



**EPA's Proposed Risk Management of  
Trichloroethylene Under the Toxic  
Substances Control Act (TSCA)  
88 Fed. Reg. 74,712 (October 31, 2023)**

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- EPA proposes to:
  - Prohibit all manufacture (including import), processing, and distribution in commerce of TCE;
  - Prohibit industrial and commercial use of TCE for all uses;
  - Prohibit the disposal of TCE to industrial pre-treatment, industrial treatment, or publicly owned treatment works, with a time-limited exemption for cleanup projects;
  - Establish recordkeeping and downstream notification requirements
- Obviously, many firms in compliance with the OSHA standard will be unable to meet the proposed ECEL. Indeed, EPA assumes that the workplace conditions of use it proposes to ban will not be able to achieve the proposed ECEL. Thus, any workplace in the banned categories may no longer use TCE even if it could show compliance with the much lower limits.

- For certain conditions of use, EPA proposes longer compliance timeframes/time-limited exemptions, including for:
  - manufacture (including import) and processing of TCE as an intermediate for the manufacturing of hydrofluorocarbon-134a (HFC-134a)
  - two batch vapor degreasing conditions of use in open-top and closed-loop batch vapor degreasers;
  - industrial and commercial use of TCE as a solvent for closed-loop batch vapor degreasing for rayon fabric scouring for end use in rocket booster nozzle production for Federal agencies and their contractors;
  - manufacture (including import), processing, distribution in commerce, and use of TCE as a processing aid for battery separator manufacturing; and
  - manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for human-rated rocket engine cleaning by the National Aeronautics and Space Administration (NASA) and its contractors.
- For these conditions of use EPA would require strict workplace controls. WCCPs would be required when TCE use is permitted for more than one year after publication of the final rule, including for:
  - HFC-134a manufacture;
  - battery separator manufacture; and
  - closed-loop batch vapor degreasing.

- WCPPs must have an existing chemical exposure limit (ECEL) of 0.0011 ppm (8-hour time-weighted average (TWA)).
- Compare this to other TCE limits in effect:
  - OSHA PEL 100 ppm (8-hour TWA)
  - ACGIH Threshold Limit Value 10 ppm (8-hour TWA); 25 ppm (STEL)
  - Cal/OSHA PEL 25 ppm (8-hour TWA)
- EPA apparently recognizes the infeasibility of achieving the ECEL, as it proposes not that owners or operators comply with the ECEL but that they ensure *to the extent possible* that no person is exposed to an airborne concentration of TCE in excess of the ECEL.
- In addition to being infeasible, the ECEL limit cannot be reliably measured in the workplace. Indeed, 1 ppb is a typical background TCE concentration in urban air.
- WCPPs must also include very burdensome requirements on exposure limits, regulated areas, exposure monitoring, methods of compliance, respiratory and dermal protection, and training.

- Proposed primary alternative:
  - Longer phaseout/time-limited exception periods for certain conditions of use, including:
    - starting one year later for HFC-134a manufacture.
    - a 7-year TSCA § 6(g) exemption for the industrial and commercial use of TCE in open-top and closed-loop batch vapor degreasing for essential aerospace parts and narrow tubing used in medical devices.
  - Higher (but still unachievable) ECEL of 0.004 ppm based on a different health endpoint (immunotoxicity).
- Table 2 provides a summary comparison of proposed regulatory action versus its primary alternative.

# Comparison of TCE ECEL to other ECELS and OSHA and Foreign Workplace Limits

Chemical Name	Foreign Country PELs*				OSHA PEL*	EPA ECEL	PEL/EPA ECEL
	France PEL	Germany PEL	Canada (Ontario) PEL	Mexico PEL			
Methylene Chloride	20	50	100	100	25	2	12.5
Perchloroethylene	20	10	25	25	100	0.14	714
Carbon Tetrachloride	1	0.5	5	5	10	0.030	333
Trichloroethylene	10	6	10	10	100	0.0011 or 0.004	90,909 or 25,000

\*Units in parts per million (ppm)

France: <https://www.inrs.fr/media.html?refINRS=outil65>

Canada: <https://www.ontario.ca/laws/regulation/900833>

Mexico: [http://dof.gob.mx/nota\\_detalle.php?codigo=5342372&fecha=28/04/2014](http://dof.gob.mx/nota_detalle.php?codigo=5342372&fecha=28/04/2014)

Germany: [TRGS-900.pdf](#) & [TRGS-910 \(1\).pdf](#)

- How does EPA justify a value over 90,000 times lower than the existing OSHA limit?
- The ECEL value of 0.0011 ppm is intended to protect workers against developmental effects.
- This approach is not scientifically defensible:
  - The Johnson *et al.* study on which it is based is not reproducible.
  - No increase in cardiac malformations was observed in two EPA guideline studies, despite high inhalation doses and techniques capable of detecting the effects reported by Johnson *et al.*
  - The dose-response relationship reported in Johnson *et al.* (2003) has been considered improbable by most reviewers and has also not been replicated.
  - The National Academy of Sciences concluded that "no causal relationship has been identified between TCE exposure during human pregnancy and CHD [congenital heart defects]," and that the Johnson *et al.* study has design flaws and reporting errors that suggest high risk of bias.
  - EPA's own Science Advisory Committee on Chemicals (SACC) advised against use of the study as a basis for regulation.

