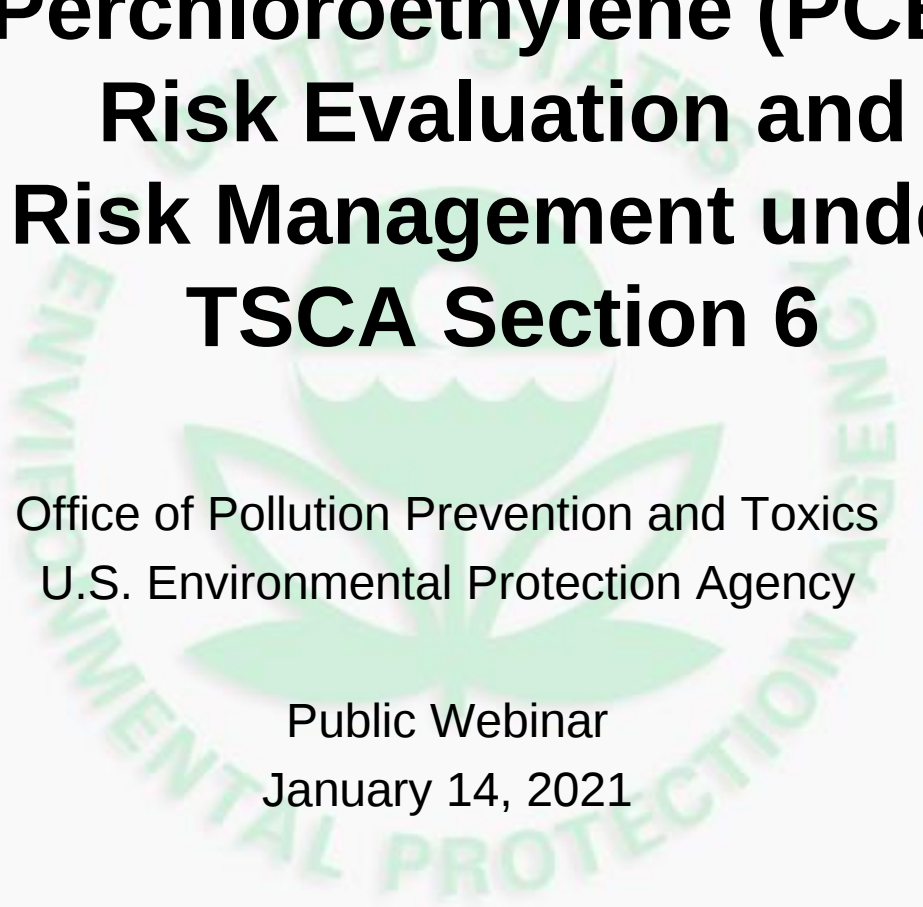




Perchloroethylene (PCE): Risk Evaluation and Risk Management under TSCA Section 6

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

Public Webinar
January 14, 2021





Agenda

- Background on Risk Evaluations
- Findings from Risk Evaluation for Perchloroethylene (PCE)
- Risk Management Requirements under TSCA
- Types of Information to Inform Risk Management
- Principles for Transparency During Risk Management
- Additional Information

