Trichloroethylene (TCE) 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-trichloroethylene-tce

Agenda

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

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

- In June 2016, Congress amended the Toxic Substances Control Act (TSCA)
  - EPA must assess and address risks from chemicals currently in commerce
  - Statutory timeframes for regulation
  - Protection for the public and predictability for the regulated community
- TCE was identified in 2016 as one of the first chemicals for risk evaluation
  - 2020 Risk Evaluation followed a public draft and peer review process
  - 2023 Revised Unreasonable Risk Determination
  - EPA determined TCE presents an unreasonable risk under its conditions of use

Purpose and Overview Of Rulemaking

- Addresses the unreasonable risk identified in the risk evaluation of TCE
- Rule will prevent consumer and occupational illness through a prohibition, while providing identified essential uses with longer timeframes until prohibition, contingent on strict workplace protections
- Public comment period open until **December 15, 2023**
- EPA will consider public comments and finalize regulation of TCE under TSCA

TCE Background

- Volatile chemical used in wide-ranging industrial, commercial, and consumer applications
- Risks to workers, consumers, and bystanders for 52 of the 54 conditions of use contribute to the unreasonable risk from TCE
- Timeline:
  - November 2016 – EPA designates TCE as one of the first ten chemicals for risk evaluation
  - November 2020 – Risk Evaluation for TCE
  - January 2023 – Revised Risk Determination
  - **October 2023 – EPA Proposal for the Regulation of TCE under Section 6(a)**

Basis for TCE Proposed Rulemaking: Workers, ONUs, Consumers, and Bystander Risk

Acute Effects

- Developmental toxicity
- Immunosuppression

Chronic Non-Cancer Effects

- Liver toxicity
- Kidney toxicity
- Neurotoxicity
- Autoimmunity
- Reproductive toxicity
- Developmental toxicity

Cancer

- Liver
- Kidney
- Non-Hodgkin Lymphoma

- 2020 Risk Evaluation identified several endpoints for acute, chronic non-cancer, and cancer effects
- Unreasonable risk determination is based on the immunotoxicity endpoint
- EPA's risk evaluation is based on the immunotoxicity endpoint, but the developmental toxicity endpoint also described in detail in the RE provides the basis for EPA's proposed ECEL in the WCPP for uses with longer compliance dates
- The proposed action to address the developmental toxicity endpoint will address the unreasonable risk from all other effects
- 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 for a consistent approach, facilitate compliance, and avoid duplicative requirements
  - DOD and NASA for uses that might affect U.S. critical infrastructure or national security and to facilitate compliance
  - SBA Advocacy and OMB/OIRA for 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
- Have been 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 unreasonable risk

- EPA must consider:
  - Effects and magnitude of exposure to human health and the environment
    - Potentially Exposed or Susceptible Subpopulations
    - When appropriate, potential risks from the ambient air pathway to fenceline communities and potential risks from water pathway to fenceline communities
  - Benefits of a chemical substance
  - Economic consequences of the rule
  - Availability of alternatives
- Proposal is based on best available science and reasonably available information

Developing Effective Regulations (cont.)

EPA's goal is practical and protective regulations

- Familiar regulatory framework for occupational and consumer exposure
- Ensures consumers would not have access to TCE-containing products
- Prohibits all occupational uses, with longer compliance timeframes until prohibition for certain uses and time-limited exemptions for critical uses
- Mandates worker protection requirements for uses continuing for longer timeframes
- 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.)

- Requesting comment on all elements of the proposed and alternative regulatory action
- EPA may in the final rule modify elements of the proposed regulatory action
- Public comments could result in changes when this rule is finalized

The Proposed Regulation

EPA's proposed rule would:

- Prohibit manufacture, processing, and distribution of TCE for all consumer use
- Prohibit all industrial and commercial uses, with longer timeframes for certain uses
- Provide an 8.5-year phaseout for processing TCE as an intermediate to make HFC-134a
- Provide a 10-year phaseout for TCE use in vapor degreasing to make rocket booster nozzle for Federal agencies
- Include six critical use exemptions under TSCA section 6(g)
- Require a Workplace Chemical Protection Program (WCPP) for uses continuing for more than one year until prohibition
- Establish recordkeeping and downstream notification requirements

Proposed Regulation: Consumer Uses

- EPA determined TCE 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
  - Provides time for retailers to phase out their consumer product inventory
  - Available information suggests minimal ongoing use or that alternatives are available

Proposed Regulation: Consumer Uses

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

- Cleaners and degreasers
- Automotive care products (brake cleaner and parts cleaner, tire cleaner)
- Aerosol cleaner
- Non-aerosol cleaner
- Lubricants and greases (tap and die fluid, lubricants and penetrating oils)
- Adhesives for arts and crafts
- Solvent based mold release
- Solvent based adhesives and sealants

