environmental media. The fate endpoints of interest include volatilization, sorption to organic matter in soil and sediments, water solubility, aqueous and atmospheric photolysis rates, aerobic and anaerobic biodegradation rates, and potential bioconcentration and bioaccumulation. These endpoints will be used in exposure calculations.

3) **Conduct a weight-of-evidence evaluation of physical-chemical properties and environmental fate data, including qualitative and quantitative sources of information.** During risk evaluation, EPA plans to evaluate and integrate the physical-chemical properties and environmental fate evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2 Exposure

EPA plans to analyze exposure levels for surface water, sediment, soil, aquatic biota, and terrestrial biota associated to exposure to *trans*-1,2-dichloroethylene. EPA has not yet determined the exposure levels in these media or how they may be applied in the risk evaluation. Exposure scenarios are combinations of sources (uses), exposure pathways, and exposed receptors. Draft release/exposure scenarios corresponding to various conditions of use for *trans*-1,2-dichloroethylene are presented in Appendix F, Appendix G, and Appendix H. EPA plans to analyze scenario-specific exposures.

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. Exposure level(s) can be characterized through a combination of available monitoring data and modeling approaches.

2.7.2.1 Environmental Releases

EPA plans to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze 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 described in Appendix E. EPA plans to continue to review data sources as identified during risk evaluation using the evaluation strategy in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Potential sources of environmental release data are summarized in Table 2-5 below:

Table 2-5. Categories and Sources of Environmental Release Data

U.S. EPA TRI Data
U.S. EPA Generic Scenarios
OECD Emission Scenario Documents
Discharge Monitoring Report (DMR) surface water discharge data for *trans*-1,2-dichloroethylene from NPDES-permitted facilities

2) **Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies).** EPA has reviewed key release data sources including the TRI, and the data from this source is summarized in Section 2.3.3. EPA plans to continue to review relevant data sources as identified during risk evaluation. EPA plans to match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA plans to attempt to address data gaps identified as described in steps 3 and 4 below by considering potential surrogate data and models.

Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Occupational Exposures and Releases ChemSTEER (U.S. EPA, 2013).

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.**
If surrogate data are identified, these data will be matched with applicable conditions of use for potentially filling data gaps. Measured or estimated release data for other chlorinated solvents may be considered as surrogates for *trans*-1,2-dichloroethylene.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.**
This item will be performed after completion of #2 and #3 above. EPA plans to evaluate relevant data to determine whether the data can be used to develop, adapt or apply models for specific conditions of use (and corresponding release scenarios). 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. EPA plans to 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.**
EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the April 2015 ESD on Use of Adhesives (OECD, 2015) and the September 2011 ESD on the Chemical Industry (OECD, 2011) may be useful. EPA intends to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed.

EPA Generic Scenarios are available at the following: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.

OECD Emission Scenario Documents are available at the following: http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm

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 of use to a release assessment scenario(s).**
EPA has identified release scenarios and mapped (i.e. grouped) them to relevant conditions of use as shown in Appendix F. EPA may further refine the mapping/grouping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of environmental release data.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. The data integration strategy will be designed to be fit-for-purpose in which EPA plan to 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.

2.7.2.2 Environmental Exposures

EPA plans to analyze the following in developing its environmental exposure assessment of *trans*-1,2-dichloroethylene:

1) **Review available environmental and biological monitoring data for all media relevant to environmental exposure.**
   For *trans*-1,2-dichloroethylene, environmental media which will be analyzed include aquatic and terrestrial species, sediment, soil, air and surface water.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.**
   Available environmental exposure models that meet the TSCA Science Standards and that estimate surface water, sediment, and soil concentrations will be analyzed and considered alongside available surface water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: direct release into surface water, sediment, or soil, indirect release into surface water, sediment, or soil (i.e., air deposition), fate and transport (partitioning within media) and characteristics of the environment (e.g., river flow, volume of lake, meteorological data).

3) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**
   Monitoring data or modeled estimates will be reviewed to determine how use patterns have changed over recent years and will determine how representative environmental concentrations are of ongoing use patterns.

   Any studies which relate levels of *trans*-1,2-dichloroethylene in the environment or biota with specific sources or groups of sources will be evaluated.

4) **Group each condition(s) of use to environmental assessment scenario(s).**
   Refine and finalize exposure scenarios for environmental receptors by considering combinations of sources (use descriptors), exposure pathways including routes, and populations exposed. For *trans*-1,2-dichloroethylene, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:
   - Estimates of ambient air, surface water concentrations, sediment concentrations and soil concentrations near industrial point sources based on available monitoring data.
   - Generally, consider the following modeling inputs: release into the media of interest, fate and transport and characteristics of the environment.
   - Reasonably available biomonitoring data. Monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.

- Applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to the extent that data are available, and characterize exposed aquatic and terrestrial populations.
- Weight of the scientific evidence of environmental occurrence data and modeled estimates

5) **Evaluate the weight of the scientific evidence of environmental occurrence data and modeled estimates.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.2.3 Occupational Exposures

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

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.**
EPA plans to review exposure data including 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 not identified available monitoring data from OSHA and NIOSH for *trans*-1,2-dichloroethylene. However, EPA has identified some data sources that may contain relevant monitoring data for the various conditions of use. EPA plans to review these sources and extract relevant data for consideration and analysis during risk evaluation.

   EPA plans to consider the influence of applicable regulatory limits and recommended exposure guidelines on occupational exposures in the occupational exposure assessment. The following are some data sources identified thus far:

Table 2-6. Potential Sources of Occupational Exposure Data

1996 ATSDR Toxicological Profile for *trans*-1,2-dichloroethylene

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to *trans*-1,2-dichloroethylene.**
EPA plans to 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 example, methylene chloride is a volatile liquid used in various degreasing applications and may provide surrogate data for these conditions of use.

3) **For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.**
EPA has identified potentially relevant OECD emission scenario documents (ESDs) and EPA generic scenarios (GSs) corresponding to some conditions of use. For example, the April 2015 ESD on Use of Adhesives (OECD, 2015) may be used to estimate occupational exposures. EPA plans 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 the use of *trans*-1,2-dichloroethylene as a laboratory chemical. EPA

plans to perform additional targeted research in order to better 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.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.**
This step will be performed after Steps #2 and #3 are completed. Based on information developed from Steps #2 and #3, EPA plans to 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.

5) **Consider and incorporate applicable engineering controls (EC) and/or personal protective equipment into exposure scenarios.**
EPA plans to review potentially relevant data sources on EC and personal protective equipment as identified in Appendix E to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA plans to assess worker exposure pre- and post-implementation of EC, using reasonably 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 occupational exposure scenarios and mapped them to relevant conditions of use (see Appendix F). EPA was not able to identify occupational scenarios corresponding to some conditions of use (e.g. recycling, construction and demolition). EPA plans to perform targeted research to understand those uses which may inform identification of occupational exposure scenarios. EPA may further refine the mapping/grouping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the scientific evidence of occupational exposure data, which may include qualitative and quantitative sources of information.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. EPA plans to 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 plans to 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.

2.7.2.4 Consumer Exposures

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

1) **Group each condition of use to consumer exposure assessment scenario(s).**
   Refine and finalize exposure scenarios for consumers by considering combinations of sources (ongoing consumer uses), exposure pathways including routes, and exposed populations.

   For *trans*-1,2-dichloroethylene, the following are noteworthy considerations in constructing consumer exposure scenarios:
   - Conditions of use and type of consumer products
   - Duration, frequency and magnitude of exposure
   - Weight fraction of chemical in products
   - Amount of chemical used

2) **Evaluate the relative potential of indoor exposure pathways based on available data.**
   Indoor exposure pathways expected to be relatively higher include inhalation of indoor air. Indoor exposure pathways expected to be relatively lower include dermal contact liquids or vapor. The data sources associated with these respective pathways have not been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air, indoor dust concentrations, or indoor dust surface loadings.**
   Indoor exposure models that estimate emissions from consumer products are available. These models generally consider physical-chemical properties (e.g., vapor pressure, molecular weight), product specific properties (e.g., weight fraction of the chemical in the product), use patterns (e.g., duration and frequency of use), user environment (e.g., room of use, ventilation rates), and receptor characteristics (e.g., exposure factors, activity patterns). The OPPT's Consumer Exposure Model (CEM) and other similar models can be used to estimate indoor air exposures from consumer products.