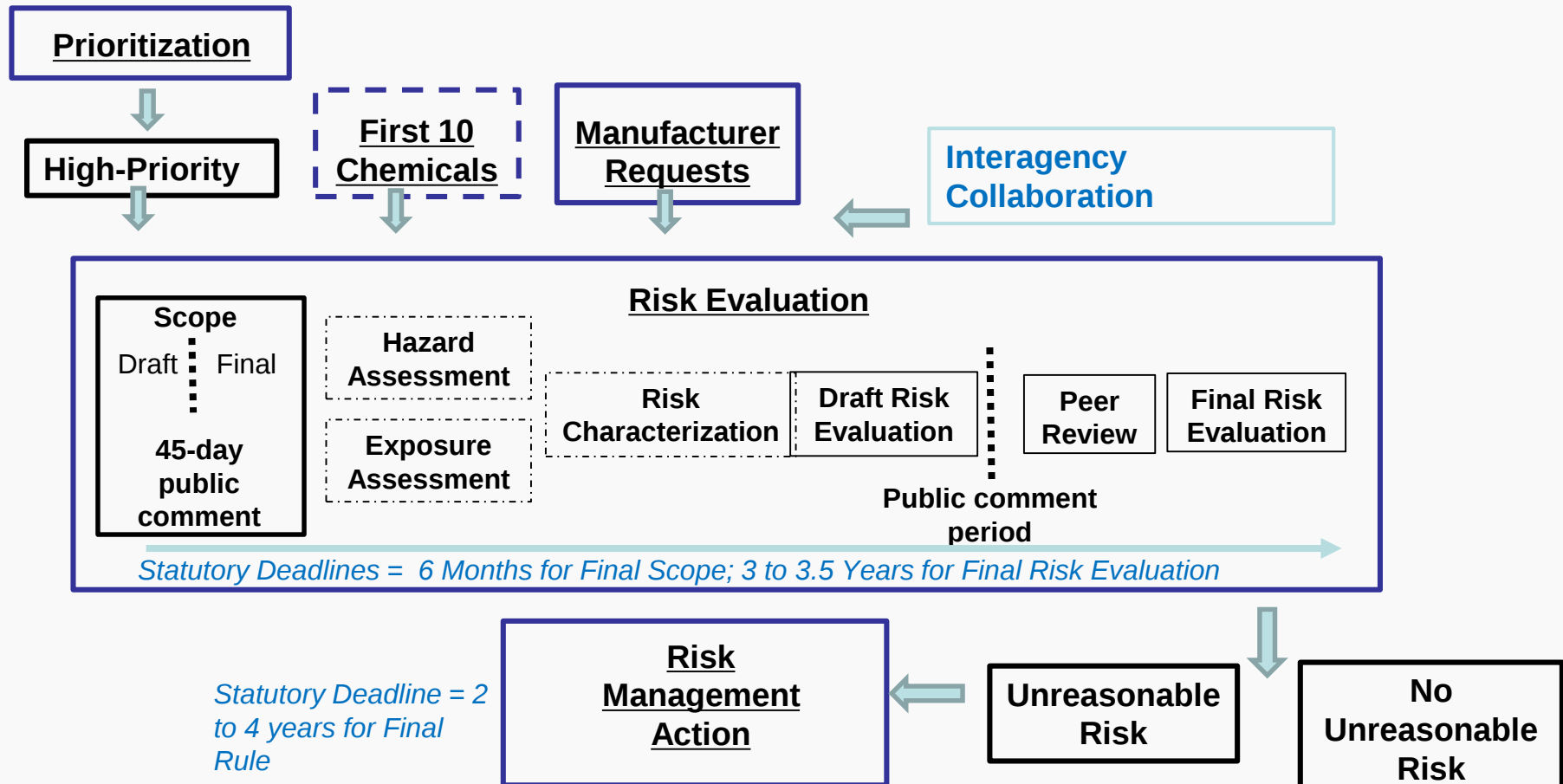


Risk Evaluation Statutory Requirements

- 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 PCE

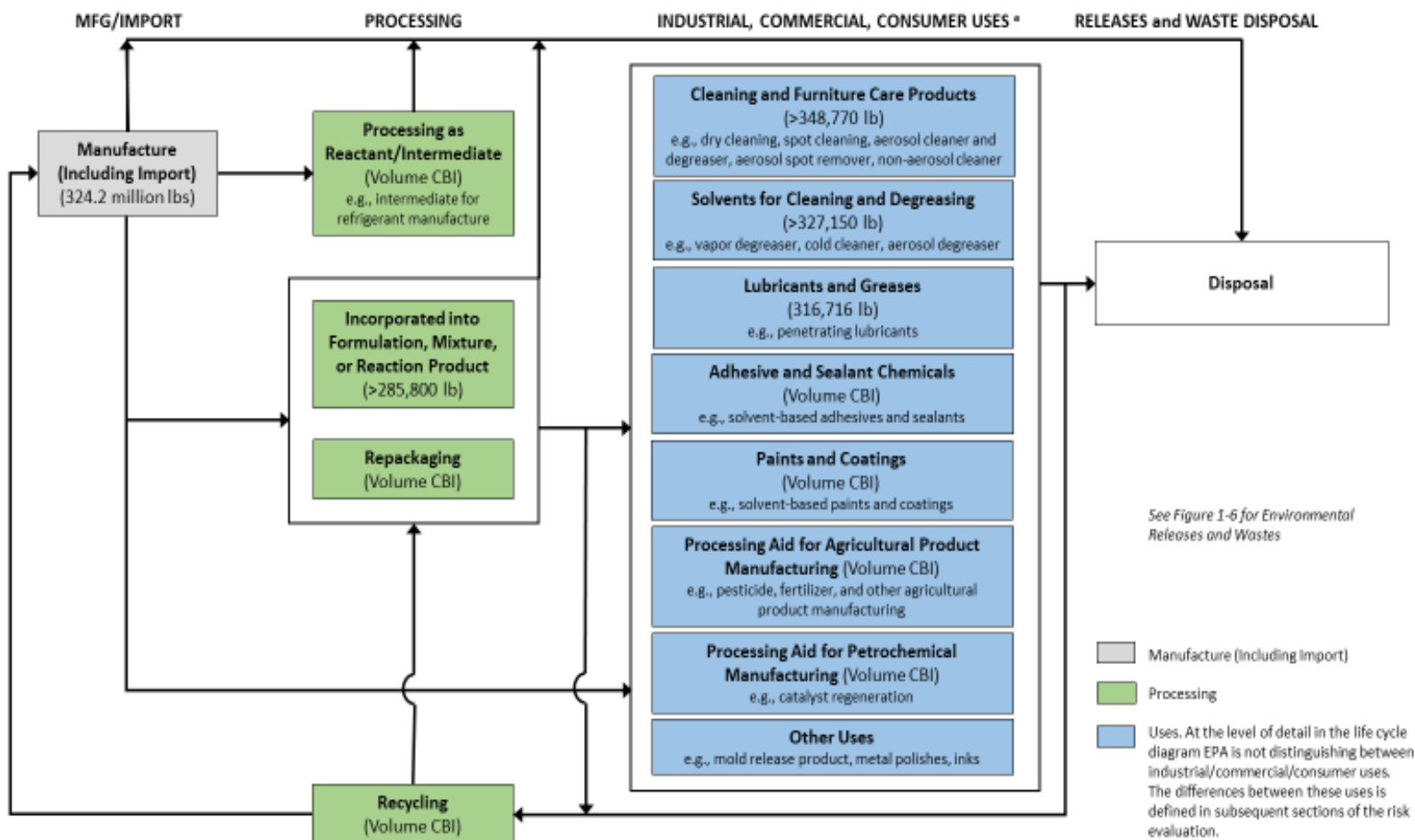
- Final risk evaluation published December 18, 2020
 - 61 conditions of use were evaluated
 - Final risk evaluation follows a series of risk evaluation activities
 - Perchloroethylene (PCE) draft risk evaluation: April 2020; PCE problem formulation: May 2018; PCE scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
 - 28 public comments received on the draft risk evaluation (comment period closed July 6, 2020)
 - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (May 2020)
- The final risk evaluation and supplemental materials are in docket [EPA-HQ-OPPT-2019-0502](#), with additional materials supporting the risk evaluation process in docket [EPA-HQ-OPPT-2016-0732](#), on www.regulations.gov



