

Perchloroethylene (PCE) Proposed Rulemaking under TSCA Section 6(a)

Public Webinar

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Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

For more information: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-perchloroethylene-pce>



Agenda

- Purpose and Overview of Rulemaking
- PCE Background
- TSCA Regulatory Toolbox
- Developing Effective Regulations
- Proposed Regulation
- Alternative Regulatory Actions
- Benefits
- Requests for Comment and Opportunities for Engagement
- Next Steps
- Additional Resources



EPA's Proposal and the Toxics Substances Control Act (TSCA)

- In June 2016, Congress amended the Toxic Substances Control Act (TSCA)
 - Amended TSCA requires EPA to assess and address risks from chemicals currently in commerce
 - Amended TSCA imposes statutory timeframes for regulation
 - Provides protection for the public and predictability for the regulated community
- PCE was identified in 2016 as one of the first chemicals for risk evaluation
 - 2020 Risk Evaluation followed a public draft and peer review process
 - EPA determined that PCE presents an unreasonable risk under its conditions of use



Purpose and Overview Of Rulemaking

- The proposal addresses the unreasonable risk identified in the TSCA section 6 risk evaluation of PCE (December 2020) which assessed all uses subject to TSCA
- The proposed rule, when finalized, will prevent consumer and occupational illness while ensuring identified essential uses can continue safely where possible
 - EPA’s proposal would allow select uses to continue with strict workplace protections, while prohibiting all remaining uses
- EPA’s proposed rule is open for public comment until **August 15, 2023**
- EPA will then consider public comments and finalize new regulations of PCE under TSCA



PCE Background

- PCE is a volatile chemical used in a wide range of industrial, commercial, and consumer applications
- Proposed Rule is informed by the TSCA risk evaluation for PCE and the Final Revised Risk Determination for PCE
- EPA found that unreasonable risk from PCE is driven by risks to workers, consumers, and bystanders for 60 of the 61 conditions of use
- Timeline
 - November 2016 – EPA designates PCE as among the first ten chemicals to undergo risk evaluation under amended TSCA
 - December 2020 – EPA publishes Final Risk Evaluation for PCE
 - December 2022 – EPA publishes Revised Risk Determination
 - **June 2023 – EPA Proposal for the Regulation of PCE under Section 6(a) signed and published**



PCE Risk Evaluation: Unreasonable Risk for Workers and Consumers

Neurotoxicity from
chronic inhalation and
dermal exposures

Neurotoxicity from
acute inhalation
and dermal
exposures

Chronic cancer
effects (liver tumors)
from inhalation and
dermal exposures

- **Neurotoxicity from chronic exposure is the most robust and sensitive endpoint driving unreasonable risks**
 - Additional effects from exposure include cancer, kidney and liver effects, immune system toxicity, and developmental toxicity
- No unreasonable risk to environment



TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
 - Distributors
 - Manufacturers (including importers) 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 levels 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(a) Regulatory Options (cont.)

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture (includes import), 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

The section 6(a) menu of regulatory options can be applied alone or in combination.



Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement during risk management helps EPA develop practical and protective regulations
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Consultation and coordination with other Federal agencies
 - OSHA, NIOSH, and CPSC to promote a consistent approach, facilitate compliance, and avoid duplicative requirements
 - DOD and NASA to determine uses that might affect U.S. critical infrastructure or national security and to facilitate compliance
 - SBA Advocacy and OMB/OIRA to convene a Small Business Advocacy Review panel to obtain advice and recommendations from small entity representatives
- Extensive dialogue helps people understand risk evaluation findings, the TSCA risk management process, and available options 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



Developing Effective Regulations

EPA's priority is to address identified unreasonable risks

- TSCA additionally requires EPA's proposal to consider:
 - Effects and magnitude of exposure to human health and the environment
 - For this, EPA assessed potential risks from the surface water, drinking water, and ambient air pathways to fence-line communities (EPA's analysis identified a potential risk to fence-line communities from the ambient air pathway for a small number of facilities)
 - Benefits of a chemical substance
 - Economic consequences of the rule
 - Availability of alternatives
- EPA's proposal is based on best available science and reasonably available information



Developing Effective Regulations (cont.)

