FINAL REPORT

of the

Small Business Advocacy Review Panel on

EPA's Planned Proposed Rule

Toxic Substances Control Act (TSCA)
Section 6(a)
for Trichloroethylene (TCE)

April 4, 2023

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1. INTRODUCTION

This report is presented by the Small Business Advocacy Review Panel (SBAR Panel or Panel) that convened to review the planned proposed rulemaking by the U.S. Environmental Protection Agency (EPA) under section 6(a) of the Toxic Substances Control Act (TSCA) to regulate trichloroethylene (TCE), which was the subject of a TSCA risk evaluation under section 6(b). Section 6 of TSCA requires that EPA issue regulations to address identified unreasonable risks resulting from the manufacture (including import), processing, distribution in commerce, or use of the chemical, as well as any manner or method of disposal of TCE. Section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), requires EPA to convene a Panel prior to publication of the initial regulatory flexibility analysis (IRFA) that EPA may be required to prepare under the RFA. In addition to EPA's Small Business Advocacy Chairperson, the Panel consists of the Deputy Director of the Office of Pollution Prevention and Toxics, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel for Advocacy of the Small Business Administration.

This report includes the following:

- Background information on the proposed rule being developed;
- Information on the types of small entities that may be subject to the proposed rule;
- A description of efforts made to obtain the advice and recommendations of representatives of those small entities; and
- A summary of the comments that have been received to date from those representatives.

Section 609(b) of the RFA directs the Panel to consult with and report on the comments of small entity representatives (SERs) and make findings on issues related to elements of an IRFA under section 603 of the RFA. Those elements of an IRFA are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of projected reporting, record keeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. This analysis shall discuss any significant alternatives such as:
    - the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
    - the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
    - the use of performance rather than design standards; and
    - an exemption from coverage of the rule, or any part thereof, for such small entities.

Once completed, the Panel report is provided to the agency issuing the proposed rule and is included in the rulemaking record. The agency is to consider the Panel's findings when completing the draft of the proposed rule. In light of the Panel report, and where appropriate, the agency is also to consider whether changes are needed to the IRFA for the proposed rule or the decision on whether an IRFA is required.

The Panel's findings and discussion are based on the information available at the time the final report is drafted. Given EPA's ongoing consideration of exposure pathways such as ambient air and drinking water to the general population and fenceline communities, there is a chance that some impacts of the proposed rulemaking may not have been fully considered by the Panel during its work. If EPA considers additional requirements impacting small businesses related to exposure pathways that were not presented to Small Entity Representatives (SERs) during the Panel Outreach meeting, then EPA will determine whether those additional requirements may have a significant impact on a substantial number of small entities. Under these unique circumstances, EPA would organize a supplemental opportunity for the Panel to consult with the SERs and additional small entities that might be significantly impacted prior the rule's proposal. EPA continues to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process.

Any options identified by the Panel for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, environmentally sound, and consistent with TSCA and its amendments.

2. BACKGROUND AND DESCRIPTION OF RULEMAKING

2.1 Risk Evaluation for TCE

In December 2016, EPA selected TCE as one of the first 10 chemicals for risk evaluation under section 6 of TSCA. EPA published the risk evaluation for TCE in November 2020. 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 conduct risk evaluations "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." EPA published the scope of the risk evaluation document[1] in July 2017 (82 FR 31592, July 7, 2017), the TCE problem formulation document[2] in June 2018 (83 FR 26998, June 11, 2018), and the TCE draft risk evaluation[3] in February 2020 (85 FR 11079, February 26, 2020). EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of TCE in March 2020. Public comments and external scientific peer review informed the development of the TCE risk evaluation[4] (85 FR 75010, November 24, 2020). With input from comments and peer review, EPA

[1] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0737-0057.

[2] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0737-0083.

[3] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0500-0002.

[4] Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0737-0127.

published a draft revision to the risk determination for the TCE risk evaluation in July 2022 (87 FR 40520, July 7, 2022)[5] and a final revision in January 2023 (88 FR 1222, January 9, 2023).

In the 2020 Risk Evaluation for TCE, EPA evaluated risks associated with 54 conditions of use within the following categories: manufacture (including import), processing, distribution in commerce, industrial and commercial use, consumer use, and disposal. The 2020 Risk Evaluation for TCE identified significant adverse health effects associated with exposure to TCE, including immunosuppression effects from acute inhalation and dermal exposures, autoimmunity effects from chronic inhalation and dermal exposures, and cancer effects from chronic inhalation and dermal exposures to TCE.

Small business may be regulated under all conditions of use that drive EPA's unreasonable risk determination for TCE. EPA's unreasonable risk determination for TCE is based on unreasonable risk of injury to health for workers, occupational non-users (ONUs) (workers who do not directly handle TCE but perform work in an area where TCE is present), and to consumers and bystanders to consumer use. EPA did not identify an unreasonable risk of injury to the environment from TCE under the conditions of use.

On June 30, 2021, EPA announced policy changes intended to enhance public trust, provide regulatory certainty, and ensure that all populations that may be exposed to the first ten priority chemical substances, including TCE, are protected from unreasonable risk. The policy changes announced that EPA intends to move forward by revisiting the risk evaluations for the first ten chemical substances within a narrow scope that is supported by science and the law, including:

- Consideration of exposure pathways such as ambient air and drinking water to the general population and fenceline communities;
- Revisiting the assumption that personal protective equipment (PPE) is always used in occupational settings when making a risk determination for a chemical. Rather, EPA will no longer assume that PPE is always used when determining whether a chemical substance presents unreasonable risk; and
- Making the determination of unreasonable risk for the whole chemical rather than on a condition of use basis.

EPA will continue to provide risk calculations with no PPE and with various levels of PPE in the risk characterization section of the risk evaluation to help inform possible risk management options.

EPA has moved forward with the final revised risk determination for TCE, which determines that TCE, as a whole chemical substance, presents an unreasonable risk of injury to health under the conditions of use. This revision, published on January 9, 2023 (88 FR 1222), supersedes the condition of use-specific risk determination in the November 2020 TCE risk evaluation. In addition, the risk determination at the time of the Pre-Panel Outreach meeting reflected an assumption that workers always and appropriately wear personal protective equipment (PPE); this assumption has changed. The final revised risk determination does not reflect an assumption that all workers always appropriately wear PPE. EPA understands that there could be adequate occupational safety protections in place at certain workplace

[5] The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0500, with the July 2022 draft revised unreasonable risk determination, January 2023 final revised unreasonable risk determination, and additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0737, on www.regulations.gov.

locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health,"[6] or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.

As a result of this revision, removing the assumption that workers always and appropriately wear PPE does not change the conditions of use that drive the unreasonable risk for TCE; an additional route of exposure (i.e., inhalation) has been identified as driving the unreasonable risk to workers in many of those 52 conditions of use; and additional risks for acute non-cancer effects and cancer effects from inhalation and dermal exposures drive the unreasonable risk in many of those 52 conditions of use (where previously those conditions of use were identified as presenting unreasonable risk only for chronic non-cancer effects and cancer).

As described in the final revised unreasonable risk determination, the same 52 conditions of use identified in the November 2020 risk evaluation drive the unreasonable risk determination for TCE, listed below:

- Manufacturing (domestic manufacturing)
- Manufacturing (import)
- 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 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 functional fluid in heat exchange fluid
- 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 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

[6] Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. *https://www.osha.gov/annotated-pels*.

- 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 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 adhesive and sealant
- 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

Two conditions of use do not drive EPA's unreasonable risk determination for TCE:

- Distribution in commerce
- Consumer use in pepper spray

2.2 Regulatory History

TCE is subject to numerous Federal laws and regulations in the United States and is also subject to regulatory actions by States and other countries. A summary of the regulatory history for TCE and a list of related regulations (EPA, Federal, State, and International) for TCE is provided in this section.

Actions under EPA pertaining to TCE include:

- *Toxics Substances Control Act (TSCA) – Section 6(b):* EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments. TCE is on the initial list of chemicals evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).

- *Toxic Substances Control Act (TSCA) – Section 5(a):* Under a Significant New Use Rule (SNUR), (81 FR 20535; April 8, 2016), TCE is subject to reporting for manufacture (including import) or processing of TCE for use in a consumer product except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants and pepper spray. This SNUR ensures that EPA will have the opportunity to review any new consumer uses of TCE and, if appropriate, take action to prohibit or limit those uses.

- *Toxics Substances Control Act (TSCA) – Section 8(a):* The TSCA Section 8(a) Chemical Data Reporting (CDR) Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States. TCE manufacturing (including importing), processing, and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).

- *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA):* TCE was first registered as an antimicrobial and conventional chemical in 1985 pursuant to FIFRA. EPA removed TCE from its list of inert ingredients used in pesticide products in 1998 (63 FR 34384, June 24, 1998).

- *Clean Air Act (CAA)*: TCE is designated as a hazardous air pollutant (HAP) under CAA section 112(b)(1) (42 U.S.C. 7412(b)(1)). Under section 112(d), EPA has established national emission standards for hazardous air pollutants (NESHAPs) for a number of source-specific categories that emit TCE, including synthetic organic chemical manufacturing (40 CFR part 63, subparts F, G, and H z; 59 FR 19402, April 22, 1994), miscellaneous organic chemical manufacturing (40 CFR part 63, subpart FFFF; 85 FR 49084, August 12, 2020), and aerospace manufacturing and rework facilities (40 CFR part 63, subpart GG; 80 FR 76151, December 7, 2015). Under Section 112(d) and 112(f), EPA has promulgated a number of risk and technology review (RTR) NESHAPs, including the RTR NESHAP for Halogenated Solvent Cleaning (40 CFR part 63, subpart T; 72 FR 25138, May 3, 2007). Under the CAA section 612, EPA's Significant New Alternatives Policy (SNAP) program listed TCE as an acceptable substitute for methyl chloroform and chlorofluorocarbon (CFC)-113 in metals, electronics, and precision cleaning; as an alternative to CFC-11, CFC-113, methyl chloroform, and hydrochlorofluorocarbon (HCFC)-141b for aerosol solvent use; and as an alternative for methyl chloroform for use as a carrier solvent in adhesives, coatings, and inks (59 FR 13044, March 18, 1994). TCE was also noted to have essentially no ozone depletion potential and cited as a volatile organic compound (VOC)-exempt solvent and acceptable substitute for ozone-depleting substances (72 FR 30142, May 30, 2007). TCE is also listed under the National Volatile Organic Compound Emission Standards for Aerosol Coatings (40 CFR part 59, subpart E). Under the American Innovation and Manufacturing Act (AIM Act) that directs EPA to phase down the production and consumption of HFCs, EPA set HFC production and consumption baseline levels from which reductions will be made (86 FR 55116, October 5, 2021). The rule also establishes an initial methodology for allocating and trading HFC allowances for 2022 and 2023. TCE is identified as a feedstock chemical for HFC production, including for HFC-125 and HFC-134a.

- *Clean Water Act (CWA)*: TCE is designated as a toxic pollutant under section 307(a)(1) of the Clean Water Act and as such is subject to effluent limitations. Also under section 304, TCE is included in the list of total toxic organics (TTO) (40 CFR 413.02(i)). In 2015, EPA published updated ambient water quality criteria for TCE, including recommendations for "water + organism" and "organism only" human health criteria for States and authorized tribes to consider when adopting criteria into their water quality standards (80 FR 36986, June 29, 2015). TCE is also subject to National Primary Drinking Water Regulations (NPDWR) under the Safe Drinking Water Act (SDWA) with a maximum contaminant level goal (MCGL) of zero and an enforceable maximum contaminant level (MCL) of 0.005 mg/L (40 CFR 141.50; 40 CFR 141.61).

- *Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)*: TCE is listed as a hazardous substance under the CERCLA, meaning that releases of TCE in excess of 100 pounds must be reported (40 CFR 302.4).

- *Resource Conservation and Recovery Act (RCRA)*: In RCRA section 3001, TCE is identified as a characteristic and listed hazardous waste under the following RCRA Hazardous Waste Codes: D040 (Toxicity); F001, F002; and U228 (40 CFR 261.24(b), 261.31(a), 261.33(f)). In 2013, EPA modified its hazardous waste management regulations to conditionally exclude solvent-contaminated wipes that have been cleaned and reused from the definition of solid waste under RCRA and to conditionally exclude solvent-contaminated wipes that are disposed from the definition of hazardous waste (78 FR 46448, July 31, 2013). However, TCE-contaminated wipes were not eligible for this exclusion due to health and safety concerns.

Other Federal actions pertaining to TCE include:

- *Federal Food, Drug, and Cosmetic Act (FFDCA)*: The Food and Drug Administration (FDA) established tolerances for residues of TCE resulting from its use as a solvent in the manufacture of decaffeinated coffee and spice oleoresins (21 CFR 173.290).

- *Occupational Safety and Health Act (OSH Act):* In 1971, OSHA established the permissible exposure limit (PEL) for TCE at 100 parts per million (ppm) as an 8-hour time weighted average (TWA) with an acceptable ceiling concentration of 200 ppm and an acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift of 300 ppm, based on the maximum duration of 5 minutes in any 2 hours (29 CFR 1910.1000).

- *Atomic Energy Act (AEA)*: The Department of Energy (DOE) Worker Safety and Health Program requires as part of the Worker Safety and Health Program the use of the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV) of 10 ppm and a short-term limit of 25 ppm (10 CFR 851.23).

- *Federal Hazardous Material Transportation Act (HMTA)*: The Department of Transportation (DOT) has designated TCE as a hazardous material, and there are special requirements for marking, labeling, and transporting it (49 CFR part 171, 49 CFR part 172, 40 CFR 173.202 and 40 CFR 173.242).

State actions pertaining to TCE include:

- Two states, Minnesota, and New York have taken action to ban use(s) of TCE. In Minnesota, after June 1, 2022, an owner or operator of a facility required to have an air emissions permit issued by the Pollution Control Agency may not use TCE at its permitted facility, including in any manufacturing, processing, or cleaning processes, subject to certain exceptions (Minn. Stat. 116.385). Beginning December 1, 2022, New York State prohibits the use of TCE as a vapor degreaser, an intermediate chemical to produce other chemicals, a refrigerant, or an extraction solvent or in any other manufacturing or industrial cleaning process or use (S.6829/A.8829-A).

- Some States regulate TCE as a VOC and these regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from State to State, and could include contact and aerosol adhesives, aerosols, electronic cleaners, footwear or leather care products, and general degreasers, among other products. Examples of States that have VOC regulations or limits for consumer products include Connecticut (R.C.S.A Sections 22a-174-40, 22a-174-41, and 22a-174-44), Delaware (Adm. Code Title 7, 1141), District of Columbia (Rules 20-720, 20-721, 20-735, 20-736, 20737), Illinois (35 Adm Code 223), Indiana (326 IAC 8-15), and several more.

- Most states have set PELs identical to the OSHA's 100 ppm 8-hour TWA PEL. Nine states have PELs of 50 ppm. California's PEL of 25 ppm is the most stringent (CCR, Title 8, Table AC-1). All of these PELs are significantly higher than the exposure levels at which EPA identified unreasonable risk for TCE uses.

- TCE is on the California Office of Environmental Health Hazard Assessment (OEHHA)'s Proposition 65 (first published in 1987) list of chemicals known to cause cancer, birth defects or other reproductive harm and California's CCR Title 27, section 27001, Chemicals Known to the State to Cause Cancer or Reproductive Toxicity. TCE is also on California's Safer Consumer Products Regulations list of chemicals that exhibit a hazard trait and are on an authoritative list (CCR Title 22, Chapter 55).

International actions pertaining to TCE include:

- Based on the European Chemicals Agency (ECHA)'s recommendation in 2011, the European Commission added TCE to the Regulation, Evaluation, Authorisation and Restriction of Chemicals (REACH) authorization list (Annex XIV) in 2013, due to its carcinogenic effects. In 2016, companies in the European Union (EU) without authorization were required to stop using TCE (REACH).

- Several countries, including Australia, Belgium, Finland, South Korea, and Spain have occupational exposure limits (OELs) for TCE (GESTIS International limit values for chemical agents OELs database, Accessed July 8, 2022).

2.3. Estimates of Exposed Populations

Populations exposed to TCE under the conditions of use include workers, ONUs, consumer users, and bystanders to consumers using products containing TCE. EPA estimates the exposed population includes 108,000 workers and 17,500 ONUs. The number of consumers that use products containing TCE each year is unknown.

For the conditions of use that drive the unreasonable risk, EPA has identified industry sectors that are likely affected (see Table 4.1), and the number of entities associated with those sectors (see Table 4.2). EPA estimates that the proposed rulemaking would affect approximately 20,611 small entities. Most (10,900) of these small entities are commercial users of TCE in liquid cleaner and degreaser applications EPA also estimates that 4,928 of these small entities use TCE in dry cleaning applications, 4,008 of these small entities use TCE in aerosol spray cleaning/degreasing, 336 of these small entities use TCE in lubricants and greases, and 268 use TCE in open-top vapor degreasing. Additional estimates are provided in Table 4.2.

2.4. Description of Section 6(a) Regulatory Options and Scope

EPA is developing a proposed regulation under section 6(a) of TSCA to address the unreasonable risk of the chemical substance TCE so that TCE no longer presents an unreasonable risk under the conditions of use. As explained above, in the November 2020 Risk Evaluation for TCE, EPA determined that 52 conditions of use present an unreasonable risk, and according to the final revised unreasonable risk determination published on January 9, 2023 (88 FR 1222), the same 52 conditions of use drive the unreasonable risk for TCE.

EPA is considering an array of approaches under TSCA section 6(a) to determine which option will address the unreasonable risk from TCE. Table 2.4.1 below summarizes regulatory requirements EPA can utilize, separately or in combination, under TSCA section 6(a).

Table 2.4.1. Regulatory Requirements Available 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.[7]

[7] 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.

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.

EPA would consider regulatory options that would not duplicate other federal regulations. EPA has determined that current federal regulations discussed in Section 2.2 do not address the unreasonable risk that EPA has identified for TCE.

2.5. Overview of Options under Consideration

EPA is considering a number of regulatory options under TSCA section 6(a) for TCE. The following options listed below, as presented to SERs, are currently being evaluated by EPA, and are not final at this time. Feedback from SERs on these options is in Section 7. EPA is considering the National Institute for Occupational Safety and Health (NIOSH) hierarchy of controls when developing risk management actions. As described by NIOSH, the hierarchy of controls can be used to implement feasible and effective controls to protect workers; it typically includes elimination, substitution, engineering controls, administrative controls, and PPE on a scale of most to least protective.[8] Any regulatory option can be used alone or in combination so that TCE no longer presents an unreasonable risk under the conditions of use.

2.5.1 Prohibition of manufacturing (including import), processing, and/or distribution

Under this option, EPA would prohibit the manufacturing (including import), processing, and/or distribution of TCE. Such prohibition would reduce exposures to TCE throughout the supply chain and possibly affect the distribution in commerce condition of use, which does not drive unreasonable risk. EPA may also prohibit conditions of use that have minimal ongoing use or have been or will be phased out. Under TSCA section 6(c)(2)(C), in deciding whether to prohibit or restrict in any manner that substantially prevents a specific condition of use, and in setting an appropriate transition period for such action, EPA is required to consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

Costs of prohibitions would vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation, shutting down the operation and more. Costs associated with product reformulation range from approximately $60,000 to $100,000 per product, depending on the reformulation approach. A SER representing product formulators specified that reformulating a degreasing product could cost close to $100,000, including reformulation, testing, certification, and labeling. The costs of switching products includes both the costs of the substitute products and differences in efficacy of these products, which are not quantified and which may include additional labor costs. Costs associated with substitute methods vary by job rates; for vapor degreasing, costs for alternative process development are estimated to range from $36,000 to $300,000, initial

[8] NIOSH Hierarchy of Controls Overview: https://www.cdc.gov/niosh/topics/hierarchy/default.html

capital costs are estimated to range from $30,000 to $2,000,000, and incremental ongoing costs of alternative processes are estimated to average $20,000 annually. Additional SER estimates are provided in Unit 8 (Panel Findings and Discussion). More precise cost estimates will require input from potentially regulated entities.

2.5.2 Use of an Existing Chemical Exposure Limit (ECEL)

For processing, industrial, and commercial uses involving occupational exposures, an ECEL could be used to decrease exposure to TCE. An ECEL establishes a performance-based airborne concentration limit and is non-prescriptive, enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace and the ability to combine prescriptive controls. Industries are already familiar with PELs, and methods of compliance. EPA and OHSA have ongoing dialogue in reference to risk management requirements under TSCA. For TCE, based on the immunotoxicity endpoint, the ECEL(I) would be 4.0 parts per billion (ppb) (0.021 mg/m^3) for an 8-hour time-weighted average (TWA). The Agency is also considering occupational safety measures to be based on a different, more sensitive endpoint (fetal cardiac defects), which would result in an ECEL(F) of 1.1 ppb (0.0059 mg/m^3) for an 8-hour TWA.

The ECEL value is based on the chronic non-cancer human equivalent concentration (HEC) for autoimmunity. If ambient exposures are kept below the 8-hour TWA of 4.0 ppb, EPA expects that a worker or ONU is also protected against mortality due to immunosuppression resulting from an acute (8-hour) exposure and from excess risk of cancer above the $1x10^{-4}$ benchmark resulting from lifetime exposure. The ECEL(I) is above the limits of detection or quantification, which generally range from about ≤0.5 ppb to 0.43 ppm. Several monitoring methods exist, which were described to SERs in a handout before the Pre-Panel and Panel Outreach meetings. EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL(I) will eliminate the unreasonable risk of injury to health resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk.

ECEL(I) or ECEL(F) costs would vary based on the complexity of the site and how many times the site would require monitoring to demonstrate compliance. Potential monitoring costs include $400 per facility ($70-$1,600 annualized per facility), and $220 per worker ($40-$800 annualized per worker). Additionally, EPA estimates that potential recordkeeping costs would be $400 per facility ($60 annualized per facility), and $20-$100 per worker. Costs of engineering controls or PPE to achieve the ECEL(I) or ECEL(F) level would vary by control type and the needs of the user, so they are not captured in these estimates.

2.5.3 Engineering/Administrative Controls (e.g., use of particular equipment)

Under this option, EPA would require specific prescriptive controls to reduce the exposure to TCE to workers and ONUs for processing, industrial, and commercial conditions of use.

The requirements could include, but are not limited to:

- Engineering controls that reduce worker or ONU exposure by implementing physical changes to the workplace. Examples of engineering controls that could be installed to reduce exposure to TCE include:
    - Closed-loop vapor degreasers;

    - Spraying booths or laboratory fume hoods for laboratory applications; and
    - Enclose or confine operations to avoid or reduce employee exposure.
- Administrative controls could reduce exposures to workers or ONUs by implementing processes or procedures in the workplace. An example of an administrative control could be to prohibit ONU access to the work area where the chemical or product containing the chemical is being handled.