General Information on PCE

- PCE is a colorless liquid and a volatile organic compound (VOC) with an 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 PCE, such as manufacturing (including import), processing, distribution in commerce, use (industrial, commercial, and consumer), and disposal
- PCE has a wide range of uses, including production of fluorinated compounds and as a solvent in dry cleaning and vapor degreasing
- A variety of consumer and commercial products use PCE, such as adhesives (arts and crafts, as well as light repairs), aerosol degreasers, brake cleaners, aerosol lubricants, sealants, stone polish, stainless steel polish, and wipe cleaners
- The total aggregate production volume ranged from 324 to 388 million pounds between 2012 and 2015

PCE Life Cycle Diagram





Determinations of No Unreasonable Risk

- EPA determined that PCE does not present an unreasonable risk to the environment under the conditions of use
- EPA determined that the following two of the 61 conditions of use of PCE do not present an unreasonable risk of injury to health or the environment:
 - Distribution in commerce
 - Industrial and commercial use in lubricants and greases for penetrating lubricants and cutting tool coolants
- 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 59 of the 61 conditions of use of PCE 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
 - Consumers and bystanders during exposures to consumer use
- EPA's risk evaluation identified unreasonable risks for non-cancer adverse effects (neurotoxicity) from acute and chronic inhalation and dermal exposures, and cancer (liver) from chronic inhalation and dermal exposures to PCE



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

- Manufacturing (domestic manufacturing)
- Manufacturing (import)
- Processing: As a reactant/intermediate
- Processing: Incorporation into formulation, mixture or reaction product in cleaning and degreasing products
- Processing: Incorporation into formulation, mixture or reaction product – adhesive and sealant products
- Processing: Incorporation into formulation, mixture or reaction product – paint and coating products
- Processing: Incorporation into formulation, mixture or reaction product – other chemical products and preparations
- Processing: Repackaging
- Processing: Recycling
- Industrial and commercial use as solvent for open-top batch vapor degreaser
- Industrial and commercial use as solvent for closed-loop batch vapor degreaser
- Industrial and commercial use as solvent for in-line conveyorized vapor degreaser
- Industrial and commercial use as solvent for in-line web cleaner vapor degreaser
- Industrial and commercial use as solvent for cold cleaning
- Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
- Industrial and commercial use as a lubricant and grease in aerosol lubricants
- Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants
- Industrial and commercial use in paints and coatings as solvent-based paints and coatings
- Industrial and commercial use in paints and coatings as a maskant for chemical milling
- Industrial and commercial use as a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing
- Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing
- Industrial and commercial use in cleaning and furniture care products in wipe cleaning