EPA's goal is to promulgate regulations that are both practical and protective. EPA's proposal:

- Presents a familiar regulatory framework for occupational and consumer exposure
- Ensures that consumers do not have access to PCE-containing products
- Prohibits certain occupational uses where EPA determined there would likely be an inability to comply with the proposed worker protection requirements
- Meets TSCA requirement to address risk to the extent necessary so that it is no longer unreasonable, including risk to potentially exposed or susceptible subpopulations (PESS)
- Requires recordkeeping to ensure rule is enforceable



Developing Effective Regulations (cont.)

- EPA requests comment on all elements of the proposed and alternative regulatory actions in the proposed rulemaking
- Based on consideration of new or additional information submitted to EPA on the proposed rule, EPA may in the final rule modify elements of the proposed regulatory action
- Public comments could result in changes to elements of the proposed regulatory actions when this rule is finalized, for example:
 - Timelines for phase out could be lengthened or shortened
 - WCPP could have conditions added, modified, or eliminated



The Proposed Regulation

EPA's proposed rule would:

- Prohibit manufacture, processing, and distribution of PCE for all consumer use
- Prohibit most industrial and commercial uses
- De minimis level of 0.1%
- Provide a 10-year phaseout for dry cleaning
- Require a Workplace Chemical Protection Program (WCPP) for certain uses
- Require workplace controls for laboratory use
- Include one critical use exemption under TSCA section 6(g)
- Establish recordkeeping and downstream notification requirements



Proposed Regulation: Consumer Uses

- EPA determined PCE could not be used safely in consumer products
 - TSCA allows EPA to regulate upstream of consumers to address unreasonable risk
 - The proposed rule would prohibit manufacturing (including import), processing, and distribution for consumer use, and provides time for retailers to phase out their consumer product inventory
 - EPA concluded that some alternate approaches were not feasible. As an example, a protective weight fraction limit would be so low that it would essentially function as a prohibition
 - In almost all cases, alternatives are available



Proposed Regulation: Consumer Uses

EPA is prohibiting manufacture, processing, and distribution in commerce of PCE for all consumer use, including in:

- Cleaners and degreasers
- Automotive care products (brake cleaner and parts cleaner)
- Aerosol cleaner (vandalism mark and stain remover)
- Non-aerosol cleaner (marble and stone polish)
- Lubricants and greases (cutting fluid, lubricants and penetrating oils)
- Adhesives for arts and crafts (industrial adhesive, gun ammunition sealant, livestock grooming adhesive, column adhesive, caulk and sealant)
- Solvent-based paints and coatings (outdoor water shield, coatings and primers, rust primer and sealant, metallic overglaze)
- Metal (e.g., stainless steel) and stone polishes
- Inks and ink removal products
- Welding
- Metal mold cleaning, release and protectant products



Proposed Prohibitions: Industrial and Commercial Use

- EPA considers each use individually including factors such as:
 - Aspects of particular work activities that may create challenges for Workplace Chemical Protection Program (WCPP) implementation (e.g., challenges with meeting the ECEL or preventing dermal contact, developing an industrial hygiene program)
 - Potential for regrettable substitution, among other factors
- Uncertainty about WCPP implementation ability is a driving factor
- Staggered implementation within the supply chain to assure orderly phase out
- Products containing PCE at de minimis levels less than 0.1% would not be subject to the prohibition
 - EPA determined that use of products containing PCE at levels less 0.1% by weight would not contribute to the unreasonable risk from PCE



Proposed Prohibitions: Industrial and Commercial Uses

All industrial and commercial uses would be prohibited, unless proposed to be addressed with workplace controls. Conditions of use that would be prohibited include industrial and commercial use of PCE for:

