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EPA Finalizes TSCA Risk Management Rules for PCE and TCE

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Two more chlorinated solvents have been wholly or partially banned by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA). Following the May 8, 2024 final rule on methylene chloride, EPA published final risk management rules restricting the manufacture (including import), processing, and distribution in commerce of perchloroethylene (PCE) and trichloroethylene (TCE) on December 18 and December 17, respectively. The rules follow risk evaluations determining that both PCE and TCE present an "unreasonable risk of injury to human health or the environment" per TSCA section 6(b). The final rules ban most uses of PCE and all uses of TCE on highly nuanced phase-out timelines.

Both rules have effective dates prior to Inauguration Day, January 20, 2025. That means they will not be subject to the anticipated 60-day regulatory freeze and potential pull-back by the incoming Trump administration. They are, however, potentially subject to invalidation under the Congressional Review Act. In the absence of such action, judicial review of both rules is likely.

EPA plans to release guidance to help companies comply with these complex rules in the coming months.

Background

PCE, also known as perc and tetrachloroethylene, is a solvent widely used in industrial, commercial, and consumer applications, including dry cleaning, fabric manufacturing, adhesives, and brake cleaners. According to EPA, PCE is a neurotoxicant considered "likely to be carcinogenic to humans by all routes of exposure" linked with certain cancers. TCE is used as a solvent in similar applications such as cleaning and degreasing, as well as in the manufacture of a common refrigerant, HFC-134a. EPA has determined that TCE presents adverse health effects such as neurotoxicity, immunosuppression, and reproductive toxicity, as well as certain cancers.

Under TSCA section 6(b)(4), EPA must conduct risk evaluations of certain chemical substances to determine whether they present an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors. In <u>2022</u> and <u>2023</u>, EPA finalized risk evaluations for

PCE and TCE, respectively, finding that the chemicals presented an unreasonable risk under certain "conditions of use," which are the circumstances under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

On <u>June 16, 2023</u> and <u>October 31, 2023</u>, respectively, EPA published proposed rules regulating PCE and TCE, finding that the vast majority of identified conditions of use for PCE and TCE contribute to the determination that the chemicals present an unreasonable risk of injury to human health. After receiving tens of thousands of public comments, EPA finalized, with modifications, both proposed rules.

The TCE rule is long-awaited. A proposed rule banning certain uses of TCE was initially published under the Obama EPA in <u>January 2017</u> but was subsequently delayed and <u>withdrawn</u> by the first Trump EPA, which decided to instead go through a full risk evaluation process. With a second Trump administration taking office in January, we may see further shifts in approach as well as multiple challenges to one or both rules under TSCA section 19.

The Perchloroethylene Final Rule

EPA is prohibiting and phasing out the manufacture (including import), processing, and distribution in commerce of PCE for all consumer uses, as well as most industrial/commercial uses. 40 C.F.R. Part 751, Subpart G. However, particular industrial and commercial uses are allowed to continue if certain workplace controls are followed (discussed below).

Complete Bans with Phase-Outs

The manufacture, processing, and distribution of PCE for many uses of PCE are banned, with varied phase-out periods largely within three years of the final rule's publication. These are the phase-out dates for some, although not all, of the banned conditions of use:

- June 11, 2026:
 - All manufacturing of PCE for consumer use; and all industrial and commercial use of PCE, except as specified elsewhere.
- September 9, 2026:
 - All processing of PCE, including PCE-containing products, for consumer use.
 - All processing of PCE for industrial and commercial use of PCE, except as specified elsewhere.
- December 8, 2026:
 - All distribution of PCE, including PCE-containing products, to retailers for any use other than dry cleaning.
- March 8, 2027:
 - All distribution by retailers of PCE, including PCE-containing products.
 - All distribution of PCE, including PCE-containing products, for consumer use and industrial and commercial uses other than as specified elsewhere.
- June 7, 2027:
 - All industrial and commercial use of PCE, including PCE-containing products, except as specified elsewhere.

Uses That May Continue

Conditions of use without a phase-out date may continue indefinitely, as long as affected companies develop and implement a Workplace Chemical Protection Program (WCPP). These include, among others:

- Manufacturing and processing for export
- Manufacturing (domestic and import)
- Processing as a reactant/ intermediate
- Processing into formulation, mixture, or reaction product
- Repackaging
- Industrial and commercial use as solvent for open-top batch vapor degreasing
- Industrial and commercial use as solvent for closed-loop batch vapor degreasing
- 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
- Recycling
- Disposal

In addition, the use of PCE in laboratories and energized electrical cleaners may continue, subject to specific workplace requirements.

Workplace Chemical Protection Program

The WCPP requirements apply to conditions of use without a phase-out date (other than use in laboratories and energized electrical cleaners) and to conditions of use with phase-out dates until those dates arrive. The WCPP provision sets forth specific safety measures designed to manage exposure in the workplace. They include an Existing Chemical Exposure Limit (ECEL) and ECEL action level, exposure monitoring, regulated areas, exposure control procedures and plans, workplace information and training, and personal protective equipment (PPE).

The ECEL is 0.14 ppm (8-hour time-weighted average (TWA)). This is much more stringent than the OSHA permissible exposure limit (PEL) for perchloroethylene of 100 ppm TWA in 29 C.F.R. § 1910.1000, Table Z-2 (specified as tetrachloroethylene). Starting March 13, 2026, the owner or operator must ensure that no person is exposed to PCE above the ECEL (taking PPE into account if necessary).

Air concentrations at or above the ECEL action level of 0.10 ppm TWA would trigger more frequent periodic monitoring of exposures to PCE, consistent with the action level approach utilized by OSHA.