Costs of implementing engineering and administrative controls would vary by control type and user needs and are dependent on the user's current practices. Potential impacts to small businesses could include (but may not be limited to) the cost of capital investments for engineering controls, maintenance, and other expenses related to implementing industrial hygiene practices, as well as potential costs associated with utilities and labor. Administrative controls could result in increased costs associated with developing and implementing new work practices.

2.5.4 Personal Protective Equipment (PPE)

Under this option, EPA would require a specific PPE to minimize exposure. This may limit flexibility for the regulated entity. PPE may include respirators with an assigned protection factor (APF) or gloves. For TCE, only a respirator with APF 10,000 may be able to mitigate such risk; EPA recognizes the challenges associated with using such respirators and notified SERs that the Agency is interested in SER feedback on this type of PPE during the Pre-Panel and Panel Outreach meetings. EPA could require the use of specific gloves that meet certain standards such as providing an impervious barrier to the chemical during expected durations and normal conditions of exposure.

Potential impacts to small businesses include (but may not be limited to) the cost of purchase of equipment, routine cleaning of equipment, training, fit-testing, and medical clearance for estimated baseline PPE use. Respirator costs are associated with the APF level and range from $660-$970 per worker per year for APF 25 respiratory protection to $1,800-$2,500 per worker per year for APF 10,000 respiratory protection. Total cost depends on the prevalence of current use and number of workers required to use the respirators.

For gloves, costs include purchase of equipment. EPA estimates these costs would be $130 - $180 annualized cost ($4 per pair and 50 pairs per year) assuming PVA gloves. Input from potentially regulated entities is needed regarding which glove material type would be used.

2.5.5 Recordkeeping, downstream notification, and other support for implementation

The TSCA section 6(a) activities listed below are options that could support the implementation of the regulatory approaches outlined in the preceding sections.

- Recordkeeping would require records and documentation for the purposes of demonstrating compliance with any option described above. Recordkeeping would aim to consist of ordinary business records already maintained to the extent possible.

- Downstream notification would support any of the control options described above (e.g., prescriptive controls, prohibitions) to disseminate information about restrictions and requirements through the supply chain.

- Labeling: For example, EPA could require that a prominent label be securely attached to each container with specific directions, limitations, and precautions, or that describes the health endpoints.

Potential impacts to small businesses associated with recordkeeping could include the annual labor and material costs associated with documentation of ordinary business records, estimated at $200 -$325 per firm. Downstream notification costs are per product (estimated cost $112 -$125) and include labor and material costs to update the product's safety data sheet (SDS).

For labeling, EPA estimates that costs could range from $750 to $8,000 per product. Costs would vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor. Due to uncertainties and variations in product types, this estimate does not include potential impacts on sales.

3. APPLICABLE SMALL ENTITY DEFINITIONS

The Regulatory Flexibility Act (RFA) defines small entities as including "small businesses," "small governments," and "small organizations" (5 USC 601). The RFA references the definition of "small business" found in the Small Business Act, which authorizes the Small Business Administration to further define "small business" by regulation. The SBA definitions of small business by size standards using the North American Industry Classification System (NAICS) can be found at 13 CFR 121.201.

The detailed listing of SBA definitions of small business for affected industries or sectors, by NAICS code, is included in Table 4.1 of Section 4, below.

4. SMALL ENTITIES THAT MAY BE SUBJECT TO THE PROPOSED REGULATION

Table 4.1 shows the SBA size standards by affected industry sector. Table 4.2 shows the estimated number of small firms by condition of use (COU).

Table 4.1. Industry Sectors and Definitions

NAICS	NAICS description	SBA Size Standard
111421	Nursery and Tree Production	$2.75 million
111422	Floriculture Production	$3.25 million
111998	All Other Miscellaneous Crop Farming	$2.25 million
112210	Hog and Pig Farming	$3.5 million
112990	All Other Animal Production	$2.5 million
211120	Crude Petroleum Extraction	1,250 employees
212111	Bituminous Coal and Lignite Surface Mining	1,250 employees
212210	Iron Ore Mining	750 employees
212312	Crushed and Broken Limestone Mining and Quarrying	750 employees
212321	Construction Sand and Gravel Mining	500 employees
212399	All Other Nonmetallic Mineral Mining	500 employees
221112	Fossil Fuel Electric Power Generation	750 employees
221113	Nuclear Electric Power Generation	750 employees

NAICS	NAICS description	SBA Size Standard
221117	Biomass Electric Power Generation	250 employees
221118	Other Electric Power Generation	250 employees
221121	Electric Bulk Power Transmission and Control	500 employees
221122	Electric Power Distribution	1,000 employees
221210	Natural Gas Distribution	1,000 employees
221310	Water Supply and Irrigation Systems	$36 million
221320	Sewage Treatment Facilities	$315 million
221330	Steam and Air-Conditioning Supply	$26.5 million
237310	Highway, Street, and Bridge Construction	$39.5 million
2383	Building Finish Contractors	$16.5 million
311119	Other Animal Food Manufacturing	500 employees
311211	Flour Milling	1,000 employees
311221	Wet Corn Milling	1,250 employees
311224	Soybean and Other Oilseed Processing	1,000 employees
311423	Dried and Dehydrated Food Manufacturing	750 employees
311611	Animal (except Poultry) Slaughtering	1,000 employees
311615	Poultry Processing	1,250 employees
311812	Commercial Bakeries	1,000 employees
311911	Roasted Nuts and Peanut Butter Manufacturing	750 employees
311919	Other Snack Food Manufacturing	1,250 employees
312120	Breweries	1,250 employees
312130	Wineries	1,000 employees
312140	Distilleries	1,000 employees
312230	Tobacco Manufacturing	1,500 employees
313210	Broadwoven Fabric Mills	1,000 employees
313230	Nonwoven Fabric Mills	750 employees
313310	Textile and Fabric Finishing Mills	1,000 employees
313320	Fabric Coating Mills	1,000 employees
314999	All Other Miscellaneous Textile Product Mills	500 employees
321113	Sawmills	500 employees
321114	Wood Preservation	500 employees
321211	Hardwood Veneer and Plywood Manufacturing	500 employees
321212	Softwood Veneer and Plywood Manufacturing	1,250 employees
321213	Engineered Wood Member (except Truss) Manufacturing	750 employees
321214	Truss Manufacturing	500 employees
321219	Reconstituted Wood Product Manufacturing	750 employees
321911	Wood Window and Door Manufacturing	1,250 employees
321912	Cut Stock, Resawing Lumber, and Planing	500 employees
321918	Other Millwork (including Flooring)	500 employees
321920	Wood Container and Pallet Manufacturing	500 employees
321992	Prefabricated Wood Building Manufacturing	500 employees

NAICS	NAICS description	SBA Size Standard
321999	All Other Miscellaneous Wood Product Manufacturing	500 employees
322110	Pulp Mills	750 employees
322121	Paper (except Newsprint) Mills	1,250 employees
322122	Newsprint Mills	750 employees
322130	Paperboard Mills	1,250 employees
322211	Corrugated and Solid Fiber Box Manufacturing	1,250 employees
322220	Paper Bag and Coated and Treated Paper Manufacturing	750 employees
323111	Commercial Printing (except Screen and Books)	500 employees
323113	Commercial Screen Printing	500 employees
324110	Petroleum Refineries	1,500 employees
324121	Asphalt Paving Mixture and Block Manufacturing	500 employees
324122	Asphalt Shingle and Coating Materials Manufacturing	750 employees
324191	Petroleum Lubricating Oil and Grease Manufacturing	750 employees
324199	All Other Petroleum and Coal Products Manufacturing	500 employees
325110	Petrochemical Manufacturing	1,000 employees
325120	Industrial Gas Manufacturing	1,000 employees
325130	Synthetic Dye and Pigment Manufacturing	1,000 employees
325180	Other Basic Inorganic Chemical Manufacturing	1,000 employees
325193	Ethyl Alcohol Manufacturing	1,000 employees
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	1,250 employees
325199	All Other Basic Organic Chemical Manufacturing	1,250 employees
325211	Plastics Material and Resin Manufacturing	1,250 employees
325212	Synthetic Rubber Manufacturing	1,000 employees
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1,000 employees
325311	Nitrogenous Fertilizer Manufacturing	1,000 employees
325320	Pesticide and Other Agricultural Chemical Manufacturing	1,000 employees
325411	Medicinal and Botanical Manufacturing	1,000 employees
325412	Pharmaceutical Preparation Manufacturing	1,250 employees
325510	Paint and Coating Manufacturing	1,000 employees
325520	Adhesive Manufacturing	500 employees
325611	Soap and Other Detergent Manufacturing	1,000 employees
325612	Polish and Other Sanitation Good Manufacturing	750 employees
325613	Surface Active Agent Manufacturing	750 employees
325910	Printing Ink Manufacturing	500 employees
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1,500 employees
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 employees
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	750 employees
326122	Plastics Pipe, Pipe Fitting, and Unlaminated Profile Shape Manufacturing	750 employees

NAICS	NAICS description	SBA Size Standard
326140	Polystyrene Foam Product Manufacturing	1,000 employees
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	750 employees
326199	All Other Plastics Product Manufacturing	750 employees
326211	Tire Manufacturing (except Retreading)	1,500 employees
326212	Tire Retreading	500 employees
326220	Rubber and Plastics Hoses and Belting Manufacturing	750 employees
326299	All Other Rubber Product Manufacturing	500 employees
327310	Cement Manufacturing	1,000 employees
327320	Ready-Mix Concrete Manufacturing	500 employees
327390	Other Concrete Product Manufacturing	500 employees
327420	Gypsum Product Manufacturing	1,500 employees
331110	Iron and Steel Mills and Ferroalloy Manufacturing	1,500 employees
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	1,000 employees
331221	Rolled Steel Shape Manufacturing	1,000 employees
331222	Steel Wire Drawing	1,000 employees
331315	Aluminum Sheet, Plate, and Foil Manufacturing	1,250 employees
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	1,000 employees
331420	Copper Rolling, Drawing, Extruding, and Alloying	1,000 employees
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing and Extruding	750 employees
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	750 employees
331511	Iron Foundries	1,000 employees
331513	Steel Foundries (except Investment)	500 employees
331523	Nonferrous Metal Die-Casting Foundries	500 employees
332111	Iron and Steel Forging	750 employees
332112	Nonferrous Forging	750 employees
332114	Custom Roll Forming	500 employees
332117	Powder Metallurgy Part Manufacturing	500 employees
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	500 employees
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	750 employees
332216	Saw Blade and Handtool Manufacturing	750 employees
332321	Metal Window and Door Manufacturing	750 employees
332322	Sheet Metal Work Manufacturing	500 employees
332323	Ornamental and Architectural Metal Work Manufacturing	500 employees
332410	Power Boiler and Heat Exchanger Manufacturing	750 employees
332420	Metal Tank (Heavy Gauge) Manufacturing	750 employees
332431	Metal Can Manufacturing	1,500 employees
332439	Other Metal Container Manufacturing	500 employees

NAICS	NAICS description	SBA Size Standard
332510	Hardware Manufacturing	750 employees
332613	Spring Manufacturing	500 employees
332618	Other Fabricated Wire Product Manufacturing	500 employees
332710	Machine Shops	500 employees
332721	Precision Turned Product Manufacturing	500 employees
332722	Bolt, Nut, Screw, Rivet, and Washer Manufacturing	500 employees
332811	Metal Heat Treating	750 employees
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	500 employees
332813	Electroplating, Plating, Polishing, Anodizing and Coloring	500 employees
332911	Industrial Valve Manufacturing	750 employees
332912	Fluid Power Valve and Hose Fitting Manufacturing	1,000 employees
332913	Plumbing Fixture Fitting and Trim Manufacturing	1,000 employees
332919	Other Metal Valve and Pipe Fitting Manufacturing	750 employees
332991	Ball and Roller Bearing Manufacturing	1,250 employees
332992	Small Arms Ammunition Manufacturing	1,250 employees
332993	Ammunition (except Small Arms) Manufacturing	1,500 employees
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing	1,000 employees
332996	Fabricated Pipe and Pipe Fitting Manufacturing	500 employees
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	750 employees
333111	Farm Machinery and Equipment Manufacturing	1,250 employees
333112	Lawn and Garden Tractor and Home Lawn and Garden Equipment Manufacturing	1,500 employees
333120	Construction Machinery Manufacturing	1,250 employees
333131	Mining Machinery and Equipment Manufacturing	500 employees
333132	Oil and Gas Field Machinery and Equipment Manufacturing	1,250 employees
333241	Food Product Machinery Manufacturing	500 employees
333242	Semiconductor Machinery Manufacturing	1,500 employees
333243	Sawmill, Woodworking, and Paper Machinery Manufacturing	500 employees
333244	Printing Machinery and Equipment Manufacturing	750 employees
333249	Other Industrial Machinery Manufacturing	500 employees
333314	Optical Instrument and Lens Manufacturing	500 employees
333316	Photographic and Photocopying Equipment Manufacturing	1,000 employees
333318	Other Commercial and Service Industry Machinery Manufacturing	1,000 employees
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	500 employees
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	500 employees
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	1,250 employees
333511	Industrial Mold Manufacturing	500 employees
333514	Special Die and Tool, Die Set, Jig and Fixture Manufacturing	500 employees
333515	Cutting Tool and Machine Tool Accessory Manufacturing	500 employees

NAICS	NAICS description	SBA Size Standard
333517	Machine Tool Manufacturing	500 employees
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	500 employees
333611	Turbine and Turbine Generator Set Units Manufacturing	1,500 employees
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	750 employees
333613	Mechanical Power Transmission Equipment Manufacturing	750 employees
333618	Other Engine Equipment Manufacturing	1,500 employees
333911	Pump and Pumping Equipment Manufacturing	500 employees
333912	Air and Gas Compressor Manufacturing	1,000 employees
333913	Measuring, Dispensing, and Other Pumping Equipment Manufacturing	750 employees
333921	Elevator and Moving Stairway Manufacturing	1,000 employees
333922	Conveyor and Conveying Equipment Manufacturing	500 employees
333923	Overhead Traveling Crane, Hoist, and Monorail System Manufacturing	1,250 employees
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	750 employees
333991	Power-Driven Handtool Manufacturing	500 employees
333992	Welding and Soldering Equipment Manufacturing	1,250 employees
333993	Packaging Machinery Manufacturing	500 employees
333994	Industrial Process Furnace and Oven Manufacturing	500 employees
333995	Fluid Power Cylinder and Actuator Manufacturing	750 employees
333996	Fluid Power Pump and Motor Manufacturing	1,250 employees
333997	Scale and Balance Manufacturing	500 employees
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	500 employees
334111	Electronic Computer Manufacturing	1,250 employees
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	1,000 employees
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	1,250 employees
334310	Audio and Video Equipment Manufacturing	750 employees
334413	Semiconductor and Related Device Manufacturing	1,250 employees
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	500 employees
334417	Electronic Connector Manufacturing	1,000 employees
334418	Printed Circuit Assembly (Electronic Assembly) Manufacturing	750 employees
334419	Other Electronic Component Manufacturing	750 employees
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing	1,250 employees
334512	Automatic Environmental Control Manufacturing for Residential, Commercial and Appliance Use	500 employees
334513	Instruments and Related Products Manufacturing for Measuring, Displaying, and Controlling Industrial Process Variables	750 employees

NAICS	NAICS description	SBA Size Standard
334515	Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals	750 employees
335110	Electric Lamp Bulb and Part Manufacturing	1,250 employees
335121	Residential Electric Lighting Fixture Manufacturing	750 employees
335122	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing	500 employees
335129	Other Lighting Equipment Manufacturing	500 employees
335220	Major Household Appliance Manufacturing	1,500 employees
335311	Power, Distribution, and Specialty Transformer Manufacturing	750 employees
335312	Motor and Generator Manufacturing	1,250 employees
335313	Switchgear and Switchboard Apparatus Manufacturing	1,250 employees
335314	Relay and Industrial Control Manufacturing	750 employees
335912	Primary Battery Manufacturing	1,000 employees
335921	Fiber Optic Cable Manufacturing	1,000 employees
335931	Current-Carrying Wiring Device Manufacturing	500 employees
335932	Noncurrent-Carrying Wiring Device Manufacturing	1,000 employees
335991	Carbon and Graphite Product Manufacturing	750 employees
336111	Automobile Manufacturing	1,500 employees
336112	Light Truck and Utility Vehicle Manufacturing	1,500 employees
336120	Heavy Duty Truck Manufacturing	1,500 employees
336211	Motor Vehicle Body Manufacturing	1,000 employees
336212	Truck Trailer Manufacturing	1,000 employees
336213	Motor Home Manufacturing	1,250 employees
336214	Travel Trailer and Camper Manufacturing	1,000 employees
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	1,000 employees
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	1,000 employees
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	1,000 employees
336340	Motor Vehicle Brake System Manufacturing	1,250 employees
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	1,500 employees
336360	Motor Vehicle Seating and Interior Trim Manufacturing	1,500 employees
336370	Motor Vehicle Metal Stamping	1,000 employees
336390	Other Motor Vehicle Parts Manufacturing	1,000 employees
336411	Aircraft Manufacturing	1,500 employees
336412	Aircraft Engine and Engine Parts Manufacturing	1,500 employees
336413	Other Aircraft Part and Auxiliary Equipment Manufacturing	1,250 employees
336414	Guided Missile and Space Vehicle Manufacturing	1,250 employees
336415	Guided Missile and Space Vehicle Propulsion Unit and Propulsion Unit Parts Manufacturing	1,250 employees
336419	Other Guided Missile and Space Vehicle Parts and Auxiliary Equipment Manufacturing	1,000 employees
336510	Railroad Rolling Stock Manufacturing	1,500 employees

NAICS	NAICS description	SBA Size Standard
336611	Ship Building and Repairing	1,250 employees
336612	Boat Building	1,000 employees
336991	Motorcycle, Bicycle, and Parts Manufacturing	1,000 employees
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	1,500 employees
336999	All Other Transportation Equipment Manufacturing	1,000 employees
337110	Wood Kitchen Cabinet and Counter Top Manufacturing	750 employees
337121	Upholstered Household Furniture Manufacturing	1,000 employees
337122	Nonupholstered Wood Household Furniture Manufacturing	750 employees
337124	Metal Household Furniture Manufacturing	750 employees
337125	Household Furniture (except Wood and Metal) Manufacturing	750 employees
337127	Institutional Furniture Manufacturing	500 employees
337211	Wood Office Furniture Manufacturing	1,000 employees
337212	Custom Architectural Woodwork and Millwork Manufacturing	500 employees
337215	Showcase, Partition, Shelving, and Locker Manufacturing	500 employees
339112	Surgical and Medical Instrument Manufacturing	1,000 employees
339113	Surgical Appliance and Supplies Manufacturing	750 employees
339114	Dental Equipment and Supplies Manufacturing	750 employees
339910	Jewelry and Silverware Manufacturing	500 employees
339920	Sporting and Athletic Goods Manufacturing	750 employees
339991	Gasket, Packing, and Sealing Device Manufacturing	500 employees
339993	Fastener, Button, Needle and Pin Manufacturing	750 employees
339995	Burial Casket Manufacturing	1,000 employees
339999	All Other Miscellaneous Manufacturing	500 employees
42331	Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers	150 employees
423510	Metal Service Centers and Other Metal Merchant Wholesalers	200 employees
423830	Industrial Machinery and Equipment Merchant Wholesalers	100 employees
423840	Industrial Supplies Merchant Wholesalers	125 employees
423910	Sporting and Recreational Goods and Supplies Merchant Wholesalers	100 employees
423930	Recyclable Material Merchant Wholesalers	125 employees
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	100 employees
424690	Other Chemical and Allied Products Merchant Wholesalers	175 employees
424710	Petroleum Bulk Stations and Terminals	225 employees
441110	New Car Dealers	200 employees
441120	Used Car Dealers	$27million
443142	Electronics Stores	$35 million
444110	Home Centers	$41.5 million
451110	Sporting Goods Stores	$23.5 million
454310	Fuel Dealers	100 employees
481111	Scheduled Passenger Air Transportation	1,500 employees
484121	General Freight Trucking, Long-Distance, Truckload	$30 million
488190	Other Support Activities for Air Transportation	$35 million

NAICS	NAICS description	SBA Size Standard
488210	Support Activities for Rail Transportation	$30 million
493110	General Warehousing and Storage	$30 million
493190	Other Warehousing and Storage	$32 million
512110	Motion Picture and Video Production	$35 million
512290	Other Sound Recording Industries	$20 million
517311	Wired Telecommunication Carriers	1,500 employees
525990	Other Financial Vehicles	$35 million
531120	Lessors of Nonresidential Buildings (except Miniwarehouses)	$30 million
531190	Lessors of Other Real Estate Property	$16.5 million
541330	Engineering Services	$22.4 million
541380	Testing Laboratories	$16.5 million
541512	Computer Systems Design Services	$30 million
541620	Environmental Consulting Services	$15.5 million
541714	Research and Development in Biotechnology (Except Nanobiotechnology)	1,000 employees
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	1,000 employees
541720	Research and Development in the Social Sciences and Humanities	$24.5 million
541940	Veterinary Services	$9 million
551112	Offices of Other Holding Companies	$40 million
561499	All Other Business Support Services	$19 million
561599	All Other Travel Arrangement and Reservation Services	$28.5 million
561740	Carpet and Upholstery Cleaning Services	$7.5 million
561790	Other Services to Buildings and Dwellings	$8 million
561990	All Other Support Services	$14 million
562111	Solid Waste Collection	$41.5 million
562112	Hazardous Waste Collection	$41.5 million
562211	Hazardous Waste Treatment and Disposal	$41.5 million
562212	Solid Waste Landfill	$31.5 million
562213	Solid Waste Combustors and Incinerators	$31.5 million
562219	Other Nonhazardous Waste Treatment and Disposal	$31.5 million
562910	Remediation Services	$22 million
562920	Materials Recovery Facilities	$22 million
562998	All Other Miscellaneous Waste Management Services	$14.5 million
611110	Elementary and Secondary Schools	$17.5 million
611210	Junior Colleges	$28.5 million
611310	Colleges, Universities, and Professional Schools	$30.5 million
622110	General Medical and Surgical Hospitals	$41.5 million
624110	Child and Youth Services	$13.5 million
721110	Hotels (except Casino Hotels) and Motels	$35 million
811111	General Automotive Repair	$8 million

NAICS	NAICS description	SBA Size Standard
811112	Automotive Exhaust System Repair	$8 million
811113	Automotive Transmission Repair	$8 million
811118	Other Automotive Mechanical and Electrical Repair and Maintenance	$8 million
811121	Automotive Body, Paint and Interior Repair and Maintenance	$8 million
811122	Automotive Glass Replacement Shops	$15.5 million
811191	Automotive Oil Change and Lubrication Shops	$9.5 million
811198	All Other Automotive Repair and Maintenance	$9 million
811211	Consumer Electronics Repair and Maintenance	$22.5 million
811212	Computer and Office Machine Repair and Maintenance	$30 million
811213	Communication Equipment Repair and Maintenance	$19.5 million
811219	Other Electronic and Precision Equipment Repair and Maintenance	$22million
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	$11 million
811411	Home and Garden Equipment Repair and Maintenance	$8 million
811412	Appliance Repair and Maintenance	$16.5 million
811430	Footwear and Leather Goods Repair	$8 million
811490	Other Personal and Household Goods Repair and Maintenance	$8 million
812210	Funeral Homes and Funeral Services	$11 million
812220	Cemeteries and Crematories	$22 million
812310	Coin-Operated Laundries and Drycleaners	$11.5 million
812320	Drycleaning and Laundry Services (except Coin-Operated)	$7 million
812332	Industrial Launderers	$41.5 million
812910	Pet Care (except Veterinary) Services	$8 million
921110	Executive Offices	NA*
921120	Legislative Bodies	NA*
921190	Other General Government Support	NA*
922140	Correctional Institutions	NA*
922190	Other Justice, Public Order, and Safety Activities	NA*
924110	Administration of Air and Water Resource and Solid Waste Management Programs	NA*
924120	Administration of Conservation Programs	NA*
926120	Regulation and Administration of Transportation Programs	NA*
927110	Space Research and Technology	NA*
928110	National Security	NA*

* Small business size standards are not established for these Sectors. Establishments in the Public Administration Sectors are Federal, state, and local government agencies which administer and oversee government programs and activities that are not performed by private establishments.
Source: U.S. Small Business Administration Table of Small Business Size Standards, available at: https://www.sba.gov/document/support-table-size-standards, accessed July 14, 2022.