Proposed Regulations: 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 developing an industrial hygiene program)
  - Potential for regrettable substitution
- Uncertainty about WCPP implementation is a driving factor
- Staggered implementation within the supply chain to assure orderly phase out

Proposed Regulations: Industrial and Commercial Use

- High magnitude of risk with unique challenges in exposure reduction
- Proposed inhalation exposure limit (Existing Chemical Exposure Limit, or ECEL): 8-hour time-weighted average of 0.0011 ppm
- Meeting the ECEL presents significant challenges
  - Cannot be achieved just through engineering and administrative controls: would require workers to be in PPE of Assigned Protection Factor (APF) 10,000 or above, which is not feasible long term
  - Cannot reliably monitor to ECEL of 0.0011 ppm, or to action level
    - Current OSHA approved method has personal breathing zone limit of detection at 0.018ppm
- Prohibition is the only regulatory action that ensures that the unreasonable risk is addressed

Proposed Prohibitions: Industrial and Commercial Uses

All industrial and commercial uses would be prohibited. Conditions of use that would be prohibited within a shorter timeframe are industrial and commercial use of TCE for:

- As a solvent for vapor degreasing (open-top, closed-loop, in-line conveyorized, in-line web)
- As a solvent for cold cleaning
- As a solvent for aerosol spray degreaser/cleaner and mold release
- As a lubricant and grease in tap and die fluid
- As a lubricant and grease in penetrating lubricant
- As an adhesive and sealant in solvent-based adhesives and sealants (in tire repair and mirror edge sealant)
- As a functional fluid in heat exchange fluid
- As a solvent in paints and coatings as a diluent in solvent-based paints and coatings
- In cleaning and furniture care products in carpet cleaner and wipe cleaning
- In laundry and dishwashing products in spot remover
- In arts, crafts, and hobby materials in fixatives and finishing spray coatings
- In corrosion inhibitors and anti-scaling agents
- As a processing aid or process solvent
- As ink, toner and colorant products in toner aid
- In automotive care products in brake parts cleaner
- In apparel and footwear care products in shoe polish
- In other miscellaneous uses, including hoof polish, gun scrubber, and pepper spray

Proposed Regulations: Industrial and Commercial Use

- Several conditions of use have a longer timeframe before prohibition, and would be subject to the proposed WCPP during that time
- Phaseouts and exemptions would be provided for uses which require a longer timeframe to replace TCE or proposed to be critical and essential, and EPA expects workplaces have sophisticated controls in place already that could bring exposures as close to the ECEL as possible
- The staggered timeframes and longer compliance dates were informed by engagement with external stakeholders and Federal agencies

Proposed Regulation: Industrial and Commercial Uses with Longer Timeframes Until Prohibition

- Uses with timeframes beyond one year would need strong worker protections:
  - Manufacturing TCE: both domestic and imported
  - Processing TCE : recycling and repackaging
  - Processing TCE: as a reactant/intermediate (refrigerant HFC-134a)
  - Industrial and commercial use of TCE as solvent for closed-loop vapor degreasing:
    - For human-rated rocket engine cleaning by NASA and its contractors
    - For rayon fabric scouring for end use in rocket booster nozzle production by Federal Agencies and their contractors
  - Industrial and commercial use of TCE for Department of Defense naval vessels and their systems
    - And in the maintenance, fabrication, and sustainment for and of such vessels and systems
  - Industrial and commercial use of TCE as a processing aid for battery separator manufacturing
  - Industrial and commercial use of TCE as a laboratory chemical for essential laboratory activities and some research and development activities
  - Emergency industrial and commercial use of TCE in furtherance of NASA's mission:
    - For specific conditions which are critical or essential and for which no technically and economically feasible safer alternative is available
  - Disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works for cleanup projects

Proposed Compliance Dates

- Prohibitions related to all consumer and most commercial and industrial uses would become effective:
  - 3 months for manufacturers, 6 months for processors and distribution in commerce, and 9 months for industrial and commercial users after publication date of final rule
- Prohibitions related to vapor degreasing, unless otherwise exempted, would become effective:
  - 6 months for manufacturers, 9 months for processors, and 1 year for industrial and commercial users
- Prohibitions related to processing of TCE as a reactant/intermediate and the industrial and commercial use of TCE as a processing aid, unless otherwise exempted, would become effective:
  - 18 months for manufacturers, and 2 years for processors and industrial and commercial users
- Compliance with a WCPP for the uses specified in slide 20 would be required:
  - 3 months for monitoring, 6 months for designating a regulated area, 9 months for implementation of an exposure control plan after publication date of final rule

Proposed Phaseout for Processing TCE for HFC-134a

- EPA is proposing to prohibit processing TCE as an intermediate in the manufacture of refrigerant HFC-134a, using an 8.5-year phaseout
- For timeframe, EPA aligned and considered the phasedown of HFC-134a under the American Innovation and Manufacturing Act (AIM Act)
  - The use of HFC-134a is expected to decline as users switch to refrigerants with lower global warming potential
  - Alternatives are available, such as production of HFC-134a with PCE

