

Carbon Tetrachloride: Risk Evaluation and Risk Management under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Public Webinar
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Agenda

- Background on Risk Evaluations
- Findings from Risk Evaluation for Carbon Tetrachloride
- Risk Management Requirements under TSCA
- Types of Information to Inform Risk Management
- Principles for Transparency During Risk Management
- Additional Information

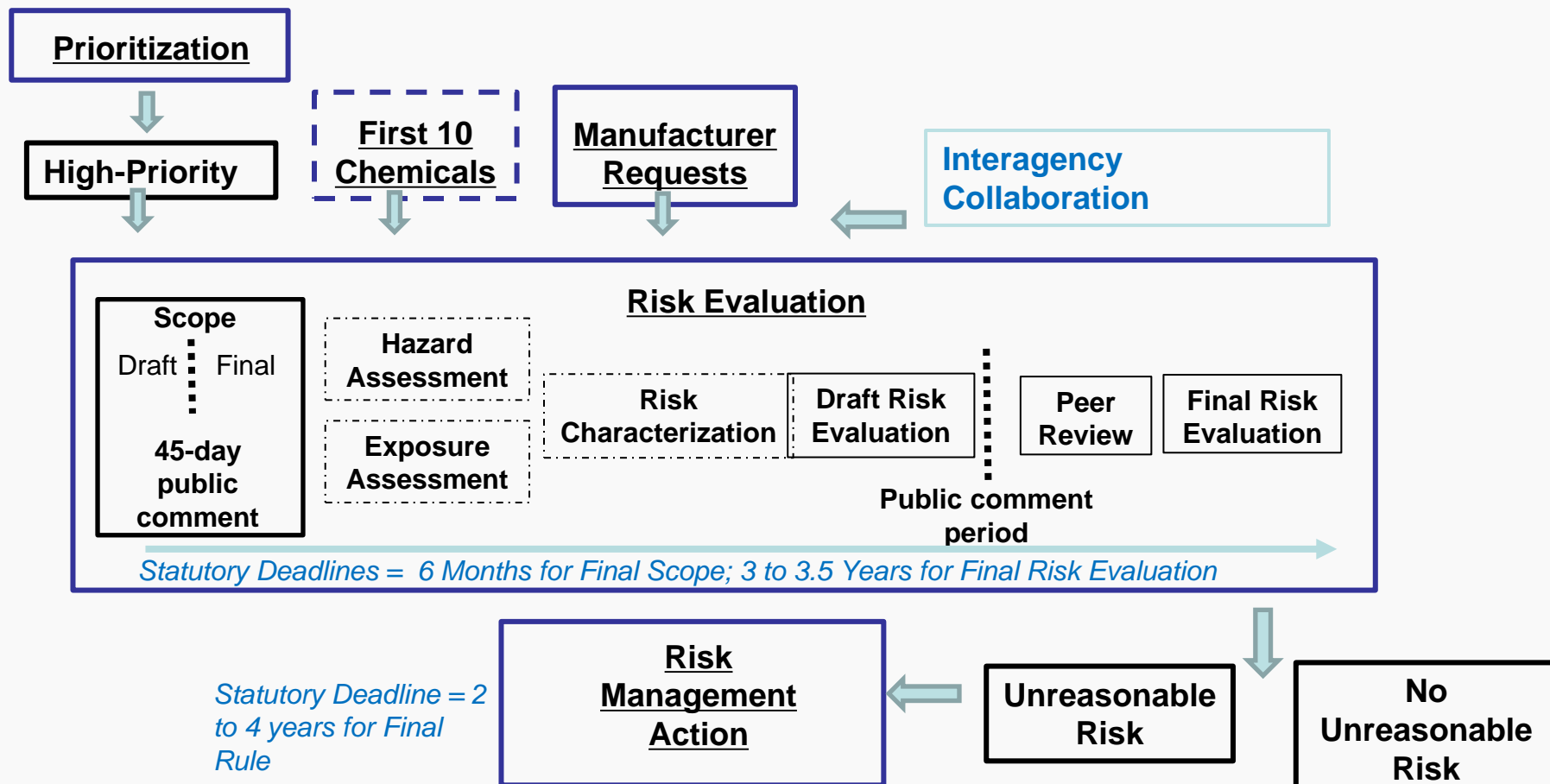


Risk Evaluation Statutory Requirements

- EPA must evaluate the risks presented by a chemical under the conditions of use and determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use
 - Without consideration of cost or other non-risk factors
 - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within 3 – 3.5 years



Risk Evaluation Process and Timeline





Overview of Risk Evaluation for Carbon Tetrachloride

- Final risk evaluation published November 3, 2020
 - 15 conditions of use were evaluated
 - Final risk evaluation follows a series of risk evaluation activities
 - Carbon Tetrachloride (CCl₄) draft risk evaluation: January 2020; CCl₄ problem formulation: May 2018; CCl₄ scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
 - 19 public comments received on the draft risk evaluation (comment period closed March 27, 2020)
 - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (February 2020)
- The final risk evaluation and supplemental materials are in docket [EPA-HQ-OPPT-2019-0499](https://www.regulations.gov/docket/EPA-HQ-OPPT-2019-0499), with additional materials supporting the risk evaluation process in docket [EPA-HQ-OPPT-2016-0733](https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0733), on www.regulations.gov