Table 4.2. Estimated Number of Small Firms by Condition of Use (COU)

Use Category	Number of Affected Firms	Estimated Number of Small Firms Affected	Percentage of Firms Meeting SBA Definition of a Small Business
Manufacturing (domestic manufacturing)	2	0	0%
Import and Processing: Repackaging	9	4	44%
Processing as a reactant/intermediate: HFC Manufacturing	2	0	0%
Processing as a reactant/intermediate: HCl Manufacturing	30	1	3%
Incorporation into Formulation, Mixture, or Reaction Product	28	16	57%
Processing: Incorporation into articles	0	0	0%
Waste Handling, Disposal, Treatment, and Recycling	20	18	90%
Open-Top Vapor Degreasing	350	268	77%
Enclosed Vapor Degreasing	7	5	71%
Conveyorized Vapor Degreasing	8	6	75%
Web Vapor Degreasing	1	1	100%
Batch Cold Cleaning	52	40	77%
Aerosol Spray Cleaning/Degreasing	4,366	4,008	92%
Mold Release	17	16	94%
Liquid Cleaners and Degreasers	11,815	10,900	92%
Lubricants and Greases	345	336	97%
Adhesives, Sealants, Paints and Coatings	65	61	94%
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 use in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture: Battery Manufacture	4	1	25%
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 use in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture: Fluoroelastomer Manufacture	2	0	0%
Dry Cleaning and Spot Removers	4,980	4,928	99%
Laboratory Use	10	1	10%
Total	22,113	20,611	93%

5. LIST OF SMALL ENTITY REPRESENTATIVES

EPA consulted with Advocacy to develop the list of small entity representatives (SERs) in Table 5.1. EPA issued a press release inviting self-nominations by affected small entities to serve as potential SERs. The press release directed interested small entities to a web page where they could indicate their interest in serving as a SER. EPA launched the website November 30, 2020, and accepted self-nominations until December 14, 2020. EPA recruited additional potential SERs during and after the self-nomination process to address potential underrepresentation from certain affected industries. EPA sent Advocacy a Formal Notification with the suggested list of potential SERs on February 10, 2021, and Advocacy responded on February 25, 2021.

Table 5.1: List of Small Entity Representatives

Entity	Contact
Berryman Products, Inc. - TX	Dan Nowlan Chemist, R&D
Colonial Coatings, Inc. - CT	Richard Castorina Vice President represented by: Mary Angelicola (Industrial Compliance Solutions LLC)
Halogenated Solvents Industry Alliance, Inc. (HSIA) - VA	Christopher Bevan Director of Scientific Programs
Household & Commercial Products Association - DC	Nicholas Georges Vice President, Scientific & International Affairs
National Cleaners Association - NY	Nora Nealis Executive Director
Parts Cleaning Technologies - MI	Dave Crandall President

6. SUMMARY OF PRE-PANEL SMALL ENTITY OUTREACH

After identifying a list of potential SERs, EPA conducted a Pre-Panel Outreach meeting with potential SERs on October 28, 2022. To help SERs prepare for the virtual meeting/teleconference, EPA sent materials to each of the potential SERs via email on October 14, 2022. A list of the materials shared with the potential SERs during the pre-Panel outreach meeting is contained in Appendix A. For the October 28 Pre-Panel outreach meeting with the potential SERs, EPA also invited representatives from the Office of Advocacy of the Small Business Administration and the Office of Information and Regulatory Affairs within the Office of Management and Budget. A total of 5 potential SERs participated in the meeting. EPA presented an overview of the SBAR Panel process, section 6 of TSCA, an explanation of the forthcoming rulemaking, potential regulatory approaches, and cost estimates. EPA also provided opportunities for questions and feedback, with a meeting structure that aimed to provide productive discussion by grouping conditions of use.

The Pre-Panel outreach meeting was held to solicit feedback from the potential SERs on their suggestions for the upcoming rulemaking. EPA asked the potential SERs to provide written comments by November 14, 2022. Comments raised during the October 28 outreach meeting and written comments submitted by the potential SERS are summarized in sections 7.1 and 7.2, respectively, of this document. Written comments submitted after the meeting appear in Appendix B1.

The Panel conducted an outreach meeting with the SERs via a virtual meeting/teleconference on January 31, 2023. To help SERs prepare for the virtual meeting/teleconference, EPA sent materials to each of the SERs via email on January 17, 2023. A list of the materials shared with the SERs during the Panel outreach meeting is contained in Appendix A2. A total of 4 SERs participated in the meeting. EPA summarized SER comments during the pre-Panel outreach meeting and presented an overview of the SBAR Panel process, section 6 of TSCA, an explanation of the forthcoming rulemaking, potential regulatory approaches, and cost estimates.

This Panel outreach meeting was held to solicit feedback from the SERs on their suggestions for the upcoming rulemaking. EPA asked the SERs to provide written comments by February 14, 2022. Comments raised during the January 31, 2023, Panel outreach meeting and written comments submitted by the SERs are summarized in sections 7.3 and 7.4, respectively, of this document. Written comments submitted after the meeting appear in Appendix B2.

7. SUMMARY OF COMMENTS FROM POTENTIAL SMALL ENTITY REPRESENTATIVES

7.1. Summary of the Pre-Panel Outreach Meeting Discussion

At the Pre-Panel outreach meeting, SERs provided information on the number and type of entities that would be affected (including how their products are used); potential compliance requirements (including current exposure monitoring and reduction practices, and anticipated impacts of potential prohibitions); related Federal rules; and potential regulatory flexibility alternatives (including considerations for substitute chemicals).

Verbal comments from the meeting are summarized in the following subsections.

7.1.1. Number and Types of Entities Affected

SERs discussed their processing or use of TCE, their customer base and how their products are used, as well as how the COVID-19 pandemic has affected the dry cleaning industry. Specifically, SERs described:

- Degreasing:
    - A trade association SER described how members use TCE in several niche applications as a cleaning (or degreasing) agent, which the SER described as very effective. For these niche applications, the SER described how reformulation is less likely to occur due to lack of viable alternatives from a technology standpoint.
    - For TCE use in electrical cleaning applications, SERs explained that use of a nonflammable solvent is critical. SERs noted that potential alternatives include fluorinated compounds, but manufacturers would require additional testing to ensure they can provide proper cleaning, especially to avoid damaging the energized equipment (e.g., circuit board).
    - SERs provided additional examples where TCE use as a degreaser may be essential, such as to remove grease where there has been significant buildup overtime (e.g., oil wells).

    - For uses where TCE has likely been phased out, SERs suggested that TCE is being slowly phased out and replaced in paints and coatings, and SERs were not aware of any specific oils or greases where TCE is specifically required.
    - For TCE use in vapor degreasing, a SER noted the efforts of one small business deciding to invest in a closed degreasing system to continue use of TCE or to phaseout the use of TCE by implementing an aqueous cleaning process.
- Dry cleaning:
    - One SER explained that TCE is used in the dry cleaning industry on a limited but necessary basis. Specifically, TCE is used as a spot cleaner, separate from the garment cleaning process in which perchloroethylene or other cleaning reagents are used. The SER noted that spot cleaning products containing TCE are typically used on 8-10 garments in an 8-hour workday.
    - SER estimated that a “full service” dry cleaner might use 1-3 gallons per year, as a small amount of TCE is useful for removal of “oxidized stains” remaining on a garment after the initial cleaning and drying cycle.
    - The SER noted that dry cleaning facilities are generally well ventilated, however the SER plans to provide additional information regarding area and personal breathing zone monitoring in written comments. In addition, the SER noted that approximately 70-80% of “full service" dry cleaning entities use TCE as a spot cleaner.
    - The dry cleaning SER also noted that TCE use for spot cleaning is sporadic and estimated that an employee may be exposed to TCE for about an hour a day over the course of a year.

7.1.2. Potential Reporting, Recordkeeping, and Compliance Requirements

SERs described their exposure monitoring and reduction practices, anticipated changes due to potential requirements from EPA, and considerations for substitute chemicals or processes. Specifically, SERs described, for themselves or their customers:

- One SER explained that in industrial settings, industrial hygienists typically ensure that exposure is limited to the extent possible.
- One SER commented that dry cleaners have “good” ventilation (i.e., at least 1 workspace air change every 5 minutes) including local exhaust ventilation in the spotting board area, in addition to the general ventilation and monitoring.
- One SER discussed generally the potential to implement a breathing zone monitoring badge, suggesting a cost of $60 to $70 per sample. The SER noted that the suggested cost accounted for the labor to place and pay for the order, take the sample, send it back, and receive the monitoring information.
- SERs noted that for several uses (e.g., brake and parts cleaners, as a lubricant for spray applications) TCE is preferred due to certain characteristics (non-flammable, degreasing performance, rapid evaporation).

  - SERs noted that perchloroethylene is the primary chemical in most of the degreasing market, and that chlorinated solvents are preferred for quick evaporation for aerosol applications and application by the user (e.g., mechanic).
  - SERs also noted that chlorinated brake and parts cleaners are preferred among alternative chemicals and explained that to comply with lower volatile organic compound (VOC) limits, companies tend to put in one or two exempt compounds (e.g., acetone or methyl acetate) which have less preferred cleaning or degreasing ability.
- A SER noted that available alternatives for lubricants in spray applications are mostly fluorinated organic compounds; although non-fluorinated options may exist, there are concerns for future potential regulatory activity.

7.1.3. Related Federal Rules

When discussing related Federal rules:

- A SER mentioned that restrictions on the use of TCE for open-top and closed-loop vapor degreasing may present implications for cleaning and degreasing of parts where Federal Aviation Administration and Department of Defense specifications need to be met.
- A SER stated that industry works to minimize exposure to TCE to meet OSHA or other recommended requirements by implementing: PPE, administrative controls (e.g., isolating the work area so that only trained employee can enter), and engineering controls.
- A trade organization SER mentioned the American Innovation and Manufacturing Act (AIM Act), and stated that some hydrofluorocarbons, which TCE is used as a feedstock to manufacture, will be restricted in some applications under the AIM Act.
- Additionally, a trade organization SER mentioned that some fluorinated alternatives to TCE are under increased regulatory scrutiny, especially at state levels, because they may be subject to state per and polyfluoroalkyl substances (PFAS) laws based on their chemical structure and properties.

7.1.4. Regulatory Flexibility Alternatives

SERs identified several potential regulatory flexibility alternatives, challenges for small businesses, questions for EPA regarding the Agency’s regulatory approach, and provided recommendations:

- One SER noted that small businesses are primarily concerned about viability of TCE alternatives, especially fluorinated chemicals, due to regulatory scrutiny.
- Several SERs discussed certification programs:
  - In cases of niche or critical uses of TCE where alternatives were not considered by SERs to be feasible, several SERs noted that small businesses would appreciate the potential regulatory option of a training and certification program in which a small entity would have to be certified to purchase a TCE-containing product from a retailer, such as industrial supply stores or online retailers.
  - A paint and coating SER stated that there would be inventory issues with stocking products formulated with TCE if regulations limited where they could be bought and if

certification was required to purchase them, unless there was a rollout period allowing for stock to be depleted and for the supply chain to adjust to the change.

- A trade organization SER described how many of its members anticipate future TCE regulations and are looking at transitioning away from the chemical but find the commercial viability of potential alternatives challenging. The SER also stated that companies are reluctant to be the first on the market to produce a product using alternatives, which would be at a higher cost than TCE, because they do not wish to see their businesses suffer as a result passing on the cost increases of production to end users.

- In the case of a ban, SERs requested that the potential regulatory option include a *de minimis* level in the case of an impurity or trace amounts of TCE in products.

- Regarding dry cleaning:
    - One dry cleaning SER discussed how prohibiting TCE use for dry cleaners would cause higher costs in thousands of dollars compared to current conditions in additional labor and running time and would also cause adverse effects to production.
    - A dry cleaning SER mentioned that using an alternative spot removing product may take 5-15 minutes longer to try and remove a stain, while TCE's high efficacy helps to remove stains without much abrasive action, which increases a garment's useful life and prevents excess textile waste. The SER further noted that the transition to a substitute is a question of time and utility – adding an hour a day to stain removal also adds an hour a day to processing time, compressor time, and labor, and decreases customer satisfaction because of the increased time required to process a garment.

7.2. Summary of Written Comments Following the Pre-Panel Outreach Meeting

SERs provided written responses to the Pre-Panel outreach questions for discussion, which aimed to seek feedback on TCE processing and use, workplace-specific practices, and experiences with TCE, importance of TCE to the individual business, and current risk management controls. One SER provided written comments: Industrial Compliance Solutions.

7.2.1. Number and Types of Entities Affected

Written comments from the consulting SER pertained to the aerospace, metals manufacturing, and automotive repair/manufacturing/storage industries. The consulting SER stated that a typical vapor degreasing operation consumes about 325 gallons of TCE a year. This SER also stated that one of its client's vapor degreasers is 20 years old and has several modifications made to it including solvent recovery and additional emission controls, with the last upgrade made in 2016. They mention that the remaining life on the unit would be 10 years or more if properly maintained.

7.2.2. Potential Reporting, Recordkeeping, and Compliance Requirements

In written comments, the consulting SER gave examples of several replacement chemicals that are currently being marketed as drop-in replacements for TCE as a degreaser, such as proprietary fluorinated compounds, >70% by weight *trans*-1,2-dichloroethylene, and other organic solvents such as isopropyl alcohol or acetone.

- The SER noted potential concerns with some of these alternatives, namely that *trans*-1,2-dichloroethylene is currently undergoing risk evaluation within EPA as required by TSCA, and that isopropyl alcohol is labeled a “severe fire hazard” by the National Fire Protection Association.

- This SER also mentioned that in the automotive industry, alternatives that have been tested have increased cycle times and tend to have their own hazard profile, which can include flammability and toxicity.

The consulting SER stated that TCE is specifically required in the aerospace industry within specifications for acceptable solvent degreasers. They also stated that phasing out TCE use is not possible without changes to specifications from customers, commonly the Department of Defense.

- This SER also mentioned how employee exposure to TCE is controlled in the aerospace industry in regard to protections during vapor degreasing operations.
- This SER also stated that TCE is used for brake cleaning and parts degreasing in the industrial and commercial automotive industry and cautioned that if the concentration of TCE was limited in one of these types of products, the product would most likely not be compliant with the specifications which are driving its use.
- This SER also mentioned that TCE exposure is brief in industrial and commercial automotive repair, as it is applied via aerosol spray in short bursts. Additionally, the SER cautioned that an air supplied respirator would impose unreasonable costs on facilities by requiring them to implement a respiratory protection program and that this type of respirator would restrict the movement of mechanics in and around the equipment they are working on.
- The SER also stated that worker exposure is not applicable in the industrial and commercial automotive materials warehousing and distribution industry, as the materials are stored in closed containers as consumer commodities. They also stated that TCE exposure to a consumer would be based on how the materials is used.

7.2.3. Related Federal Rules

In written comments, the consulting SER expressed concern that many of the alternatives to TCE are also chemicals that have been identified by the Agency as part of the TSCA risk evaluation process as having unreasonable risk to health and/or the environment.

- The SER mentioned that the Hazard Communication Standard was implemented because chemicals are inherently used as part of manufacturing processes, and that manufacturing employers are responsible for ensuring the safety of their employees and properly educating them on the hazards pertaining to each chemical they use as part of their work. The SER also mentioned the expense and time invested into infrastructure, education, and disposal for use of chemicals such as TCE, and state that forthcoming rule under TSCA creates the appearance that these companies are being asked to start this process again with a different chemical.
- The SER stated that TCE is regulated under the Clean Air Act and that metal manufacturing facilities must account for their TCE usage and emissions from any process using TCE due to its classification as a Hazardous Air Pollutant, or volatile organic compound. They also mention that TCE usage and emissions are controlled using VOC destruction technologies and require continuous monitoring as defined in site specific permit requirements.

7.2.4. Regulatory Flexibility Alternatives

In written comments, the consulting SER stated that TCE is being replaced with alternatives in the metals manufacturing industry due to regulatory pressure and a reduction in supply, with viable alternatives already in place and reformulated coatings created to exclude chlorinated compounds.

- The consulting SER also stated that there are some potential alternatives to TCE for use in the aerospace industry as a solvent degreaser, but that these alternatives are currently very expensive and have additional hazards, such as flammability and toxicity.
- Additionally, this SER mentioned that a ban on TCE for use in the aerospace industry would have major implications, including the inability to operate, because, as they described, TCE is required to meet many specifications for production which take great effort, expense, and time to modify and/or change.

7.3. Summary of the Panel Outreach Meeting Discussion

At the Panel outreach meeting, SERs provided information on the number and type of entities that would be affected (including descriptions of their processing and use of TCE, their customer base, and how their products are used); potential compliance requirements (including current exposure reduction practices and anticipated impacts of potential prohibitions); related Federal rules; and potential regulatory flexibility alternatives (including descriptions of challenges for small businesses and questions for EPA regarding the regulatory approach).

Verbal comments from the meeting are summarized in the following subsections.

7.3.1. Number and Types of Entities Affected

SERs discussed their processing or use of TCE, as well as their customer base and how their products are used. Specifically:

- A SER who provides TCE and machines to vapor degreasers discussed the different types of machines and their uses:
    - The SER noted that some machines that are closed-loop degreasers can clean 30 baskets of parts a day. The SER described how the closed-loop machines have emissions only where the parts enter and exit the machine. The SER mentioned that the vapor degreasing machines do not have alarms to indicate exposure.
    - The SER, who is also a product formulator, described how, in their experience, use of TCE allowed for diverse degreasing processes, so that customers could have up to 10 production lines cleaning different lubricants or soils.
    - The SER also described a decrease in demand for TCE and degreasing machines using TCE; the SER stated that their business has not sold a new TCE-based vapor degreaser in 15 years. The SER mentioned that in recent years, they attempt to install aqueous degreasing equipment in customer facilities, when possible.
- A dry cleaning SER stated that the dry cleaning industry uses a small amount of TCE as a stain removal agent (in spot cleaning), before the garment is run through machines.
    - The SER mentioned that TCE is preferred to other alternative dry cleaning solvents because it is very efficient at removing stains.
    - This SER also mentioned that, in their experience, an average dry cleaning operation may use 1-2 gallons of TCE per year.

7.3.2. Potential Reporting, Recordkeeping, and Compliance Requirements

SERs described their exposure monitoring and reduction practices, anticipated changes due to potential requirements from EPA, and considerations for substitute chemicals or processes. Specifically, SERs described, for themselves or their customers:

- A SER who provides TCE and machines for vapor degreasing discussed, for vapor degreasers:
  - PPE:
    - The SER mentioned that some workers use PPE around the degreasing machines. The SER noted that typically PPE being worn depends on the type of degreaser being used (e.g., closed-loop degreasers have tighter controls in place), the amount of parts being cleaned, or the temperature in the building, in addition to other considerations.
    - The SER also noted that when working 40 hours a week, bulky PPE (e.g., self-contained breathing apparatus) would be hard to implement.
    - The SER also stated that, in their experience, machine maintenance activities, are the activity type that causes the greatest amount of worker exposure to TCE, and that workers performing maintenance should be required to wear PPE.
  - Administrative controls:
    - The SER noted that larger companies may be more easily able to afford to put a vapor degreasing machine in a separate room; for small companies, changing the footprint of the facility is often challenging.
    - The SER approximated that less than 5-10% of their work force is in the vicinity of the machines.
  - Engineering controls:
    - The SER described how open-top degreasers can clean large batches of parts, but have been redesigned to reduce emissions. They now have side walls, covers and other controls to comply with NESHAPs. The SER also described additional ways this design limits exposure, including how the parts should be lowered into and removed from the degreaser slowly so as not to disrupt the solvent vapor blanket.
    - Closed-loop degreasers have an additional box or vacuum to further reduce emissions and limit exposure to the worker handling the degreasing machines. The SER described how a vacuum system might have a cycle of an hour instead of 10 minutes, and so increase productivity by making the system larger (up to five times) so that more product can be cycled at once. The SER noted that these systems work better for degreasing smaller parts, and that they become more expensive the larger they get, because seals and segments of the systems are expensive. However, the SER noted there is uncertainty as to whether a closed-loop, vacuum degreasing system could limit TCE exposures to 4.0 ppb.
  - Alternative chemicals and methods:
    - A product formulation and vapor degreasing SER discussed the challenges of alternatives chemicals. Specifically, the SER described how most alternatives to TCE are flammable, boil at a much lower temperature, and, in their experience, perform worse at cleaning parts as TCE. The SER mentioned other solvents often used as alternatives to TCE (e.g., 1-bromopropane, *trans*-1,2-dichloroethylene) and expressed concern regarding potential future regulations of these chemicals. The SER provided an example of a solvent mixture they

have used before, containing varying percentages of *trans*-1,2 dichloroethylene. The SER also stated that, in their experience, solvents using fluorinated compounds and *trans*-1,2 dichloroethylene tend to have a higher amount of *trans*-1,2 dichloroethylene than the fluorinated compounds, making the resulting solvent mixture flammable.
        - The SER also described challenges of aqueous cleaning methods, including how in certain regions it is difficult to justify installation of these systems due to limited water availability. The SER provided an account about one of their customers, who had an aqueous cleaning system installed and was unable to source the required amount of water to run it.
- For repackaging and processing TCE, the SER described:
    - Workers wear PPE for repackaging the TCE products that are distributed to customers.
    - Products are currently labeled, and the SER prefers that distributors not be responsible for ensuring compliance by customers.
- A dry cleaning SER:
    - Reiterated the challenges of alternatives:
        - Some alternatives to TCE are known as a Class 3A solvents and flammable, while TCE is desirable because it has no flash point.
        - The SER described how alternatives to TCE for dry cleaning require more labor to remove the same type of stain, and so, in their view, TCE is more efficient.
    - Discussed disposal:
        - The dry cleaning SER stated that TCE residue present in dry cleaning machines eventually becomes distilled with other cleaning agents present and is disposed of as hazardous waste. The SER also mentioned that, in their experience, there are no disposal issues with TCE and that there are minimal worker exposure issues.

