



Public Webinar

Regulation of PCE under TSCA Section 6(a)

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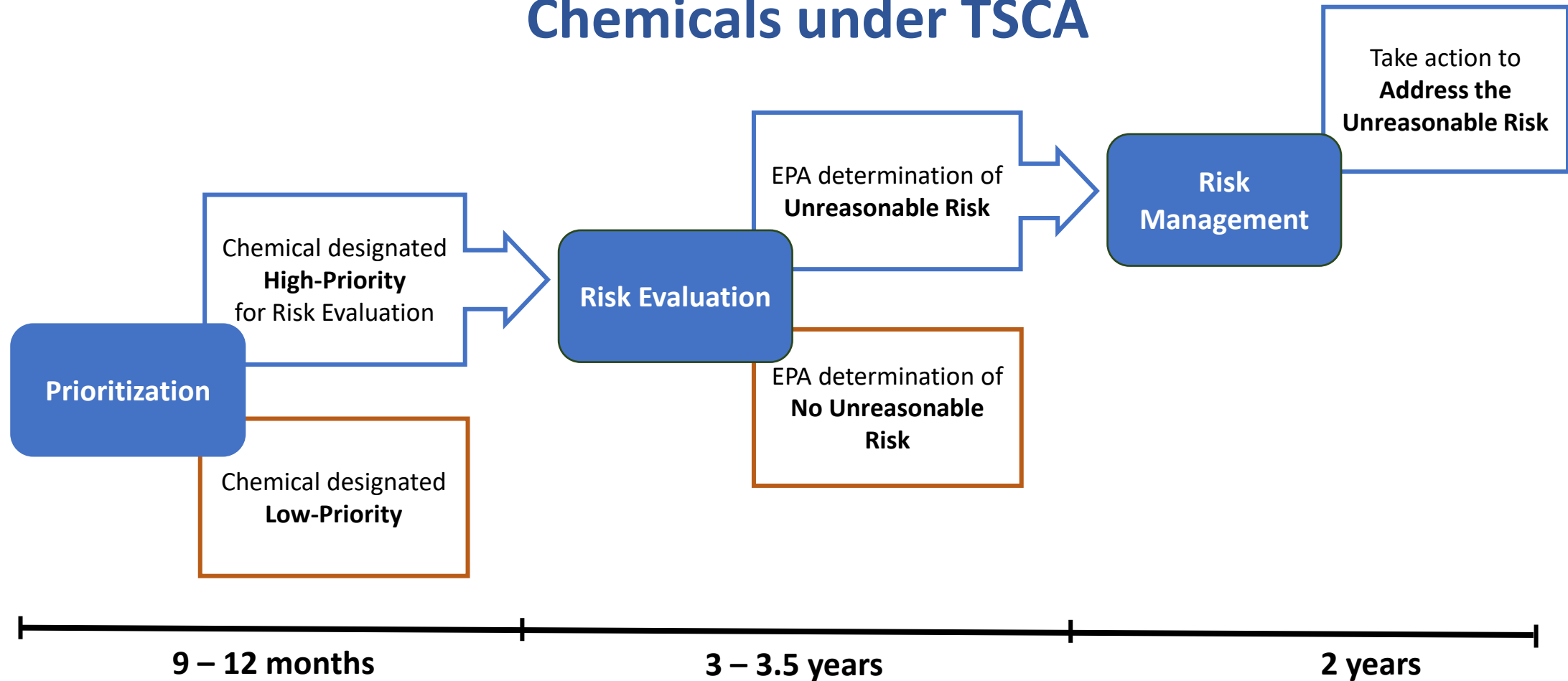
Agenda

- Overview of Toxic Substances Control Act (TSCA)
- Overview of PCE Rulemaking
- Summary of Proposed Regulation
- Public Comment and Outreach
- Final Regulation
- Benefits
- Next Steps
- Opportunities for Engagement
- Additional Resources

Overview of 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 predictable process for the regulated community
- PCE was identified as one of the first chemicals for risk evaluation
- Per TSCA section 6(b)(4)(A) risk evaluation and determination of “unreasonable risk of injury to health or the environment under the conditions of use,” EPA must by rule apply requirements such that the “chemical substance or mixture no longer presents such risk.”

