

Environmental Justice Consultation Fact Sheet:

Proposed Rulemaking Under TSCA Section 6(a) for Perchloroethylene

Background Information for this Consultation

EPA is developing proposed regulations under section 6(a) of the Toxic Substances Control Act (TSCA) to address the unreasonable risk presented by perchloroethylene (PCE) under the conditions of use. EPA made the determination of unreasonable risk in the final risk evaluation for PCE, completed in December 2020. EPA is initiating this action to address the unreasonable risks presented by PCE.

EPA is seeking input from communities during this consultation and encourages participation and comments to inform EPA's upcoming proposed regulation. Input from all stakeholders is critical to the risk management process. EPA is committed to developing risk management actions for chemicals in a way that is transparent and includes proactive, meaningful outreach and education with the public and other stakeholders.

While outreach and stakeholder engagement on risk management activities for this chemical will continue to move forward, EPA is actively reviewing the final risk evaluation to ensure it uses the best available science and protects human health and the environment, in accordance with the Executive Orders and other direction provided by the Biden-Harris Administration. The Agency will keep stakeholders updated as decisions are made, and next steps are determined.

PCE and EPA's Risk Evaluation

PCE has a wide range of uses, including production of fluorinated compounds and as a solvent in dry cleaning and vapor degreasing. There are also a variety of consumer and commercial products that contain PCE, such as adhesives (arts and crafts, as well as light repairs), aerosol degreasers, brake cleaners, aerosol lubricants, sealants, stone polish, stainless steel polish, and wipe cleaners.

EPA evaluated 61 conditions of use of PCE, and, in the final risk evaluation published on December 18, 2020, determined that 59 conditions of use present an unreasonable risk. This includes unreasonable risks to workers and occupational non-users when domestically manufacturing or importing the chemical; processing the chemical for a variety of uses; and when used in a variety of industrial and commercial applications. This also includes unreasonable risks to consumers from all consumer uses, and when exposed to dry cleaned articles, and to bystanders for most consumer uses.

For risks to the environment, EPA assessed PCE exposures to aquatic organisms and has determined that PCE does not present an unreasonable risk of injury to the environment from all conditions of use, based on the risk estimates, the environmental effects of PCE, the exposures, physical-chemical properties of PCE, and consideration of uncertainties.

For the conditions of use found to present an unreasonable risk of injury to human health, EPA's determination is based on unreasonable risks of injury to workers and occupational non-users

during occupational exposures, and to consumers and bystanders during exposures to consumer use.

EPA found that there was unreasonable risk of neurotoxicity (changes in visual contrast detection) from acute (single-day) inhalation and dermal (through the skin) exposures, and neurotoxicity (changes in color discrimination and alteration in visual-spatial functions) and cancer from chronic (long-term) inhalation and dermal exposures to PCE.

The conditions of use with unreasonable risks include manufacturing (including import); processing as a reactant or intermediate and incorporation into a formulation, mixture or reaction product; repackaging and recycling; a variety of industrial and commercial uses, including several types of degreasing uses, lubricants, adhesives, paints and coatings, automotive care products, metal and stone polishes, welding, textile processing, use in wood furniture manufacturing, foundry application, use by Department of Defense for oil analysis and water pipe repair, and various dry cleaning-related uses; and all consumer uses including exposure to dry cleaned articles.

The risk evaluation was conducted pursuant to TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to evaluate the manufacture (including import), processing, distribution in commerce, use, and disposal of existing chemical substances and identify those conditions of use which present unreasonable risks to health or the environment. Public comments on and external scientific peer review of the draft risk evaluation¹ informed the development of the final risk evaluation. The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0502, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0732, on www.regulations.gov. More information about the final risk evaluation is at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-perchloroethylene>.

Unreasonable Risks

EPA's unreasonable risk determinations for conditions of use of PCE are based on unreasonable risk of injury to health for workers and occupational non-users during occupational exposures, and for consumers and bystanders during exposures to consumer use. EPA's unreasonable risk determination is due to neurotoxicity from acute inhalation and dermal exposures, non-cancer neurotoxic effects from chronic inhalation and dermal exposure, and cancer from chronic inhalation and dermal exposures to PCE.

The list below shows the conditions of use of PCE that EPA has determined present an unreasonable risk of injury to human health.