7.3.3. Related Federal Rules

When discussing related Federal rules:
- A SER who provides TCE and machines for vapor degreasing discussed their understanding that a previous exposure limit for TCE was 100 ppm.
- The SER described how NESHAPs currently require a permit to own and operate a vapor degreaser.
    - The SER described the process of complying with the NESHAP, including that the owner has to run tests, take readings, and file a report to show that the controls that the facility is using are compliant with state and Federal regulations.
    - The SER recommended that EPA expand on the NESHAP recordkeeping practice that is already in place rather than ask companies to comply with a new recordkeeping practice.
- SERs discussed generally how waste containing TCE has to be disposed of as a hazardous waste.

7.3.4. Regulatory Flexibility Alternatives

SERs identified several potential regulatory flexibility alternatives, challenges for small business, questions for EPA regarding the regulatory approach, and provided recommendations:
- A SER who provides TCE and machines for vapor degreasing expressed concern with their customers' ability to comply with the proposed ECEL of 4.0 ppb. The SER asked that EPA to

consider an option where the ECEL is calculated using exposure over 30 days instead of an 8-hour time weighted average. The SER mentioned that, in their experience, not every worker is consistently exposed to TCE for an 8-hour shift, 5 days a week, and asked how ECEL requirements would be imposed on a company in which a worker would be exposed to TCE for 4 hours, 1 day per week.

- This SER stated that the PPE EPA described in its presentation would be difficult for their business for a large project, but that it may be possible for a smaller, more limited product. This SER recommended that EPA establish criteria for a certification process for the end user to comply with recordkeeping practices, but noted their preference that distributors should not be held responsible for a client's recordkeeping practice.
- SERs discussed challenges with potential compliance timeframes under TSCA.
    - A vapor degreasing SER stated that a 5-year compliance timeframe might not be enough for some businesses. The SER further described the challenges to reformulation, including that testing compatibility, meeting specifications, sign off, equipment design and build, and installation would each require processes that could take several months.
    - The SER stated that longer compliance timeframes would be needed for processes for cleaning parts for national defense or cleaning medical devices.
- A SER who provides TCE and machines for vapor degreasers provided information on expected costs for implementing alternative processes not requiring the use of TCE.
    - The SER noted that a customer reformulating a degreasing product could cost close to $100,000, including reformulation, testing, certification, and labeling.
    - The SER also provided information from customers transitioning to aqueous systems. The SER noted that they have not sold new TCE-based vapor degreasing machines in the last 15 years, since vapor degreasing formulators and equipment manufacturers have been attempting to install aqueous degreasing equipment in customer facilities, when possible.
        - The SER described an approximate cost of $3,000,000 for an aqueous cleaning process, compared to $600,000 for a new closed-loop, vacuum degreasing system using TCE.
        - The SER described how a customer replacing TCE may have had up to 10 production lines with different lubricants, and may need four different aqueous solutions to clean parts to similar desired level of cleanliness.
        - The SER stated that new TCE-based vapor degreasing machines have not been sold in up to 15 years, since in recent years, vapor degreasing formulators and equipment manufacturers attempt to install aqueous degreasing equipment in customer facilities, when possible.
        - The SER noted the importance of the temperature of the bath, in order to melt the lubricant off the parts. The SER described how parts typically need to sit in an aqueous bath for much longer to remove the lubricant, because water boils at a lower temperature than TCE, and so the TCE removes the lubricant more efficiently.
        - In addition, according to the SER, a degreasing business may use 100-200 times more water than the amount of solvent for degreasing, which in turn also increases the cost of disposal. This can lead to water limits in some states, decreasing the amount of water available to run cleaning batches.
- A dry cleaning SER stated that TCE is essential to the dry cleaning industry for spot cleaning and stain removal.

7.4. Summary of Written Comments Following the Panel Outreach Meeting

SERs had the opportunity to provide written responses to the Panel outreach questions for discussion, which aimed to seek feedback on TCE processing and use, workplace-specific practices, and experiences with TCE, importance of TCE to the individual business, and current risk management controls. One SER provided written comments: the National Cleaners Association.

7.4.1. Number and Types of Entities Affected

The SER provided written comments on the use of TCE in dry cleaning. The SER stated that TCE is used as a stain removal agent and is integral to the stain removal process. The SER stated that TCE is on average used for 56 minutes a day for the cleaning of 2 garments, or approximately 2.5 hours a week. The SER emphasized that small volume dry cleaning operations would be particularly impacted by this rule, particularly the very small firms that have annual sales of $250,000 to $300,000. The SER described these firms as having small profit margins and comprising a major percentage of the dry cleaning industry.

7.4.2. Potential Reporting, Recordkeeping, and Compliance Requirements

The SER stated that alternatives for TCE as a stain removal are available; however, the SER emphasized that, in their experience, these alternatives are not as effective as TCE when used in spot cleaning applications. The SER noted that switching to an alternative could more than quadruple the labor costs of dry cleaning a garment, with significant impacts on the dry cleaning industry, which is predominantly small businesses.

- The SER stated their belief that switching to available alternatives to TCE would increase labor, supply, and utility costs because stained garments would need to be reprocessed, resulting in significantly more cleaning time than with TCE. The SER calculated that if a TCE alternative were used, the labor hours for spot cleaning would increase to 8.5 hours per week, compared to 2.5 hours per week when using TCE.
- The SER stated that the increased labor costs of working with an alternative would be especially burdensome to small volume dry cleaning firms. According to the SER, the average labor cost/week when using TCE is $77.00, and if an alternative to TCE were used, the average labor cost/week would be $327.50.

7.4.3. Related Federal Rules

The SER did not describe or discuss related Federal rules in their written comment.

7.4.4. Regulatory Flexibility Alternatives

The SER did not describe or discuss regulatory flexibility alternatives in their written comment. The SER stated that alternatives for TCE as a stain removal agent do exist and are available. However, the SER emphasized that they believe these alternatives are not as effective as TCE when used in spot cleaning applications.

- The SER stated that it is their belief that switching to available alternatives to TCE would increase labor, supply, and utility costs by having to reprocess stained garments and a lot more cleaning time than with TCE. The consulting SER calculated that when a TCE alternative would be used, the labor hours for spot cleaning would increase to 8.5 hours per week, as compared to 2.5 hours per week when using TCE.

- The SER stated that the increased labor costs of working with an alternative would be especially burdensome to small volume dry cleaning operations. According to the consulting SER, the average labor cost/week when using TCE is $77.00, and when an alternative to TCE is used, the average labor cost/week is $327.50.

8. PANEL FINDINGS AND DISCUSSION

8.1. Number and Types of Entities Affected

The proposed rule potentially affects businesses that manufacture (including import), process, use distribute, or dispose of TCE which impacts industries that include aerospace (including Department of Defense), metals manufacturing, automotive/repair/manufacturing/storage and dry cleaning. During the Panel outreach meeting, SERs discussed the types of small entities affected and included information on their sale and use of TCE, with a focus on vapor degreasing and dry cleaning. SERs commented on the approximate quantity of TCE that they use, the types of machines in use for vapor degreasing (open-top and closed-loop systems), the types of articles cleaned or degreased, including specialty parts, and the investments already made to upgrade machines. SERs representing the vapor degreaser use noted the use of TCE in niche applications, including for defense or aeronautical uses.

Based on feedback from a SER representing the dry cleaning industry, the limited use of TCE is currently an integral part of the stain removal process. According to the SER, available alternative chemicals are not as efficient. This SER also provided that small volume dry cleaners, which compromise a majority of their industry, may be disproportionately impacted because these firms have small profit margins.

EPA estimates of the small entities to which the proposed rule may apply are described in Section 4 of this document. As shown in Table 4.2, 20,611 small entities could potentially be impacted by the rule. Not all of the small firms indicated in the Table, however, are expected to be impacted by the proposed rule as elaborated on in Section 4.

8.2. Potential Reporting, Recordkeeping, and Compliance Requirements

SERs described their exposure monitoring and reduction practices and considerations for substitute chemicals or processes. Specifically, vapor degreasing SERs described their current exposure monitoring practices, ventilation, engineering controls such as equipment upgrades or replacement, administrative controls, and use of PPE. A dry cleaning SER described the quantity of TCE use and waste disposal, as well as the labor process and duration of use of TCE in spot cleaning. While SERs did not describe their current exposures, they described their interest in a higher exposure limit than the EPA ECELs of 4 ppb and 1.1 ppb, and the challenges of monitoring exposures below 4 ppb. SERs, notably those associated with vapor degreasing. indicated during the pre-panel and panel discussions that small businesses could have trouble complying with the TCE ECELs of 4 ppb or 1.1 ppb.

Regarding PPE use, a SER noted that it will depend on the type of degreaser being used (e.g., open-top or closed-loop) and the type of activity (e.g., machine maintenance). The SER also provided feedback on potential administrative controls such as moving a vapor degreasing machine into a separate space as not being an affordable option for small businesses. The SER explained that while closed-loop degreasers have features that can reduce emissions and limit worker exposure, it is unclear whether using such a degreasing system could limit the TCE exposure to 4.0 ppb. This SER also discussed the use of PPE in repackaging and processing TCE products.

Most SERs described their preference for continuing to use TCE, and provided their rationales. Specifically, a trade association SER described how TCE is used as a cleaning agent or degreaser for several niche applications, in which TCE's property as a nonflammable solvent is critical. Although this SER noted that potential alternatives exist, they described how new formulations would require additional testing to ensure they can provide proper cleaning, especially to avoid damaging the energized equipment (e.g., circuit board). A SER representing product formulators specified that reformulating a degreasing product could cost close to $100,000, including reformulation, testing, certification, and labeling. Many of this SER's members anticipate future TCE regulations and are looking at transitioning away from the chemical but find the commercial viability of potential alternatives challenging. Other SERs described how niche cleaning applications of TCE, such as in the aerospace industry or automotive manufacturing and industrial cleaning, must meet high cleaning specificity standards that complicate switching to an alternative chemical. The consulting SER stated that TCE is specifically required in the aerospace industry within specifications for acceptable solvent degreasers. They also stated that phasing out TCE use is not possible without changes to specifications from customers, commonly the Department of Defense. The SER explained that the modification of such specifications is time-consuming and expensive.

SERs also emphasized the flammability of certain alternatives, the challenges of aqueous systems (which require large quantities of water and may need additional or reconfigured facility space), and their concerns for potential regulation for substitute chemicals. A SER representing degreaser system providers described how an aqueous cleaning process can cost $3,000,000 and noted that it requires more time to be as effective as TCE in removing lubricants. SERs specifically expressed concerns that many of the alternative chemicals to TCE may be subject to future regulation by EPA for potentially posing unreasonable risks. In addition, a trade organization SER highlighted that some fluorinated alternatives to TCE are under increased regulatory scrutiny, especially at state levels, because they may be subject to state PFAS laws based on their chemical structure and properties.

A dry cleaning SER described the labor process and duration of use of TCE in spot cleaning noting that alternatives chemicals are less efficient. The dry cleaning SER stated that switching to available alternatives to TCE would increase labor, supply, and utility costs because stained garments would need to be reprocessed. The SER also provided cost information related to increasing labor hours due to switching from TCE in spot cleaning. This dry cleaning SER estimated that the cost of using an alternative would significantly increase the average labor cost, increasing from an average labor cost/week when using TCE at $77.00, to an average labor cost/week of $327.50 based on the use of a TCE alternative.

SERs expressed concerns regarding compliance time with any regulation that would result in the use of an alternative chemical. For example, a SER representing the users of TCE in vapor degreasers emphasized that 5-year compliance timeframe would not be sufficient to adopt to using alternatives given the challenges of reformulation, testing, meeting specifications, etc. This SER also noted that processes for cleaning parts for national defense or cleaning medical devices would likely require longer compliance timeframes.

8.3. Related Federal Rules

Most SERs described compliance under existing NESHAPS under the CAA, which resulted in equipment changes and upgrades, as well as regulations on hazardous waste. SERs also stated that they comply with TCE emission standards as a volatile organic compound, and TCE usage and emissions are controlled using VOC destruction technologies and require continuous monitoring as defined in site specific permit requirements. A SER stated that industry works to minimize exposure to TCE to meet OSHA or other recommended requirements by implementing: PPE, administrative controls (e.g., isolating the work area so that only trained employee can enter), and engineering controls. A trade organization SER referenced the AIM Act to highlight that some hydrofluorocarbons, which TCE is used as a feedstock to manufacture, will be restricted in some applications under the AIM Act.

8.4. Regulatory Flexibility Alternatives

The SERs suggested the following regulatory flexibilities to reduce the impact of a potential regulation on TCE under section 6 of TSCA:

1. A training and certification program in which a small entity would have to be certified to purchase a TCE-containing product from a retailer, such as industrial supply stores or online retailers.
2. Longer compliance timeframes for transition to alternatives for uses requiring reformulation and cleaning processes for cleaning parts for national defense or cleaning medical devices.
3. In the case of a ban, SERs requested that the potential regulatory option include a *de minimis* level in the case of an impurity or trace amounts of TCE in products.

The Panel recommends that EPA consider additional activities listed below to determine if they are appropriate to provide flexibility to lessen impacts to small entities. Many of the recommended flexibilities may lessen impacts to all entities, and not only small entities:

Regulatory Options

Based on SER comments:

1. With respect to the possible establishment of an Existing Chemical Exposure Limit, the Panel recommends that EPA consult and communicate with OSHA to clearly explain respective regulatory requirements applicable to workers and workplaces who must comply with standards set by both agencies, and to minimize confusion by aligning definitions, reporting intervals, and other requirements where possible. In addition, EPA and OSHA should communicate on implementing or sharing information in instances of duplicative regulatory requirements, such as record keeping or monitoring. EPA should also provide clear and specific guidance for complying with any potential ECEL. The Panel recommends that EPA request public comment in the notice of proposed rulemaking (NPRM) on the extent to which a regulation under TSCA section 6(a) could minimize requirements, such as testing and monitoring protocols, recordkeeping, and reporting requirements, which may exceed those already required under OSHA's regulations for TCE.

2. The Panel recommends that EPA continue to engage with Federal partners to work towards establishing a policy on its relationships to other Federal laws administrated by EPA and/or other Federal agencies to ensure transparency and that the statutory obligations under TSCA to address the unreasonable risk are met. Specifically, the panel recommends that EPA describe in its communications materials relating to the proposed rule a crosswalk to similar relevant OSHA regulations and a crosswalk of any final regulations to similar relevant pre-existing regulations, as part of required small entity compliance guides (as in the case of OSHA PELs and EPA ECELs).

3. The Panel recommends that EPA provide and request comment in the NPRM on reasonable compliance timeframes for small businesses. Specifically, the Panel recommends that EPA request comment on whether and how to provide longer compliance timeframes for transitioning to alternatives for uses requiring reformulation and cleaning processes for cleaning parts for national defense or cleaning medical devices. As part of this effort, the Panel recommends that EPA consider compliance timelines based on the expected availability of technically and economically feasible alternatives, as well as any information that could be provided by other agencies that set requirements for certification or standards relevant to degreasing, parts cleaning, or other uses of TCE. The Panel also recommends that EPA request comment in the NPRM on differing compliance or reporting requirements or timetables that account for the resources available to small entities. Additionally, the Panel recommends that EPA consider reasonable compliance timeframes for prohibitions or phase-outs on use of TCE for vapor degreasing and other uses, in response to SER input and other appropriate factors, such as the lifespan of equipment, and capital costs for new equipment. In addition, the Panel recommends that EPA take comment on any additional appropriate factors for identifying reasonable compliance timeframes and how to weigh the factors for vapor degreasing and other industries.

4. The Panel recommends that EPA provide readily available information on potential costs that could be incurred using strategies to meet requirements for any proposed ECEL, such as engineering, administrative, or prescriptive controls (e.g., use of specialized ventilation systems, add-ons to equipment to reduce emissions, cost of new equipment, etc.), as they apply to each relevant COU. The Agency should also provide its analysis on whether it is feasible to implement these strategies for the regulated entities. The Panel further recommends that EPA request public comment in the NPRM about the feasibility of entities complying with and monitoring for a potential ECEL of either 4.0 ppb or 1.1 ppb. Specifically, regarding the public comment request, the panel recommends that EPA aim to obtain more information on potential costs that could be incurred using strategies to meet the requirements of such a standard, such as engineering, administrative, or prescriptive controls and how feasible it would be for entities to implement these strategies in their operations.

5. The Panel recommends that EPA provide details and request public comment in the NPRM about the feasibility of use of alternatives to TCE and their availability for conditions of use that drive the unreasonable risk. Specifically, the Panel recommends that EPA provide, to the extent practicable, costs for the use of alternatives and information on the hazard profile of the alternatives. The Panel recommends that EPA should ensure that entities, with emphasis on small entities, are provided as much information as is available to the Agency about suitable alternatives for these conditions of use, potentially through the form of information generated as part of the rulemaking process (such as an alternatives assessment). Additionally, the Panel recommends that EPA describe in the NPRM known problems and/or risks with available alternatives including those indicated by the SERs, such as flammability, toxicity, and water limitations due to drought.

6. The Panel recommends that EPA provide an analysis for each use identified by SERs that would be subject to prohibition to demonstrate whether technically and economically feasible alternatives to TCE that benefit health or the environment, compared to the use proposed to be prohibited or restricted, would be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

7. The Panel recommends that EPA consider and request comment in the NPRM on a training and certification program for a commercial user to obtain a TCE-containing product from a retailer, such as industrial supply stores or online retailers.

8. The Panel recommends that EPA provide an explanation of consideration for providing an exemption under TSCA section 6(g) for the Department of Defense, National Aeronautical and Space Administration, and Federal Aviation Administration-related and aviation uses, such as vapor degreasing for parts in aerospace vehicles. In addition, the Panel recommends that EPA engage, as appropriate, with relevant agencies.

9. The Panel recommends that EPA consider and request public comment in the NPRM on a *de minimis* level in the case of an impurity or trace amounts of TCE in products.

10. The Panel recommends that EPA request comment on whether to allow the use of TCE by entities that could, based on demonstrated ability through monitoring data, meet the ECEL under a workplace chemical protection program.

11. The Panel recommends that EPA discuss the concerns regarding availability of feasible alternatives that could be subject to market forces that may impact availability of alternatives (e.g., certain fluorinated chemicals) or potentially be subject to future EPA regulations. The panel recommends that EPA request public comment on how the rulemaking should consider TCE alternatives in light of ongoing regulatory scrutiny.

12. The panel recommends that EPA's RFA and cost-benefit analyses consider the impact of excluding, as viable alternatives, any chemicals identified by the Agency as part of the TSCA risk evaluation process as presenting an unreasonable risk of injury to health or the environment. The Panel recommends that EPA request comment on whether these chemicals as well as chemicals undergoing risk evaluation would be likely to be considered as viable alternatives and, if so, in which circumstances.

13. The Panel recommends that EPA request public comment in the NPRM on potential challenges associated with monitoring TCE below 4 ppb and 1 ppb.

14. The Panel recommends that EPA request public comment in the NPRM on whether the use of TCE in a closed-loop vapor degreasing system, when combined with requirements of a potential workplace chemical protection program, could meet the ECELs for TCE.

APPENDIX A: Materials Shared with Small Entity Representatives for the Pre-Panel and Panel Outreach Meetings

Appendix A1 (separate document) is a compilation of all outreach materials shared with SERs for the Pre-Panel Outreach meeting held on October 28, 2022. Below is a list of those materials.

- Agenda
- Panel Process Presentation
- Pre-Panel Rulemaking Presentation
- Industry Sectors with Small Entities Potentially Affected by the Rulemaking Document
- Related Regulations (EPA, Federal, State, and International) Document
- Pre-Panel Outreach SER Questions for Discussion
- Existing Chemical Exposure Limit (ECEL) for Occupational Use of TCE Memorandum
- Second Existing Chemical Exposure Limit (ECEL) (Developmental Toxicity) for Occupational Use of TCE Memorandum
- Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown Document
- Potential Regulatory Options and Estimated Costs Document

Appendix A2 (separate document) is a compilation of all outreach materials shared with SERs for the Panel Outreach meeting held on January 31, 2023. Below is a list of those materials.

- Agenda
- Panel Process Presentation
- Pre-Panel Rulemaking Presentation
- Industry Sectors with Small Entities Potentially Affected by the Rulemaking Document
- Related Regulations (EPA, Federal, State, and International) Document
- Pre-Panel Outreach SER Questions for Discussion
- Existing Chemical Exposure Limit (ECEL) for Occupational Use of TCE Memorandum
- Second Existing Chemical Exposure Limit (ECEL) (Developmental Toxicity) for Occupational Use of TCE Memorandum
- Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown Document
- Potential Regulatory Options and Estimated Costs Document
- Key Takeaways from Pre-Panel Outreach Meeting

Appendix A1: Materials Shared with Small Entity Representatives for the Pre-Panel Outreach Meeting held on October 28, 2022

Table of Contents

Agenda

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Trichloroethylene (TCE) under TSCA Section 6(a)

October 28, 2022, 10:00am-1:00pm, Eastern time zone

Agenda

10:00 Welcome and Opening Remarks

- Bill Nickerson (EPA Small Business Advocacy Chair / Office of Policy)
- Brian Symmes (Acting Director, Existing Chemicals Risk Management Division, EPA Office of Chemical Safety and Pollution Prevention)
- Tayyaba Zeb (Small Business Administration, Office of Advocacy)
- Austin Mudd (Office of Management and Budget, Office of Information and Regulatory Affairs)

10:15 SER Introductions

10:25 Presentation on Panel process (Bill Nickerson, EPA SBAC)

10:35 Presentation on proposed rulemaking for TCE under TSCA section 6(a) (Office of Chemical Safety and Pollution Prevention)

- Consultations with Small Entity Representatives (SERs)
- Overview of the unreasonable risk determinations and the risk management requirements under TSCA
- Overview of conditions of use in the rulemaking and basis for unreasonable risk determination
- Section 6 risk management overview: EPA's authority to regulate occupational and consumer risks, key "tools in the toolbox" for managing unreasonable risks
- Potential regulatory options

11:05 Discussion on conditions of use (COU) within the scope of the regulation (*See list at end for all conditions of use by group*).