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.**
   To the extent other organizations have already modeled a *trans*-1,2-dichloroethylene consumer exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if other chemicals similar to *trans*-1,2-dichloroethylene have been modeled for similar uses, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

5) **Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with indoor monitoring data reporting *trans*-1,2-dichloroethylene in specific media (e.g., dust or indoor air).**
   The availability of *trans*-1,2-dichloroethylene concentration for various ongoing uses will be evaluated. This data provides the source term for any subsequent indoor modeling. Source attribution between overall indoor air and dust levels and various indoor sources will be analyzed.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further refined.**
   During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

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

2.7.2.5 General Population

EPA plans to analyze general population exposures as follows:

1) **Refine and finalize exposure scenarios for general population by considering combinations of sources and uses, exposure pathways including routes, and exposed populations.**

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

   EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data,

modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. In an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA plans to consider source apportionment across exposure scenarios during risk evaluation. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Appendix H. Source apportionment characterizes the relative contribution of any of the following: a use/source toward a total media concentration, a media concentration toward a total exposure route, or an exposure route toward a total external or internal dose. This consideration may be qualitative, semi-quantitative, or quantitative, and is dependent upon available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with available monitoring data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to unique receptor groups. If available, EPA plans to compare multiple scenario-specific and background exposure doses estimated from media-specific concentrations and exposure factors with available biomonitoring data. The forward-calculated and back-calculated exposures could be compared to characterize the relative contribution from defined exposure scenarios.

After refining and finalizing exposure scenarios, EPA plans to quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is readily available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. First-tier analyses were conducted during problem formulation and are expected to continue during risk evaluation. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative, and require careful consideration of variability and uncertainty. Should data become available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2) **For exposure pathways where empirical data is not available, review existing exposure models that may be applicable in estimating exposure levels.**
For *trans*-1,2-dichloroethylene, media where exposure models will be considered for general population exposure include models that estimate ambient air concentrations, surface water concentrations, sediment concentrations, soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

3) **Review available exposure modeled estimates. For example, existing models developed for a previous *trans*-1,2-dichloroethylene chemical assessment may be applicable to the EPA's assessment. In addition, another chemical's assessment may also be applicable if model parameter data are available.**
To the extent other organizations have already modeled *trans*-1,2-dichloroethylene general population exposure scenario that is relevant to the OPPT's assessment, EPA plans to evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical chemical properties and similar uses are available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

4) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.**
The expected releases from industrial facilities are changing over time. Any modeled concentrations based on recent release estimates will be carefully compared with available monitoring data to determine representativeness.

5) **Review reasonably available information about population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).**
For *trans*-1,2-dichloroethylene, exposure scenarios that involve potentially exposed or susceptible subpopulations will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for dust, soil, and diet than adults.

6) **Evaluate the weight of the scientific evidence of general population exposure estimates based on different approaches.**
During risk evaluation, EPA plans to evaluate and integrate the exposure evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

2.7.3 Hazards (Effects)

2.7.3.1 Environmental Hazards

EPA plans to conduct an environmental hazard assessment of *trans*-1,2-dichloroethylene 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).**
EPA plans to analyze the hazards of *trans*-1,2-dichloroethylene to aquatic and/or terrestrial organisms, including plants, invertebrates (e.g., insects, arachnids, mollusks, crustaceans), and vertebrates (e.g., mammals, birds, amphibians, fish, reptiles) across exposure durations and conditions if potential environmental hazards are identified through systematic review results and public comments. Additional types of environmental hazard information will also be considered (e.g., analogue and read-across data) when characterizing the potential hazards of *trans*-1,2-dichloroethylene to aquatic and/or terrestrial organisms.

   Environmental hazard data will be evaluated using the environmental toxicity data quality criteria outlined in the systematic review documentation that EPA plans to publish prior to finalizing the scope 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.

   Hazard endpoints (e.g., mortality, growth, immobility, reproduction) will be evaluated, while considering data availability, relevance, and quality.

2) **Derive hazard thresholds for aquatic and/or terrestrial organisms.**
Depending on the robustness of the evaluated data for a particular organism or taxa (e.g., aquatic invertebrates), environmental hazard values (e.g., EC_x. LC_x, NOEC, LOEC) may be derived and used to further understand the hazard characteristics of *trans*-1,2-dichloroethylene to aquatic and/or terrestrial species. Identified environmental hazard thresholds may be used to derive concentrations of concern (COC), based on endpoints that may affect populations of organisms or taxa analyzed.

3) **Evaluate the weight of scientific evidence of environmental hazard data.**
During risk evaluation, EPA plans to evaluate and integrate the environmental hazard evidence identified in the literature inventory using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

4) **Consider the route(s) of exposure, based on available monitoring and modeling data and other available approaches to integrate exposure and hazard assessments.**
EPA plans to consider aquatic (e.g., water and sediment exposures) and terrestrial pathways in the *trans*-1,2-dichloroethylene conceptual model. These organisms may be exposed to *trans*-1,2-dichloroethylene via a number of environmental pathways (e.g., surface water, sediment, soil, diet).

5) **Conduct an environmental risk characterization of *trans*-1,2-Dichloroethylene.**
EPA plans to conduct a risk characterization of *trans*-1,2-dichloroethylene to identify if there are risks to the aquatic and/or terrestrial environments from the measured and/or predicted concentrations of *trans*-1,2-dichloroethylene in environmental media (i.e., water, sediment, soil). Risk quotients (RQs) may be derived by the application of hazard and exposure benchmarks to characterize environmental risk (U.S. EPA, 1998; Barnthouse et al., 1982).

6) **Consider a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of *trans*-1,2-dichloroethylene.**
EPA plans to consider the persistence, bioaccumulation, and toxic (PBT) potential of *trans*-1,2-dichloroethylene after reviewing relevant physical-chemical properties and exposure pathways. EPA plans to assess the available studies identified from the systematic review process relating to bioaccumulation and bioconcentration (e.g., BAF, BCF) of *trans*-1,2-dichloroethylene. In addition, EPA plans to integrate traditional environmental hazard endpoint values (e.g., LC_{50}, LOEC) and exposure concentrations (e.g., surface water concentrations, tissue concentrations) for *trans*-1,2-dichloroethylene with the fate parameters (e.g., BAF, BCF, BMF, TMF).

2.7.3.2 Human Health Hazards

EPA plans to analyze human health hazards as follows:

1) **Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).**
EPA plans to use systematic review methods to evaluate the epidemiological and toxicological literature for *trans*-1,2-dichloroethylene. EPA plans to publish the systematic review documentation prior to finalizing the scope document.

   Relevant mechanistic evidence will also be considered, if reasonably available, to inform the interpretation of findings related to potential human health effects and the dose-repose

assessment. Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

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 *trans*-1,2-dichloroethylene hazard(s). Susceptibility of particular human receptor groups to *trans*-1,2-dichloroethylene will be determined by evaluating information on factors that influence susceptibility.

   EPA has reviewed some sources containing hazard information associated with susceptible populations and lifestages such as pregnant women and infants. Pregnancy (i.e., gestation) and childhood are potential susceptible lifestages for *trans*-1,2-dichloroethylene exposure. EPA plans to review the current state of the literature in order to potentially quantify these differences for risk evaluation purposes.

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 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 systematic review data quality criteria described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document. Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (e.g., oral, dermal, 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 may be used if the data meet data quality criteria and if additional information on the identified hazard endpoints are not available or would not alter the analysis.

   The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. If cancer hazard is determined to be applicable to *trans*-1,2-dichloroethylene, EPA plans to evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005).