- The proposed alternative ECEL value of 0.004 ppm to protect against immunotoxicity also lacks scientific justification.
- The scientific validity problems with reliance on the serum DNA autoantibody findings include:
  - Lack of analytical verification of dosing concentrations.
  - Lack of biological plausibility with no accompanying pathological changes and the same effects not seen in autoimmune-prone mouse strain.
  - Lack of dose-response seen for most measurements at most time points throughout the study.
  - Inadequate number of dose groups for dose-response modeling.
- Alternative high quality immunotoxicity studies for the ECEL value are available and should have been used.

- EPA should not have used the Charbotel *et al.* (2006) case-control study on renal cell carcinoma (RCC) as the basis for its Risk Evaluation. EPA originally used the study in its 2011 IRIS assessment. A new meta-analysis published thereafter shows that TCE is not a risk factor for kidney cancer;
- A National Academy of Sciences review stated:

“There appear to be insufficient epidemiologic data to support quantitative dose-response modeling for trichloroethylene and cancer. The committee recommends that toxicologic data be used to fit the primary dose-response model(s) and that the available epidemiologic data be used only for validation. The committee does not believe that the available information is sufficient to determine the best dose-response model for trichloroethylene.”
- Much more can be said about the Risk Evaluation; suffice to say here that it reflects neither the “best available evidence” nor the “weight of the scientific evidence” as required by TSCA.

# Section 6(g) Exemptions

- TSCA § 6(g) provides for time-limited critical use exemptions in certain circumstances.
- Relevant proposed exemptions include:
  - A 10-year TSCA § 6(g) exemption for the manufacture (including import), processing, distribution in commerce, and use of TCE as a processing aid for battery separator manufacturing;
  - A 10-year TSCA § 6(g) exemption for industrial uses for Department of Defense naval vessel requirements;
  - A 7-year TSCA § 6(g) exemption for the manufacture (including import), processing, distribution in commerce, and industrial and commercial use of TCE as a solvent in closed loop vapor degreasing necessary for human-rated rocket engine cleaning by the National Aeronautics and Space Administration (NASA) and its contractors; and
  - A 10-year TSCA § 6(g) exemption for the emergency industrial and commercial use of TCE in furtherance of the NASA mission for specific conditions that are critical or essential and for which there is no feasible alternative.
- A WCPP would be required for time-limited exemptions

- The proposed rule does not include a *de minimis* exception for TCE; it does exclude some production as byproduct.
- EPA requests comment on whether it should consider a *de minimis* level of TCE in formulations to account for impurities (e.g., 0.1% or 0.5%) when finalizing the prohibitions on TCE industrial and commercial use and distribution in commerce as well as on manufacturing, processing, and distribution in commerce for consumer use.
- If EPA should consider a *de minimis* level of TCE in formulations to account for impurities, EPA requests information on, and rationale for, any level that should be considered *de minimis*.

# Alternatives Assessment

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- Given EPA's conclusion that most users will never be able to achieve the ECEL, clearly great effort would be required to meet the TSCA § 6(c) mandate that if a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must consider "whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute."
- Here, EPA proposes eliminating over time the entire TCE market, including uses for HFC-134a, vapor degreasing and brake cleaning that originated decades ago and continue to be important.
- There are 258,000 independent (mom and pop) auto repair shops. These are small businesses and for the most part they do brake cleaning. Given sources of flame/spark, some rely on TCE as a nonflammable alternative.
- EPA's economic analysis, however, completely fails to quantify the impact on the economy of prohibiting such uses.

- EPA identified several hundred commercially available alternative products that do not contain TCE and listed them in the Alternatives Assessment.
- The analysis is intended “to enable EPA to compare the human health hazards, environmental hazards, potential persistence, and bioaccumulative properties of each chemical for each product in each product category,” an exercise of no practical utility if the alternatives considered do not perform the functions for which TCE is used. The discussion is limited to a comparison of hazards and physical properties, not an evaluation of the actual feasibility of replacement. On this critical point the analysis—essentially a list comparing physical characteristics and health effects of potential alternatives—is silent.
- EPA’s Alternatives Analysis does not address the fundamental question of whether the alternatives identified are “reasonably available” “technically and economically feasible alternatives.” Indeed, it acknowledges that:
  - “EPA did not find it practicable to consider alternative processes that may be reasonably available as a substitute for processes involving TCE when the proposed prohibitions or restrictions would take effect. . . .”

... This is due to numerous considerations including uncertainties about alternative processes that may be reasonably available, the difficulty of ascertaining whether any alternative processes may be technically and economically feasible, and the challenges of comparing the benefits of alternative processes to the benefits of the TCE-containing processes.”