- Detailed description of TCE use
- Your experience with exposure control and risk reduction
- Possible risk management actions
- Cost associated with implementations
- Available alternatives
- Other implementation considerations

TCE COU Group 1: Manufacturers, Processors, and Disposal
TCE COU Group 2a: Industrial Vapor Degreasing and Cold Cleaning Uses
TCE Group 2b: Industrial and Commercial Aerosol Uses

11:50 Break

12:00 Discussion (continued)

TCE COU Group 2c: Other Industrial and Commercial Uses – Industrial and Large Commercial
TCE COU Group 2d: Other Industrial and Commercial Uses – Small Commercial
TCE COU Group 3: Consumer Uses

12:45 Closing session

- Closing remarks from EPA, SBA, and OMB
- Wrap up and next steps (what to expect next)

1:00 Adjourn

Condition of Use Discussion Groups

Group 1: Manufacturers, processors, and disposal

- Includes the following conditions of use:
  - Manufacturing (domestic manufacturing)
  - Manufacturing (import)
  - Processing: repackaging
  - Processing as a reactant/intermediate
  - Processing: incorporation into formulation, mixture or reaction product
  - Processing: incorporation into articles
  - Processing: recycling
  - Disposal

TCE Group 2a: Industrial Vapor Degreasing and Cold Cleaning Uses

- Includes the following conditions of use:
  - 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 penetrating lubricant
  - Industrial and commercial use in automotive care products in brake parts cleaner

TCE Group 2b: Industrial and Commercial Aerosol Uses

- Includes the following conditions of use:
  - 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 penetrating lubricant
  - Industrial and commercial use in automotive care products in brake parts cleaner

TCE Group 2c: Other Industrial and Commercial Uses – Industrial and Large Commercial

- Includes the following conditions of use:
  - Industrial and commercial use as a lubricant and grease in tap and die fluid
  - 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 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

TCE Group 2d: Other Industrial and Commercial Uses – Small Commercial

- Includes the following conditions of use:
  - Industrial and commercial use in laundry and dishwashing products in spot remover
  - Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning
  - Industrial and commercial use as ink, toner and colorant products in toner aid
  - Industrial and commercial use in apparel and footwear care products in shoe polish
  - Industrial and commercial use in hoof polish, gun scrubber, and pepper spray

TCE Group 3: Consumer Uses

- Includes the following conditions of use:
  - 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 adhesive and sealant
  - 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

Panel Process Presentation

An Overview of the Small Business Advocacy Review (SBAR) Panel Process

October 28, 2022

Office of the Administrator
Office of Policy
Office of Regulatory Policy and Management

Why does EPA convene an SBAR Panel?

The Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to:

“assure that small entities have been given an **opportunity to participate** in the rulemaking process” for any rule “which will have a **significant economic impact** on a substantial number of small entities.”

What is an SBAR Panel?

An EPA Small Business Advocacy Review (SBAR) Panel is made up of **four** managers from **three** federal agencies:

- EPA's Small Business Advocacy **Chair** (EPA's SBAC is from OP)
- A **manager** from the EPA program responsible for writing the rule

- The Small Business Administration's **Chief Counsel** for Advocacy

- The **Administrator** of the Office of Management and Budget's (OMB's) Office of Information and Regulatory Affairs (OIRA)

What does an SBAR Panel do?

The RFA tasks the Panel with **reviewing the material** the Agency has available concerning the rulemaking, and **collecting advice and recommendations** from small entity representatives (SERs) on issues related to the following **four** elements:

- Who are the small entities to which the proposed rule will apply?
- What are the anticipated compliance requirements of the upcoming proposed rule?
- Are there any existing federal rules that may overlap or conflict with the regulation?
- Are there any significant regulatory alternatives that could minimize the impact on small entities?

SERs Participation in the Pre-panel and Panel process

SERs are invited to 2 meetings: Pre-panel Outreach meeting and Panel Outreach meeting

- At each meeting, SERs participate in the discussion about how the rule might impact them and provide suggestions about how to minimize that impact.
- Panel Outreach meeting will focus on further refining SER advice and recommendations from the Pre-panel Outreach

SERs are invited to supplement the verbal meeting discussions with **written comments** (due 2 weeks after each meeting)

SER FAQ webpage https://www.epa.gov/reg-flex/frequent-questions-small-entities.

Where does the Panel process fit within the rulemaking process?

EPA's Pre-Panel Outreach Meeting with SERs → Panel Outreach Meeting with SERs → Panel Report to EPA's Administrator → Notice of Proposed Rulemaking → Public Comment Period → Final Rule

It is EPA's goal to host SBAR Panels well **before a proposed rule** is written so there is adequate time to incorporate Panel recommendations into senior management decision-making about the proposed rule

SER participation in the Pre-panel and Panel Outreach meetings **does not preclude** or take the place of participation in the normal public comment period at the time the rule is proposed

What does the Panel do with the information, advice, and recommendations from SERs?

The Panel prepares a Panel Report

- SER comments are **summarized**, and written comments are included as an appendix
- SER information, advice, and recommendations are **synthesized** into a set of Panel recommendations
- **Submitted** to the EPA Administrator
- Considered during senior-management decision-making **prior** to the issuance of the proposed rule
- Placed in the **rule's docket** when the proposed rule is published

Thank You

We realize that small entities make significant sacrifices to participate in this process

Thank you for taking time and effort away from your business or organization to assist the Panel in this important work

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Pre-Panel Rulemaking Presentation

Trichloroethylene (TCE) Small Entity Consultation on Proposed Rulemaking under TSCA Section 6

Office of Pollution Prevention and Toxics

U.S. Environmental Protection Agency

Small Business Advocacy Review Pre-Panel Outreach Meeting

October 28, 2022

Overview

- SERs and the regulatory process
- Findings from the risk evaluation for TCE
- Overview of conditions of use (COU) in the rulemaking
- Basis for unreasonable risk determination
- Risk management requirements under TSCA
- EPA's authority and “tools in the toolbox”
- Potential regulatory options
- Additional discussion with Small Entity Representatives
- Closing remarks

Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)

- EPA will use this information to inform the agency's decision on potential regulatory options and to develop a regulatory flexibility analysis, which becomes part of the record for the potential regulation

Consultation with Small Entity Representatives

- Key elements in this regulatory flexibility analysis:
  - Number of small entities to which the potential rule would apply
  - Projected compliance requirements of the potential rule
  - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the potential rule
  - Any significant alternatives to the potential rule which accomplish the stated objectives, and which minimize significant economic impact of the potential rule on small entities

Potentially Affected Entities

- The potential affected industries/sectors for this proposed rule are identified by its NAICS code, SBA thresholds and U.S. Census Bureau Statistics of U.S. Business datasets, published annually
- A list of these industries/sectors potentially affected by the proposed rule is included as a handout
- 349 industries/sectors and their associated NAICS code have been identified although not all of the small firms indicated in the attachment are necessarily expected to be impacted by the proposed rule
- SBA size standards vary greatly by NAICS code and range from $.75-$41.5 million and 100-1500 employees
- The attachment "Industry Sectors with Small Entities Potentially Affected by the Rulemaking" provides small firm statistics (number of and employee size) for each industry/sector
- EPA estimates 250-300 small entities may be impacted by the proposed rule
- As more specific information about each entity is identified, it is possible that some entities could be dropped from the list

SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
  – Provide specific examples of impacts
  – Provide cost data, if available
  – Please see detailed questions in a separate handout

SERs and the Regulatory Process

- We are also seeking alternative methods of regulating these risks
  - Suggest other relevant options, including data costs and information on how to ensure compliance
  - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions

- We would like to minimize duplication
  - Provide information on any duplicative or contradictory federal, state, county, or city regulations you are aware of
  - For a list of existing regulations, please see summary of Federal regulations

Overview of the Risk Evaluation for TCE

- Risk evaluation published November 24, 2020:
  - 54 conditions of use were evaluated
  - Risk evaluation follows a series of opportunities for public input into EPA's TCE risk evaluation activities
  - TCE draft risk evaluation: February 2020; TCE problem formulation: June 2018; TCE scope document: June 2017

Overview of the Risk Evaluation for TCE

- Public comments and external scientific peer review informed the final risk evaluation
  - 70 public comments received on the draft risk evaluation (comment period closed April 27, 2020)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (March 2020)

- The 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

Determination of Unreasonable Risk

- In the November 2020 risk evaluation, EPA determined that TCE presented unreasonable risk to health and the environment. In that risk evaluation, EPA determined that 52 of the 54 conditions of use (COU) of TCE presented unreasonable risk.

- With EPA's policy change to a whole chemical approach, EPA has issued a draft revised risk determination proposing a whole chemical unreasonable risk determination without presuming use of PPE. The changes from that revised determination have not yet been finalized but are included in this presentation to indicate the approach that EPA is now taking.

- There may be some conditions of use in the final risk evaluation that EPA has determined do not drive the unreasonable risk but may still be subject to regulation due to uses elsewhere in the supply chain that drive the unreasonable risk.

Recent Proposed Changes to the Risk Determination

- EPA released for public comment a draft revision to the unreasonable risk determination for TCE on July 7, 2022
- EPA is now addressing comments and expects to publish the final revised risk determination this fall
- Incorporates policy changes announced in June 2021
- Specifically, EPA proposes that:
  - Making an unreasonable risk determination for TCE as a whole chemical substance, rather than unreasonable risk determinations separately on each individual condition of use in the risk evaluation, is the most appropriate approach to TCE under the statute and implementing regulations
  - The risk determination should be explicit that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce workers' exposures; rather, the use of PPE would be considered during risk management as appropriate

Recent Proposed Changes to the Risk Determination

- Removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for TCE would:
  - Not alter the conditions of use that drive the unreasonable risk determination for TCE
  - Result is additional risks for acute non-cancer and cancer effects from inhalation and dermal exposures would also drive the unreasonable risk in many of those conditions of use (where previously those conditions of use were identified as presenting unreasonable risk from chronic non-cancer effects and cancer).
- Overall, 52 conditions of use out of 54 EPA evaluated would drive the TCE whole chemical unreasonable risk determination
- EPA has not conducted new scientific analysis on TCE; the risk evaluation continues to characterize risks associated with individual conditions of use
- The draft risk determination is in docket EPA-HQ-OPPT-2016-0737 at regulations.gov

Recent Proposed Changes to the Risk Determination

- Separately, EPA is conducting a screening approach to assess potential risks from the air and water pathways for several of the first 10 chemicals, including TCE
  - This screening analysis was presented to the SACC in March and EPA is currently incorporating comments from the SACC and public commenters on revisions to the analysis
- Exposure pathways that were or could be regulated under another EPA-administered statute were excluded from the 2020 TCE risk evaluation, resulting in certain air and water pathways not being fully assessed
- EPA's screening approach will identify if there are risks that were unaccounted for in the risk evaluation for TCE
- If the results suggest there is additional risk, EPA will determine if the risk management approach being contemplated for TCE will protect against these risks or if the risk evaluation will need to be formally supplemented or revised

TCE Manufacturing, Processing, Industrial, and Commercial Uses that Drive the Unreasonable Risk

- Manufacturing (domestic manufacturing)
- Manufacturing (import)
- 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 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

TCE Industrial and Commercial Uses that Drive the Unreasonable Risk

- Industrial and commercial use as a functional fluid in heat exchange fluid
- 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 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

TCE Industrial and Commercial Uses and Disposal that Drive the Unreasonable Risk

- 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
- Disposal

TCE Consumer Uses that Drive the 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 adhesive and sealant

TCE Consumer Uses that Drive the Unreasonable Risk

- 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

Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures to TCE:
  - Immunosuppression effects from acute inhalation and dermal exposures
  - Autoimmunity effects from chronic inhalation and dermal exposures
  - Cancer effects (kidney) from chronic inhalation and dermal exposures

- Consideration of Personal Protective Equipment (PPE):
  - The OSHA permissible exposure limit (PEL) for TCE is set at 100 ppm as an 8-hr time-weighted average
  - EPA does not assume that workers are always provided or appropriately wear PPE, for the purposes of unreasonable risk determination
  - EPA does not assume that it is a standard industry practice that workers in some small commercial facilities (e.g., those performing spot cleaning, wipe cleaning, shoe polishing, hoof polishing, or commercial printing and copying) have a respiratory protection program or regularly employ dermal protection; therefore, the use of respirators and gloves is unlikely for workers in these facilities
  - When no PPE is assumed to be in place, 52 of the 54 COUs drive the unreasonable risk
  - As previously noted, this assumption did not result in additional COUs driving the unreasonable risk determination

Basis for Unreasonable Risk Determination: Consumers and Bystanders

- The unreasonable risk determinations for consumers and bystanders are based on the following health hazards during consumer exposures to TCE:
  - Immunosuppression effects from acute inhalation and dermal exposure

- EPA does not assume dermal exposure to TCE for bystanders

- The unreasonable risk determinations were based on the high intensity risk estimates for consumers and bystanders; unreasonable risk was also presented for moderate intensity use risk estimates for many COUs

- EPA did not evaluate chronic exposures to TCE for consumer users and bystanders because EPA considered the frequency of consumer product use to be too low to create chronic risk concerns

Related Regulations and TSCA Section 6 Authority

- TCE is subject to numerous federal laws and regulations in the United States and is also subject to regulatory actions by states
  - For example, OSHA established a PEL for TCE at 100 ppm as an 8-hour TWA. Most states have set PELs identical to OSHA. Nine states have PELs of 50 ppm. California's PEL of 25 ppm is the most stringent (CCR, Title 8, Table AC-1).
  - See separate document "Related Regulations (EPA, other Federal, State, and International)" for more information on the regulatory history of TCE
- EPA determined that TCE presents an unreasonable risk to workers, ONUs, consumers, and bystanders in the TSCA risk evaluation even though the chemical substance is currently regulated under other statutes (e.g., CERCLA, CAA (NESHAPs))
- Therefore, EPA is required to develop risk management actions under TSCA to address the unreasonable risk
- TSCA Section 9 allows EPA to use statutory authorities other than TSCA to reduce or eliminate identified risk to health or the environment

Risk Management Requirements

- Under TSCA, EPA is required to take action, to the extent necessary, to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process and EPA is seeking stakeholder input now during the SBAR process and during the public comment period following the proposed rule

TSCA Section 6(a)

- TSCA provides EPA with authority to address unreasonable risks, and to regulate entities including:
  - Manufacturers (including importers) and processors (e.g., formulators)
  - Distributors
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
  - Under TSCA, EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
  - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

Critical or Essential Uses: TSCA Section 6(g)

TSCA section 6(g) allows EPA to grant, by rule, a time-limited exemption from a section 6(a) rule for a specific condition of use

- To provide an exemption, EPA must find that:
  - The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available;
  - Compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or
  - The specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety
- In granting an exemption, EPA must:
  - Provide a time limit for the exemption
  - Analyze the need for the exemption and make the analysis public
  - Include conditions, such as recordkeeping, monitoring, and reporting requirements, to the extent EPA determines they are necessary to protect health and the environment while achieving the purposes of the exemption

Availability of Alternatives: TSCA Section 6(c)(2)(C)

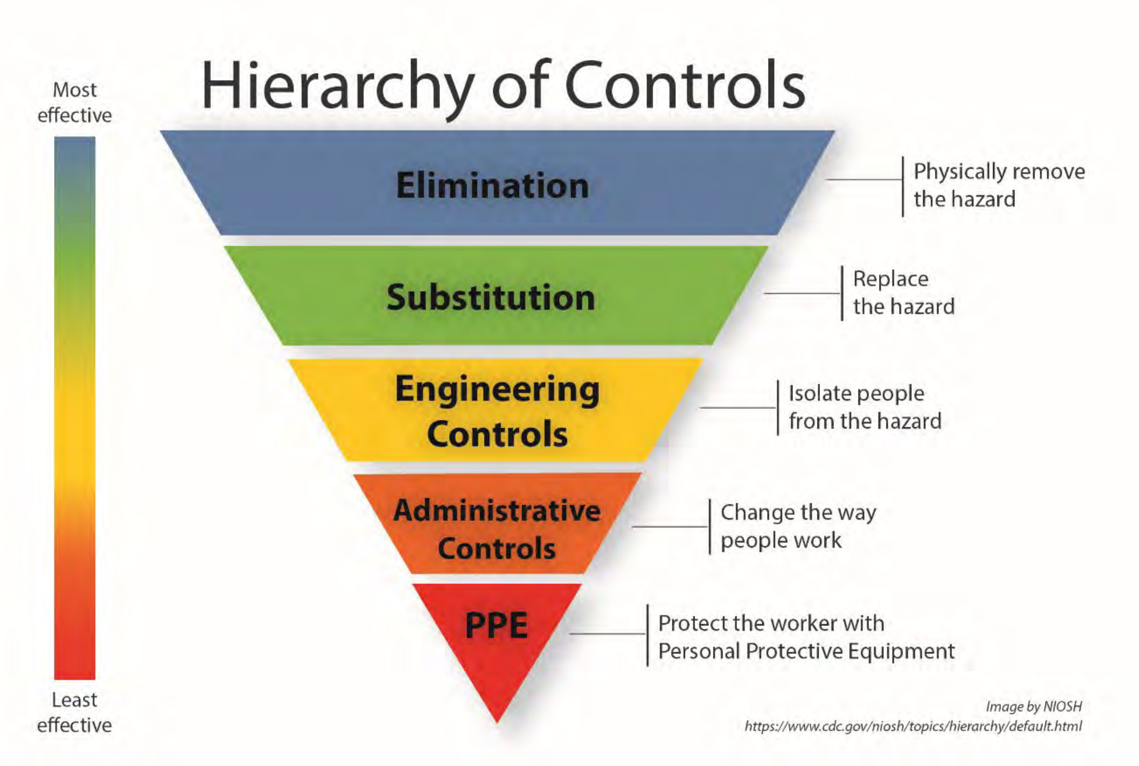
- TSCA section 6(c)(2)(C) requires EPA "…in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action…to the extent practicable, whether technically and 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 when the proposed prohibition or other restriction takes effect"
  - Substitute products and methods vary by condition of use
  - For example, alternatives to TCE in in vapor degreasing include solvent-based alternatives like 1,2-trans-dichloroethylene and aqueous systems which use detergents and other additives to clean, while alternatives for cleaning and furniture care might include different solvents such as glycol ethers.

Effective Dates: TSCA Section 6(d)

- TSCA section 6(d) describes effective dates and compliance dates for TSCA section 6(a) rules
- In these rules, EPA must specify an effective date, which must be as soon as practicable
- Except for uses exempted under TSCA section 6(g), EPA must:
  - Specify mandatory compliance dates for all rule requirements, no later than five years after promulgation of the rule, or, in the case of a ban or phase-out:
    - Specify mandatory compliance dates for the start of a ban or phase-out requirements, which shall be as soon as practicable and no later than five years after promulgation of the rule, and
    - Specify mandatory compliance dates for full implementation of a ban or phase-out requirements, which shall be as soon as practicable
- EPA must also provide for a reasonable transition period

Hierarchy of Controls

- EPA is considering the NIOSH/OSHA hierarchy of controls when developing risk management actions
  - As described by NIOSH (https://www.cdc.gov/niosh/topics/hierarchy/default.html), the hierarchy of controls can be used to implement feasible and effective controls to protect workers
  - It typically includes elimination, substitution, engineering controls, administrative controls, and PPE on a scale of most to least protective
- Any regulatory option can be used alone or in combination so that TCE no longer presents an unreasonable risk under the conditions of use



Potential Regulatory Options

- EPA has considered several regulatory options under TSCA section 6(a), and a wide range of risk reduction practices and options

- Through Agency review and stakeholder input, the following potential options have been identified as reducing exposures, so TCE no longer presents an unreasonable risk of injury to health

- These options are currently being considered and evaluated by EPA, and are not final at this time. EPA has not made a decision at this point about what regulatory options to propose

- Regulatory options could be used alone or in combination so that TCE no longer presents an unreasonable risk under any condition of use

Potential Regulatory Options

- Prohibit or restrict manufacturing, processing, and distribution
- Prohibit or restrict manufacturing, processing, and distribution for a particular use
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive PPE controls
- Prescriptive administrative controls
- Prescriptive engineering controls
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Potential Regulatory Options: ECEL

- EPA has not decided on the primary regulatory options to propose in the rule
- EPA is considering the following regulatory options and is seeking feedback on the impacts of applying one or more of the following regulatory options to the conditions of use of TCE that drive the unreasonable risk
- For processing, industrial, and commercial uses (occupational exposures):
  - Existing Chemical Exposure Limit (ECEL)
    - Establishes a performance-based airborne concentration limit and is non-prescriptive, enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace and the ability to combine prescriptive controls
    - Industries are already familiar with PELs, and methods of compliance. EPA and OHSA have ongoing dialogue in reference to risk management requirements under TSCA
    - The TCE ECEL(I) based on the immunotoxicity endpoint would be 4.0 ppb (0.021 mg/m3) for an 8-hour time-weighted average (TWA)
    - EPA is also considering occupational safety measures to be based on a different, more sensitive endpoint (fetal cardiac defects), which would result in an ECEL(F) of 1.1ppb (0.0059 mg/m3) for an 8-hour TWA

Potential Regulatory Options: ECEL, cont.

