

Conditions of Use Development

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Agenda

- Condition of Use definition from TSCA
- Structure of the Condition of Use tables
- Chemical Data Reporting rule codes to organize the Conditions of Use tables
- Public comments and other sources of information
- Example
- Topics for discussion

Conditions of Use Definition

TSCA section 3 (14):

The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

Conditions of Use Tables

Life Cycle Stage	Category	Subcategory	Reference(s)
Manufacturing	Domestic manufacturing	Domestic manufacturing	CDR, public comments, other
Manufacturing	Importing	Importing	CDR, public comments, other
Processing	Processing as a reactant	Industrial function category and chemical sector	CDR, public comments, other
Processing	Processing – incorporation into formulation, mixture or reaction product	Industrial function category and chemical sector	CDR, public comments, other
Processing	Processing – incorporation into articles	Industrial function category and chemical sector	CDR, public comments, other
Processing	Repackaging	Industrial function category and chemical sector	CDR, public comments, other
Processing	Recycling	Recycling	CDR, public comments, other
Distribution in commerce	Distribution in commerce	Distribution in commerce	(Usually assumed)
Industrial use	Industrial function category and chemical sector	Additional information and examples	CDR, public comments, other
Commercial use	Product Category	Additional information and examples	CDR, public comments, other
Consumer use	Product Category	Additional information and examples	CDR, public comments, other
Disposal	Disposal	Disposal	(Usually assumed)

CDR: Chemical Data Reporting

Conditions of Use Tables

Structure of the Table

- First column: Life cycle stage
 - follows the conditions of use definition: manufacturing, processing, distribution in commerce, use (industrial, commercial and consumer), and disposal
- Second column: Category
 - provides additional information for each life cycle stage, usually using Chemical Data Reporting codes (processing codes, functional use code, industrial sector codes, or product codes).
- Third column: Subcategory
 - more detailed information and examples to illustrate the condition of use. The examples are intended to illustrate key exposure circumstances (e.g., closed system vs. open top).

Conditions of Use Tables (cont)

Additional observations regarding the structure:

- Although EPA has identified both industrial and commercial uses here for purposes of distinguishing scenarios in this document, the Agency interprets the authority over “any manner or method of commercial use” under TSCA Section 6(a)(5) to reach both.
- While the Chemical Data reporting data and codes are used to create the structure of the table, public comments and other reasonably available information is used to identify applications/products or articles. That additional information is classified using the CDR codes and added to the table.
- Not every application/product/article results in an individual condition of use. The table groups these applications/products/articles based on CDR reporting codes.

Chemical Data Reporting

How the Chemical Data Reporting codes are used to organize the COU tables

(Instructions for Reporting 2020 TSCA Chemical Data Reporting – Appendix D:

https://www.epa.gov/sites/default/files/2020-12/documents/instructions_for_reporting_2020_tsca_cdr_2020-11-25.pdf)

- Manufacturing:
 - CDR information identifies whether the chemical substance is manufactured, imported, or both
- Processing:
 - CDR reporting codes:
 - processing as a reactant
 - incorporation into formulation, mixture or reaction products
 - incorporation into articles
 - repackaging
 - Additional CDR information indicates if all or portion of the chemical substance is recycled
- Distribution in commerce is usually assumed

Chemical Data Reporting

- Use:
 - Industrial use: CDR reporting code: Use—non-incorporative activities.
 - Functional use: CDR reporting codes:
 - 2016 CDR reporting codes U001 to U034 and U999
 - 2020 CDR reporting codes F001 to F116 and F999
 - Industrial sector: CDR reporting codes (equivalent to the North American Industry Classification System (NAICS) codes - <https://www.census.gov/naics/>)
 - Commercial and Consumer uses:
 - Product codes: CDR reporting codes:
 - 2016 CDR reporting codes: C101 to C110, C201 to C207, C301 to C307, C401 to C407 and C909 and C980
 - 2020 CDR reporting codes: CC101 to CC138, CC201 to CC222, CC301 to CC317, CC401 to CC418 and CC980 and CC990
- Disposal is usually assumed