- As processing aid in pesticide, fertilizer and other agricultural chemical manufacturing
- In specialty DOD uses (oil analysis and water pipe repair)
- In solvent-based paints and coatings
- Dry cleaning and spot cleaning post-2006 dry cleaning
- Dry cleaning and spot cleaning 4th/5th generation only dry cleaning
- As solvent for aerosol spray degreaser/cleaner
- As solvent for cold cleaning
- In other textile processing
- In wood furniture manufacturing
- As solvent for aerosol lubricants
- In wipe cleaning
- In other spot cleaning and spot removers, including carpet cleaning
- In automotive care products (e.g., engine degreaser and brake cleaner)
- In non-aerosol cleaner
- In metal (e.g., stainless steel) and stone polishes
- In foundry applications
- In welding
- For mold release
- As solvent for penetrating lubricants and cutting tool coolants
- For photographic film
- In inks and ink removal products (based on printing)
- In inks and ink removal products (based on photocopying)
- In mold cleaning, release, and protectant products



Proposed Dry Cleaning Phaseout

- EPA is proposing to prohibit PCE use in dry cleaning through a 10-year phaseout to provide dry cleaners time to transition to an alternative process
- For the phaseout timeframe, EPA considered precedents set by state regulations, the dry cleaning NESHAP, and information provided by stakeholders, including:
 - The average lifespan of a PCE dry cleaning machine is 15 to 25 years and few new machines are produced or sold in the U.S.
 - Alternatives are available, such as wet cleaning, hydrocarbons, and multi-solvent dry cleaning machines
 - Use of PCE in dry cleaning is declining as machines are retired and alternatives are adopted

Phaseout Timing (after publication date of the final rule)	
6 months	<ul style="list-style-type: none">• Prohibition on use of PCE in any dry cleaning machine acquired 6 months or later
3 years	<ul style="list-style-type: none">• Prohibition on use of 3rd generation PCE machines
10 years	<ul style="list-style-type: none">• Prohibition on the use of PCE in all dry cleaning and spot cleaning, including in 4th and 5th generation machines• Prohibition on the manufacturing, processing, and distribution in commerce of PCE for use in dry cleaning solvent



Proposed Regulation: Workplace Chemical Protection Program

- A Workplace Chemical Protection Program (WCPP) protects people from unreasonable risk posed by occupational exposures from certain conditions of use
 - Workers are one of the potentially exposed or susceptible subpopulations (PESS) under TSCA
 - EPA consulted with OSHA and NIOSH on WCPP development, and aligned requirements where possible
- EPA considers multiple factors in deciding risk management for industrial and commercial conditions of use
- Uncertainty regarding ability to comply with an ECEL or preventing direct dermal contact can influence whether a condition of use is considered to be a candidate for WCPP or whether prohibition is more appropriate
 - EPA acknowledges inquiries by certain entities who believe they can successfully operate under the WCPP and is requesting data to support requested shifts in the approach for the final rule



Proposed Regulation: Workplace Chemical Protection Program (cont.)

- Workplace Chemical Protection Program (WCPP)
 - Proposed inhalation exposure limit (Existing Chemical Exposure Limit, or ECEL):
 - 8-hour time-weighted average (TWA): 0.14 ppm
 - For comparison, OSHA PEL is 100 ppm
 - Includes additional monitoring, recordkeeping requirements, dermal requirements
 - Provides flexibility for preventing exceedances of the identified EPA exposure limit and preventing direct dermal contact
 - Aligns with existing OSHA requirements wherever possible



Proposed Regulation: Workplace Chemical Protection Program (cont.)