Phaseout Timing (after publication date of the final rule)	
6 months	Manufacturers of HFC-134a must establish a baseline annual volume of TCE
9 months	Workplaces continuing to manufacture and process TCE for HFC-134a must enact workplace protections
2.5 years	Manufacturers cannot process TCE at a volume above 75% of their baseline
4.5 years	Manufacturers cannot process TCE at a volume above 50% of their baseline
6.5 years	Manufacturers cannot process TCE at a volume above 25% of their baseline
8.5 years	Prohibition on manufacturing, distribution in commerce, and processing TCE for HFC-134a

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

Proposed Regulation: Exemptions Under TSCA Section 6(g)

- EPA is proposing
  - 7-year exemption for use of TCE in closed-loop vapor degreasing necessary for rocket engine cleaning by NASA
  - 10-year exemption for emergency uses of TCE in furtherance of NASA's mission
  - 10-year exemption for use of TCE as a processing aid in battery separator manufacturing
  - 10-year exemption for use of TCE to meet DoD naval vessel requirements
  - 50-year exemption for TCE in essential laboratory use
  - 50-year exemption for disposal of contaminated wastewater to facilitate cleanup
- Entities must document efforts to comply with provisions of the WCPP to the extent feasible

Proposed Regulation: Workplace Chemical Protection Program

- A Workplace Chemical Protection Program (WCPP) protects people from risk posed by occupational exposures from certain conditions of use
- Uncertainty regarding ability to comply with an ECEL influences whether a condition of use is a candidate for WCPP or whether prohibition is more appropriate
- For TCE, EPA is proposing WCPP only until prohibitions come into effect
- WCPP applies to Owners or Operators and Potentially Exposed Persons
  - Broader definition than “employers” and “employees”

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): 0.0011 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
  - Aligns with existing OSHA requirements wherever possible

Proposed Requirements for Recordkeeping and Downstream Notification

- Downstream notification of the prohibitions would be carried out through Safety Data Sheet updates
  - Downstream notification spreads awareness throughout the supply chain of the restrictions on TCE under TSCA and provides information to commercial end users about timeframes for allowable uses of TCE
- Recordkeeping requirements include maintenance of normal business records and records related to WCPP requirements, monitoring, and compliance

Primary Alternative Regulatory Action

- Primary alternative regulatory action considered is a full prohibition with staggered timeframes and WCPP for certain uses until prohibition
- Includes longer compliance timeframes than the proposed action
- Would exempt two more conditions of use under TSCA section 6(g) than the proposed regulatory action:
  - 7-year exemption for industrial and commercial use of TCE in batch vapor degreasing for essential aerospace parts and components and narrow tubing used in medical devices.
  - 15-year exemption for industrial and commercial use of TCE as a processing aid for specialty polymeric microporous sheet materials
- Would require WCPP, using an ECEL calculated from a different endpoint, for certain industrial and commercial uses
  - 8-hour time-weighted average (TWA): 0.0040 ppm
  - Based on the chronic non-cancer occupational endpoint for autoimmunity

Benefits of Proposed Rule

- ✓ Would address unreasonable risks for consumers and bystanders
- ✓ Would address unreasonable risks for workers and occupational non-users
- ✓ Would blanket all facilities, addressing the potential exposures to the neighboring communities
- ✓ Would allow certain industrial and commercial uses to continue for longer timeframes to allow for a smoother transition, using workplace controls to protect workers (for example, uses in national security, aerospace, 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

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 0.0011 ppm or 0.0040ppm as an 8-hr TWA
- Timeframes for implementation of the requirements
- Specific engineering or administrative controls that would address the unreasonable risk
- The appropriateness of the TSCA section 6(g) exemptions proposed in the rule
- Feasibility of alternatives to TCE and their availability
- Any uses that are currently proposed to be prohibited that may need a longer timeframe

Types of Information that Best Inform Comments

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

- Occupational monitoring data
  - 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 TCE in docket (EPA-HQ-OPPT-2020-0642) and open comment period	October 31, 2023
Closure of comment period: EPA will review and consider new information submitted	December 15, 2023
Publication of Final Rule for TCE (estimated)	2024
Prohibition for most uses and WCPP for uses with longer timeframes would be in full effect 12 months after date of the final rule (estimated)	2025

Additional Resources

- Risk management for TCE: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-trichloroethylene-tce
- TCE risk evaluation, supplemental risk evaluation materials, and proposed rulemaking are in dockets EPA-HQ-OPPT-2019-0500, EPA-HQ-OPPT-2016-0737, and EPA-HQ-OPPT-2020-0642 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-2020-0642
- For general questions, email EPA at TCE.TSCA@epa.gov