¹ In 2016, the Office of Pollution Prevention and Toxics (OPPT) identified and selected PCE as one of the first 10 chemicals for risk evaluation under section 6 of TSCA. EPA published the scope of the risk evaluation document in June 2017, the PCE problem formulation document in May 2018, and the PCE draft risk evaluation in April 2020. EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of PCE on May 26-29, 2020.

Conditions of Use of PCE that Present an Unreasonable Risk

Manufacturing that Presents an Unreasonable Risk

- Manufacturing (domestic manufacturing)
- Manufacturing (import)

Processing that Present an Unreasonable Risk

- As a reactant/intermediate
- Incorporation into formulation, mixture or reaction product in cleaning and degreasing products
- Incorporation into formulation, mixture or reaction product in adhesive and sealant products
- Incorporation into formulation, mixture or reaction product in paint and coating products
- Incorporation into formulation, mixture or reaction product in other chemical products and preparations
- Repackaging
- Recycling

Industrial and Commercial Uses that Present an Unreasonable Risk

- Industrial and commercial use as solvent for open-top batch vapor degreaser
- Industrial and commercial use as solvent for closed-loop batch vapor degreaser
- Industrial and commercial use as solvent for in-line conveyORIZED vapor degreaser
- Industrial and commercial use as solvent for in-line web cleaner vapor degreaser
- Industrial and commercial use as solvent for cold cleaning
- Industrial and commercial use as solvent for aerosol spray degreaser/cleaner
- Industrial and commercial use as a lubricant and grease in aerosol lubricants
- Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants
- Industrial and commercial use in paints and coatings as solvent-based paints and coatings
- Industrial and commercial use in paints and coatings as a maskant for chemical milling
- Industrial and commercial use as a processing aid in pesticide, fertilizer and other agricultural chemical manufacturing
- Industrial and commercial use as a processing aid in catalyst regeneration in petrochemical manufacturing
- Industrial and commercial use in cleaning and furniture care products in wipe cleaning
- Industrial and commercial use in cleaning and furniture care products in other spot cleaning and spot removers, including carpet cleaning

- Industrial and commercial use in cleaning and furniture care products for mold release
- Industrial and commercial use in cleaning and furniture care products in dry cleaning and spot cleaning post-2006 dry cleaning
- Industrial and commercial use in cleaning and furniture care products in dry cleaning and spot cleaning 4th/5th gen only dry cleaning
- Industrial and commercial use in cleaning and furniture care products in automotive care products (e.g., engine degreaser and brake cleaner)
- Industrial and commercial use in cleaning and furniture care products in non-aerosol cleaner
- Industrial and commercial use in metal (e.g., stainless steel) and stone polishes
- Industrial and commercial use in laboratory chemicals
- Industrial and commercial use in welding
- Industrial and commercial use in other textile processing
- Industrial and commercial use in wood furniture manufacturing
- Industrial and commercial use in foundry applications
- Industrial and commercial use in specialty Department of Defense uses (oil analysis and water pipe repair)
- Commercial use in inks and ink removal products (based on printing)
- Commercial use in inks and ink removal products (based on photocopying)
- Commercial use for photographic film
- Commercial use in mold cleaning, release and protectant products

Consumer Uses that Present an Unreasonable Risk

- Consumer use in cleaning and furniture care products in cleaners and degreasers (other)
- Consumer use in cleaning and furniture care products in dry cleaning solvent
- Consumer use in cleaning and furniture care products in automotive care products (brake cleaner)
- Consumer use in cleaning and furniture care products in automotive care products (parts cleaner)
- Consumer use in cleaning and furniture care products in aerosol cleaner (vandalism mark and stain remover)
- Consumer use in cleaning and furniture care products in non-aerosol cleaner (e.g., marble and stone polish)
- Consumer use in lubricants and greases (cutting oils)
- Consumer use in lubricants and greases (lubricants and penetrating oils)
- Consumer use in adhesives for arts and crafts (including industrial adhesive, arts and crafts adhesive, gun ammunition sealant)
- Consumer use in adhesives for arts and crafts (livestock grooming adhesive)

- Consumer use in adhesives for arts and crafts (column adhesive, caulk and sealant)
- Consumer use in paints and coatings as solvent-based paints and coatings (outdoor water shield (liquid))
- Consumer use in paints and coatings as solvent-based paints and coatings (coatings and primers (aerosol))
- Consumer use in paints and coatings as solvent-based paints and coatings (rust primer and sealant (liquid))
- Consumer use in paints and coatings as solvent-based paints and coatings (metallic overglaze)
- Consumer use in metal (e.g., stainless steel) and stone polishes
- Consumer use in inks and ink removal products
- Consumer use in welding
- Consumer use in mold cleaning, release and protectant products