- The PCE WCPP reduces compliance burdens by following a familiar framework:
 - Initial monitoring to determine frequency of periodic monitoring
 - Periodic monitoring every 3 months, 6 months, or 5 years, based on ECEL and ECEL action level
 - Requirements to reduce exposures based on the NIOSH hierarchy of controls
 - Respirator selection criteria to protect workers from any remaining risks
- EPA's WCPP applies to Owners or Operators and Potentially Exposed Persons
 - Broader definition than “employers” and “employees”



Proposed Regulation: Industrial and Commercial Uses Continuing with WCPP

- Uses that are not prohibited would continue with strong, achievable, worker protections:
 - Manufacturing (Domestic)
 - Manufacturing (Import)
 - Processing: processing as a reactant (AIM Act refrigerants)
 - Processing: incorporation into a formulation, mixture, or reaction products
 - Processing: recycling
 - Processing: repackaging
 - Industrial and commercial use as solvent for vapor degreasing (open-top batch, closed-loop batch, in-line conveyORIZED, in-line web cleaner)
 - Industrial and commercial use in maskant for chemical milling
 - Industrial and commercial use in solvent-based adhesives and sealants
 - Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing
 - Disposal



Proposed Regulation: Workplace Controls for Laboratory Use

- For the industrial and commercial use of PCE as a laboratory chemical, the proposed rule would require owners and operators to:
 - Ensure fume hoods are in use and functioning properly to minimize exposures when using PCE in laboratory settings
 - Provide dermal PPE (e.g., impervious gloves) to prevent direct dermal contact
- EPA considered existing good laboratory practices and OSHA's Occupational exposure to hazardous chemicals in laboratories standard at 29 CFR 1910.1450



Proposed Regulation: Exemptions Under TSCA Section 6(g)

- Section 6(g) permits an exemption if EPA finds that:
 - The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available;
 - Compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or
 - The specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety
- EPA is proposing
 - 10-year exemption for emergency uses of PCE in furtherance of NASA's mission
 - Exempt uses must document efforts to comply with provisions of the WCPP to the extent feasible



Proposed Requirements for Recordkeeping and Downstream Notification

- Downstream notification of the prohibitions would be carried out through SDS updates
 - For conditions of use that would not be prohibited under the proposed regulation, the Safety Data Sheets (SDSs) must be updated by adding information on prohibitions and relevant dates
 - Downstream notification is to spread awareness throughout the supply chain of the restrictions on PCE under TSCA as well as provide information to commercial end users about allowable uses of PCE
- Recordkeeping requirements include maintenance of normal business records and records related to WCPP and laboratory requirements, monitoring, and compliance



Proposed Effective Dates

- Prohibitions related to consumer and most commercial uses would become effective:
 - 12 months for manufacturers, 15 months for processors, 18 months for distribution to retailers, 21 months for retailers, and 24 months for commercial users after publication date of final rule
- Prohibition of dry cleaning through a 10-year phaseout
 - Would begin with a prohibition on use of PCE in any dry cleaning machine acquired 6 months or later after the final
 - Followed by a prohibition on use of 3rd generation PCE machines 3 years after the final rule
- Compliance with a WCPP for the uses specified in slide 22 would be required:
 - 6 months for monitoring, 9 months for designating a regulated area, 12 months for implementation of an exposure control plan after publication date of final rule
- Compliance with workplace controls for laboratory use would be required 12 months after publication date of final rule



Primary Alternative Regulatory Action

- As with the proposed action, the primary alternative regulatory action considered is a combination of prohibition, WCPP, and prescriptive controls
- Includes longer compliance timeframes than the proposed action
- Would prohibit fewer uses than the proposed regulatory action:
 - Most prohibitions would begin to come into effect at 18 months
 - 15-year phaseout for dry cleaning would begin to come into effect at 12 months
- Would require WCPP for lab use and certain industrial and commercial uses prohibited in proposed action
 - Uses include: Specialty DOD uses (oil analysis and water pipe repair); paints and coatings; aerosol spray degreaser/cleaner; processing aid for agricultural manufacturing
 - EPA has less certainty that these uses could implement the WCPP successfully such that unreasonable risk is addressed; requests comment
- Would require prescriptive controls for uses subject to WCPP in proposed action
 - Concentration limit of 1% for adhesives and sealants
 - Respirators and dermal PPE for other uses; request comment on risk reduction from other engineering and administrative controls