Process to Assessing and Managing Existing Chemicals under TSCA



TSCA Section 6 – Risk Management Consideration and Regulatory Scope

- Requires addressing unreasonable risk with consideration of alternatives, selecting among options, statement of effects, and economic analysis
- Input from stakeholders is essential to the process, and robust coordination with interagency partners is necessary
- TSCA provides authority to regulate entities including:
 - Manufacturers (including importers) and processors (e.g., formulators)
 - Distributors
 - 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

- 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

Overview of PCE under the Toxics Substances Control Act (TSCA)

- PCE is a volatile chemical used in a wide range of industrial, commercial, and consumer applications
- PCE is a neurotoxicant and carcinogen, and chronic exposure is associated with liver and kidney effects, immune system toxicity, developmental/reproductive toxicity, and cancer
- EPA found that 60 of 61 conditions of use of PCE contribute to the unreasonable risk of injury to health of workers, consumers, and bystanders

Previous TSCA Actions on PCE

- December 2016: EPA designates PCE among the first ten chemicals to undergo risk evaluations under amended TSCA
- December 2020: Risk Evaluation released after peer review of draft risk evaluation
- December 2022: Final Revised Risk Determination published
- June 2023: EPA Proposal for the Regulation of PCE under Section 6(a) signed and published

Summary of Proposed Rule for PCE Under TSCA 6(a)

- On June 16, 2023, EPA proposed to:
 - Prohibit manufacture, processing, and distribution for all consumer uses
 - Prohibit most industrial and commercial uses
 - Provide a 10-year phaseout for dry cleaning
 - Allow some industrial and commercial uses to continue under a Workplace Chemical Protection Program (WCPP)
 - Require workplace controls for laboratory use
 - Grant time-limited exemption under TSCA section 6(g) for emergency uses in furtherance of NASA's mission
 - Provide a de minimis regulatory threshold level of 0.1%
 - The alternative regulatory actions included several additional uses under WCPP and longer compliance timeframes
- The proposed rule was open for public comment from June 16 to August 15, 2023 (60 days)

Summary of Comments

- Received 749 total comments on various aspects of the proposed rule
- Vast majority of comments, received from a mass mailer campaign, requested that EPA strengthen or maintain the proposed risk mitigations
- Other commenters requested additional time for compliance, additional prohibitions with shorter timelines, and additional section 6(g) exemptions
- Specific information was provided from several industry sectors supporting changes from the proposed rule

Developing Effective Regulations

EPA's mandate is to address identified unreasonable risk

- TSCA additionally requires EPA to consider:
 - Effects and magnitude of exposure to human health and the environment
 - Benefits of a chemical substance
 - Economic consequences of the rule
 - Availability of alternatives
- EPA's proposed rule and final rule are based on best available science and reasonably available information
- EPA's final rule includes information received from commenters and targeted outreach
- EPA considered all information received on the proposed rule and modified elements of the proposed regulatory action
- EPA's goal is to promulgate regulations that are both practical and protective

The Final Regulation

EPA's final rule will:

- Prohibit manufacture, processing, and distribution of PCE for all consumer uses
- Prohibit industrial and commercial uses where successful implementation of stringent workplace controls cannot be accomplished
- Require a Workplace Chemical Protection Program (WCPP) for 16 specified conditions of use (see slide 20)
- Require workplace controls for laboratory use
- Require workplace controls for energized electrical cleaning
- Establish recordkeeping and downstream notification requirements
- Provide regulatory threshold of 0.1% for regulation
- Time-limited exemption under TSCA section 6(g) for NASA emergency uses

Final Regulation: Applicability

- TSCA Chemical Substance: the provisions of this final rule only apply to chemical substances as defined under TSCA section 3, which excludes:
 - *“any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device” and “any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide.”*
- Regulatory Threshold for Compliance:
 - EPA’s final rule is adopting a regulatory threshold of 0.1% to account for impurities and the unintended presence of PCE
 - In other words, the provisions of this rulemaking only apply when PCE is present in a formulation at 0.1% or greater

Final Regulation: Prohibition of Consumer Use

- EPA determined PCE could not be used safely in consumer products
 - As with the proposed rule, the final rule will prohibit manufacturing (including import), processing, and distribution for consumer use, and provides time for retailers to phase out their consumer product inventory
 - In almost all cases, alternatives are available
- EPA is prohibiting manufacture, processing, and distribution in commerce of PCE for all consumer use, including:
 - 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)
 - Cleaners and degreasers
 - 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

Final Regulation: Prohibition of Industrial and Commercial Use

All industrial and commercial uses would be prohibited, except for uses covered by WCPP or prescriptive controls.

Prohibited industrial and commercial uses of PCE include:

- 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

* Some applications will continue. These are discussed later in this presentation.