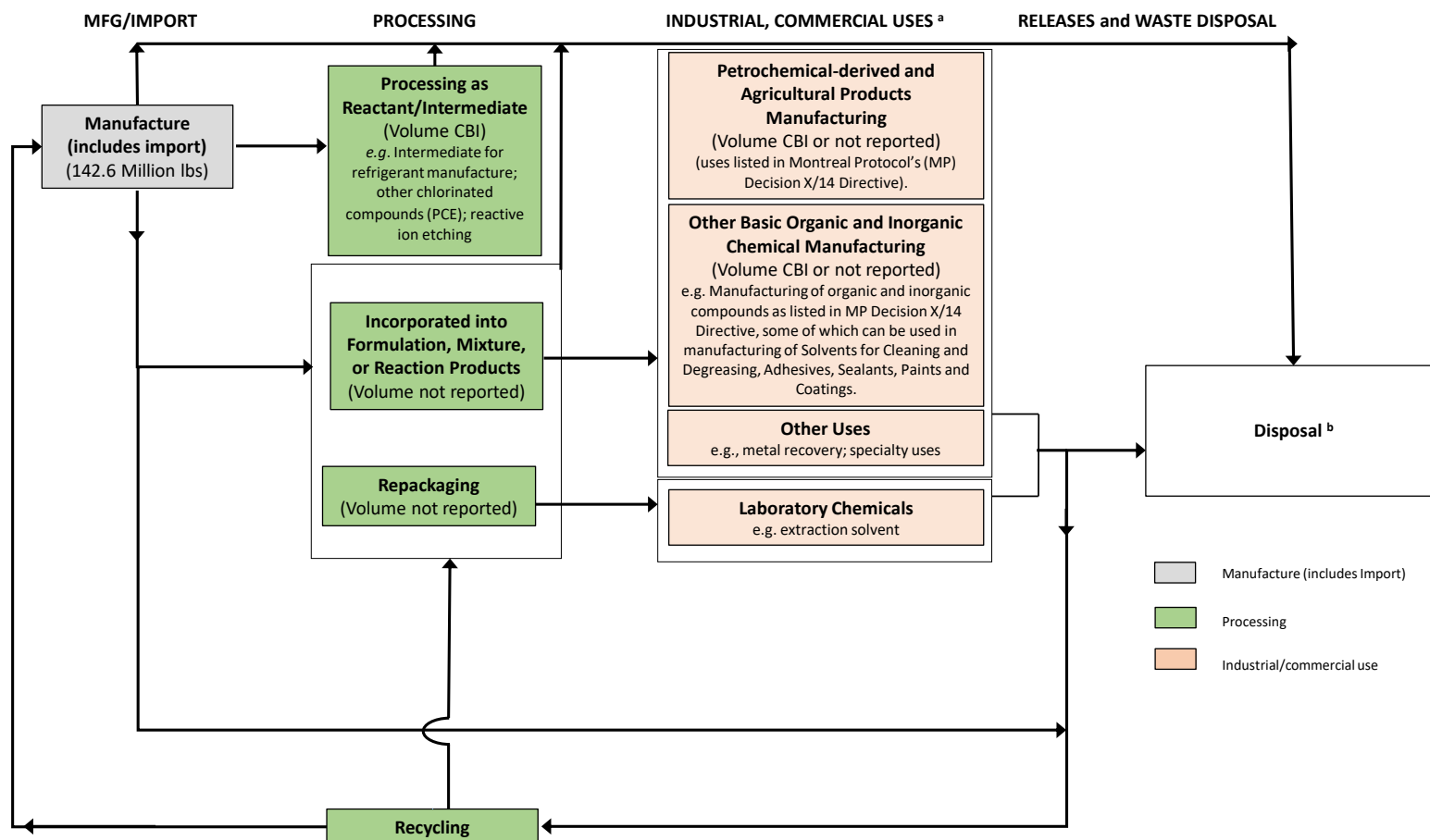


General Information on CCl₄

- CCl₄ is a colorless liquid and a volatile organic chemical with a sweet odor resembling chloroform
- It is both produced in and imported into the United States
- EPA identified conditions of use during various life cycle stages of CCl₄, such as manufacturing (including import), processing, distribution in commerce, use (industrial and commercial), and disposal
- CCl₄ has a wide range of uses, including as a solvent, intermediate, processing aid, or additive in the manufacturing of other chemicals
 - As a reactant or intermediate in HCFCs, HFCs, HFOs, and PCE
 - A variety of commercial products are made using CCl₄ as a solvent or processing aid in organic and inorganic chemical manufacturing
- The total aggregate production volume was between 100 and 250 million pounds in 2015



Carbon Tetrachloride Life Cycle Diagram





Determinations of No Unreasonable Risk

- EPA determined that CCl_4 does not present an unreasonable risk to the environment under the conditions of use
- EPA determined that the following two of the 15 conditions of use of CCl_4 do not present an unreasonable risk of injury to health or the environment:
 - Reactive ion etching
 - Distribution in commerce
- These no unreasonable risk determinations are considered final agency actions and are issued by order pursuant to TSCA section 6(i)(1)



Unreasonable Risk Determinations