Second Alternative Regulatory Action

- As with the proposed action, the second alternative regulatory action considered is a combination of prohibition, WCPP, and prescriptive controls
- Includes shorter compliance timeframes than the proposed action
- Would prohibit more uses than the proposed regulatory action
 - Would provide a 10-year time-limited exemption under TSCA section 6(g) for maskant for chemical milling and vapor degreasing by military and civilian aerospace that EPA proposes are critical to national security and infrastructure
 - Most prohibitions would be in effect at 12 months
 - 5-year phaseout for dry cleaning would begin to come into effect at effective date
- Would require WCPP for manufacture (domestic and import), processing as reactant/intermediate, repackaging, recycling, industrial and commercial use in petrochemical manufacturing, and disposal
- Would require prescriptive workplace controls for laboratory use



Benefits of Proposed Rule

- ✓ Would address unreasonable risks for consumers and bystanders
- ✓ Would address unreasonable risks for workers and occupational non-users
- ✓ Would blanket the majority of facilities, addressing the potential exposures to the neighboring communities
- ✓ Would allow many industrial and commercial uses to continue where workplace controls could be implemented (for example, uses in national security, aviation, other critical infrastructure, and the Agency's efforts to combat the climate crisis)
- ✓ Would provide regulated community with confidence in a protected and healthier workforce



Request for Comments

EPA is requesting comments and substantiative information regarding several topics, including:

- The Workplace Chemical Protection Program (WCPP) and its various components (e.g., monitoring frequency, engineering controls, process changes)
- Feasibility of complying with and monitoring for an Existing Chemical Exposure Limit (ECEL) of 0.14 ppm as an 8-hr TWA
- Timeframes for implementation of the requirements
- What regulatory flexibilities may be afforded to certain uses under the WCPP to reduce burden with compliance
- Special considerations for laboratories
- Estimated impacts to the dry cleaning industry, including regarding expected closures
- Specific engineering or administrative controls that would address the unreasonable risk
- Feasibility of alternatives to PCE and their availability
- Any uses that are currently proposed to be prohibited that may need a longer timeframe or could meet the requirements of the WCPP



Types of Information that Best Informs Comments

Examples of potentially useful information for key areas of uncertainty should include information within the last 20 years containing:

- Occupational monitoring data from the relevant condition of use
 - Personal breathing zone
 - Area monitoring
- Process emission factors
- Descriptions of commercial worker activities and associated sources of exposure
- Product formulation information
- Relevant unpublished data



Next Steps

Process Step	Date
Publication of proposed rule on PCE in docket (EPA-HQ-OPPT-2020-0720) and open comment period	June 16, 2023
Closure of comment period: EPA will review and consider new information submitted	August 15, 2023
Publication of Final Rule for PCE (estimated)	2024
WCPP and requirements for lab use would be in full effect 12 months after date of the final rule (estimated)	2025
Prohibitions for most uses would be in full effect 24 months after date of publication of final rule (estimated)	2026
Prohibition for use in dry cleaning would be in full effect 10 years after date of publication of the final rule (estimated)	2034



Additional Resources

- Risk management for PCE: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-perchloroethylene>
- PCE risk evaluation, supplemental risk evaluation materials, and proposed rulemaking are in dockets [EPA-HQ-OPPT-2019-0502](#), [EPA-HQ-OPPT-2016-0732](#), and [EPA-HQ-OPPT-2020-0720](#) respectively, and may be accessed through www.regulations.gov
- General TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>
- Chemicals Undergoing Risk Evaluation under TSCA: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca>
- Current Chemical Risk Management Activities: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>



Contact Us

- All comments in order to be considered should be submitted to the docket at [EPA-HQ-OPPT-2020-0720](https://www.epa.gov/dockets/epa-hq-oppt-2020-0720)
- For general questions, email EPA at PCE.TSCA@epa.gov