



**EPA's Proposed Risk Management of
Perchloroethylene Under the Toxic Substances
Control Act (TSCA)
88 Fed. Reg. 39652 (June 16, 2023)**

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Highlights of Proposed Rule

- EPA proposes to ban 43 industrial, commercial, and consumer conditions of use.
- EPA estimates that the ban would account for about one-fifth of the total annual production volume of perc.
- For the following conditions of use, EPA proposes implementation of a Workplace Chemical Protection Plan (WCPP) as an alternative to a ban:
 - Manufacturing (domestic manufacturing);
 - Manufacturing (import);
 - Processing as a reactant/intermediate;
 - Processing into formulation, mixture, or reaction product in cleaning and degreasing products;
 - Processing into formulation, mixture, or reaction products in paint and coating products;
 - Processing into formulation, mixture, or reaction products in adhesive and sealant products;

Highlights of Proposed Rule, cont.

- Processing by 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 as solvent for in-line conveyORIZED vapor degreasing;
- Industrial and commercial use as solvent for in-line web cleaner vapor degreasing;
- Industrial and commercial use in maskant for chemical milling;
- Industrial and commercial use in solvent-based adhesives and sealants; and
- Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing.

- WCPPs must have an existing chemical exposure limit (ECEL) of 0.14 ppm (8-hour time-weighted average (TWA)).
- Compare this to other limits in effect:
 - OSHA PEL 100 ppm (8-hour TWA)
 - ACGIH Threshold Limit Value 25 ppm (8-hour TWA); 100 ppm (15-minute STEL)
 - Cal/OSHA PEL 25 ppm (8-hour TWA)
- Obviously, many firms in compliance with the OSHA standard will be unable to meet the proposed ECEL. Indeed, EPA assumes that the 24 workplace conditions of use it proposes to ban will not be able to achieve the proposed ECEL. Thus, EPA apparently intends that any workplace in the banned categories may no longer use perc even if it can show compliance with the much lower limits.
- WCPPs must also include requirements on exposure limits, regulated areas, exposure monitoring, methods of compliance, respiratory and dermal protection, and training.

- How does EPA justify a value 99.86% lower than the existing OSHA limit?
- The ECEL value of 0.14 ppm is intended to protect workers against cancer and neurotoxicity risks.
- Major epidemiology studies of thousands of workers exposed to perc for decades at U.S. dry cleaning facilities have shown no overall increased cancer risk. The final Risk Evaluation itself recognizes the weakness of the association:
 - “There is a pattern of epidemiological evidence associating PCE exposure with NHL. There is some evidence for bladder cancer and multiple myeloma (MM) but results are mixed. Additional epidemiological data were available showing weaker support for cancers at other sites, including esophageal, lung, and blood (lymphoma). Studies provide more limited support for associations with breast cancer, with little or no support for associations with kidney, esophagus, or liver cancer, and no useful information for cervical cancer.”
- Although it concluded that there was little or no support for an association of perc with liver cancer, that is the endpoint EPA relied upon.

- EPA's Science Advisory Committee on Chemicals (SACC), in its peer review of the draft Risk Evaluation, did not agree with EPA's interpretation of the proposed liver tumor mode of action (MOA) and felt that "the supportive evidence for some of the proposed mouse liver cancer MOA was minimal and/or circumstantial." The final report of the SACC peer review also states that "the evidence for genotoxicity in the mouse liver stemming from PCE exposure was not convincing to most Committee members."
- Perc appears to produce mouse liver tumors through the activation of the nuclear receptor, peroxisome proliferator-activated receptor alpha (PPAR α). It is generally accepted by experts in liver carcinogenesis that an increase in rodent liver tumors by a PPAR α MOA does not indicate human cancer risk.
- Nevertheless, EPA dismissed PPAR α activation as the primary MOA for perc-induced mouse liver tumors.

