Environmental Justice Consultation Fact Sheet:

Proposed Rulemaking Under TSCA Section 6(a) for Trichloroethylene (TCE)

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 trichloroethylene (TCE) under the conditions of use. EPA made the determination of unreasonable risk in the final risk evaluation for TCE, completed in November 2020. EPA is initiating this action to address the unreasonable risks presented by TCE.

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.

TCE and EPA's Risk Evaluation

TCE has a wide range of uses, including as a solvent in vapor degreasing, as a processing aid, and in paints and coatings. A variety of consumer and commercial products use TCE as a solvent in adhesives and sealants, paints and coatings, automotive care products, and cleaning and furniture care products.

EPA evaluated 54 conditions of use of TCE, and, in the final risk evaluation published on November 24, 2020, determined that 52 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 and bystanders for most consumer uses.

For risk to the environment, the Agency assessed the impact of TCE on aquatic and sediment-dwelling organisms through surface water and sediment exposures, and to terrestrial organisms. After reviewing this data, EPA found no unreasonable risk to the environment.

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/or to consumers and bystanders during exposures to consumer use.

EPA found that there was unreasonable risk of immunosuppression effects (suppression of the body's immune system and its ability to fight infections and other diseases) from acute (single-day) inhalation and dermal (through the skin) exposures, and autoimmunity effects (when the body's natural defense system against disease targets and attacks one's own cells instead of only foreign cells or viruses) and cancer from chronic (long-term) inhalation and dermal exposures.

The conditions of use for which unreasonable risks were found include manufacturing (including import), processing into a formulation, industrial and commercial uses such as solvents for degreasing and cleaning, and consumer uses such as in cleaning and furniture care products. EPA determined that two conditions of use did not present an unreasonable risk (distribution in commerce and consumer use of TCE in pepper spray).

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 evaluation informed the development of the final risk evaluation. The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0500, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0737, on www.regulations.gov. More information about the final risk evaluation is at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-trichloroethylene-tce-0.

Unreasonable Risks

EPA's unreasonable risk determinations for conditions of use of TCE 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 immunosuppression effects from acute inhalation and dermal exposures and autoimmunity effects and cancer from chronic inhalation and dermal exposures to TCE.

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

Conditions of Use of TCE that Present an Unreasonable Risk

Manufacturing that Presents an Unreasonable Risk

• Manufacturing: domestic manufacture

• Manufacturing: import

¹ In 2016, the Office of Pollution Prevention and Toxics (OPPT) identified and selected TCE 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 TCE problem formulation document in May 2018, and the TCE draft risk evaluation in February 2020. EPA held a peer review meeting of the Science Advisor Committee on Chemicals (SACC) on the draft risk evaluation of TCE on March 24-27, 2020.

Processing that Present an Unreasonable Risk

- Processing: processing as a reactant/intermediate
- Processing: incorporation into a formulation, mixture or reaction product
- Processing: incorporation into articles
- Processing: repackaging
- Processing: recycling

Industrial and Commercial Uses that Present an Unreasonable Risk

- Industrial and commercial use as a solvent for open-top batch vapor degreasing
- Industrial and commercial use as a solvent for closed-loop batch vapor degreasing
- Industrial and commercial use as a solvent for in-line conveyorized vapor degreasing
- Industrial and commercial use as a solvent for in-line web cleaner vapor degreasing
- Industrial and commercial use as a solvent for cold cleaning
- Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release
- Industrial and commercial use as a lubricant and grease in tap and die fluid
- Industrial and commercial use as a lubricant and grease in penetrating lubricant
- Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants; tire repair cement/sealer; mirror edge sealant
- Industrial and commercial use as a functional fluid in heat exchange fluid
- Industrial and commercial use in paints and coatings as a diluent in solvent-based paints and coatings
- Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning
- Industrial and commercial use in laundry and dishwashing products in spot remover
- Industrial and commercial use in arts, crafts, and hobby materials in fixatives and finishing spray coatings
- Industrial and commercial use in corrosion inhibitors and anti-scaling agents.
- Industrial and commercial use as processing aids in process solvent used in battery manufacture; process solvent used in polymer fiber spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture
- Industrial and commercial use as ink, toner and colorant products in toner aid
- Industrial and commercial use in automotive care products in brake parts cleaner
- Industrial and commercial use in apparel and footwear care products in shoe polish
- Industrial and commercial use in hoof polish; gun scrubber; pepper spray; other miscellaneous industrial and commercial uses

Consumer Uses that Present an Unreasonable Risk

- Consumer use as a solvent in brake and parts cleaner
- Consumer use as a solvent in aerosol electronic degreaser/cleaner

- Consumer use as a solvent in liquid electronic degreaser/cleaner
- Consumer use as a solvent in aerosol spray degreaser/cleaner
- Consumer use as a solvent in liquid degreaser/cleaner
- Consumer use as a solvent in aerosol gun scrubber
- Consumer use as a solvent in liquid gun scrubber
- Consumer use as a solvent in mold release
- Consumer use as a solvent in aerosol tire cleaner
- Consumer use as a solvent in liquid tire cleaner
- Consumer use as a lubricant and grease in tap and die fluid
- Consumer use as a lubricant and grease in penetrating lubricant
- Consumer use as an adhesive and sealant in solvent-based adhesives and sealants
- Consumer use as an adhesive and sealant in mirror edge sealant
- Consumer use as an adhesive and sealant in tire repair cement/sealer
- Consumer use as a cleaning and furniture care product in carpet cleaner
- Consumer use as a cleaning and furniture care product in aerosol spot remover
- Consumer use as a cleaning and furniture care product in liquid spot remover
- Consumer use in arts, crafts, and hobby materials in fixative and finishing spray coatings
- Consumer use in apparel and footwear products in shoe polish
- Consumer use in fabric spray
- Consumer use in film cleaner
- Consumer use in hoof polish
- Consumer use in toner aid

Disposal that Presents an Unreasonable Risk

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 TCE presents an unreasonable risk of injury to health.

EPA is now moving to risk management for TCE, 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 TCE 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.

TSCA Section	Option
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 manufacturing, processing, industrial and commercial uses as well as disposal of TCE 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 TCE 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 TCE contact: Amanda Hauff, Office of Chemical Safety and Pollution Prevention's National Environmental Justice Program Manager, hauff.amanda@epa.gov, 202-566-0603 or Katelan McNamara, Office of Pollution Prevention and Toxics, mcnamara.katelan@epa.gov, 202-564-4361.

Risk management and upcoming outreach for TCE: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-trichloroethylene-tce

TCE Final Risk Evaluation: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-trichloroethylene-tce-0

U.S. EPA Nontechnical Summary of the Risk Evaluation for TCE: https://www.epa.gov/sites/production/files/2020-11/documents/tce_nontechnical_summary_finalre.pdf