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. 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's *Benchmark*

Dose Technical Guidance Document. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of the scientific evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

EPA plans to 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 standard exposure durations (e.g., lifetime continuous exposure). If application of the PBPK model is not possible, oral PODs may be adjusted by $BW^{3/4}$ scaling in accordance with U.S. EPA (2011), and inhalation PODs may be adjusted by exposure duration and chemical properties in accordance with U.S. EPA (1994).

5) **Evaluate the weight of the scientific evidence of human health hazard data.** During risk evaluation, EPA plans to evaluate and integrate the human health hazard evidence identified in the literature inventory under acute and chronic exposure conditions using the methods described in the systematic review documentation that EPA plans to publish prior to finalizing the scope document.

6) **Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.** Following systematic review, EPA plans to conduct a dose-response analysis and/or benchmark dose modeling for the oral route of exposure based on the results. This may include using route-to-route extrapolation methods where appropriate. EPA plans to also evaluate any potential human health hazards following dermal and inhalation exposure to *trans*-1,2-dichloroethylene, which could be important for worker, consumer, and general population risk analysis. Available data will be assessed to determine whether or not a point of departure can be identified for the dermal and inhalation routes.

   If sufficient toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation 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)* (U.S. EPA, 2004) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures

2.7.4 Summary of Risk Approaches for Characterization

Risk characterization is an integral component of the risk assessment process for both environmental and human health risks. EPA plans to derive the risk characterization in accordance with the EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in the 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.

The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR) (U.S. EPA, 2000). EPA plans to also present information in this section consistent with approaches described in the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726). For instance, in the risk characterization summary, EPA plans to 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 plans to also be guided by the EPA's Information Quality Guidelines (U.S, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA plans to 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.

2.8 Peer Review

Peer review will be conducted in accordance with EPA's regulatory procedures for chemical risk evaluations, including using EPA's Peer Review Handbook and other methods consistent with Section 26 of TSCA (See 40 CFR 702.45). As explained in the Risk Evaluation Rule, the purpose of peer review is for the independent review of the science underlying the risk assessment. Peer review will therefore address aspects of the underlying science as outlined in the charge to the peer review panel such as hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. The draft risk evaluation for *trans*-1,2-dichloroethylene will be peer reviewed.

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APPENDICES

Appendix A LIST OF GRAY LITERATURE SOURCES

Table_Apx A-1. Gray Literature Sources for *trans*-1,2-Dichloroethylene

Source/Agency	Source Name	Source Type	Source Category
ATSDR	ATSDR Tox Profile Updates and Addendums	Other US Agency Resources	Assessment or Related Document
ATSDR	ATSDR Toxicological Profiles (original publication)	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Soil Screening	Other US Agency Resources	Assessment or Related Document
CAL EPA	Technical Support Documents for regulations: Drinking Water Public Health Goals	Other US Agency Resources	Assessment or Related Document
CDC	CDC Biomonitoring Tables	Other US Agency Resources	Database
ECHA	ECHA Documents	International Resources	Assessment or Related Document
Env Canada	Priority Substances List Assessment Report; State of Science Report, Environment Canada Assessment	International Resources	Assessment or Related Document
Env Canada	Chemicals at a Glance (fact sheets)	International Resources	Assessment or Related Document
EPA	Office of Water: STORET and WQX	US EPA Resources	Database
EPA	EPA Office of Water: Ambient Water Quality Criteria documents	US EPA Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
EPA	TSCA Data Needs Assessments or Problem Formulation	US EPA Resources	Assessment or Related Document
EPA	TSCA Hazard Characterizations	US EPA Resources	Assessment or Related Document
EPA	IRIS Tox Review	US EPA Resources	Assessment or Related Document
EPA	IRIS Summary	US EPA Resources	Assessment or Related Document
EPA	Other EPA: Misc sources	US EPA Resources	General Search
EPA	EPA: AP-42	US EPA Resources	Regulatory Document or List
EPA	TRI: Envirofacts Toxics Release Inventory 2017 Updated Dataset	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 non-CBI CDR database)	US EPA Resources	Database
EPA	Chemical Data Reporting (2012 and 2016 CBI CDR database)	US EPA Resources	Database
EPA	EPA: Generic Scenario	US EPA Resources	Assessment or Related Document
EPA	EPA Discharge Monitoring Report Data	US EPA Resources	Database
EPA	EPA Ambient Monitoring Technology Information Center – Air Toxics Data	US EPA Resources	Database
EPA	Office of Water: CFRs	US EPA Resources	Regulatory Document or List
EPA	Office of Water: Drinking Water Standards Health Effects Support Documents	US EPA Resources	Regulatory Document or List

Source/Agency	Source Name	Source Type	Source Category
EPA	Office of Air: National Emissions Inventory (NEI) - National Emissions Inventory (NEI) Data (2014, 2011, 2008)	US EPA Resources	Database
EPA	Office of Air: CFRs and Dockets	US EPA Resources	Regulatory Document or List
Japan	Japanese Ministry of the Environment Assessments - Environmental Risk Assessments (Class I Designated Chemical Substances Summary Table)	International Resources	Regulatory Document or List
KOECT	Kirk-Othmer Encyclopedia of Chemical Technology Journal Article	Other Resource	Encyclopedia
NIOSH	CDC NIOSH - Health Hazard Evaluations (HHEs)	Other US Agency Resources	Assessment or Related Document
NIOSH	CDC NIOSH - Publications and Products	Other US Agency Resources	Assessment or Related Document
NLM	National Library of Medicine's Hazardous Substance Databank	Other US Agency Resources	Database
NLM	National Library of Medicine's HazMap	Other US Agency Resources	Database
NTP	Additional NTP Reports	Other US Agency Resources	Assessment or Related Document
OECD	OECD Emission Scenario Documents	International Resources	Assessment or Related Document
OECD	OECD: General Site	International Resources	General Search
OSHA	U.S. OSHA Chemical Exposure Health Data (CEHD) program data [ERG]	Other US Agency Resources	Database
RIVM	RIVM Reports: Risk Assessments	International Resources	Assessment or Related Document

Source/Agency	Source Name	Source Type	Source Category
TERA	Toxicology Excellence for Risk Assessment	Other Resources	Assessment or Related Document

Appendix B PHYSICAL AND CHEMICAL PROPERTIES OF *trans*-1,2-DICHLOROETHYLENE

This appendix provides p-chem information and data found in preliminary data gathering for *trans*-1,2-dichloroethylene. Table_Apx B-1 summarizes the p-chem property values preliminarily selected for use in the risk evaluation from among the range of reported values collected as of March 2020. This table differs from that presented in the *Proposed Designation of trans-1,2-Dichloroethylene (CASRN 156-60-5) as a High-Priority Substance for Risk Evaluation* (U.S. EPA, 2019) and may be updated as EPA collects additional information through systematic review methods. All p-chem property values that were extracted and evaluated as of March 2020 are presented in the supplemental file *Data Extraction and Data Evaluation Tables for Physical Chemical Property Studies* (EPA-HQ-OPPT-2018-0465).