Disposal that Presents an Unreasonable Risk
<ul style="list-style-type: none"> • Disposal

Reason for This Action

Section 6 of TSCA requires EPA to address unreasonable risks that EPA has determined are presented by a chemical substance under the conditions of use. The risk evaluation was conducted pursuant to TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to evaluate the manufacture (including import), processing, distribution in commerce, use, and disposal of existing chemical substances and identify those conditions of use that present unreasonable risks to health or the environment. Following a risk evaluation carried out under the authority of TSCA section 6, EPA has determined that PCE presents an unreasonable risk of injury to health.

EPA is now moving to risk management for PCE, the next step in the process required by TSCA. With stakeholder input, EPA is developing ways to address the unreasonable risks identified and has up to one year to propose and take public comments on risk management actions.

Risk Mitigation Approaches Under Section 6

Under TSCA section 6(a), 15 U.S.C. § 2605(a), “If the Administrator determines ... that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk.”

The table below summarizes regulatory options available under TSCA section 6(a).

The proposed regulation under development would address the unreasonable risk presented by PCE under each condition of use listed above. EPA is currently in the early stages of the rulemaking process and is interested in receiving information during this consultation to inform the development of regulatory options.

Options under TSCA Section 6(a)

TSCA Section	Option
6(a)(1)	A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.
6(a)(2)	A requirement (A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.
6(a)(3)	A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.
6(a)(4)	A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.
6(a)(5)	A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.
6(a)(6)	(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.
6(a)(7)	A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Potential Environmental Justice Impacts

EPA recognizes that decisions concerning TSCA section 6(a) regulations have consequences for stakeholders concerned about environmental justice issues. Environmental justice communities may be affected to the extent that individuals in these communities engage in the processing, industrial uses, commercial uses and disposal of PCE that EPA determined present an unreasonable risk.

In addition to general comments, EPA requests input on any disproportionate public health or economic impacts that the unreasonable risks presented by PCE may have in the context of environmental justice issues.

Opportunity for Participation in Environmental Justice Consultation

E.O. 12898 aims to focus federal attention on the environmental and human health effects of federal actions on minority and low-income populations with the goal of achieving environmental protection for all communities. During this consultation process, EPA invites members of the public and national, local and non-governmental organizations, communities, and other interested stakeholders to participate in this process by attending the consultation sessions and providing written comments. After the conclusion of the Environmental Justice consultation process, all stakeholders are encouraged to also participate in the public comment process.

Additional Outreach

There are several opportunities for public and stakeholder engagement throughout the risk management process. This includes required consultations with certain groups, public meetings/webinars, one-on-one meetings with stakeholders, and public comment periods.

EPA is carrying out engagement opportunities in compliance with several executive orders. Some consultations will be open to the public, and in the interest of promoting transparency and encouraging participation, the dates and point of contacts for those consultation meetings will be listed on <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities>.

Also, in support of EPA's commitment to implementing TSCA in an open and transparent manner, the Agency has organized webinars on current risk management activities, including rulemakings such as this one. The purpose of these stakeholder engagement events is to educate stakeholders on various proposals, announcements, or policy decisions, as well as to provide a forum for the public to provide feedback or input during the risk management process.

EPA also holds meetings with stakeholders to educate them about TSCA implementation, listen to feedback, and obtain information that will benefit EPA's work. Finally, as part of the rulemaking process, EPA will solicit and obtain comments on proposed rules. To do this, the Agency will open a public comment period for each proposed rule. These public comment periods relevant to TSCA implementation are announced by the Agency through press releases/listservs and by publication in the Federal Register.

Additional Information

For more information on this consultation or the rulemaking under TSCA section 6 for PCE contact: Amanda Hauff, Office of Chemical Safety and Pollution Prevention's National Environmental Justice Program Manager, hauff.amanda@epa.gov, 202-566-0603 or Kelly Summers, Office of Pollution Prevention and Toxics, summers.kelly@epa.gov, 202-564-2201.

Risk management and upcoming outreach for PCE:

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-perchloroethylene>

PCE Final Risk Evaluation: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-perchloroethylene>

U.S. EPA Nontechnical Summary of the Risk Evaluation for PCE:

https://www.epa.gov/sites/production/files/2020-12/documents/pce.nontechnical_summary_12102020_0.pdf