Industrial and Commercial Uses and Disposal that Present an Unreasonable Risk

- Industrial and commercial use in cleaning and furniture care products in other spot cleaning and spot removers, including carpet cleaning
- Industrial and commercial use in cleaning and furniture care products for mold release
- Industrial and commercial use in cleaning and furniture care products in dry cleaning and spot cleaning post-2006 dry cleaning
- Industrial and commercial use in cleaning and furniture care products in dry cleaning and spot cleaning 4th/5th gen only dry cleaning
- Industrial and commercial use in cleaning and furniture care products in automotive care products (e.g., engine degreaser and brake cleaner)
- Industrial and commercial use in cleaning and furniture care products in non-aerosol cleaner
- Industrial and commercial use in metal (e.g., stainless steel) and stone polishes
- Industrial and commercial use in laboratory chemicals
- Industrial and commercial use in welding
- Industrial and commercial use in other textile processing
- Industrial and commercial use in wood furniture manufacturing
- Industrial and commercial use in foundry applications
- Industrial and commercial use in specialty Department of Defense uses (oil analysis and water pipe repair)
- Commercial use in inks and ink removal products (based on printing)
- Commercial use in inks and ink removal products (based on photocopying)
- Commercial use for photographic film
- Commercial use in mold cleaning, release and protectant products
- Disposal



Consumer Uses that Present an Unreasonable Risk

- Consumer use in cleaning and furniture care products in cleaners and degreasers (other)
- Consumer use in cleaning and furniture care products in dry cleaning solvent
- Consumer use in cleaning and furniture care products in automotive care products (brake cleaner)
- Consumer use in cleaning and furniture care products in automotive care products (parts cleaner)
- Consumer use in cleaning and furniture care products in aerosol cleaner (vandalism mark and stain remover)
- Consumer use in cleaning and furniture care products in non-aerosol cleaner (e.g., marble and stone polish)
- Consumer use in lubricants and greases (cutting oils)
- Consumer use in lubricants and greases (lubricants and penetrating oils)
- Consumer use in adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive, gun ammunition sealant)



Consumer Uses that Present an Unreasonable Risk, cont.

- Consumer use in adhesives for arts and crafts (livestock grooming adhesive)
- Consumer use in adhesives for arts and crafts (column adhesive, caulk and sealant)
- Consumer use in paints and coatings as solvent-based paints and coatings (outdoor water shield (liquid))
- Consumer use in paints and coatings as solvent-based paints and coatings (coatings and primers (aerosol))
- Consumer use in paints and coatings as solvent-based paints and coatings (rust primer and sealant (liquid))
- Consumer use in paints and coatings as solvent-based paints and coatings (metallic overglaze)
- Consumer use in metal (e.g., stainless steel) and stone polishes
- Consumer use in inks and ink removal products
- Consumer use in welding
- Consumer use in mold cleaning, release and protectant products



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 PCE:
 - Neurotoxicity from acute inhalation and dermal exposures
 - Neurotoxicity from chronic inhalation and dermal exposures
 - Cancer effects (liver) from chronic inhalation and dermal exposures
- Personal Protective Equipment (PPE):
 - The OSHA Perchloroethylene Standard sets a permissible exposure limit (PEL) of 100 ppm as an 8-hr time-weighted average
 - Many conditions of use presented an unreasonable risk to workers even with use of respirators APF 25 or 50 and gloves with PF 10 or 20
 - EPA does not assume that it is a standard industry practice that workers in some small commercial facilities (e.g., dry cleaning and spot cleaning, wipe cleaning and metal/stone polishes, other spot cleaning/spot remover, and other commercial uses) have a respiratory protection program or regularly employ dermal protection; therefore, the use of respirators and gloves is unlikely for workers in these facilities
 - EPA does not assume ONUs use PPE because they do not handle the chemical



Basis for Unreasonable Risk Determination: Consumers and Bystanders

- The unreasonable risk determinations for consumers and bystanders are based on the following health hazards during consumer exposures of PCE:
 - Neurotoxicity from acute inhalation or dermal exposure
- EPA does not assume dermal exposure to PCE for bystanders
- EPA does not assume consumers or bystanders use PPE
- The unreasonable risk determinations were based on the high intensity use risk estimates for consumers and bystanders; unreasonable risk was also presented for moderate intensity use risk estimates for many COUs
- EPA did not evaluate chronic exposures to PCE for consumers and bystanders because EPA considered the frequency of consumer product use to be too low to create chronic risk concerns



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 TSCA 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



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
- Cannot directly regulate consumer users
 - Under TSCA, EPA has authority to regulate at the manufacturing, processing, and distribution level in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
 - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers



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
 - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives



Executive Orders Relevant to TCSA Section 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
- 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>
- PCE Risk Management: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-perchloroethylene>
- PCE: Tyler Lloyd (lloyd.tyler@epa.gov, 202-564-4016)
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)