Table_Apx B-1. Physical and Chemical Properties of *trans*-1,2-Dichloroethylene

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	$C_2H_2Cl_2$	NA	NA
Molecular weight	96.94 g/mol	NA	NA
Physical state	Liquid	Rumble, 2018	High
Physical properties	Colorless, light liquid, sweetish scent	NLM, 2018	High
Melting point	-49.8°C	Rumble, 2018	High
Boiling point	47.64°C	Rumble, 2018	High
Density	1.2565 g/cm^3 at 20°C	O'Neil, 2013	High
Vapor pressure	331 mm Hg at 25°C	NLM, 2018	High
Vapor density	3.67 at 47.64°C (at bp at 760 mm Hg)	NLM, 2018	High
Water solubility	5,300 mg/L at 25°C	Rumble, 2018	High
Log Octanol/water partition coefficient (Log Kow)	2.09	O'Neil, 2013	High
Henry's Law constant	9.47×10^{-3} atm·m^3/mol at 25°C	Rumble, 2018	High
Flash point	Not available		

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Auto flammability	Not available		
Viscosity	0.317 cP at 25°C	Rumble, 2018	High
Refractive index	1.4454	Rumble, 2018	High
Dielectric constant	2.35	Elsevier, 2019	High

[a] Measured unless otherwise noted.
NA = Not applicable

Appendix C ENVIRONMENTAL FATE AND TRANSPORT PROPERTIES OF *trans*-1,2-DICHLOROETHYLENE

Table_Apx C-1. Environmental Fate Properties of *trans*-1,2-Dichloroethylene

Property or Endpoint	Value[a]	Reference
Direct Photodegradation	UV absorption at <240 nm with minor absorption between 290 and 380 nm; direct photolysis is not expected to be an important fate process	ATSDR (1996); HSDB (2018)
Indirect Photodegradation	$t_{1/2}$ = 5 days (based on·OH reaction rate constant of 4.5×10^{-12} cm^3/mol·second at 25 °C)	ATSDR (1996) citing Goodman et al. (1986)
	$t_{1/2}$ = 44 days (based on ozone reaction rate)	ATSDR (1996) citing Tuazon et al. (1984)
	$t_{1/2}$ = 6.9 hours (based on OH reaction rate constant of 2.34×10^{-12} cm^3/mol·second at 25 °C and 5×10^5·OH radicals/cm^3)	HSDB (2018) citing Kwok and Atkinson (1994)
	$t_{1/2}$ = 57 days (based on ozone reaction rate of 2.0×10^{-19} cm^3/mol·second and 7×10^{11} ozone molecules/cm^3 at 25 °C)	HSDB (2018) citing Kwok and Atkinson (1994)
	$t_{1/2}$ = 310 days (based on nitrate reaction rate of 1.07×10^{-16} cm^3/mol·second at 25 °C and 2.4×10^8 nitrate radicals/cm^3)	HSDB (2018) citing Kwok and Atkinson, 1994
Hydrolysis	Stable; *trans*-1,2-dichloroethylene is not expected to undergo hydrolysis based on its chemical structure, which lacks functional groups known to undergo hydrolysis under environmental conditions	HSDB (2018) citing Callahan et al. (1979)
Biodegradation (Aerobic)	Water: 0% after 28 days based on BOD (Japanese MITI test)	NITE (2018); HSDB (2018)
	Water: 0%/time not specified (river die-away test and shake-flask test)	HSDB (2018) citing Mudder (1981), Mudder and Musterman (1982)
	Water: 67%/7 days with 33% loss due to volatilization in 10 days (enrichment biodegradability screening test with wastewater inoculum; test substance concentration of 5 ppm)	HSDB (2018) citing Fogel et al. (1986)

Property or Endpoint	Value[a]	Reference
	Soil and water: Durban, KwaZulu-Natal, South Africa $t_{1/2}$ = 21 days in soil A (52% sand, 26.5% clay, 21.5% silt, microbial concentration 6.5 × 105cfu/g) $t_{1/2}$ = 23 days in soil B (80.25% sand, 8.25% clay, 11.5% silt, microbial concentration 3.0 × 10^5 cfu/g) $t_{1/2}$ = 27 days in water A (pH 6.98, microbial concentration 13.25 × 10^5 cfu/g) $t_{1/2}$ = 26 days in water B (pH 6.94, microbial concentration 3.4 × 10^5 cfu/g)	HSDB (2018) citing Olaniran et al. (2006)
Biodegradation (Anaerobic)	18%/40 weeks (serum bottle) vinyl chloride was the primary degradation product	HSDB (2018) citing Wilson et al. (1986)
	73%/6 months (microcosms with uncontaminated organic sediment from the Everglades); vinyl chloride was the degradation product	HSDB (2018) citing Barrio-Lage et al. (1986)
Wastewater Treatment	$t_{1/2}$ = 24 minutes by evaporation from water (1 ppm aqueous solution with still air, an average depth of 6.5 cm, at 25 °C) 90% evaporation after 83 minutes (1 ppm solution at 25 °C)	HSDB (2018) citing Verschueren (2001)
	79% total removal (0.04% by biodegradation, 0.90% by sludge and 78% by volatilization to air; estimated)[b]	U.S. EPA (2012a)
Bioconcentration Factor	11 (estimated)[b]	U.S. EPA (2012a)
Bioaccumulation Factor	13 (estimated)[b]	U.S. EPA (2012a)
Soil Organic Carbon:Water Partition Coefficient (Log K_{OC})	1.77 (K_{OC} = 59)	HSDB (2018) citing Chu and Chan (2000); Mackay et al. (2006)

[a] Measured unless otherwise noted
[b] EPI Suite™ physical property inputs: Log K_{OW} = 2.09, BP = 48.7 ºC, MP = –49.8 ºC, VP = 331 mm Hg, WS = 4,520 mg/L, SMILES C(=CCl)Cl.
·OH = hydroxyl radical; MITI = Ministry of International Trade and Industry; BOD = biochemical oxygen demand

Appendix D REGULATORY HISTORY

The chemical substance, *trans*-1,2-dichloroethylene (trans-DCE), is subject to federal and state laws and regulations in the United States (Table_Apx D-1 and Table_Apx D-2). Regulatory actions by other governments, tribes and international agreements applicable to *trans*-1,2-dichloroethylene are listed in Table_Apx D-3.

D.1 Federal Laws and Regulations

Table_Apx D-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxic Substances Control Act (TSCA) – Section 6(b)	EPA is directed to identify high-priority chemical substances for risk evaluation; and conduct risk evaluations on at least 20 high priority substances no later than three and one-half years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.	Trans-DCE is one of the 20 chemicals EPA designated as a High-Priority Substance for risk evaluation under TSCA (84 FR 71924, December 30, 2019). Designation of trans-DCE as high-priority substance constitutes the initiation of the risk evaluation on the chemical.
Toxic Substances Control Act (TSCA) – Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	Trans-DCE manufacturing (including importing), processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
Toxic Substances Control Act (TSCA) – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured (including imported) or processed in the United States.	Trans-DCE was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 (60 FR 16309, March 29, 1995).
Toxic Substances Control Act (TSCA) – Section 8(d)	Provides EPA with authority to issue rules requiring producers, importers, and (if specified) processors of a chemical substance or mixture to submit lists and/or copies of ongoing and completed, unpublished health and safety studies.	4 health and safety studies received for trans-DCE (1994) (U.S. EPA, ChemView. Accessed April 18, 2019).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Toxic Substances Control Act (TSCA) – Section 8(e)	Manufacturers (including importers), 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.	Two risk reports received for trans-DCE (1994; 2000) (U.S. EPA, ChemView. Accessed April 4, 2019).
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 TRI-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (e.g., quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (i.e., air, land and water).	DCE (mixture of the cis & trans isomers; CAS 540-59-0) is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 01, 1987.
Clean Air Act (CAA) – Section 612	Under Section 612 of the 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 alternative is unacceptable, or acceptable only with conditions, is made through rulemaking.	Under the SNAP program, EPA listed trans-DCE as an acceptable substitute for methyl chloroform and CFC-113 in metals, electronics, and precision cleaning and in aerosol solvents (59 FR 44240, August 26, 1994). Later, EPA listed trans-DCE as an acceptable substitute for methyl chloroform and CFC-113 in adhesives (61 FR 47012, September 5, 1996). EPA also listed Transcend™ Technologies, which contains trans-DCE, when used as an additive to other SNAP-approved foam blowing agents, in blends making up to 5% by weight of the total foam