Final Regulation: Timeframe of Prohibition of Industrial and Commercial Use

- Compliance dates for prohibition are staggered according to the supply chain and for specific uses

Lifecycle Designation	Final Prohibition Date	Implementation Timeframe from Publication of Final Rule
Manufacturers	June 11, 2026	18 months
Processors	September 9, 2026	21 months
Distributing to retailers	December 8, 2026	24 months
Retailers distributing	March 8, 2027	27 months
All other distributors	March 8, 2027	27 months
Industrial and commercial use	June 7, 2027	30 months
Dry cleaning and spot cleaning	December 19, 2034	10 years

Final Regulation: Dry Cleaning Phaseout

- EPA is prohibiting PCE use in dry cleaning and spot cleaning through a 10-year phaseout to provide dry cleaners time to transition to an alternative process
- Considered earlier state regulations, dry cleaning NESHAP, and stakeholder information:
 - Average lifespan of PCE dry cleaning machine: 15 - 25 years
 - Few new machines produced or sold in the U.S.
 - Alternatives are available (wet cleaning, hydrocarbons, multi-solvent dry cleaning machines)
 - Dry cleaners are mostly small businesses; can be located in densely populated communities

Phaseout Provision	Final Prohibition Dates	Phaseout Timing
Prohibition on use of PCE in any newly acquired dry cleaning machine	June 16, 2025	6 months
Prohibition on use of 3rd generation PCE machines	December 20, 2027	3 years
Full implementation of prohibition, including: <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	December 19, 2034	10 years

Final Regulation: Exemption Under TSCA Section 6(g)

- Section 6(g) permits EPA to grant 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 finalizing:
 - 10-year exemption for emergency uses of PCE in furtherance of NASA's mission until December 19, 2034
 - Must document efforts to comply with provisions of the WCPP, to the extent technically feasible in light of the emergency, until prohibition takes effect

Final 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's WCPP applies to owners or operators and potentially exposed persons, which in some cases is broader definition than “employers” and “employees”
 - EPA consulted with OSHA and NIOSH and coordinated on WCPP development and finalization, and aligned requirements where possible
 - Includes requirements to meet an exposure limit, prevent skin contact, and implement an exposure control plan, among other requirements

Final Regulation: Workplace Chemical Protection Program (cont.)

The following uses will continue with strict controls under the WCPP in the final rule:

- Manufacturing (Domestic)
- Manufacturing (Import)
- Processing: processing as a reactant*
- Processing: incorporation into a formulation, mixture, or reaction products (cleaning and degreasing products, adhesive and sealant products, paint and coating products, other chemical products and preparations)*
- Processing: recycling
- Processing: repackaging
- Industrial and commercial use as solvent for vapor degreasing (open-top batch, closed-loop batch)*
- 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
- Industrial and commercial use as a processing aid in sectors other than petrochemical manufacturing*
- Industrial and commercial use for cold cleaning of tanker vessels
- Disposal

