

Consultation Plan: Proposed Rulemaking under TSCA Section 6(a) for Trichloroethylene (TCE)

Background Information on this Initiative

The EPA is developing proposed regulations under Section 6(a) of the Toxic Substances Control Act (TSCA) for trichloroethylene (TCE) when used for commercial degreasing (open top vapor degreasing and spray degreasing), as a spotting agent in dry cleaning, and in some consumer products (spray degreasing and clear protective coating sprays).

TCE is used in industrial and commercial processes, and also has some limited uses in consumer products. The EPA identified and chose these chemicals for risk evaluation as part of EPA's TSCA Work Plan for Chemical Assessment.¹ Cancer and developmental toxicity effects are associated with certain uses of TCE.

Section 6(a) of TSCA provides authority for EPA to address risks resulting from the manufacture (including import), processing, distribution in commerce, use, and disposal of chemicals. Specifically, EPA will determine whether the continued use of TCE in commercial degreasing operations, use as a spotting agent in dry cleaning, and in certain consumer products pose an unreasonable risk to human health and the environment and what requirements may be necessary to protect against such risks.

1. Background on TCE

TCE is a volatile organic compound (VOC) and hazardous air pollutant (HAP) that is classified as a human carcinogen. TCE consumption in the United States is 255 million pounds (lbs) per year.² TCE is widely used in industrial and commercial processes, and also has some limited uses in consumer products. The majority (~83.6%) of TCE is used as an intermediate for manufacturing refrigerant chemicals (this use is not part of the TSCA Section 6(a) rulemaking). Much of the remainder (~14.7%) is used as a solvent for metals degreasing, leaving a relatively small percentage (~1.7%) to account for all other uses, including use in consumer products.

OPPT's final TCE risk assessment² evaluated human health risks to consumers and workers, including bystanders, from inhalation exposures. Single (acute) or short-term exposure can potentially affect the developing fetus. High acute concentrations of TCE vapors can irritate the respiratory system and skin and induce central nervous system (CNS) effects such as light-headedness, drowsiness, and headaches. Repeated (chronic) or prolonged exposure to TCE has been associated with adverse effects in the liver, kidneys, immune system, reproductive system, and central nervous system. EPA also has concerns for effects in the developing fetus from chronic exposure. Chronic TCE exposure is carcinogenic to humans by all routes of exposure.

¹ TSCA Work Plan Chemicals: <http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html>.

² Final TSCA Work Plan Chemical Risk Assessment of Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses: http://www.epa.gov/oppt/existingchemicals/pubs/TCE_OPPTWorkplanChemRA_FINAL_062414.pdf.

2. Reason for This Action

EPA is undertaking various regulatory and voluntary actions, including this action under TSCA Section 6(a), to adequately protect against these risks. The EPA's rationale for this rulemaking includes an assessment of the risks to human health, the availability of substitutes for these chemicals, and a need for regulation.

- **Risks to human health:** As discussed above, EPA's risk assessments found acute and chronic risks from the use of TCE.
- **Availability of substitutes:** The EPA's research to date indicates that effective and economically feasible substitute products for TCE are currently available.
- **Need for regulation:** Despite widespread acknowledgement of risk from the use of TCE, consumers and businesses continue to use products containing these chemicals.

4. The Proposed Regulation

Uses being considered for regulation under TSCA Section 6(a) are:

- Commercial use of TCE in open top vapor degreasing at commercial shops (both precision and non-precision cleaning).
- Consumer and commercial use of TCE in spray degreasers.
- Consumer use of TCE in clear protective coating sprays.
- Commercial use of TCE as a spotting agent in dry cleaning.

Table 1 below summarizes regulatory options available under TSCA Section 6(a).

Table 1: Options under TSCA Section 6(a)

TSCA Section	Option	Summary
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.	Prohibit or limit manufacture
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.	Prohibit or limit for particular use or above a set concentration
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.	Require warnings and instructions
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.	Require recordkeeping and testing
6(a)(5)	A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.	Prohibit or regulate manner or method of commercial use
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. ³	Prohibit or regulate manner or method of disposal
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.	Direct manufacturers/processors to give notice of risk and replace or repurchase

³ A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

Potential Impact to Tribes

The EPA recognizes that decisions concerning TSCA Section 6(a) regulations have consequences for Tribes. Tribes may be affected to the extent that tribal populations are exposed to TCE. Additionally, businesses in Indian Country using these products may be affected by any finalized regulations under TSCA Section 6(a).

In addition to general comments, EPA requests input on any disproportionate public health or economic impacts that TCE may have on tribal populations.

Opportunity for Tribes to Participate

The tribal consultation process establishes a timeline for government-to-government consultation and coordination. After the conclusion of the tribal consultation process, tribes may also participate in any public review and comment process.

Tribes may access related consultation information on the EPA Tribal Portal under Tribal Consultation Opportunities, located at: yosemite.epa.gov/oia/TConsultation.nsf/TC?OpenView.

More information on TCE is located at:
<http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html>.

The combined goal of all these efforts is to ensure there is sufficient information for tribal officials to make an informed decision about the desire to continue with consultation and to understand how to provide informed input.

Additional Information

US EPA TCE final risk assessment (June 2014):
http://www.epa.gov/oppt/existingchemicals/pubs/TCE_OPPTWorkplanChemRA_FINAL_062414.pdf

Expert Public Workshop on Alternatives and Risk Reduction Approaches to Trichloroethylene (July 2014): <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2014-0327-0001>