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		formulation, as a substitute for CFCs and HCFCs in a number of polyurethane foam end-uses (71 FR 15589, March 29, 2006). Most recently, EPA has also listed the refrigerant blend HFO-1336mzz(Z)/ dichloroethylene blend (74.7/25.3) (also known as R-514A), which contains 25.3 percent trans-DCE by weight, as acceptable for use in centrifugal chillers and positive displacement chillers (81 FR 32241, May 23, 2016).
Clean Water Act (CWA) - Section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for trans-DCE, including a recommendation of 100 (µg/L) for "Human Health for the consumption of Water + Organism" and 4000 (µg/L) for "Human Health for the consumption of Organism Only" for states and authorized tribes to consider when adopting criteria into their water quality standards. [EPA-HQ-OW-2014-0135-0249]
Clean Water Act (CWA) – Section 301, 304, 306, 307, and 402	Clean Water Act Section 307(a) establishes a list of toxic pollutants or combination of pollutants under the CWA. The statue specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR Part 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, see Section 402(a)(1)(B). EPA identifies the best	Trans-DCE is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to effluent limitations. Under CWA section 304, trans-DCE is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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.	
Safe Drinking Water Act (SDWA) – Section 1412	Requires EPA to publish non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	Trans-DCE is subject to NPDWR under the SDWA with a MCLG of 100 ppb and an enforceable MCL of 100 ppb (Section 1412).
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 degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Trans-DCE is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: U079, FO24, and F025 (40 CFR 261.33).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 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	Trans-DCE is a hazardous substance under CERCLA. Releases of trans-DCE in excess of 1,000 pounds must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	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.	
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.	Trans-DCE 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		
Occupational Safety and Health Act (OSHA)	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 (29 U.S.C section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative control measures, and respiratory protection.	In 1971, OSHA issued occupational safety and health standards for DCE (mixture of the cis & trans isomers; CAS 540-59-0) that included a PEL of 200 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1000). OSHA has recognized that many of its PELs are outdated and inadequate for ensuring the protection of worker health.
Federal Hazardous Materials Transportation Act (HMTA)	Section 5103 of the Act directs the Secretary of Transportation to: • Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material, and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an	Trans-DCE is listed as a hazardous material with regard to transportation and is subject to regulations prescribing requirements applicable to the shipment and transportation of listed hazardous materials (70 FR 34381, June 14 2005).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	unreasonable risk to health and safety or property. • Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	

D.2 State Laws and Regulations

Table_Apx D-2. State Laws and Regulations

State Actions	Description of Action
State Air Regulations	Allowable Ambient Levels: New Hampshire (Env-A 1400: Regulated Toxic Air Pollutants). Rhode Island (Air Pollution Regulation No. 22).
State Drinking Water Standards and Guidelines	Arizona (14 Ariz. Admin. Register 2978, August 1, 2008), California (Cal Code Regs. Title 26, § 22-64444), Delaware (Del. Admin. Code Title 16, § 4462), Connecticut (Conn. Agencies Regs. § 19-13-B102), Maine (10 144 Me. Code R. Chap. 231), Massachusetts (310 Code Mass. Regs. § 22.00), Michigan (Mich. Admin. Code r.299.44 and r.299.49, 2017), Minnesota (Minn R. Chap. 4720), New Jersey (7:10 N.J Admin. Code § 5.2), Pennsylvania (25 Pa. Code § 109.202), Rhode Island (Rules and Regulations Pertaining to Public Drinking Water R46-13-DWQ), Texas (30 Tex. Admin. Code § 290.104).
State PELs	California PEL for DCE mixture (CAS 540-59-0) of 200 ppm (Cal Code Regs. Title 8, § 5155). Hawaii PEL DCE mixture (CAS 540-59-0) of 200 ppm (Hawaii Administrative Rules section 12-60-50).
State Right-to-Know Acts	Massachusetts (105 Code Mass. Regs. § 670.000 Appendix A), New Jersey (N.J.A.C. 7:1G) and Pennsylvania (P.L. 734, No. 159 and 34 Pa. Code § 323).
Chemicals of High Concern to Children	Several states have adopted reporting laws for chemicals in children's products containing trans-DCE, including Minnesota (Toxic Free Kids Act Minn. Stat. 116.9401 to 116.9407).
Other	Trans-DCE is listed as a Candidate Chemical under California's Safer Consumer Products Program established under Health and Safety Code § 25252 and 25253 (California, Candidate Chemicals List. Accessed April 18, 2019). California lists Trans-DCE as a designated priority chemical for biomonitoring under criteria established by California SB 1379 (Biomonitoring California, Priority Chemicals, February 2019). Trans-DCE is on the MA Toxic Use Reduction Act (TURA) list of 2019 (301 CMR 41.00).

D.3 International Laws and Regulations

Table_Apx D-3. Regulatory Actions by other Governments, Tribes, and International Agreements

Country/ Organization	Requirements and Restrictions
Canada	Trans-DCE is on the Domestic Substances List. (Government of Canada. Managing substances in the environment. Substances search. Database accessed April 12, 2019).
European Union	Trans-DCE is registered in the European Union under regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). (European Chemicals Agency (ECHA) database. Accessed April 12, 2019).
Australia	Trans-DCE was assessed under Human Health Tier I of the Inventory Multi-Tiered Assessment and Prioritisation (IMAP). (National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Chemical inventory. Database accessed April 12, 2019).
Japan	Trans-DCE 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 (National Institute of Technology and Evaluation [NITE] Chemical Risk Information Platform [CHRIP]. Accessed April 12, 2019).
Belgium, Canada, Denmark, Finland, Germany, Switzerland	Occupational exposure limits for trans-DCE (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2019.

Appendix E PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data identification and evaluation for *trans*-1,2-dichloroethylene.

E.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.

E.1.1.1 Manufacture

1,2-Dichloroethylene can be produced by direct chlorination of acetylene at 40 degrees C. It is often produced as a by-product in the chlorination of chlorinated compounds and recycled as an intermediate for the synthesis of more useful chlorinated ethylenes. 1,2-Dichloroethylene can also be formed by continuous oxychlorination of ethylene by use of a cupric chloride–potassium chloride catalyst, as the first step in the manufacture of vinyl chloride (Snedecor, et al., 2004).

E.1.1.2 Import

Commodity chemicals such as *trans*-1,2-Dichloroethylene may be imported into the United States in bulk via water, air, land, and intermodal shipments (Tomer, 2015). These shipments take the form of oceangoing chemical tankers, railcars, tank trucks, and intermodal tank containers. Chemicals shipped in bulk containers may be repackaged into smaller containers for resale, such as drums or bottles. Domestically manufactured commodity chemicals may be shipped within the United States in liquid cargo barges, railcars, tank trucks, tank containers, intermediate bulk containers (IBCs)/totes, and drums. Both imported and domestically manufactured commodity chemicals may be repackaged by wholesalers for resale; for example, repackaging bulk packaging into drums or bottles. The type and size of container will vary depending on customer requirement. In some cases, QC samples may be taken at import and repackaging sites for analyses. Some import facilities may only serve as storage and distribution locations, and repackaging/sampling may not occur at all import facilities.

In the 2016 CDR, one company reported importing a formulation containing less than 1 percent *trans*-1,2-dichloroethylene (U.S. EPA, 2016).

E.1.2 Processing and Distribution

E.1.2.1 Processing as a Reactant or Intermediate

Processing as a reactant or intermediate is the use of *trans*-1,2-dichloroethylene as a feedstock in the production of another chemical via a chemical reaction in which *trans*-1,2-dichloroethylene is consumed to form the product. EPA has not identified specific process information for the processing of *trans*-1,2-dichloroethylene as a reactant but EPA plans to evaluate this condition of use during the risk evaluation.

E.1.2.2 Incorporation into Formulation, Mixture, or Reaction Product

Incorporation into formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a product or mixture. *trans*-1,2-Dichloroethylene can be incorporated into solvents for cleaning or degreasing, adhesives and sealants, foam blowing additives, and as a carrier solvent in other product formulations.

Formation processes specific to *trans*-1,2-dichloroethylene were not identified; however, several OECD ESDs provide general process descriptions for some of these types of products. For example, adhesive formulation involves mixing together volatile and non-volatile chemical components in sealed, unsealed or heated processes (OECD, 2009). Sealed processes are most common for adhesive formulation because many adhesives are designed to set or react when exposed to ambient conditions (OECD, 2009). Lubricant formulation typically involves the blending of two or more components, including liquid and solid additives, together in a blending vessel (OECD, 2004).