- EPA derived the 0.14 ppm ECEL value by averaging the Lowest-Observed-Adverse-Effect Level (LOAEL) from two studies that investigated perc neurotoxicity in workers at dry cleaning facilities.
- EPA concluded that “based on numerous identified functional outcomes in human studies supported by both clinical and mechanistic findings in animals, neurotoxicity following PCE exposure is supported by the weight of the scientific evidence.”
- Overall, the epidemiologic evidence suggests that high-level exposure (>40-50 ppm) to perc may be associated with subtle neurobehavioral effects such as color discrimination. The data on lower-level exposures are much more difficult to interpret. The subtle nature of these effects makes it difficult to tease out risks related to perc from those related to other factors.
- In light of the foregoing, EPA should not have determined that subtle behavioral effects at low levels of exposure to perc constitute unreasonable risk.

- TSCA § 6(g) provides for time-limited critical use exemptions in certain circumstances. Here, EPA proposes the following:
 - NASA Emergency Exemption: EPA proposes that use of perc by NASA and its contractors in an emergency be exempt from the requirements of the rule because it is a critical or essential use, provided that (i) there is an emergency; and (ii) NASA selected perc because there are no technically and economically feasible safer alternatives available during the emergency. NASA would have to comply with the WCPP during the emergency, to the extent feasible. This would be a ten-year exemption.
 - Spaceflight Exemption: EPA proposes a ten-year exemption for emergency use of perc in furtherance of NASA's mission for the following specific conditions of use: Industrial and commercial use as solvent for cold cleaning; Industrial and commercial use in wipe cleaning. EPA is also proposing to include additional requirements as part of the exemption, including required notification and controls for exposure. EPA specifically references NASA but does not address other spaceflight operators such as SpaceX or Blue Origin. NASA would have to comply with the WCPP during the emergency, to the extent feasible.

- One improvement over the methylene chloride proposal is inclusion of a *de minimis* exception for products containing less than 0.1% of perc. EPA states that: “[F]or most industrial/commercial and consumer conditions of use, the concentration limit of less than 0.1% is so low that it is highly unlikely that perc would still serve its functional purpose in the product or formulation. EPA thus concluded that a weight fraction would essentially function as a prohibition for most industrial/commercial and consumer conditions of use.”
- Nevertheless, this exception, which is based on a similar provision for carcinogens in the OSHA Hazard Communication Standard, may be important for certain formulations.

Alternatives Assessment

- 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 to eliminate uses constituting most of the perc market, including uses such as vapor degreasing and aerosol 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, they rely on perc as a nonflammable alternative.
- EPA's economic analysis, however, completely fails to consider the impact on the economy of eliminating such uses by adopting a workplace limit a thousand times lower than those in other countries.

- EPA identified several hundred commercially available alternative products that do not contain perc, 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 perc 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 PCE 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 PCE-containing processes.”
- Many small business participants at the SBAR submitted information demonstrating that perc-based formulations are the most efficient products available. Equally, they submitted information demonstrating that the alternatives available do not work effectively. Only by ignoring these submissions was EPA able to conclude, incorrectly, that alternative products are technically and economically feasible.
- EPA did not assess the comparative fire risks of perc-based products and alternatives, nor address concerns about their fire risk and overall safety.
 - One SBAR participant noted that during testing of alternatives employees experienced contact dermatitis, rashes, and allergic reactions, several quite severe.
 - A participant located on the West Coast noted that limited water availability and its high cost of use, due to disruptions in the water supply and drought restrictions/regulations, make water undesirable as a potential alternative to perc.

- Again, however, EPA punted on this analysis:
 - “Except for liquid and batch spray cold cleaning and dry cleaning machines, no cost impacts are estimated for users of products that contain PCE who will need to switch to alternative products that do not contain PCE (e.g., PCE aerosol spray cleaners and degreasers). . . in some cases some effort might be required by firms using PCE 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 in the Economic Analysis.”
- 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 uses constituting much of the perc market. EPA’s economic analysis, however, completely fails to consider the impact on American manufacturing competitiveness of banning such uses.