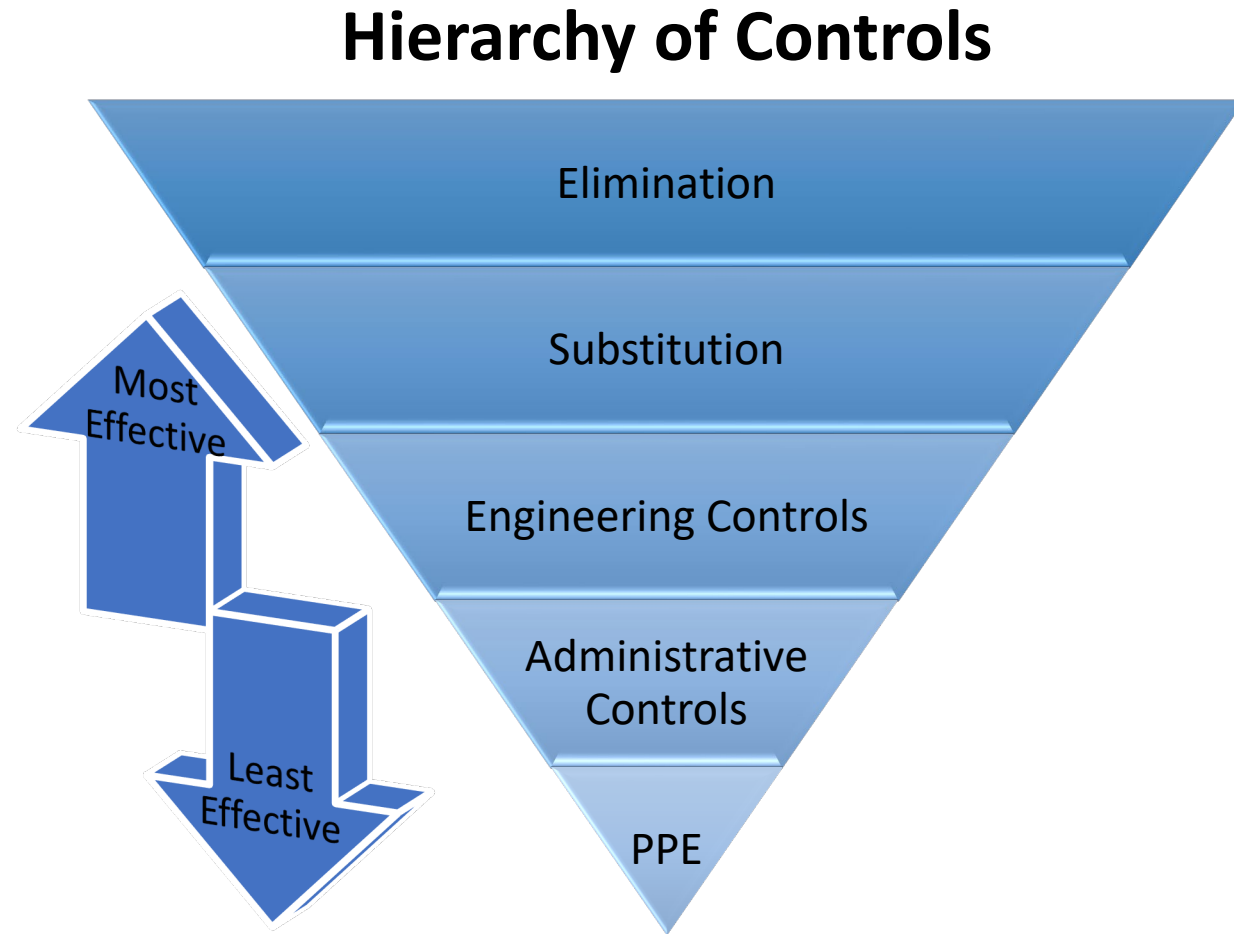
Uses marked with an asterisk (*) are trichloroethylene (TCE) uses prohibited in the [TCE regulation](#), and for which PCE may be a viable alternative.

Final Regulation: Workplace Chemical Protection Program (Cont.)

- The WCPP finalizes an inhalation exposure limit (Existing Chemical Exposure Limit, or ECEL):
 - 8-hour time-weighted average (TWA): 0.14 ppm (OSHA PEL is 100 ppm)
 - Includes monitoring, recordkeeping requirements, dermal and respiratory protection requirements
 - Provides flexibility for preventing exceedances of the identified EPA exposure limit

Final Regulation: Workplace Chemical Protection Program (cont.)

- The 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



Final Regulation: Timeframe for Workplace Chemical Protection Program

- WCPP uses will have additional time to achieve successful implementation

WCPP Compliance Phase	Final Compliance Dates & Implementation Timeframes from Publication of Final Rule	
	General Industry	Federal Agencies and Federal Contractors
Initial Monitoring	December 15, 2025 / 12 months	June 21, 2027 / 30.5 months
ECEL	March 13, 2026 / 15 months	September 20, 2027 / 33.5 months
DDCC, PPE/Respirators	March 13, 2026 / 15 months	September 20, 2027 / 33.5 months
Establish Regulated Area	March 13, 2026 / 15 months	September 20, 2027 / 33.5 months
Exposure Control Plan	June 7, 2027 / 30 months	December 20, 2027 / 36.5 months

Final Regulation: Workplace Controls for Laboratory Use

- For the industrial and commercial use of PCE as a laboratory chemical, owners and operators are required to:
 - Ensure ventilated lab safety devices (e.g., 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
- Prescriptive controls are required by December 15, 2025 (within 360 days of publication)
- EPA considered existing good laboratory practices and OSHA's Occupational exposure to hazardous chemicals in laboratories standard at 29 CFR 1910.1450

Final Regulation: Workplace Controls for Energized Electrical Cleaning

- EPA considered the lack of currently available alternatives that do not pose a flammability risk for the industrial and commercial use of PCE as an energized electrical cleaner
- Workplace controls: EPA is requiring *either*:
 - 1) Specific prescriptive controls including dermal protection, such impermeable gloves and protective clothing, and the use of respiratory protection in confined/enclosed spaces and within a minimum approach distance, as well as comprehensive training; *or*
 - 2) Implementation of the WCPP

TCE use as an energized electrical cleaner is prohibited by December 18, 2027, in the TCE regulation. PCE can be a viable alternative. Until the TCE prohibition is in effect, workplace controls are required.