E.1.2.3 Incorporation into Articles

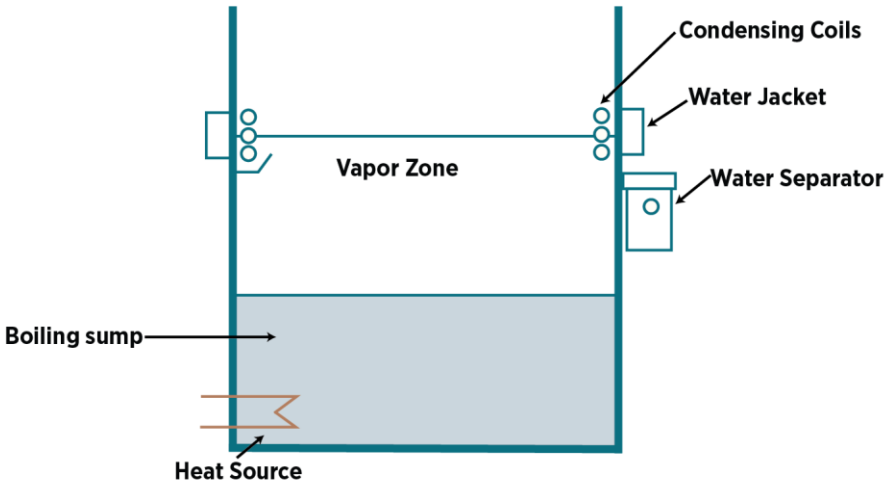
Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article that is distributed for industrial, trade, or consumer use. Exact process operations involved in the incorporation of *trans*-1,2-dichloroethylene are dependent on the article. EPA plans to evaluate the potential use of *trans*-1,2-dichloroethylene in this type of process during the risk evaluation.

E.1.3 Uses

E.1.3.1 Batch Open-Top Vapor Degreasing

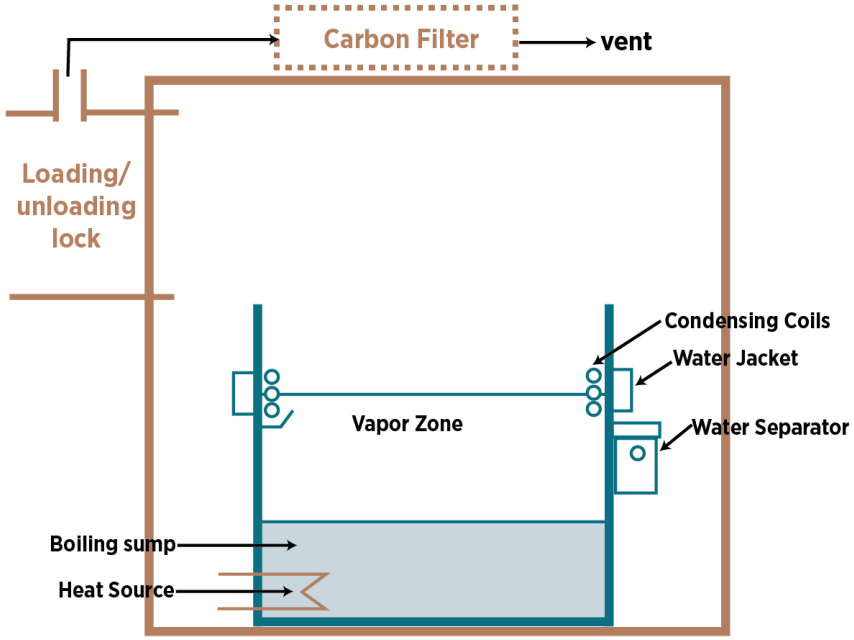
trans-1,2-Dichloroethylene is a component in vapor degreasing formulations. Section E.1.3.1 and Section E.1.3.2 provide example process description for batch vapor degreasing systems.

In batch open top vapor degreasers (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 E-1 illustrates a standard OTVD.



Figure_Apx E-1. Open Top Vapor Degreaser

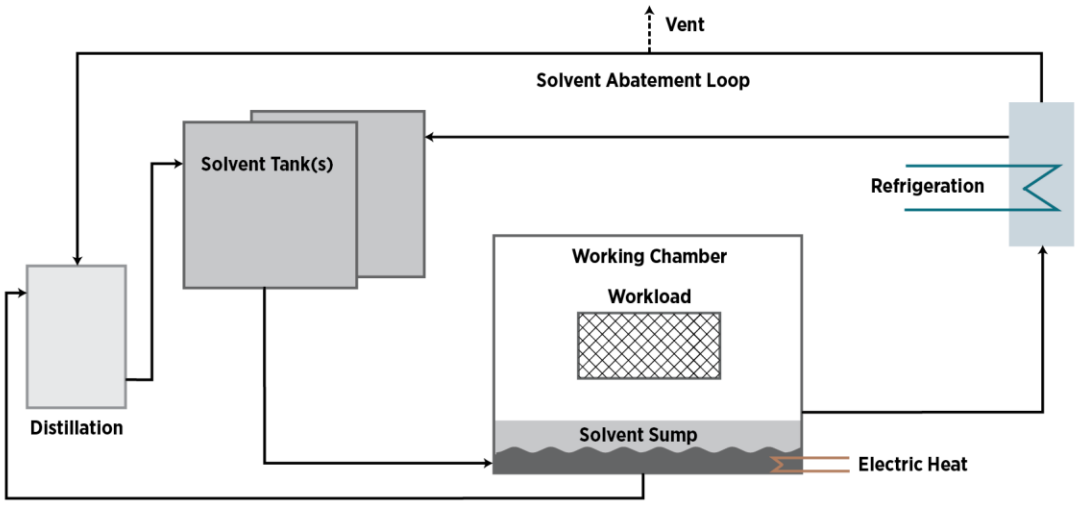
OTVDs with enclosures operate the same as standard OTVDs except that the OTVD is enclosed on all sides during degreasing. The enclosure is opened and closed to add or remove parts to/from the machine, and solvent is exposed to the air when the cover is open. Enclosed OTVDs may be vented directly to the atmosphere or first vented to an external carbon filter and then to the atmosphere (U.S. EPA, ICF Consulting, 2004). Figure_Apx E-2 illustrates an OTVD with an enclosure. The dotted lines in Figure_Apx E-2 represent the optional carbon filter that may or may not be used with an enclosed OTVD.



Figure_Apx E-2. Open Top Vapor Degreaser with Enclosure

E.1.3.2 Batch Closed-Top Vapor Degreasing

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, 2011). Figure_Apx E-3 illustrates a standard closed-loop vapor degreasing system.



Figure_Apx E-3. Closed-Loop/Vacuum Vapor Degreaser

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, 2011; NEWMOA, 2001; U.S. EPA, 2001).

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 E-3 for closed-loop systems except that the work chamber is under vacuum during various stages of the cleaning process.

E.1.3.3 Aerosol Degreasing

Aerosol degreasing is a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts. A propellant is used to aerosolize the formulation, allowing it to be sprayed onto substrates. The aerosol droplets bead up on the fabricated part and then drip off, carrying away any contaminants and leaving behind a clean surface. Similarly, aerosol lubricant products use an aerosolized spray to help free frozen parts by dissolving rust and leave behind a residue to protect surfaces against rust and corrosion.

Figure_Apx E-4 illustrates the typical process of using aerosol degreasing to clean components in commercial settings. One example of a commercial setting with aerosol degreasing operations is repair shops, where service items are cleaned to remove any contaminants that would otherwise compromise

the service item's operation. Internal components may be cleaned in place or removed from the service item, cleaned, and then re-installed once dry (U.S. EPA, 2014).

Figure_Apx E-4. Overview of Aerosol degreasing

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.

E.1.3.4 Industrial and Commercial Cleaning and Furniture Care Products

In the 2016 CDR, one company reported commercial use in cleaning and furniture care products at a concentration of at least 90 percent (U.S. EPA, 2016). EPA has not identified specific process information for the use of cleaning and furnishing care products containing *trans*-1,2-dichloroethylene but EPA plans to evaluate this condition of use during the risk evaluation.