- For dry cleaning, EPA proposes a phaseout of perc use, as follows:
 - “EPA is proposing to prohibit the manufacturing, processing, distribution in commerce, and industrial and commercial use of PCE for dry cleaning and spot cleaning, including in 3rd generation (dry-to-dry machines with refrigerated condenser) and 4th/5th generation (dry-to-dry machines with refrigerated condenser and carbon adsorber process controls) machines.
 - The phaseout would start with a prohibition on the use of perc in any dry cleaning machine acquired 6 months or later after the publication date of the rule, followed by a prohibition on the use of perc in 3rd generation machines 3 years after the publication date of the rule. Full implementation of the phaseout would be achieved with a prohibition on the use of perc in all dry cleaning and spot cleaning, including in 4th and 5th generation machines.
- Such a prohibition is unnecessary; as documented by the exposure information submitted by New York State, dry cleaners using 4th or 5th generation machines achieve remarkably low perc concentration levels over an 8-hour averaging period.

- There is support for requiring that perc be used in dry cleaning only in 4th and 5th generation machines. This requirement should be in place for 15 years after the publication date of the final rule to ensure consistency with EPA's Dry Cleaning NESHAP finding that such equipment has a useful life of 15 years.
- At the end of 15 years, dry cleaners that can monitor and comply with the ECEL should be able to continue to use perc in compliance with a WCPP. Having determined that compliance with WCPPs eliminates unreasonable risk, there is no justification for a time limit on such compliant use: once such a WCPP is implemented, the unreasonable risk asserted by EPA has been eliminated.
- EPA should carefully consider the exposure data made available by New York State which has been submitted to the docket.

- 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.” Worker health and safety falls under the jurisdiction of the federal OSHA, and use of perc 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 options are available to regulate “to the extent necessary so that chemical no longer presents such risk,” it is inconsistent with TSCA for EPA to conclude: “The uncertainties related to whether users under certain conditions of use could comply with the requirements of a PCE WCPP, combined with the severity of the risks of PCE, the prevalence of alternative processes and products (Unit V.B), and in some cases reasonably available information indicating a use is no longer ongoing (Refs. 56, 3), has led EPA to propose prohibitions for most industrial and commercial uses of PCE. . . .”
- HSIA submits that EPA’s “uncertainty” as to whether most users can comply with its ECEL is not a sufficient reason to eliminate any compliance option for these users, most of which are small businesses. The only justification for such a ban is that it would present an “unreasonable risk,” which EPA has determined is not present where the user is in compliance with a WCPP.
- 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 August 15. Commenters may want to describe in detail:
 - their uses of perc 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 transitioning to an alternative; and
 - the dates by which transition to an alternative would be possible.

Commercial Uses Proposed to be Banned

- As a 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;
- As solvent for aerosol spray degreaser/cleaner;
- As solvent for cold cleaning;
- In other textile processing;
- In wood furniture manufacturing;
- As a 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 a 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); and
- In metal mold cleaning, release and protectant products.
- The upstream processing condition of use for some of the prohibited uses: processing into formulation, mixture or reaction product in other chemical products and preparations.

Consumer Uses Proposed to be Banned, cont.

- In cleaners and degreasers (other);
- In automotive care products (brake cleaner);
- In automotive care products (parts cleaner);
- In aerosol cleaner (vandalism mark and stain remover);
- In non-aerosol cleaner (e.g., marble and stone polish);
- In lubricants and greases (cutting fluid);
- In lubricants and greases (lubricants and penetrating oils);
- In adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive, gun ammunition sealant);
- In adhesives for arts and crafts (livestock grooming adhesive);
- In adhesives for arts and crafts (column adhesive, caulk and sealant);
- In solvent-based paints and coatings (outdoor water shield (liquid));
- In solvent-based paints and coatings (coatings and primers (aerosol));

Consumer Uses Proposed to be Banned, cont.

- In solvent-based paints and coatings (rust primer and sealant (liquid));
- In solvent-based paints and coatings (metallic overglaze);
- In metal (e.g., stainless steel) and stone polishes;
- In inks and ink removal products;
- In welding; and
- In metal mold cleaning, release and protectant products.