Final Regulation: Workplace Controls for Energized Electrical Cleaning (Cont.)

- Workplace controls are required by March 13, 2026 (within 15 months of publication)
- Owners or operators must attest that they are in compliance with the energized electrical cleaning provisions by providing a self-certification statement
- A label must be provided and attached to each PCE-containing energized electrical cleaning product

Final Regulation: Recordkeeping and Downstream Notification

- SDS updates are required for downstream notification of the prohibitions
 - For conditions of use that are not prohibited under the final regulation, the Safety Data Sheets (SDSs) must be updated by adding information on prohibitions and relevant dates
 - Downstream notification spreads 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 prohibitions and restrictions of this rule

Benefits of Final Rule

- ✓ Addresses unreasonable risks for consumers and bystanders
- ✓ Addresses unreasonable risks for workers and occupational non-users
- ✓ Encompasses the majority of facilities, addressing the potential exposures to the neighboring communities
- ✓ Directly addresses conditions of use that have previously resulted in injuries and illnesses
- ✓ Provides regulated community with confidence in a protected and healthier workforce
- ✓ Ensures adequate time for successful phase out, implementation of workplace controls, and scaling up of the safety industry to meet demand
- ✓ Ensures operational continuity of federal agencies towards critical infrastructure and national security needs
- ✓ Includes a regulatory threshold to aid with implementation
- ✓ Includes additional uses from the proposal under the WCPP and use-specific workplace controls

Next Steps: Overview of Compliance Dates

Timeframes for Restrictions	General Industry	Federal Agencies (and Federal Contractors)
WCPP - Initial Monitoring	December 15, 2025	June 21, 2027
WCPP - ECEL, DDCC, PPE/Respirator, Regulated Area	March 13, 2026	September 20, 2027
WCPP - Exposure Control Plan	June 7, 2027	December 20, 2027
Prescriptive controls - laboratory use	December 15, 2025	December 15, 2025
Prescriptive controls - energized electrical cleaning	March 13, 2026	March 13, 2026
Downstream notification - manufacturers update SDS	February 18, 2025	February 18, 2025
Downstream notification - processors and distributors update SDS	June 16, 2025	June 16, 2025
Recordkeeping	February 18, 2025	February 18, 2025

Timeframes for Prohibitions	Final Prohibition Date
Manufacturers	June 11, 2026
Processors	September 9, 2026
Distributing to retailers	December 8, 2026
Retailers distributing	March 8, 2027
All other distributors	March 8, 2027
Industrial and commercial use	June 7, 2027

Dry Cleaning Phaseout Timeframes	Final Prohibition Date
Prohibition on use of PCE in any newly acquired dry cleaning machine	June 16, 2025
Prohibition on use of PCE in 3rd generation machines	December 20, 2027
Full implementation of prohibition, including: <ul style="list-style-type: none"> • 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 	December 19, 2034

Additional Resources

- Risk management for PCE: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-perchloroethylene-pce>
 - PCE risk evaluation, supplemental risk evaluation materials, and proposed rulemaking are in dockets [EPA-HQ-OPPT-2019-0502](https://www.regulations.gov), [EPA-HQ-OPPT-2016-0732](https://www.regulations.gov), and [EPA-HQ-OPPT-2020-0720](https://www.regulations.gov) respectively, and may be accessed through www.regulations.gov
- Risk management for TCE: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-trichloroethylene-tce>
- 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>
- PCE Fact Sheet: https://www.epa.gov/system/files/documents/2024-12/pce-fact-sheet_english.pdf
 - Spanish: https://www.epa.gov/system/files/documents/2025-01/pce-fact-sheet_-spa.pdf
 - Korean: https://www.epa.gov/system/files/documents/2025-01/pce-fact-sheet_kor.pdf
- PCE Dry Cleaning Compliance Guide: <https://www.epa.gov/system/files/documents/2025-01/pce-dry-cleaner-compliance-guide.pdf>
 - Spanish: https://www.epa.gov/system/files/documents/2025-01/pce-dry-cleaner-compliance-guide_spa.pdf
 - Korean: https://www.epa.gov/system/files/documents/2025-01/pce-dry-cleaner-compliance-guide_kor.pdf
- PCE Energized Electrical Cleaning Guide: <https://www.epa.gov/system/files/documents/2025-01/pce-eec-compliance-guide.pdf>
- TSCA hotline: 1-800-471-7127 and tsca-hotline@epa.gov

Contact Us

- For general questions, email EPA at:
 - PCE.TSCA@epa.gov or
 - TCE.TSCA@epa.gov.

Thank you!