E.1.3.5 Anti-Adhesive Agent

Safety data sheets reported *trans*-1,2-dichloroethylene use in mold release agents, ranging from 25 to 80 percent in formulation (Allied, 2018; Miller-Stephenson, 2016 a, b). Separately, a product data sheet for an aerosol cleaning aid and lubricant also indicated potential use as a mold release agent (Rainbow Technology, undated); therefore, aerosol use is possible. EPA has not identified specific process information for the use of mold release agents containing *trans*-1,2-dichloroethylene but EPA plans to evaluate this condition of use during the risk evaluation.

E.1.3.6 Lubricants and Greases

A safety data sheet reported use *trans*-1,2-dichloroethylene in a cleaning aid and lubricant, between 15 and 40 percent concentration (Rainbow Technology, 2019). The product data sheet indicate that it is used as a spray cleaner/degreaser in various applications (Rainbow Technology, undated). Therefore, this use may be similar use in aerosol degreasing. EPA plans to evaluate the potential use of *trans*-1,2-dichloroethylene in this type of process during the risk evaluation.

E.1.3.7 Adhesives and Sealants

trans-1,2-Dichloroethylene-specific adhesive or sealant uses were not identified. The OECD ESD for Use of Adhesives (OECD, 2013) provides general process descriptions and worker activities for industrial adhesive uses, which may include application by spray, brush, or roll coating. EPA plans to evaluate this condition of use during risk evaluation.

E.1.3.8 Refrigerant and Refrigeration System Flush

Safety data sheets report a refrigerant containing up to 25.3 percent *trans*-1,2-dichloroethylene (Opteon, 2016) and an air conditioning or refrigeration system flush treatment containing between 50 and 60 percent *trans*-1,2-dichloroethylene (Ace, 2015). EPA has not identified specific process information for

the use of refrigerants and refrigeration system flush treatments containing *trans*-1,2-dichloroethylene but will investigate during risk evaluation.

E.1.3.9 Processing Aids

trans-1,2-Dichloroethylene has potential use as an extraction solvent for rubber, dyes, perfumes, lacquers, and thermoplastics. EPA has not identified specific process information for the use of processing aids containing *trans*-1,2-dichloroethylene but EPA plans to evaluate this condition of use during risk evaluation.

E.1.3.10 Propellants and Blowing Agents

Safety data sheets list *trans*-1,2-dichloroethylene as a component of polyurethane polyol formulation between 1 and 5 percent concentration (Demilec, 2017a; Demilec, 2017b). The 2004 Draft Generic Scenario for Use of Additives in Foamed Plastics indicates that workers may potentially be exposed during transferring components from shipping containers, operation/supervision of the foam mix head or dispenser, during foam production, and transfer or handling of newly foamed articles (U.S. EPA, 2004a). EPA has not identified specific process information for the use of *trans*-1,2-dichloroethylene, EPA plans to evaluate this condition of use during risk evaluation.

E.1.3.11 Laboratory Use

A safety data sheet for *trans*-1,2-dichloroethylene (>95% percent purity) indicates recommended use as a laboratory chemical (ThermoFisher, 2018). However, specific laboratory use activities are unknown. EPA plans to investigate the laboratory use of *trans*-1,2-dichloroethylene during risk evaluation.

E.1.4 Disposal

Each of the conditions of use of *trans*-1,2-dichloroethylene may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling. Industrial sites that treat or dispose onsite wastes that they themselves generate will be assessed in each condition of use assessment. Similarly, point source discharges of *trans*-1,2-dichloroethylene to surface water will be assessed in each condition of use (point source discharges are exempt as solid wastes under RCRA). Wastes of *trans*-1,2-dichloroethylene that are generated during a condition of use and sent to a third-party site for treatment, disposal, or recycling may include the following:

- Wastewater: *trans*-1,2-Dichloroethylene may be contained in wastewater discharged to POTW or other, non-public treatment works for treatment. Industrial wastewater containing *trans*-1,2-dichloroethylene discharged to a POTW may be subject to EPA or authorized NPDES state pretreatment programs. The assessment of wastewater discharges to POTWs and non-public treatment works of *trans*-1,2-dichloroethylene will be included in each of the condition of use assessments.

- Solid Wastes: Solid wastes are defined under RCRA as any material that is discarded by being: abandoned; inherently waste-like; a discarded military munition; or recycled in certain ways (certain instances of the generation and legitimate reclamation of secondary materials are exempted as solid wastes under RCRA). Solid wastes may subsequently meet RCRA's definition of hazardous waste by either being listed as a waste at 40 CFR §§ 261.30 to 261.35 or by meeting waste-like characteristics as defined at 40 CFR §§ 261.20 to 261.24. Solid wastes that are hazardous wastes are regulated under the more stringent requirements of Subtitle C of RCRA, whereas non-hazardous solid wastes are regulated under the less stringent requirements of Subtitle D of RCRA.

trans-1,2-Dichloroethylene is a U-listed hazardous waste under code U227 under RCRA; therefore, discarded, unused pure and commercial grades of Trans-1,2-Dichloroethylene are regulated as a hazardous waste under RCRA (40 CFR § 261.33(f)). Additionally, *trans*-1,2-dichloroethylene is included in multiple waste codes under the F-list of non-specific source wastes (40 CFR § 261.31(a)).

- Wastes Exempted as Solid Wastes under RCRA: Certain conditions of use of *trans*-1,2-dichloroethylene may generate wastes of *trans*-1,2-dichloroethylene that are exempted as solid wastes under 40 CFR § 261.4(a). For example, the generation and legitimate reclamation of hazardous secondary materials of *trans*-1,2-dichloroethylene may be exempt as a solid waste.

E.2 Sources Containing Potentially Relevant Data or Information

EPA plans to consider available data and information related to worker exposure and environmental releases as they are identified during systematic review. Based on a preliminary data identification and evaluation, there are no OSHA Chemical Exposure and Health Data (CEHD) or NIOSH Health Hazard Evaluations specific to *trans*-1,2-dichloroethylene.