- Many small business participants at the SBAR submitted information demonstrating that TCE-based formulations are more efficient products than alternatives. Equally, they submitted information demonstrating that the alternatives available do not work as effectively. Only by ignoring these submissions was EPA able to conclude, incorrectly, that alternative products are technically and economically feasible.
- Additionally, EPA did not assess the impact limited water availability and its high cost of use, due to disruptions in the water supply and drought restrictions/regulations, could have on alternatives to TCE.

- Again, however, EPA punted on this analysis:
  - “For some applications, there may be additional unquantified costs associated with the alternatives or in cases where alternatives are not currently available. . . . in some cases some effort might be required by firms using TCE products to identify suitable alternatives, test them for their desired applications, learn how to use them safely and effectively, and implement new processes for using the alternative products. The information to estimate how often these costs might be incurred or what the specific costs would be per-user or per-firm when they are incurred is not available. Therefore, EPA is unable to consider these costs quantitatively.”
- TSCA § 6(c) provides that if a regulation would operate “in a manner that substantially prevents a specific condition of use of a chemical,” EPA must consider “whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute.” Here EPA proposes to eliminate all TCE uses, but EPA’s economic analysis fails to consider the impact on American manufacturing competitiveness of banning such uses.

- EPA has not met the requirements of TSCA § 9, which requires EPA to consult and coordinate with other federal agencies “for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes.”
- EPA says it has coordinated with OSHA on the proposed TCE rule, including to identify respective authorities, jurisdictions, and existing laws regarding TCE. EPA states that gaps exist between OSHA authority to set workplace standards under the OSH Act and EPA’s obligations under TSCA § 6.
- But worker health and safety falls under the jurisdiction of the federal OSHA, and use of TCE is already adequately regulated under the OSH Act. This comprehensive regulatory framework provides adequate protections with respect to the same potential adverse impacts and potential exposure pathways targeted by the current EPA initiative. Taking steps that may lead to the removal of products from the marketplace because workers or consumers failed to comply with these existing requirements is not consistent with TSCA either as initially enacted or as revised by the Lautenberg Act.
- Legislative history supports the position that TSCA was intended to fill gaps in regulation, not to supplant existing regulatory frameworks.

- The proposal clearly discriminates against small businesses. Where other long-term options are available, including WCPPs which EPA would allow for long-term phaseout and exemption periods, it is inconsistent with TSCA for EPA to conclude it “does not believe that long-term implementation of the WCPP would be a feasible means of addressing unreasonable risk indefinitely; thus prohibition of the use of TCE for affected COUs is ultimately necessary to address the risk so that it is no longer unreasonable.”
- EPA’s uncertainty as to whether most users can comply with its ECEL is not a sufficient reason to eliminate any compliance option for users, most of which are small businesses. The only justification for such a ban is that it would present an “unreasonable risk” that EPA “does not believe” is feasibly addressed through long-term WCPPs, though these same WCPPs are allowed for long-term phaseout and exemption periods.
- The proposed definition of “retailer” would also make it impossible for most small businesses to obtain product, as sales would be restricted solely to commercial suppliers.

- The comment deadline is December 15. Commenters may want to describe in detail:
  - their uses of TCE and the importance of these uses;
  - engineering controls employed to limit exposure;
  - compliance programs already in place for OSHA;
  - industrial hygiene monitoring results;
  - technical challenges in complying with ECEL or transitioning to an alternative; and
  - the dates by which compliance or transition to an alternative would be possible.

# Commercial TCE Uses Proposed to be Banned

- Use as a solvent for:
  - open-top batch vapor degreasing;
  - closed-loop vapor degreasing;
  - in-line conveyORIZED vapor degreasing;
  - in-line web cleaner vapor degreasing;
  - cold cleaning;
  - aerosol spray degreaser/cleaner and mold release
- Use as a lubricant and grease in:
  - tap and die fluid;
  - penetrating lubricant;
- Use as an adhesive and sealant in:
  - solvent-based adhesives and sealants; tire repair cement/sealer; and mirror edge sealant;
- Use as a functional fluid in:
  - heat exchange fluid;

- Use as a processing aid for:
  - battery separator manufacturing and for the manufacturing of specialty polymeric microporous sheet materials; process solvent used in polymer fabric spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactum manufacture; and precipitant used in beta-cyclodextrin manufacture
- Use in:
  - paints and coatings as a diluent in solvent-based paints and coatings;
  - cleaning and furniture care products in carpet cleaner and wipe cleaning;
  - laundry and dishwashing products in spot remover;
  - arts, crafts, and hobby materials in fixatives and finishing spray coatings;
  - corrosion inhibitors and anti-scaling agents;
  - ink, toner and colorant products in toner aid;
  - automotive care products in brake parts cleaner
  - apparel and footwear care products in shoe polish;
  - hoof polish; gun scrubber; pepper spray; and other miscellaneous industrial and commercial uses