- The value is based on the chronic non-cancer human equivalent concentration (HEC) for autoimmunity
- If ambient exposures are kept below the 8-hour ECEL(I) of 4.0 ppb, EPA expects that a worker or occupational non-user (ONU) are also protected against
  - mortality due to immunosuppression resulting from an acute (8-hour) exposure
  - excess risk of cancer above the $1x10^{-4}$ benchmark resulting from lifetime exposure
- If ambient exposures are kept below the 8-hour ECEL(F) of 1.1ppb, EPA expects that children will be protected from maternal exposure by workers or ONUs, in addition to the effects listed above
  - In the 2020 Risk Evaluation for TCE, EPA discussed both the immunotoxicity and fetal heart defects endpoints although the unreasonable risk is based on the immunotoxicity endpoint
  - In the interest of transparency, EPA is providing ECEL values for both endpoints since EPA had previously provided the ECEL for the fetal heart defects with the 2016 proposed TCE rules although the proposals were subsequently withdrawn
  - EPA is interested in hearing from SERs about the feasibility of either ECEL value since both are in the ppb
- Each ECEL is above the limits of detection or quantification, which generally range from about ≤0.5 ppb to 0.43 ppm. Monitoring methods are described in the ECEL memo attachments.
- EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk
- EPA is seeking feedback from the SERs on what current recordkeeping and monitoring is applied to the OSHA PEL and feedback on how to apply ECEL recordkeeping and monitoring based on current protocol (see attached ECEL memos for more information)

Potential Regulatory Options, cont.

- Prescriptive Controls: Engineering Controls
  - Would reduce worker or ONU exposure by requiring specific physical changes to the workplace
  - Examples: Require use of closed-loop vapor degreasers, require specific ventilation rates, require spraying booths or laboratory hoods for laboratory applications, or isolate the work area where the TCE is present
- Prescriptive Controls: Administrative Controls
  - Would reduce worker or ONU exposure by requiring processes or procedures in the workplace
  - Examples: Limit access to work areas

Potential Regulatory Options, cont.

- Prescriptive Controls: PPE Controls
  - Examples of potential regulatory option: Require use of respirators or/and highly chemical resistant gloves for use with TCE
    - As an example, EPA could require the use of respirators to address unreasonable risks driven by inhalation exposures. For TCE, only a respirator with APF 10,000 may be able to mitigate such risk; EPA recognizes the challenges associated with using such respirators and is interested in SER feedback on this type of PPE
  - See attached memo on “Personal Protective Equipment Respirator System per Worker Unit Cost Breakdown” for more information on respirator costs and Assigned Protection Factors (APFs)
- Prohibition
  - For conditions of use where ECEL or prescriptive controls are not sufficient to address the unreasonable risk

Potential Regulatory Options, cont.

- For consumer uses:
  - Regulation at key points in the supply chain (manufacturing, processing, and/or distribution) to address unreasonable risks to consumers or bystanders
    - Example: March 2019 rule to address unreasonable risks to consumers from methylene chloride in paint and coating removal prohibited manufacture (including import), processing, and distribution in commerce of methylene chloride for this use (including distribution to and by retailers)
  - Potential regulatory options:
    - Prohibition

Potential Regulatory Options, cont.

- Regulatory options applied broadly with other restrictions
  - Recordkeeping – example: ordinary business records to demonstrate compliance (for example not selling products to consumers)
  - Downstream notification – example: modify the SDS to indicate that the product should not be used in consumer products or indicate other regulatory requirements
  - Monitoring – example: of air concentration to demonstrate compliance with ECEL
  - Labeling – example: labeling products to indicate that they should not be used by consumers or to describe other regulatory requirements
  - Limited access program – example: access only to those users with certain equipment, for example product only sold to facilities with close-loop vapor degreasers

1. Manufacturers, processors, and disposal

2. Industrial and commercial uses
   a) Vapor degreasing and cold cleaning uses
   b) Aerosol uses
   c) Other industrial and large commercial uses
   d) Other small commercial uses

3. Consumer uses

TCE Group 1: Manufacturers, Processors, and Disposal

- Relevant conditions of use:
  - Manufacturing (domestic manufacturing)
  - Manufacturing (import)
  - Processing: repackaging
  - Processing as a reactant/intermediate
  - Processing: incorporation into formulation, mixture or reaction product
  - Processing: incorporation into articles
  - Processing: recycling
  - Disposal

- What is TCE used for? How is it applied?
  - TCE is domestically manufactured, imported, and repackaged from bulk containers to smaller containers for resale
  - TCE is commonly used as a feedstock in the production of refrigerants, specifically HCFCs
  - TCE may also be incorporated at varying concentrations into products such as adhesives, coatings, inks, aerosols, and other products
  - Each of the conditions of use of TCE may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling

Potential Regulatory Options (TCE Group 1: Manufacturers, Processors, and Disposal)

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory option could be used alone or in combination so that TCE no longer presents an unreasonable risk under any condition of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?

Discussion – Formulators of Products Containing TCE

- Product reformulation
  - How often do you reformulate your products?
  - What is the typical cost of reformulating your products?
  - What might reformulation costs be if you needed to reformulate your products without TCE? (For example, costs might include R&D, testing, capital costs of production changes, packaging, labeling)
- Product relabeling
  - How often do you relabel your products?
  - What is the typical cost of relabeling?

Discussion – Formulators of Products Containing TCE (Cont.)

- Alternatives
  - Do you sell another product that does not contain TCE that is designed for the same use or application as the TCE product?
    - If yes, what solvent replaces TCE in the alternative product? How does the alternative product compare in terms of safety, efficacy, and cost?
    - If no, if you needed to reformulate this product with a lower concentration of TCE, what would the implications be for the product in terms of cost and efficacy? What solvent would replace TCE? How do you think the alternative would compare in terms of efficacy and cost?
  - Is there a subset of uses for your product where using a product formulated without TCE would be problematic?

Discussion – Distributors and Retailers

- What is your experience with exposure control and risk reduction?
- If you could no longer sell products containing TCE, how would this impact your business?
- Are there particular challenges to small business doing distribution of products containing TCE that are different from large distributors?
- What is your preferred method of downstream notification?
- If you were required to limit sales of TCE containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?

TCE Group 2a: Industrial Vapor Degreasing and Cold Cleaning Uses

- Relevant conditions of use
  - 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

- What is TCE used for? How is it applied?
  - TCE is used as a degreasing solvent to remove drawing compounds, cutting fluids, coolants, and lubricants from metal parts
  - Cold cleaning operations include spraying, brushing, flushing, and immersion

Potential Regulatory Options (TCE Group 2: Industrial and Commercial Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory option could be used alone or in combination so that TCE no longer presents an unreasonable risk under any condition of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to TCE, and for how long (days/years and hours/day)?
- What is the concentration of TCE in the product you use?
- What routine worker activities result in worker exposure to TCE and what type of exposure?
- What engineering controls are used to minimize exposure to TCE? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to TCE?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to TCE?

Discussion – Degreasing Operations

- What type of degreasing operation do you use: vapor degreasing, cold cleaning, aerosol/spray degreasing?
- What is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity?
- How old is the cleaning equipment? When did you last update your degreasing system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc.)? What prompted this update?
- What are the most important factors in degreasing for you (in order): e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify)?
- Are there any restrictions or other limitations that prescribe the use of TCE to perform your services (e.g., for aerospace or DOD customers)?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?

TCE Group 2b: Industrial and Commercial Aerosol Uses

- Relevant conditions of use:
  - 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 penetrating lubricant
  - Industrial and commercial use in automotive care products in brake parts cleaner
- What is TCE used for? How is it applied?
  - Aerosol-based degreasing products containing TCE include degreasers for applications such as brake cleaning, mold cleaning, and other metal product cleaning
  - Additional aerosol products include film cleaners, coil cleaners, and various lubricants
  - Aerosol degreasing is a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts
  - Aerosol lubricant products use an aerosolized spray to help free frozen parts by dissolving rust and leave behind a residue to protect surfaces against rust and corrosion

Potential Regulatory Options (TCE Group 2: Industrial and Commercial Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory option could be used alone or in combination so that TCE no longer presents an unreasonable risk under any condition of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to TCE, and for how long (days/years and hours/day)?
- What is the concentration of TCE in the product you use?
- What routine worker activities result in worker exposure to TCE and what type of exposure?
- What engineering controls are used to minimize exposure to TCE? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to TCE?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to TCE?

Discussion – Users of Products Containing TCE

- What chemicals or processes have you considered as an alternative to using TCE or a product containing TCE?
- Do you currently use any alternatives to TCE or products containing TCE?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?
- Are there any restrictions or other limitations that prescribe the use of TCE containing products as part of your services (e.g., for aerospace or DOD customers)?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?

TCE Group 2c: Other Industrial and Commercial Uses – Industrial and Large Commercial

- Relevant conditions of use:
  - Industrial and commercial use as a lubricant and grease in tap and die fluid
  - 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 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

TCE Group 2c: Other Industrial and Commercial Uses – Industrial and Large Commercial (cont.)

- What is TCE used for? How is it applied?
  - TCE is used in various industrial and large commercial settings in adhesives and sealants, lubricants and greases, functional fluids, paints and coatings, and in a variety of cleaning products
  - As a functional fluid, it is used in industrial settings in closed systems, such as to aid with heat exchange
  - It is used as a processing aid that is added to a reaction mixture to aid in the manufacture or synthesis of another chemical substance but does not remain in the product, such as in plastics manufacturing
  - TCE is used in metalworking fluids that are used for the machining of internal and external threads using cutting tools like taps and thread-mills

Potential Regulatory Options (TCE Group 2: Industrial and Commercial Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory option could be used alone or in combination so that TCE no longer presents an unreasonable risk under any condition of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to TCE, and for how long (days/years and hours/day)?
- What is the concentration of TCE in the product you use?
- What routine worker activities result in worker exposure to TCE and what type of exposure?
- What engineering controls are used to minimize exposure to TCE? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to TCE?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to TCE?

Discussion – Users of Products Containing TCE

- What chemicals or processes have you considered as an alternative to using TCE or a product containing TCE?
- Do you currently use any alternatives to TCE or products containing TCE?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?
- Are there any restrictions or other limitations that prescribe the use of TCE containing products as part of your services (e.g., for aerospace or DOD customers)?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?

TCE Group 2d: Small Commercial Uses

- Relevant conditions of use:
  - Industrial and commercial use in laundry and dishwashing products in spot remover
  - Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning
  - Industrial and commercial use as ink, toner and colorant products in toner aid
  - Industrial and commercial use in apparel and footwear care products in shoe polish
  - Industrial and commercial use in hoof polish, gun scrubber, and pepper spray

TCE Group 2d: Small Commercial Uses (cont.)

- What is TCE used for? How is it applied?
  - Examples of these uses include, but are not limited to, mold cleaning products, shoe polish, hoof polish, pepper spray, and gun scrubber
  - For many of these uses, TCE is expected to act similarly to a cleaning solvent used to remove dirt or other contaminates from substrates
  - In dry cleaning and carpet cleaning settings, spot cleaning can involve the use of a spotting agent containing TCE that can be applied from squeeze bottles, hand-held spray bottles, or spray guns connected to pressurized tanks
  - Once applied, the cleaning person may come into further contact with TCE when using a brush, spatula, pressurized air or steam, or their fingers to scrape or flush away the stain

Potential Regulatory Options (TCE Group 2: Industrial and Commercial Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory option could be used alone or in combination so that TCE no longer presents an unreasonable risk under any condition of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to TCE, and for how long (days/years and hours/day)?
- What is the concentration of TCE in the product you use?
- What routine worker activities result in worker exposure to TCE and what type of exposure?
- What engineering controls are used to minimize exposure to TCE? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to TCE?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to TCE?

Discussion – Users of Products Containing TCE

- What chemicals or processes have you considered as an alternative to using TCE or a product containing TCE?
- Do you currently use any alternatives to TCE or products containing TCE?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?
- Are there any restrictions or other limitations that prescribe the use of TCE containing products as part of your services (e.g., for aerospace or DOD customers)?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?

TCE Group 3: Consumer Uses

- Relevant conditions of use:
  - 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 adhesive and sealant
  - 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

Potential Regulatory Options (TCE Group 3: Consumer Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory option could be used alone or in combination so that TCE no longer presents an unreasonable risk under any condition of use:

- Prohibition of manufacturing, processing or distribution of products for consumer use
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?

Discussion – Formulators of Products Containing TCE

- Product reformulation
  - How often do you reformulate your products?
  - What is the typical cost of reformulating your products?
  - What might reformulation costs be if you needed to reformulate your products without TCE? (For example, costs might include R&D, testing, capital costs of production changes, packaging, labeling)
- Product relabeling
  - How often do you relabel your products?
  - What is the typical cost of relabeling?

Discussion – Formulators of Products Containing TCE (Cont.)

- Alternatives
  - Do you sell another product that does not contain TCE that is designed for the same use or application as the TCE product?
    - If yes, what solvent replaces TCE in the alternative product? How does the alternative product compare in terms of safety, efficacy, and cost?
    - If no, if you needed to reformulate this product with a lower concentration of TCE, what would the implications be for the product in terms of cost and efficacy? What solvent would replace TCE? How do you think the alternative would compare in terms of efficacy and cost?
  - Is there a subset of uses for your product where using a product formulated without TCE would be problematic?

Discussion – Distributors and Retailers

- What is your experience with exposure control and risk reduction?
- If you could no longer sell products containing TCE, how would this impact your business?
- Are there particular challenges to small business doing distribution of products containing TCE that are different from large distributors?
- What is your preferred method of downstream notification?
- If you were required to limit sales of TCE containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Prohibition of manufacturing, processing, and distribution	Varies by condition of use.	Costs will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), shutting down the operation, and more. Requires input from potentially regulated entities.
Prohibition of Use	Varies by condition of use.	Costs will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), shutting down the operation, and more. Requires input from potentially regulated entities.

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Existing Chemical Exposure Limit (ECEL)	$400 per facility ($70-$1,600 annualized per facility) + $220 per worker. ($40-$800 annualized per worker) for monitoring $400 per facility ($60 annualized per facility) + $20-$100 per worker for recordkeeping Costs of engineering controls or PPE to achieve the ECEL level varies by control type and needs of user	ECEL costs will vary based on the complexity of the site and how many times the site will require monitoring to demonstrate compliance. Costs of engineering controls or PPE to achieve the ECEL level are not captured in these estimates. Potential costs of changes in worker productivity resulting from respirator use or changes to worker compensation for those wearing respirators are unquantified. Requires input from potentially regulated entities.
Engineering/Administrative Controls	Varies by control type and needs of user	Requires input from potentially regulated entities.
Reformulation of product to reduce or eliminate TCE concentration	$60,000 - $100,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities. Setting a concentration limit could impact the efficacy of a product or the feasibility of a process.

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Product Label or Warnings	$750 - $8,000 per product	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor. Due to uncertainties and variations in product types, does not include potential impacts on sales.
Personal Protective Equipment (PPE) – (e.g., respirators)	APF 25: $660-$970 APF 50: $750-$1,100 APF 1,000: $780-$1,150 APF 10,000: $1,800-$2,500	Costs are per employee and include purchase of equipment, routine cleaning of equipment, training, fit-testing, and medical clearance and account for estimated baseline PPE use.
Personal Protective Equipment (PPE) (dermal)	$4 per pair (50 pairs per year, $130-$180 annualized cost)	Costs are per pair of PVA gloves. Requires input from potentially regulated entities regarding which glove material type would be used.

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Substitute Products	Varies with condition of use	The costs of switching products includes both the costs of the substitute products and differences in efficacy of these products. Costs of differences in efficacy are not quantified. Some applications may need to undergo safety reviews before they could replace TCE products. These costs are unquantified.
Substitute Methods	Varies by job labor rate. For vapor degreasing, initial transition costs are estimated as \$100,000 to \$500,000 and initial capital costs as \$30,000 to \$500,000	This will primarily be labor cost and cost of alternative equipment. There may be some safety-critical applications where alternatives would need to undergo extensive safety reviews and testing before they could replace the TCE products. These costs are unquantified.
Recordkeeping	\$200 - \$325 per firm	Annual labor and material costs associated with documentation of ordinary business records.
Downstream Notification	\$112 - \$125 per product	Costs are per product and include labor and material costs to update the product’s safety data sheet (SDS).

Closing Session

- Closing remarks from EPA, SBA, and OMB
- Next steps
  - Written comments by November 14, 2022
  - The risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0500, with additional materials supporting the risk evaluation process and the draft revised unreasonable risk determination in docket EPA-HQ-OPPT-2016-0737, on www.regulations.gov

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- TCE Risk Management: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-trichloroethylene-tce
- June 2021 Policy Changes: https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations
- TCE: Katie McNamara (McNamara.Katelan@epa.gov, 202-564-4361)

Contact Information

- EPA SBAR contact: Lanelle Wiggins (wiggins.lanelle@epa.gov)
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- OMB OIRA: Austin Mudd (Austin.B.Mudd@omb.eop.gov)

Appendix

- Pre-Panel Outreach SER Questions for Discussion (separate document)
- Related regulations (EPA, other Federal, state, and international) (separate document)
- Industry Sectors with Small Entities Potentially Affected by the Rulemaking (separate document)
- Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown (separate document)
- Existing Chemical Exposure Limit (ECEL) for Occupational Use of TCE (2 separate documents)
- Example: OSHA Respiratory Protection Table (Slide 92)
- Personal Protective Equipment Glove Unit Cost Breakdown (Slide 93)

Example: OSHA Respiratory Protection Table

Minimum Requirements for Respiratory Protection for Airborne Methylene Chloride	
Methylene Chloride Airborne Concentration (ppm) or Condition of Use	Minimum Respirator Required
Up to 625 ppm (25 X PEL)	Continuous flow supplied-air respirator, hood, or helmet
Up to 1,250 ppm (50 X PEL)	(1) Full facepiece supplied-air respirator operated in negative-pressure (demand) mode (2) Full facepiece self-contained breathing apparatus (SCBA) operated in negative-pressure (demand) mode
Up to 5,000 ppm (200 X PEL)	(1) Continuous flow supplied-air respirator, full facepiece (2) Pressure demand supplied-air respirator, full facepiece (3) Positive-pressure full facepiece SCBA
Unknown concentration, or above 5,000 ppm (Greater than 200 X PEL)	(1) Positive-pressure full facepiece SCBA (2) Full facepiece pressure (demand) supplied-air respirator with an auxiliary self-contained air supply
Firefighting	Positive-pressure full facepiece SCBA
Emergency Escape	(1) Any continuous flow or pressure-demand SCBA (2) Gas mask with organic vapor canister

Personal Protective Equipment Glove Unit Cost Breakdown

Product Name	Glove Material Type	Notes	Prices
Ansell Chemical Resistant Glove	Laminate Film	Has a liner material, so appears to be made to wear alone as opposed to as a liner	$7.03 per pair
Ansell Size Knit Lined PVA Gloves	PVA	Has a liner material, so appears to be made to wear alone as opposed to as a liner	$$33.93, $30.08, and $42.25 per pair on different web sites.33.93
Silver Shield gloves	Laminate Film	Says it can be worn as a liner.	$11.60 per pair
Ansell Chemical Resistant	Butyl Viton	Abrasion resistant	$132 per pair

TCE Pre-Panel Questions for SERs

Pre-Panel Outreach Small Entity Representative (SER) Questions for Discussion on TCE

For rules that may have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA) requires agencies to evaluate regulatory alternatives that may minimize the burden on small entities expected to be regulated. The RFA notes that the regulatory alternatives must be consistent with the stated objectives of applicable statutes (i.e., TSCA), and suggests significant alternatives such as:

- the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
- the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
- the use of performance rather than design standards; and
- an exemption from coverage of the rule, or any part thereof, for such small entities.

To that end, these informal questions on your work practices and your experiences with trichloroethylene (TCE) are aimed at guiding our discussion today, and your later written feedback, towards ideas for minimizing the economic impact on your business while remaining within the constraints of TSCA. We are not seeking a structured response on each question; rather, we are interested in any feedback or details you can provide, and hope that these questions let you know what type of information would be most useful as we consider advice from the small entity representatives concerning TSCA regulation of TCE.

If you are interested in providing this or other information in writing, please see the contact information below.

We ask that you refrain from providing Confidential Business information (CBI) during the discussion or in email to EPA. If you choose to provide CBI, we will provide special instructions.

Contact Information:

Lanelle Wiggins
Office of Regulatory Policy and Management
Office of Policy
Phone: (202) 566-2372
E-mail: wiggins.lanelle@epa.gov

1) **Your business *(All SERs)***
   a. How does your organization use TCE? How much TCE does your organization use?
   b. Does your organization still use TCE? What is the trend of use? For example, has your organization increased use of TCE? Has use remained constant? Is use decreasing? Is your organization phasing out the use of TCE?
   c. Can you describe the specific use, as well as the workplace and workplace setting where TCE is used?
   d. Why does your organization use TCE? What function does TCE provide?

e. Where is your organization in the supply chain? (e.g., are you a processor – formulating another product with TCE, a distributor, or final user of TCE in an application?). Do you provide finished product to another small entity or to a large entity?
f. For what industries or applications do you provide products or services for? (e.g., aerospace, electronics, military, automotive, optics, museums/art restorations, academic, commercial laboratory, consumers, other) Can you provide a NAICs code for the products/services you provide?
g. For what process are you using TCE? (can be more than one, such as cleaning, drying, inspection, etc.)
h. If TCE were not available, how would you adjust and what would the impacts be on your business? What specific barriers would your business face in switching to an alternative?
i. If the concentration of TCE in a product was limited, would this impact the efficacy of the product and/or increase the duration of use or exposure. For which particular uses?
j. What are the benefits to your business of TCE? Are there specific benefits for small businesses using TCE as compared to benefits for larger businesses?

2) **Workplace exposure *(All SERs)***
   a. How many employees, and what fraction of your employees, are exposed to TCE, and for how long (days/year and hours/day)?
   b. If you use a product containing TCE, what product do you use and what is the concentration of TCE in the product?
   c. What work activities result in worker exposure to TCE? And what type of exposure (dermal, inhalation)?
   d. For each activity, in what physical state and concentration is TCE?
   e. Have you taken industrial hygiene monitoring data? If so, what was typical and high-end exposure to TCE?
   f. What engineering controls are used to minimize exposure to TCE? How effective are those controls?
      i. Would it be feasible to use additional engineering controls to minimize exposure to TCE? If so, what might those engineering controls be?
      ii. What is your experience with:
         - Installing or updating ventilation and local exhaust, or
         - Equipment changes to reduce exposure or cross-contamination?
   g. What administrative controls and training do you use to minimize exposure to TCE? Do you use training to minimize exposure to TCE?
   h. Is personal protective equipment (PPE) regularly worn by workers to minimize exposure to TCE?
      i. If yes, could you provide more information regarding the type of PPE that is used? And would it be feasible to use PPE that provided a level of protection beyond what you are already using? Do you have experience with air supplied respirators? Do you have experience with other PPE?

        ii. If no, would it be feasible to have workers wear PPE to minimize their exposure to TCE? And what PPE would be feasible for workers to wear? Are their workers or processes where the use of PPE would be impractical?
    i. How many employees are located in the same room where the work activities related to TCE are taking place but not necessarily handling TCE or TCE-containing products?
    j. What do you do to comply with OSHA standards for TCE?