Appendix F SUPPORTING INFORMATION - CONCEPTUAL MODEL FOR INDUSTRIAL AND COMMERCIAL ACTIVITIES AND USES

Table_Apx F-1. Worker and Occupational Non-User Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Manufacturing	Domestic manufacture	Domestic manufacture	Manufacture of trans-DCE	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
	Import	Import	Repackaging of import containers	Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
Processing	Processing as a reactant	Plating agents and surface treating agents	Manufacture of plating agents and surface treating agents	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
		Intermediate in chemical product and preparation manufacturing	Manufacture of chemical products and other chemical preparations	Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Processing	Processing – incorporation into formulation, mixture or reaction product	Solvents (for cleaning or degreasing) Solvents (which become part of product formulation or mixture) Adhesives and sealant chemicals Foam blowing additive Carrier solvent in adhesives, coatings, inks, lubricants, and silicones.	Formulation of mixture and products containing trans-DCE	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
Processing	Incorporation into articles	Propellant and blowing agent in plastics product manufacturing; flexible polyurethane foam manufacturing	Plastics product and flexible polyurethane foam manufacturing	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Processing	Repackaging Recycling	Repackaging Recycling	Repackaging to large and small containers Recycling of trans-1,2,-dichloroethylene or solvents containing trans-1,2,-dichloroethylene	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
Distribution in commerce	Distribution in commerce	Distribution in commerce	Distribution of bulk shipments of tras-DCE and formulated products	Liquid Contact, Vapor	Dermal, Inhalation	Worker, ONU	Yes	EPA plans to analyze 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 as a single distribution scenario.
Industrial/ commercial use	Solvents (for cleaning or degreasing)	Vapor degreaser	Use of vapor degreaser	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure. Exposure will depend on the specific type of degreasing system.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure. Exposure will depend on the specific type of degreasing system.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Industrial/ commercial use	Solvents (for cleaning or degreasing)	Aerosol spray cleaner/degreaser	Use of aerosol spray cleaner / degreaser	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Worker	Yes	Known products are supplied in aerosol cans, therefore, spray application is expected.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
Industrial/ commercial use	Solvents (for cleaning or degreasing)	Flux remover (liquid and aerosol)	Application of flux removers to substrates	Liquid Contact	Dermal	Worker	Yes	Workers may have dermal exposure to liquids when applying products containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
				Mist	Inhalation	Worker	Yes	Mist generation is possible for aerosol products that are spray-applied.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Commercial use	Solvents (for cleaning or degreasing)	Refrigerant flush	Use of refrigerant flush	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
Industrial/ commercial use	Cleaning and furniture care products	Spot cleaner; stain remover	Use of spot cleaner / stain remover for textile	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Worker	Yes	Stain/ink remover is spray applied to textiles, therefore, EPA plans to evaluate exposure to mist.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Industrial/ commercial use	Functional fluids (open systems)	Smoothing fluid in additive manufacturing	Additive manufacturing (3D printing)	Liquid Contact	Dermal	Worker	Yes	Workers may have incidental dermal exposure to liquids during 3D printing.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
				Mist	Inhalation	Worker	No	Mist generation is expected to be negligible during 3D printing.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
Industrial/ commercial use	Anti-adhesive agent	Mold release	Use of mold release products	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Worker	Yes	Some known products are applied via aerosol cans, therefore, spray application is expected.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Industrial/ commercial use	Solvents (which become part of product formulation or mixture)	Urethane coatings	Application of urethane coating	Liquid Contact	Dermal	Worker	Yes	Workers may have dermal exposure to liquids when applying products containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
				Mist	Inhalation	Worker	Yes	Mist generation is possible for aerosol products that are spray-applied.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure to vapor.
Industrial/ commercial use	Lubricants and greases	Liquid and spray lubricants and greases, and penetrating lubricants	Use of aerosol degreaser/cleaner	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Worker	Yes	Some known products are applied via aerosol cans, therefore, spray application is expected.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Industrial/ commercial use	Adhesives and sealants	Solvent-based adhesives and sealants; adhesive accelerant	Application of adhesives, sealants, and adhesive accelerants	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Worker	Yes	Some known products are applied via spray guns, therefore, spray application is expected.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
Industrial/commercial use	Functional fluids (closed systems)	Refrigerant	Use of refrigerant	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
Industrial/ commercial use	Functional fluids (closed systems)	Pharmaceutical and medicine manufacturing	Manufacture of pharma-ceuticals	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Industrial/ commercial use	Processing aids	Extraction solvent for thermoplastics	Use of processing solvent in industrial applications	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
Commercial use	Propellants and blowing agents	Polyurethane foam building insulation	Application of Polyurethane Foam Insulation	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Mist/Particulate	Inhalation	Worker	Yes	Several polyurethane foam products are designed to be spray-applied
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
Industrial/ commercial use	Other use	Laboratory chemicals	Use of laboratory chemicals	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Plans to Evaluate	Rationale
Disposal	Disposal	Disposal	Worker handling of wastes	Liquid Contact	Dermal	Worker	Yes	Workers are expected to routinely handle liquids containing trans-DCE.
				Vapor	Inhalation	Worker	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Liquid Contact	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers who directly handle the chemical.
				Vapor	Inhalation	ONU	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.

Appendix G SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR CONSUMER ACTIVITIES AND USES

Table_Apx G-1. Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Plans to Evaluate	Rationale
Consumer Use; Consumer Reuse and Recycling	Solvents (for cleaning or degreasing)	Aerosol spray cleaner/degreaser	Use of aerosol spray cleaner / degreaser	Liquid Contact	Dermal	Consumers	Yes	Consumers can potentially handle liquids containing *trans*-1,2-dichloroethylene.
				Vapor	Inhalation	Consumer, Bystanders	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Consumer, Bystanders	Yes	Known products are supplied in aerosol cans, therefore, spray application is expected.
	Cleaning and furnishing care products	Spot cleaners; stain removers	Use of spot cleaners; stain removers	Liquid Contact	Dermal	Consumers	Yes	Consumers can potentially handle liquids containing *trans*-1,2-dichloroethylene.
				Vapor	Inhalation	Consumer, Bystanders	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Consumer, Bystanders	Yes	Known products are supplied in aerosol cans, therefore, spray application is expected.
	Adhesives and Sealants	Solvent-based; adhesives accelerant	Use of solvent-based; adhesives accelerant	Liquid Contact	Dermal	Consumers	Yes	Consumers can potentially handle liquids containing *trans*-1,2-dichloroethylene.
				Vapor	Inhalation	Consumer, Bystanders	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure.
				Mist	Inhalation	Consumer, Bystanders	Yes	Known products are supplied in aerosol cans, therefore, spray application is expected.
	Propellants and blowing Agents	Polyurethane foam building insulation	Off-gassing of *trans*-1,2-dichloroethylene from polyurethane foam insulation	Vapor	Inhalation	Consumer, Bystanders	Yes	Due to high volatility (331 mmHg at room temperature), EPA plans to evaluate inhalation exposure

Appendix H SUPPORTING INFORMATION – CONCEPTUAL MODEL FOR ENVIRONMENTAL RELEASES AND WASTES

Table_Apx H-1. General Population and Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[8]	Rationale
All	Emissions to Air	Emissions to Air	Near facility ambient air concentrations	Inhalation	General Population	Yes	Trans-1,2-dichloroethylene ambient air and deposition to nearby bodies of water and soil are expected exposure pathways, not covered under other EPA regulations
			Indirect deposition to nearby bodies of water and soil catchments	Oral Dermal	General Population	Yes	
				TBD	Aquatic and Terrestrial Receptors	Yes	
		Hazardous and Municipal Waste Incinerator	Near facility ambient air concentrations/ Indirect deposition to nearby bodies of water and soil catchments	Inhalation	General Population	No	Stationary source releases of trans-1,2-dichloroethylene to ambient air are under the jurisdiction of the RCRA and CAA.
				TBD	Aquatic and Terrestrial Species		
	Wastewater or Liquid Wastes	Industrial pre-treatment and wastewater treatment, or POTW	Direct release into surface water and indirect partitioning to sediment	TBD	Aquatic and Terrestrial Receptors	Yes	EPA has developed Ambient Water Quality Criteria for protection of human health for trans-1,2-dichloroethylene
				Oral Dermal	General Population	No	

[8] The exposure pathways, exposure routes and hazards EPA plans to evaluate are subject to change in the final scope, in light of comments received on this draft scope and other reasonably available information. EPA continues to consider whether and how other EPA-administered statutes and any associated regulatory programs address the presence of trans-1,2-dichloroethylenein exposure pathways falling under the jurisdiction of these EPA statutes.

Life Cycle Stage	Category	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Plans to Evaluate[8]	Rationale
			Drinking Water via Surface or Ground Water	Oral Dermal and Inhalation (e.g. showering)	General Population	No	The drinking water exposure pathway for trans-1,2-dichloroethylene is currently addressed in the SDWA regulatory analytical process for public water systems.
			Biosolids: application to soil and/or migration to groundwater and/or surface water	Oral (e.g. ingestion of soil) Inhalation	General Population	No	Unlikely to be a route to general population since trans-1,2-dichloroethylene is not expected to sorb onto biosolids.
				TBD	Aquatic and Terrestrial receptors	Yes	
		Underground injection	Migration to groundwater, potential surface/drinking water	Oral Dermal Inhalation	General Population	No	Trans-1,2-Dichloroethylene is released to Class I Underground Injection Wells which are covered by SDWA and RCRA.
					Aquatic and Terrestrial Species		
				TBD			
Disposal	Solid and Liquid Wastes	Hazardous, Municipal landfill and other land disposal	Leachate to soil, ground water and/or mitigation to surface water	Oral Dermal	General Population	No	Trans-1,2-dichloroethylene is included on the list of hazardous wastes pursuant to RCRA 3001 (40 CFR §§ 261.33).
				TBD	Aquatic and Terrestrial Receptors		