Regulatory Threshold

EPA established a regulatory threshold (i.e., de minimis threshold) of 0.1%, so that products containing PCE at concentrations less than 0.1% by weight are not subject to the prohibitions or restrictions of the final rule.

Export and Import

The PCE risk management rule is clear: Companies may continue to export PCE as long as the domestic manufacture, processing, and/or distribution of PCE is in compliance with any applicable WCPP. EPA specifically noted that the intended use of PCE in the destination country, even if it would be prohibited in the U.S., is irrelevant for the purposes of compliance.

Companies will continue to be subject to import notification provisions under TSCA section 13 and the corresponding Customs and Border Protection regulations at 19 C.F.R. § 12.118-127, as well as export notification provisions under TSCA section 12(b), 40 C.F.R. Part 707, Subpart D.

Other Requirements

A downstream notification requirement applies beginning February 18, 2025 to anyone who ships PCE for any use. The notification must be made by inserting specific language into sections 1(c) and 15 of the appropriate safety data sheets (SDSs).

A recordkeeping requirement also applies after February 18, 2025.

The Trichloroethylene Final Rule

Complete Bans with Phase-Outs

Unlike PCE, EPA issued a complete ban on all uses of TCE, whether consumer, industrial, or commercial. 40 C.F.R. Part 751, Subpart D. Most phase-out periods will end within one year of publication of the final rule. A few uses have longer phase-out periods if the WCPP requirements are followed. The phase-out dates include the following, among others:

- March 17, 2025:
 - All manufacturing (including importing and manufacturing for export) except as specified elsewhere.
- June 16, 2025:
 - All processing (including processing for export) and distribution of TCE (including TCE-containing products) except as specified elsewhere.
 - All manufacturing of TCE for industrial and commercial use for batch vapor degreasing in open-top and closed-loop degreasing equipment except as specified elsewhere.
- September 15, 2025:
 - All industrial and commercial use of TCE except as specified elsewhere; all
 processing of TCE for industrial and commercial use for batch vapor degreasing in
 open-top and closed-loop degreasing equipment except as specified elsewhere.
 - All disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works except as specified elsewhere.
- December 18, 2025:
 - All industrial and commercial use of TCE for batch vapor degreasing in degreasing in open-top and closed-loop degreasing equipment except as specified elsewhere.
- June 10. 2026:
 - All manufacturing TCE for processing of TCE as a reactant/intermediate except as specified elsewhere.
 - All manufacture of TCE for processing of TCE for industrial and commercial use as a processing aid for listed applications except as specified elsewhere.
- December 18, 2026:
 - All processing TCE as a reactant/intermediate except as specified elsewhere.
 - All processing for industrial and commercial use of TCE as a processing aid for the listed applications except as specified elsewhere.
- December 18, 2029:
 - All industrial and commercial use of TCE as a processing aid for lithium battery

separator manufacturing, and the manufacturing (including importing), processing, and distribution in commerce of TCE for such use and the disposal of TCE from such that use to industrial pre-treatment, industrial treatment, or publicly owned treatment works.

- June 18, 2033:
 - All industrial and commercial use of TCE as an intermediate for manufacturing HFC-134a and manufacturing (including importing), processing, and distribution in commerce for that use.

The TCE rule has additional phase-out dates for some specialized applications, some extending out to 2074.

Workplace Chemical Protection Program

Fifteen conditions of use will be subject to WCPP requirements. They include an interim ECEL, exposure monitoring, regulated areas, interim ECEL control procedures and plan, workplace information and training, and PPE.

The interim ECEL (interim because all uses of TCE will be phased out) is 0.2 ppm TWA. This is much lower than OSHA's PEL for trichloroethylene, 100 ppm TWA. 29 C.F.R. § 1910.1000, Table Z-2. Beginning September 15, 2025, each owner and operator must ensure that no person is exposed to airborne concentrations of TCE about the interim ECEL (taking PPE into account, if needed).

Initial monitoring is designed to notify owners and operators of the magnitude of possible exposures to potentially exposed persons with respect to their work conditions and environments. In order to reduce exposures to or below the interim ECEL, companies subject to the WCPP must institute one or a combination of elimination, substitution, engineering controls, or administrative controls.

Companies must also establish regulated areas in the workplace wherever any person's exposure to PCE can reasonably be expected to exceed the ECEL. These areas must be demarcated and have limited access.

Regulatory Threshold

EPA finalized the same regulatory threshold applicable to PCE of 0.1%, meaning that TCE-containing products with a concentration of less than 0.1% by weight are not regulated by the final rule.

Downstream Notification

Manufacturers of TCE for any use must notify companies to whom TCE or TCE-containing products are shipped of the rule's restrictions by adding specific language to sections 1(c) and 15 of the appropriate SDSs. This requirement begins on February 18, 2025. Processors of TCE or TCE-containing products must do the same by June 16, 2025.

Export and Import

The TCE rule bans the manufacture of TCE for export after March 17, 2025. It bans processing and distribution of TCE for export after June 16, 2025.

The rule bans import of TCE after March 17, 2025, except as specified elsewhere.

Recordkeeping

After February 18, 2025, companies must begin maintaining records related to compliance with TCE risk management measures. The records may include ordinary business records, such as invoices and bills of lading.

Conclusion

Companies that manufacture, process, distribute, use, or export PCE or TCE in any way should evaluate the prohibitions and other requirements contained in these final rules and plan for compliance. They should also monitor developments, as the incoming Trump administration may take regulatory action, or the rules may become the subject of judicial review.

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