Opportunities to Provide Information

- Formal public comment opportunities:
 - During prioritization – two comment periods
 - During scoping – draft scope for public comment
 - During risk evaluation – draft risk evaluation for public comment
- Other public input and engagement (webinars, formal consultations, meetings with stakeholders)

Additional observations:

- Comments and other information from stakeholders are classified according to the CDR reporting codes, and then added to the COU table.
- CDR reporting data might need to be complemented with additional information (e.g., examples of products or articles)

Other Sources of Information to Complement CDR

- Reasonably available information
 - Use report
 - Conditions of use information from systematic review
 - TRI information
 - Additional research (e.g., SDS or technical information) – address CBI or other questions regarding the CDR report

Additional observations:

- Refinement of conditions of use takes place from prioritization to draft risk evaluation
- If unreasonable risk – conditions of use are also described in the proposed rulemaking

Example of a Conditions of Use Table

Life Cycle Stage	Category	Subcategory	References
Manufacturing	Domestic manufacture	Domestic manufacture	U.S. EPA (2019)
	Import	Import ^a	U.S. EPA (2019)
Processing	Processing as a reactant	Intermediate in: Petrochemical manufacturing; Plastic material and resin manufacturing; All other basic organic chemical manufacturing	U.S. EPA (2019); EPA-HQ-OPPT-2018-0427-0006 ; EPA-HQ-OPPT-2018-0427-0015
		Fuels and fuel additives: All other petroleum and coal products manufacturing	U.S. EPA (2019); EPA-HQ-OPPT-2018-0427-0006 ; EPA-HQ-OPPT-2018-0427-0015
	Processing - Incorporated into formulation, mixture, or reaction product	Functional Fluids: Pharmaceutical and medicine manufacturing	U.S. EPA (2019)
		Processing aids: specific to petroleum production	U.S. EPA (2019)
	Recycling	Recycling	U.S. EPA (2019)
Distribution in commerce	Distribution in commerce	Distribution in commerce	
Industrial Use	Adhesives and sealants	Adhesives and sealants	EPA-HQ-OPPT-2018-0427-0018
	Functional Fluids (closed systems)	Heat transferring agent	Baldwin Filters (2015)
	Lubricants and Greases	Paste lubricants and greases	EPA-HQ-OPPT-2018-0427-0005
	Oxidizing/ reducing agents	Oxidation inhibitor in controlled oxidative chemical reactions	EPA-HQ-OPPT-2018-0427-0006
	Solvents (for cleaning and degreasing)	A component of degreasing and cleaning solvents	EPA-HQ-OPPT-2018-0427-0005
Commercial Use	Plastic and rubber products	Products such as: plastic and rubber products	U.S. EPA (2019)
	Fuels and related products	Fuels and related products	U.S. EPA (2019); EPA-HQ-OPPT-2018-0427-0006
	Other use	Laboratory chemical (e.g., reagent)	ThermoFisher (2018)
		Embalming agent	Frigid Fluid Company (2015)
Consumer Use	Plastic and rubber products	Plastic and rubber products	U.S. EPA (2019); EPA-HQ-OAR-2002-0037-0203; EPA-HQ-OPPT-2018-0427-0040; Doucette, et al. (2010)
Disposal	Disposal	Disposal	

Table 2-2 of the Final Scope of the Risk Evaluation for 1,2-Dichloroethane CASRN 107-06-2
https://www.epa.gov/sites/default/files/2020-09/documents/casrn_107-06-2_12-dichloroethane_final_scope.pdf

Topics For Discussion

1. Does EPA provide enough information to identify all the applications/products/articles that are included in each of the conditions of use?
 - How EPA can describe the conditions of use so that it is clear what processes are included, so that stakeholders understand how their use fits in the COU table?
 - Are examples of products or articles sufficient to describe each condition of use?
How stakeholders know how a particular article or product fits in the COU table?
2. Any other sources of information that EPA should consider to complement the CDR reports?