3) **Regulatory options *(All SERs)***
    a. Which of the regulatory options presented today would you recommend?
    b. Cost estimates: In your experience, are the cost estimates reasonably representative? Do you have additional information to improve the cost estimates?
    c. What indirect costs to your organization do you estimate would occur as a result of this regulation?
    d. Recognizing that the cost estimates are only partial unit costs, can you provide any additional information on potential costs or cost considerations the Agency should consider when evaluating the costs of complying with potential regulatory options?
    e. Can you think of ways to add flexibility to this rulemaking for your small businesses?
    f. Are there other alternative regulatory options that the agency should consider to manage the unreasonable risks identified for PCE?
    g. How do you learn about EPA regulations and what you should do to comply?
    h. What kind of additional information or resources would help you understand the regulations and steps necessary to comply?
    i. What is the best way for EPA to reach out to members of your industry?

4) **Additional questions for users of products containing TCE: substitutes and alternatives**
    a. What chemicals or processes have you considered as an alternative to using TCE or a product containing TCE? Why? How do these chemicals or processes compare to current use containing TCE? More specifically:
        i. Do you currently use any alternatives to TCE (or product)?
        ii. Did you try to switch to another chemical, product, or process only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
        iii. What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including of exposure, effectiveness, cost, and hazard?
        iv. Provide specific information related to each substitute chemical, product, or process related to the use of alternative chemicals/products and compare to TCE:
            - Identification of alternative chemical/product/process
            - How much of the alternative product/chemical would be needed to perform the same activity
            - Capital costs including new equipment, retrofitting of old equipment, etc. of using the alternative chemical/process, loss of use of existing equipment
            - Number of workers required, amount of worker time required

- Number of workers exposed
- Costs associated with transitioning to the alternative chemical (e.g., identifying, designing, and testing the alternative chemical/process, certifying or otherwise ensuring customer or other required production standards are met, production downtime during the transition, lost productivity while learning how to use the alternative efficiently)
- Process changes required (e.g., additional time to complete task, additional steps, etc.)
- Energy and other resource (e.g., water) usage
- Other operation and maintenance costs (e.g., filters, tank cleanings, etc.)
- Changes in production or output of operation
- Releases of alternative chemicals/products
- Waste and disposal costs associated with alternative chemical/process
- Changes in your product/service quality
- Training, medical surveillance, or other employee-related costs
- Recordkeeping burden/costs
- Monitoring and testing costs
- Potential barriers/concerns with switching to alternatives

5) Additional questions for distributors and retailers (for consumer uses)

a. How much of your business is supplying products containing TCE to consumers? How much of your business is supplying products containing TCE to commercial or industrial users?
b. If you could no longer sell products containing TCE, how would this impact your business?
c. Do you also sell products designed for the same application or use that do not contain TCE?
    i. If yes, what is the relative share of sales for the product(s) containing TCE compared to the products that do not contain TCE?
d. Are there particular challenges to a small business doing distribution of products containing TCE that are different from large distributors?
e. What is your preferred method of downstream notification?
f. If you were required to limit sales of TCE containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency? Please identify any challenges you see with such a limitation.
g. If restrictions (e.g., prohibition or limit to concentration of TCE in products or articles) were placed on TCE in products or articles, how long would you need to notify downstream users? How long would it take to clear channels or trade?

6) **Additional questions for formulators of products containing TCE: substitutes and alternatives**
   a. Product reformulation:
      i. How often do you reformulate your products?
      ii. What is the typical cost of reformulating your products?
      iii. What might reformulation costs be if you needed to reformulate your products without TCE? (e.g., costs associated with research and development, testing, capital costs of production changes, packaging, labeling)
   b. Product relabeling:
      i. How often do you relabel your products?
      ii. What is the typical cost of relabeling?
   c. Alternatives:
      i. Do you sell another product that does not contain TCE that is designed for the same use or application as the TCE product?
         - If yes:
            - What solvent replaces TCE in the alternative product? Can you provide an SDS or the formulation for the alternative product?
            - How does the alternative product compare in terms of safety, efficacy, and cost to use including whether the alternative product would require more time (and how much)?

         - If no:
            - If you need to reformulate this product with a lower concentration of TCE, what would be the implications for the product in terms of cost and efficacy?
            - If you need to reformulate this product without TCE, what solvent would replace TCE in the alternative product? How do you think the alternative product would compare in terms of efficacy and cost to use including whether the alternative product would require more time (and how much)?
      ii. Is there a subset of uses for your product where using a product formulated without TCE would be problematic?

7) **Additional questions for degreasing operations:**
   a. What type of degreasing operation do you use: vapor degreasing, cold cleaning, aerosol/spray degreasing? Is TCE used in a degreaser? In a tank? As an aerosol? In a small dispenser such as a squirt bottle?
      i. What items do you degrease with for each of the types listed?
      ii. If you use vapor degreasing, what type of system do you use (open-top, closed-loop, in-line, etc.)? How many separate units of each do you have? If multiple units, are all routinely in operation or do you use one or more units for backup?
      iii. What size system do you use?
      iv. How significant is degreasing to your business overall?

v. Do any particular items or grease/oils present special challenges?

b. Current work practices related to degreasing operations:
    i. In your experience, what is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity?
    ii. Do the types of vapor degreasers we are considering (open-top, closed-loop, continuous/in-line vapor degreasers) seem representative of those currently in use for small businesses?
    iii. Is there any difference in terms of operation time for the different types of vapor degreasers or cold cleaners or aerosol degreasers (in terms of hours per day or days per year)?
c. How old is the cleaning equipment? When did you last update your degreasing system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc.)? What prompted this update? What is the remaining life of the current system you have?
d. What are the most important factors in degreasing for you (in order): (e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify))?
e. Why do you use TCE rather than somewhat similar solvents like 1-bromopropane (1-BP), perchloroethylene (PCE), other? Or a blend with *trans*-1,2-dichloroethylene (DCE)? Can you name specific factors that drive your decision to continue to use TCE? Did you consider using another non-halogenated solvent or aqueous process?
    i. When do you use TCE in the process flow in your facility, are you using other cleaning processes as well?
    ii. For example, do you do aqueous cleaning in addition to cleaning with TCE? Does aqueous cleaning happen before or after TCE?
    iii. Are you using TCE on some but not all products?
    iv. If you use one or the other, (aqueous or TCE but not both), how did you decide which to use?
f. One possibility is that TCE might have to be used in a closed-loop/airless system. Have you looked into such systems? Why or why not?
    i. Are you considering purchasing such equipment?
    ii. If not, what are the constraints?
    iii. Would you use TCE in such a system or would you use a different solvent?
g. Have you looked at any alternative processes? Any alternative solvents? Have you looked at product literature?
h. Have you tried using alternative chemicals or methods for degreasing? What were the results?
    i. Please discuss alternative methods for degreasing as well as alternative solvents or equipment in your degreasing process.
    ii. Are you aware of alternative processes or solvents that could be used to achieve similar degreasing results in your operation?
    iii. If you have tried or switched to alternative chemicals or methods, how did they do? how long did that process take? Did it require equipment modifications or new equipment purchases?

i. If TCE could no longer be used for degreasing, would the mix of alternative cleaning methods be different for you as a small businesses compared to larger businesses? For example, are there particular alternatives that are more suitable for small businesses?
j. If you had to change your cleaning process to another somewhat similar solvent like a *trans*-DCE blend, can you give an estimate of costs while considering the following?
    i. Cleaning agent
    ii. Cleaning equipment
    iii. Process development
    iv. Process verification and validation (including lab testing and/or third-party verification), i.e., proving to yourself that the process works
    v. Customer certification
    vi. Training
    vii. Insurance
    viii. Permitting
    ix. Cleaning agent management (including removal of used cleaning agent)
    x. Facilities changes
    xi. Documentation
    xii. PPE requirements
k. What if you needed to move your cleaning process to a different process like aqueous or another non-similar solvent (modified alcohols, hydrocarbons, alcohols, other blends)? Can you give an estimate of costs while considering the following?
    i. Cleaning agent
    ii. Cleaning equipment
    iii. Process development
    iv. Process verification and validation (including lab testing and/or third-party verification) (i.e., proving to yourself that the process works))
    v. Customer certification
    vi. Training
    vii. Insurance
    viii. Permitting
    ix. Cleaning agent management (including removal of used cleaning agent)
    x. Facilities changes
    xi. Documentation
    xii. PPE requirements
l. Do you have an estimate on how many vapor degreasers in the U.S. use TCE?
m. Do you have an estimate on how much TCE is used in the U.S. for vapor degreasing every year?
n. Out of all the vapor degreasers in the U.S., do you have an estimate on what percentage of those vapor degreasers use TCE versus other solvents (methylene chloride, PCE, 1-BP, *trans*-DCE blends, other designer solvents)?
o. How much TCE does a typical vapor degreasing operation consume in a year?

TCE Potential Regulatory Options and Costs & OSHA Respirator Illustrations

EPA's SBAR Pre-Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Trichloroethylene (TCE) under TSCA Section 6(a)

Potential Regulatory Options and Estimated Costs

Any regulatory option could be used alone or in combination so that TCE no longer presents an unreasonable risk under any condition of use.

Existing Chemical Exposure Limit (ECEL)

- What is an ECEL?
    - A risk management option similar to a permissible exposure limit (PEL), for industrial and most commercial conditions of use. Establishes a performance-based setting and is non-prescriptive, thus enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace. Industries are already familiar with PELs, and methods of compliance.
    - An ECEL is calculated based on the identified hazard of the chemical, such as the human equivalent concentration or the inhalation unit risk determined in the risk evaluation and considers the most sensitive endpoint.
    - The ECEL is the air concentration at or below which EPA has determined as a matter of policy would address unreasonable risk resulting from inhalation exposures in an occupational setting to workers or occupational non-users (ONUs,) including susceptible subpopulations.
        - The TCE ECEL(I) based on the immunotoxicity endpoint would be 4.0 ppb (0.021 mg/m3) for an 8-hour time-weighted average (TWA).
        - EPA is also considering occupational safety measures based on a different, more sensitive endpoint (fetal cardiac defects) which would result in an ECEL(F) of 1.1 ppb (0.0059 mg/m^3) for an 8-hour TWA.
        - In the 2020 Risk Evaluation for TCE, EPA discussed both the immunotoxicity and fetal heart defects endpoints although the unreasonable risk is based on the immunotoxicity endpoint.
        - In the interest of transparency, EPA is providing ECEL values for both endpoints since EPA had previously provided the ECEL for the fetal heart defects with the 2016 proposed TCE rules although the proposals were subsequently withdrawn.
        - EPA is interested in hearing from SERs about the feasibility of either ECEL value since both are in the ppb.
- How could it be applied?
    - If EPA sets an ECEL, businesses could meet the ECEL by changing their process or formula, using different equipment, using personal protective equipment (PPE), substituting the chemical, or some combination.
    - The decision on how to meet the ECEL is up to the business; however, an ECEL might require monitoring and recordkeeping to demonstrate compliance.

Prescriptive PPE Controls

- A risk management option that would require use of specific PPE to minimize exposure. This may limit flexibility for the regulated entity. PPE may include respirators or gloves.
    - For example, EPA could require the use of specific gloves or gloves that meet certain standards such as providing an impervious barrier to the chemical during expected durations and normal conditions of exposure.
    - As an additional example, EPA could require the use of respirators to address unreasonable risks driven by inhalation exposures. For TCE, only a respirator with APF 10,000 may be able to mitigate such risk; EPA recognizes the challenges associated with using such respirators and is interested in SER feedback on this type of PPE.

Prescriptive Administrative Controls

- A risk management option that would prescribe administrative controls to reduce exposure.
- Example: Prohibit ONU access to the work area where the chemical is being handled.

Prescriptive Engineering Controls

- A risk management option that would prescribe engineering controls, such as removing a hazardous substance through air ventilation with a specific air exchange rate or to a specific air concentration limit.
- Examples:
    - Install additional or different equipment, such as enclosed transfer liquid lines, closed loop container systems or a laboratory type fume hood, to reduce the exposure to the chemical.
    - Install or upgrade ventilation systems to help control and/or eliminate air contaminants.
    - Enclose or confine operations to avoid or reduce employee exposure.

Regulate the Manufacturing, Processing, and/or Distribution

- A risk management option for industrial, commercial, and consumer conditions of use. These authorities allow EPA to regulate at key points, including the manufacturing, processing, and distribution in commerce of a chemical or product in the supply chain.

Prohibition

- EPA could include prohibition on manufacturing, processing, distribution, use, or disposal for specific conditions of use or the chemical as a whole.

- For example, alternatives to TCE in vapor degreasing include solvent-based alternatives like 1,2-trans-dichloroethylene[1], 1-bromopropane[2], and hydrocarbon solvents, such as terpenes, alcohols, acetone, ketones, and acetates. (https://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets/Trichloroethylene_TCE_Fact_Sheet/TCE_Facts/Alternatives)

Examples of combinations of regulatory options

- A risk management option that would prescribe engineering and PPE to reduce exposure.
  - For example, EPA could mandate use of specific ventilation rate to reduce exposure as much as possible and then require a respirator to ensure exposures are below a set level that would eliminate unreasonable risk.
- A risk management option that would require prescriptive engineering, PPE, and administrative controls to reduce exposure.
  - For example, EPA could require use of specific equipment and PPE to reduce exposure to workers and then limit access to the work area to eliminate the unreasonable risk to ONUs.
- A risk management option that would set a maximum required reduction concentration limit and also require engineering controls.
  - For example, require no more than a set percentage concentration of the chemical in the product and then require use of a specific ventilation system to eliminate unreasonable risk.

Regulatory options applied broadly with other restrictions

- Recordkeeping and downstream notification – Require manufacturers, processors, and distributors to maintain ordinary business records.
  - For example, EPA could require manufacturers, processors, and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain.
- Monitoring and labeling – Require initial or periodic monitoring of occupational exposure.
  - For example, EPA could require that a prominent label be securely attached to each container with specific directions, limitations, and precautions, or that describes the health endpoints.
- Limited access program
  - For example, restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification.

[1] Currently undergoing risk evaluation within EPA (see docket number EPA-HQ-OPPT-2018-0465).
[2] Currently undergoing risk management within EPA (see docket numbers EPA-HQ-OPPT-2020-0471, EPA-HQ-OPPT-2019-0235, and EPA-HQ-OPPT-2016-0741); the risk evaluation is complete (see docket numbers EPA-HQ-OPPT-2016-0741 and EPA-HQ-OPPT-2019-0235).

Cost of Regulatory Options

Type of Cost	Estimated Compliance Cost	Notes
Prohibition of manufacturing, processing, and distribution	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives[3], reformulation (see below), shutting down the operation, and more. Requires input from potentially regulated entities.
Prohibition of Use	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), shutting down the operation, and more. Requires input from potentially regulated entities.
Existing Chemical Exposure Limit (ECEL)	$400 per facility ($70-$1,600 annualized per facility) + $220 per worker ($40-$800 annualized per worker) for monitoring $400 per facility ($60 annualized per facility) + $20-$100 per worker for recordkeeping Costs of engineering controls or PPE to achieve the ECEL level varies by control type and needs of user	ECEL costs will vary based on the complexity of the site and how many times the site will require monitoring to demonstrate compliance. Costs of engineering controls or PPE to achieve the ECEL level are not captured in these estimates. Potential costs of changes in worker productivity resulting from respirator use or changes to worker compensation for those wearing respirators are unquantified. Requires input from potentially regulated entities.
Engineering/Administrative Controls	Varies by control type and needs of user	Requires input from potentially regulated entities.

[3] TSCA section 6(c)(2)(C) requires EPA "…in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action…to the extent practicable, 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 when the proposed prohibition or other restriction takes effect."

Type of Cost	Estimated Compliance Cost	Notes
Reformulation of product to reduce or eliminate TCE concentration	$60,000 - $100,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities. Setting a concentration limit could impact the efficacy of a product or the feasibility of a process.
Product Label or Warnings	$750 - $8,000 per product	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor. Due to uncertainties and variations in product types, does not include potential impacts on sales.
Personal Protective Equipment (PPE) – (e.g., respirators)	APF 25: $660-$970 APF 50: $750-$1,100 APF 1000: $780-$1,150 APF10000: $1,800 - $2,500	Costs are per employee and include purchase of equipment, routine cleaning of equipment, training, fit-testing, and medical clearance and account for estimated baseline PPE use.
Personal Protective Equipment (PPE) (dermal)	$4 per pair (50 pairs per year, $130-$180 annualized cost)	Costs are per pair of PVA gloves. Requires input from potentially regulated entities regarding which glove material type would be used.
Substitute Products	Varies with condition of use	The costs of switching products includes both the costs of the substitute products and differences in efficacy of these products. Costs of differences in efficacy are not quantified. Some applications may need to undergo safety reviews before they could replace TCE products. These costs are unquantified.
Substitute Methods	Varies by job labor rate. For vapor degreasing, initial transition costs are estimated as $100,000 to $500,000 and initial capital costs as $30,000 to $500,000	This will primarily be labor cost and cost of alternative equipment. There may be some safety-critical applications where alternatives would need to undergo extensive safety reviews and testing before they could replace the TCE products. These costs are unquantified.
Recordkeeping	$200 - $325 per firm	Annual labor and material costs associated with documentation of ordinary business records.
Downstream Notification	$112 - $125 per product	Costs are per product and include labor and material costs to update the product's safety data sheet (SDS).

Major Types of Respirators

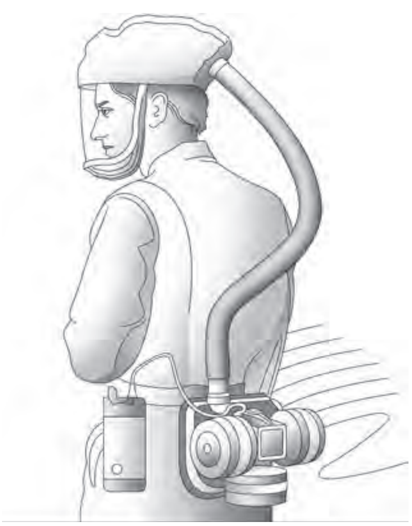
Air-purifying respirators, which remove contaminants from the air.

Half mask/Dust mask
APF=10
Needs to be fit tested

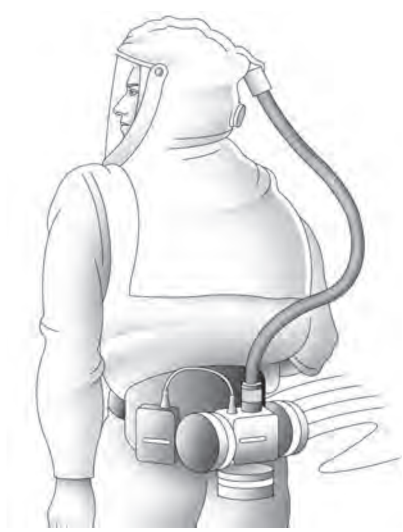
Half mask (Elastomeric)
APF=10
Needs to be fit tested

Full facepiece (Elastomeric)
APF=50
Needs to be fit tested

Original Illustrations created by Attiliis & Associates



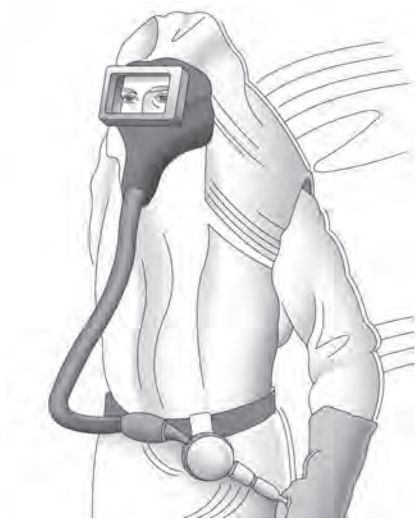
Loose-Fitting Powered Air-Purifying Respirator (PAPR)
APF= 25



Hood Powered Air-Purifying Respirator (PAPR)
APF= 25

Atmosphere-supplying respirators, which provide clean air from an uncontaminated source.