- EPA determined that 13 of the 15 conditions of use of CCl_4 present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
 - Workers and occupational non-users (ONUs) during occupational exposures
- EPA's risk evaluation identified unreasonable risks for non-cancer (liver toxicity) and cancer adverse effects from chronic inhalation and dermal exposure to CCl_4



Processing, Industrial, and Commercial Uses that Present an Unreasonable Risk

- Domestic manufacture
- Import
- Processing: as a reactant in the production of hydrochlorofluorocarbon, hydrofluorocarbon, hydrofluoroolefin, and perchloroethylene
- Processing: incorporation into formulation, mixture or reaction products – Petrochemicals-derived manufacturing, agricultural products manufacturing, and other basic organic and inorganic chemical manufacturing
- Processing: repackaging for use in laboratory chemicals
- Processing: recycling
- Industrial/Commercial Use: industrial processing aid in the manufacture of petrochemicals-derived products and agricultural products
- Industrial/Commercial Use: additive
- Industrial/Commercial Use: other Basic Organic and Inorganic Chemical Manufacturing (manufacturing of chlorinated compounds used in solvents for cleaning and degreasing, adhesives and sealants, paints and coatings, asphalt, and elimination of nitrogen trichloride in the production of chlorine and caustic)
- Industrial/Commercial Use: metal recovery
- Industrial/Commercial Use: specialty uses – Department of Defense
- Industrial/Commercial Use: laboratory chemical
- Disposal



Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures of CCl_4 :
 - Cancer effects (liver, adrenal, and brain tumors) from dermal exposures and chronic inhalation
 - Liver effects from chronic inhalation
- Personal Protective Equipment (PPE):
 - The OSHA Carbon Tetrachloride Standard sets a PEL of 10 ppm
 - Many conditions of use presented an unreasonable risk to workers even with use of gloves with a PF of 20
 - No unreasonable risk to workers due to acute and chronic inhalation exposures assuming use of respirators with APF of 50 in industrial/commercial settings
 - EPA does not assume ONUs use PPE because they do not handle the chemical



Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
 - Proposed rule one year after risk evaluation
 - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process
- Substantial increase in regulatory activities expected due to unreasonable risk findings across diverse conditions of use



TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase.



TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
 - Distributors
 - Manufacturers and processors (e.g., formulators)
 - Commercial users (workplaces and workers)
 - Entities disposing of chemicals for commercial purposes



Examples of Regulatory Options

- Provide a prominent label securely attached to import container or product with specific directions, limitations, and precautions, or that describes the health endpoints
- Prohibit importing, processing, and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls and PPE at occupational sites
- Require importers, processors, and distributors to maintain ordinary business records
- Require importers, processors and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain
- Set an occupational air exposure limit, for example, establish an Existing Chemical Exposure Limit (ECEL)



Examples of Regulatory Options

- Require monitoring of exposures in occupational settings
- Mandate administrative controls and system requirements at occupational sites
- Mandate a training program at occupational sites and measures to limit access to the chemical
- Require a hazard communication program to educate workers on label directions, warnings, etc.



TSCA Section 6(c)

In promulgating any rule under TSCA section 6(a), EPA must consider and publish a statement of effects of the rule based on reasonably available information with respect to:

- The effects and magnitude of exposure to human health
- The effects and magnitude of exposure to environment
- The benefits of the chemical for various uses
- The reasonably ascertainable economic consequences of the rule, including consideration of:
 - The likely effect on the national economy, small business, technological innovation, the environment, and public health;
 - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives; and
 - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives



Executive Orders Relevant to 6(a) Rulemakings

- EO 12866: Regulatory Planning and Review
- EO 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- EO 13045: Protection of Children from Environmental Health & Safety Risks
- EO 13132: Federalism
- EO 13175: Consultation and Coordination with Indian Tribal Governments
- EO 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- EO 13272: Proper Consideration of Small Entities in Agency Rulemaking
- EO 13771: Reducing Regulation and Controlling Regulatory Costs



Types of Information to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including current work practices, engineering, and administrative controls
- Information on essential uses, and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent



Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue will help people understand the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective



Coordination and Engagement

- In developing risk management approaches EPA:
 - Consults with stakeholders to learn about condition of use, existing engineering controls, personal protection equipment (PPE), available alternatives, or other programs to tailor effective risk management solutions
 - Conducts site visits to obtain detailed information on existing practices in chemical manufacturing, processing, and use
 - Develops an extensive network among all stakeholders to ensure regulatory approaches are fully informed and based on current conditions



Opportunities for Engagement

- One-on-one meetings
- Webinars providing overviews of final risk evaluations and unreasonable risk determinations
 - Other chemicals following their final risk evaluations
- Consultations seeking targeted feedback, with:
 - States and local governments
 - Tribes
 - Small businesses
 - Environmental justice organizations and communities



Additional Information

- General TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- Current Chemical Risk Management Activities: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>
- Carbon Tetrachloride: Claudia Menasche (Menasche.claudia@epa.gov, 202-564-3391)
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)