Full Facepiece Supplied-Air Respirator (SAR) with an auxiliary Escape Bottle
APF=1,000
APF = 10,000 (if used in "escape" mode)
Needs to be fit tested



Full Facepiece Abrasive Blasting Continuous Flow
APF=1,000
Needs to be fit tested

Full Facepiece Self-Contained Breathing Apparatus (SCBA)
Pressure demand mode is APF=10,000
Needs to be fit tested

TCE Existing Related Regulations

Related Regulations (EPA, Federal, State, and International)

Table 1 – EPA Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxics Substances Control Act (TSCA) - Section 6(a)	Provides EPA with the authority to prohibit or limit the manufacture (including import), processing, distribution in commerce, use or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment.	Proposed rule under section 6 of TSCA to address the unreasonable risks presented by TCE use in vapor degreasing (82 FR 7432; January 19, 2017). This proposed rule was withdrawn in 2021 (86 FR 3932, January 15, 2021).
TSCA - Section 6(a)	Provides EPA with the authority to prohibit or limit the manufacture (including import), processing, distribution in commerce, use or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment	Proposed rule under section 6 of TSCA to address the unreasonable risks presented by TCE use in commercial and consumer aerosol degreasing and for spot cleaning at dry cleaning facilities (81 FR 91592; December 16, 2016). This proposed rule was withdrawn in 2021 (86 FR 3932, January 15, 2021).
TSCA - Section 6(b)	Directs EPA to promulgate regulations to establish processes for prioritizing chemicals and conducting Risk Evaluations on priority chemicals. In the meantime, EPA is directed to identify and begin Risk Evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	TCE is on the initial list of chemicals evaluated for unreasonable risks under TSCA (81 FR 91927, December 19, 2016). Commercial and consumer degreasing uses, consumer arts and crafts uses, and commercial use as a spotting agent at dry-cleaning facilities were assessed in 2014, with an assessment narrower in scope than the 2020 TCE Risk Evaluation.
TSCA - Section 5(a)	Once EPA determines that a use of a chemical substance is a significant new use under TSCA section 5(a), persons are required to submit a significant new use notice (SNUN) to EPA at least 90 days before they	Significant New Use Rule (SNUR) (81 FR 20535; April 8, 2016). TCE is subject to reporting under the SNUR for manufacture (including import) or processing of TCE for use in a consumer product

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	manufacture (including import) or process the chemical substance for that use.	except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants and pepper spray. This SNUR ensures that EPA will have the opportunity to review any new consumer uses of TCE and, if appropriate, take action to prohibit or limit those uses.
TSCA - Section 8(a)	The TSCA section 8(a) CDR rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	TCE manufacturing (including importing), processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
TSCA - Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed or imported in the United States.	TCE was on the initial TSCA Inventory and was therefore not subject to EPA's new chemicals review process (60 FR 16309, March 29, 1995).
TSCA - Section 8(e)	Manufacturers (including importers), processors and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	26 substantial risk notifications received for TCE (U.S. EPA, ChemView. Accessed September 27, 2022).
TSCA - Section 4	Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Seven studies received for TCE (U.S. EPA, ChemView. Accessed September 27, 2022).
Emergency Planning and Community Right-to-Know Act (EPCRA) - Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full time equivalent employees and that manufacture, process, or otherwise use a Toxics Release Inventory	TCE is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	(TRI)-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (*e.g.,* quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (*i.e.,* air, land and water).	
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) – Sections 3 and 6	FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. Pesticides may only be registered if, among other things, they do not cause "unreasonable adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either: (1) the pesticide, labeling, or other material does not comply with FIFRA or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	TCE is no longer used as an inert ingredient in pesticide products.
Clean Air Act (CAA) - Section 112(b)	Defines the original list of CAA hazardous air pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAPs and then set emission standards for those listed	Lists TCE as a HAP (42 U.S.C. 7412(b)(1)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAPs by adding or deleting a substance.	
CAA - Section 112(d)	Directs EPA to establish, by rule, National Emission Standards for Hazardous Air Pollutants (NESHAP) for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). The standards must require the maximum degree of emission reduction that the EPA determines to be achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	EPA has promulgated a number of NESHAP regulating industrial source categories that emit trichloroethylene and other HAPs. These include, for example, the NESHAP for Halogenated Solvent Cleaning (59 FR 61801; December 2, 1994), among others.
CAA - Sections 112(d) and 112 (f)	Risk and technology review (RTR) of section 112(d) MACT standards. Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to section 112(d) MACT standards, and to determine if additional standards are needed to reduce remaining risks. Section 112(d)(6) requires EPA to review and revise the MACT standards, as necessary, taking into account developments in practices, processes and control technologies.	EPA has promulgated a number of RTR NESHAP (*e.g.*, the RTR NESHAP for Halogenated Solvent Cleaning (72 FR 25138; May 3, 2007) and will do so, as required, for the remaining source categories with NESHAP.
Clean Water Act (CWA) – Sections 301(b), 304(b), 306, and 307(b)	Requires establishment of Effluent Limitations Guidelines and Standards for conventional, toxic, and non-conventional pollutants. For toxic and non-conventional pollutants, EPA identifies the best	

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology. Regulations apply to existing and new sources.	TCE is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such, is subject to effluent limitations.
CWA - Section 307(a)	Establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in 40 CFR 401.15. The "priority pollutants" specified by those families are listed in 40 CFR part 423, Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (Section 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in National Pollutant Discharge Elimination System (NPDES) permits, see Section 4029a)(1)(B).	
Safe Drinking Water Act (SDWA) - Section 1412	Requires EPA to publish a non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a	TCE is subject to NPDWR under the SDWA with a MCLG of zero and an enforceable MCL of 0.005 mg/L (52 FR 25690, July 8, 1987).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	
Resource Conservation and Recovery Act (RCRA) - Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	TCE is included on the list of commercial chemical products, manufacturing chemical intermediates or off-specification commercial chemical products or manufacturing chemical intermediates that, when disposed (or when formulations containing any one of these as a sole active ingredient are disposed) unused, become hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Status: D040 at 0.5 mg/L; F001, F002; U228
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) - Section 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	TCE is a hazardous substance with a reportable quantity pursuant to section 102(a) of CERCLA (40 CFR 302.4) and EPA is actively overseeing cleanup of sites contaminated with TCE pursuant to the National Contingency Plan (NCP) (40 CFR 751).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
American Innovation and Manufacturing (AIM) Act	Directs EPA to address hydrofluorocarbons (HFCs) by phasing down production and consumption by 85 percent over a period ending in 2036, maximizing reclamation and minimizing releases from equipment, and facilitating the transition to next-generation technologies through sector-based restriction.	In 2021, EPA set HFC production and consumption baseline levels from which reductions will be made (86 FR 55116, October 5, 2021). The rule also establishes an initial methodology for allocating and trading HFC allowances for 2022 and 2023. TCE is identified as a feedstock chemical for HFC production.

Table 2 – Other Federal Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Other Federal Regulations		
Occupational Safety and Health Act (OSH Act)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C. section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative controls, and respiratory protection.	In 1971, OSHA issued occupational safety and health standards for TCE that included a PEL of 100 ppm as an 8-hr TWA with an acceptable ceiling concentration of 200 ppm. An acceptable maximum peak above the acceptable ceiling concentration for an 8 hour shift is 300 ppm, based on the maximum duration of 5 minutes in any 2 hours (29 CFR 1910.1000). While OSHA has established a PEL for TCE, OSHA has recognized that many of its PELs are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time. Section 6(a) of the OSH Act granted the Agency the authority

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		to adopt existing Federal standards or national consensus standards as enforceable OSHA standards. "OSHA recommends that employers consider using the alternative occupational exposure limits because the Agency believes that exposures above some of these alternative occupational exposure levels are in compliance with the relevant PELS." For TCE, the alternative occupational exposure limits are the NIOSH REL of 2 ppm (as a 60-minute ceiling) during the usage of TCE as an anesthetic agent and 25 ppm (as a 10-hour TWA) during all other exposures. https://www.osha.gov/dsg/annotated-pels/
Atomic Energy Act	The Atomic Energy Act authorizes the Department of Energy to regulate the health and safety of its contractor employees	10 CFR 851.23, Worker Safety and Health Program, requires the use of the ACGIH TLVs if they are more protective than the OSHA PEL. The 2012 TLV for TCE is 10 ppm and the short-term limit is 25 ppm (ATSDR, 2019).
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics.	Tolerances are established for residues of TCE resulting from its use as a solvent in the manufacture of decaffeinated ground coffee, decaffeinated soluble (instant) coffee extract, and spice oleoresins (25 ppm, 10 ppm and 30 ppm, respectively; 21 CFR 173.290).
Federal Hazardous Material Transportation Act	Section 5103 of the Act directs the Secretary of Transportation to: Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material	The Department of Transportation (DOT) has designated TCE as a hazardous material, and there are special requirements for marking, labeling and transporting it (49 CFR Part 171, 49 CFR 172, 40

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	CFR § 173.202 and 40 CFR § 173.242).
Occupational Safety and Health Act (OSH Act)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C. section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative controls, and respiratory protection.	In 1971, OSHA issued occupational safety and health standards for TCE that included a PEL of 100 ppm as an 8-hr TWA with an acceptable ceiling concentration of 200 ppm. An acceptable maximum peak above the acceptable ceiling concentration for an 8 hour shift is 300 ppm, based on the maximum duration of 5 minutes in any 2 hours (29 CFR 1910.1000). While OSHA has established a PEL for TCE, OSHA has recognized that many of its PELs are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time. Section 6(a) of the OSH Act granted the Agency the authority to adopt existing Federal standards or national consensus standards as enforceable OSHA standards. "OSHA recommends that employers consider using the alternative occupational exposure limits because the Agency believes that exposures above some of these alternative occupational exposure

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		levels are in compliance with the relevant PELS." For TCE, the alternative occupational exposure limits are the NIOSH REL of 2 ppm (as a 60-minute ceiling) during the usage of TCE as an anesthetic agent and 25 ppm (as a 10-hour TWA) during all other exposures. https://www.osha.gov/dsg/annotated-pels/

Table 3 – State Laws and Regulations

State Actions	Description of Action
State Actions	
California Code of Regulations (CCR), Title 17, Section 94509(a)	Lists standards for VOCs for consumer products sold, supplied, offered for sale or manufactured for use in California. As part of that regulation, use of consumer general purpose degreaser products that contain TCE are banned in California and safer substitutes are in use (17 CCR, Section 94509(a)).
State Permissible Exposure Limits (PELs)	. Nine states (Alaska, Connecticut, Hawaii, Michigan, New York, Oregon, Tennessee, Vermont, and Washington) have PELs of 50 ppm. California has a PEL of 25 ppm (CCR, Title 8, Table AC-1). Minnesota has banned TCE (see below), and its interim limit is 0.002 ppb. Other than these states, other states have set PELs identical to the OSHA 100 ppm 8hour TWA PEL
VOC regulations for consumer products	Many states regulate TCE as a VOC. These regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from state to state, and could include contact and aerosol adhesives, aerosols, electronic cleaners, footwear or leather care products and general degreasers, among other products. California (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Articles 1, 2, 3 and 4), Connecticut (R.C.S.A Sections 22a-174-40, 22a-174-41, and 22a-174-44), Delaware (Adm. Code Title 7, 1141), District of Columbia (Rules 20-720, 20-721, 20-735, 20-736, 20-737), Illinois (35 Adm Code 223), Indiana (326 IAC 8-15), Maine (Chapter 152 of the Maine Department of Environmental Protection Regulations), Maryland (COMAR 26.11.32.00 to 26.11.32.26), Michigan (R 336.1660 and R 336. 1661), New Hampshire (Env-A 4100) New Jersey (Title 7, Chapter 27, Subchapter 24), New York (6 CRR-NY III A 235),

State Actions	Description of Action
	Rhode Island (Air Pollution Control Regulation No. 31) and Virginia (9VAC5 Chapter 45) all have VOC regulations or limits for consumer products. Some of these states also require emissions reporting.
Bans	Beginning June 1, 2022, in Minnesota, an owner or operator of a facility required to have an air emissions permit issued by the Pollution Control Agency may not use TCE at its permitted facility, including in any manufacturing, processing, or cleaning processes, except for few uses (Minn. Stat. 116.385). Beginning December 1, 2022, New York State prohibits the use of TCE as a vapor degreaser, an intermediate chemical to produce other chemicals, a refrigerant, or an extraction solvent or in any other manufacturing or industrial cleaning process or use (NY. Section 37-0119).

Table 4 – International Laws and Regulations

Country/Organization	Requirements and Restrictions
Canada	TCE is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). TCE is also regulated for use and sale for solvent degreasing under *Solvent Degreasing Regulations (SOR/2003-283)* (*Canada Gazette*, Part II on August 13, 2003). The purpose of the regulation is to reduce releases of TCE into the environment from solvent degreasing facilities using more than 1000 kilograms of TCE per year. The regulation includes a market intervention by establishing tradable allowances for the use of TCE in solvent degreasing operations that exceed the 1000 kilograms threshold per year.
European Union	In 2011, TCE was added to Annex XIV (Authorisation list) of regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). Entities that would like to use TCE needed to apply for authorization by October 2014, and those entities without an authorization must stop using TCE by April 2016. The European Chemicals Agency (ECHA) has received 24 applications for authorization from entities interested in using TCE beyond April 2016. Currently, 22 of these applications have been approved and 2 are currently under review (ECHA, Accessed September 30, 2022). TCE is classified as a carcinogen category 1B, and was added to the EU REACH restriction of substances classified as carcinogen category 1A or 1B under the EU Classification and Labeling regulation (among other characteristics) in 2009. The restriction bans the placing on the market or use of TCE as substance, as constituent of other substances, or, in mixtures for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than 0.1 % w/w (Regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)).

Country/Organization	Requirements and Restrictions
	Previous regulations, such as the Solvent Emissions Directive (Directive 1999/13/EC) introduced stringent emission controls of TCE.
Australia	In 2000, TCE was assessed (National Industrial Chemicals Notification and Assessment Scheme, NICNAS (2000), *Trichloroethylene*. Accessed April, 18 2017).
Japan Chemical Substances Control Law	TCE is regulated in Japan under the following legislation: -Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) -Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof -Industrial Safety and Health Act (ISHA) -Air Pollution Control Law -Water Pollution Control Law -Soil Contamination Countermeasures Act -Law for the Control of Household Products Containing Harmful Substances (National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHIRP), Accessed April 18, 2017).
Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Japan, Latvia, New Zealand, People's Republic of China, Poland, Singapore, South Korea, Spain, Sweden, Switzerland, United Kingdom	Occupational exposure limits for TCE (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017).

Table 5 – Regulatory and Non-Regulatory Exposure Limits

Both regulatory and non-regulatory worker exposure limits have been established for trichloroethylene (TCE) by OSHA, NIOSH, and the American Conference of Government Industrial Hygienists (ACGIH).

Source	Limit Type	Exposure Limit
OSHA PEL	PEL (8-hr TWA) [a]	100 ppm [b]
	STEL (15-minute TWA)	100 ppm
	Action Level (8-hr TWA)	50 ppm
NIOSH exposure limits	IDLH [c]	150 ppm
	Recommended Exposure Limit	Ca [d]
ACGIH TLV [e]	8-hr TWA	10 ppm

Notes:

[a] PEL= Permissible exposure limit; TWA= Time-weighted average

[b] Airborne concentration conversion factor for TCE is 537 mg/m^3 per ppm and the acceptable ceiling concentration is 200 ppm with an acceptable maximum peak of 300 ppm (with a maximum duration of 5 minutes in any 3-hour period) for an 8-hour shift (NIOSH, 2005).

[c] IDLH = Immediately dangerous to life or health. IDLH values are based on effects that might occur from a 30-minute exposure.

[d] The Recommended Exposure Limit notation "Ca" is for a potential occupational carcinogen. The NIOSH Pocket Guide website has detailed policy recommendations for chemicals with "Ca" notations (NIOSH, 2005).

[e] TLV = Threshold limit value

TCE Personal Protective Equipment Respirator Cost Breakdown

Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown

OSHA's Respiratory Protection Standard (29 CFR 1910.134)[1] identifies several types of respirators and their Assigned Protection Factors (APFs). The APF denotes the level of respiratory protection that a given respirator is expected to provide employees. Table 1 presents example annualized unit costs estimates for respirators, respirator system components, training, fit testing, and medical clearance. Actual costs will vary for each rule depending on the affected industry and the analytical timeframe. Useful lives define the schedule used to discount each cost component before the estimates are annualized.

Respirators are organized by their corresponding APF. Unit cost estimates for individual respirator system components and kits are based on price data collected from retailer websites. Price data are averaged for component and kit unit cost estimates that incorporate the price of more than one product brand.

Table 1: Example Annualized PPE Unit Costs per Worker, by Respirator System

Respirator System	Component	Unit Cost	Useful Life	Annualized Unit Costs[1]	
				3%	7%
APF Factor 25					
SAR, Loose-Fitting Facepiece	Loose-Fitting Facepiece	$56.60	3	$19	$20
	Breathing Tube	$157.55	3	$54	$56
	Pump	$976.52	7	$152	$169
	Pump Installation	$53.45	7	$8	$9
	Pump Inlet Filter	$8.33	0.48	$16	$16
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Medical Evaluation Costs	$104.19	20	$7	$9
	Training Costs	$245.06	1	$230	$224
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$926	$932
APF Factor 50					
SAR, Continuous Flow Mode, Half Mask	Half Mask	$21.53	3	$7	$8
	Breathing Tube	$157.55	3	$54	$56
	Pump	$976.52	7	$152	$169
	Pump Installation	$53.45	7	$8	$9
	Pump Inlet Filter	$8.33	0.48	$16	$16
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$245.06	1	$230	$224
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$1,049	$1,052

[1] The Respiratory Protection Standard (29 CFR 1910.134), promulgated by OSHA, contains requirements for program administration, procedures for respirator selection, employee training, fit testing, medical evaluation, respirator use, APFs and Maximum Use Concentrations (MUCs), as well as other provisions.

APF Factor 1000					
SAR, Continuous Flow Mode, Full Facepiece	Full Facepiece	$194.14	3	$67	$69
	Pump (1/4 HP)	$976.52	7	$152	$169
	Breathing Tube and Airline Hose	$157.55	3	$54	$56
	Pump Installation	$53.45	7	$8	$9
	Pump Inlet Filter	$8.33	0.48	$16	$16
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$245.06	1	$230	$224
	Cleaning Costs	$395.52	0.008	$371	$361
	Total			$1,109	$1,113
SAR, Continuous Flow Mode, Helmet/Hood	Hood	$96.02	3	$33	$34
	Pump (3/4 HP)	$1,055.77	7	$165	$183
	Breathing Tube and Airline Hose	$157.55	3	$54	$56
	Pump Installation	$53.45	7	$8	$9
	Pump Inlet Filter	$12.53	0.48	$24	$24
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$245.06	1	$230	$224
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$1,096	$1,100
APF Factor 10000					
SCBA, Positive-pressure Mode, Full Facepiece	Positive-pressure SCBA System (includes full facepiece):	$2,431.38	3	$835	$866
	Air Compressor	$5,776.86	16	$591	$667
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$490.12	1	$459	$448
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$2,398	$2,483
SCBA, Positive-pressure Mode, Helmet/Hood	Positive-pressure SCBA system (includes hood)	$2,660.77	3	913	948
	Air Compressor	$5,776.86	16	591	667
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$490.12	1	$459	$448
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$2,476	$2,565

[1] Costs are annualized over a 20-year time period

Acronyms

- APF: Assigned Protection Factors
- APR: Air-Purifying Respirator
- OSHA: Occupational Safety and Health Administration
- PARP: Powered Air-Purifying Respirator
- PPE: Personal Protective Equipment
- SAR: Supplied-Air Respirator (SAR) or Airline Respirator
- SCBA: Self-Contained Breathing Apparatus

TCE Industry Sectors Potentially Affected by Rulemaking

Industry Sectors with Small Entities Potentially Affected by the Rulemaking

Entities potentially regulated by this rulemaking to address the unreasonable risks from TCE include those entities relevant to the conditions of use of TCE that EPA evaluated, including domestic manufacturing, import, processing uses of TCE, repackaging and recycling, industrial and commercial uses of TCE (such as solvents for cleaning and degreasing, adhesives and sealants, lubricants and greases, functional fluids, paints and coatings, and in a variety of cleaning products), all but one consumer use (such as cleaners and degreasers, adhesives and sealants, paints and coatings, lubricants and greases, arts and crafts glue, and other miscellaneous uses), and disposal. Entities may include manufacturers (including importers), processors, formulators, industrial and commercial users, or distributors (such as retailers) of TCE or products containing TCE within the scope of this rulemaking.

Potentially affected entities will include both employer and non-employer firms and establishments identified within these sectors by the U.S. Census for each applicable North American Industry Classification System (NAICS) code. Since the Small Business Administration (SBA) size standard varies by NAICS code, they are also included in the table below. NAICS codes of potentially affected entities may include, but are not limited to:

NAICS	NAICS description	SBA Size Standard
111421	Nursery and Tree Production	$0.75 million
111422	Floriculture Production	$0.75 million
111998	All Other Miscellaneous Crop Farming	$0.75 million
112210	Hog and Pig Farming	$0.75 million
112990	All Other Animal Production	$0.75 million
211120	Crude Petroleum Extraction	1,250 employees
212111	Bituminous Coal and Lignite Surface Mining	1,250 employees
212210	Iron Ore Mining	750 employees
212312	Crushed and Broken Limestone Mining and Quarrying	750 employees
212321	Construction Sand and Gravel Mining	500 employees
212399	All Other Nonmetallic Mineral Mining	500 employees
221112	Fossil Fuel Electric Power Generation	750 employees
221113	Nuclear Electric Power Generation	750 employees
221117	Biomass Electric Power Generation	250 employees

NAICS	NAICS description	SBA Size Standard
221118	Other Electric Power Generation	250 employees
221121	Electric Bulk Power Transmission and Control	500 employees
221122	Electric Power Distribution	1,000 employees
221210	Natural Gas Distribution	1,000 employees
221310	Water Supply and Irrigation Systems	$27.5 million
221320	Sewage Treatment Facilities	$20.5 million
221330	Steam and Air-Conditioning Supply	$16.5 million
237310	Highway, Street, and Bridge Construction	$36.5 million
2383	Building Finish Contractors	$16.5 million
311119	Other Animal Food Manufacturing	500 employees
311211	Flour Milling	1,000 employees
311221	Wet Corn Milling	1,250 employees
311224	Soybean and Other Oilseed Processing	1,000 employees
311423	Dried and Dehydrated Food Manufacturing	750 employees
311611	Animal (except Poultry) Slaughtering	1,000 employees
311615	Poultry Processing	1,250 employees
311812	Commercial Bakeries	1,000 employees
311911	Roasted Nuts and Peanut Butter Manufacturing	750 employees
311919	Other Snack Food Manufacturing	1,250 employees
312120	Breweries	1,250 employees
312130	Wineries	1,000 employees
312140	Distilleries	1,000 employees
312230	Tobacco Manufacturing	1,500 employees

NAICS	NAICS description	SBA Size Standard
313210	Broadwoven Fabric Mills	1,000 employees
313230	Nonwoven Fabric Mills	750 employees
313310	Textile and Fabric Finishing Mills	1,000 employees
313320	Fabric Coating Mills	1,000 employees
314999	All Other Miscellaneous Textile Product Mills	500 employees
321113	Sawmills	500 employees
321114	Wood Preservation	500 employees
321211	Hardwood Veneer and Plywood Manufacturing	500 employees
321212	Softwood Veneer and Plywood Manufacturing	1,250 employees
321213	Engineered Wood Member (except Truss) Manufacturing	750 employees
321214	Truss Manufacturing	500 employees
321219	Reconstituted Wood Product Manufacturing	750 employees
321911	Wood Window and Door Manufacturing	1,250 employees
321912	Cut Stock, Resawing Lumber, and Planing	500 employees
321918	Other Millwork (including Flooring)	500 employees
321920	Wood Container and Pallet Manufacturing	500 employees
321992	Prefabricated Wood Building Manufacturing	500 employees
321999	All Other Miscellaneous Wood Product Manufacturing	500 employees
322110	Pulp Mills	750 employees
322121	Paper (except Newsprint) Mills	1,250 employees
322122	Newsprint Mills	750 employees
322130	Paperboard Mills	1,250 employees
322211	Corrugated and Solid Fiber Box Manufacturing	1,250 employees

NAICS	NAICS description	SBA Size Standard
322220	Paper Bag and Coated and Treated Paper Manufacturing	750 employees
323111	Commercial Printing (except Screen and Books)	500 employees
323113	Commercial Screen Printing	500 employees
324110	Petroleum Refineries	1,500 employees
324121	Asphalt Paving Mixture and Block Manufacturing	500 employees
324122	Asphalt Shingle and Coating Materials Manufacturing	750 employees
324191	Petroleum Lubricating Oil and Grease Manufacturing	750 employees
324199	All Other Petroleum and Coal Products Manufacturing	500 employees
325110	Petrochemical Manufacturing	1,000 employees
325120	Industrial Gas Manufacturing	1,000 employees
325130	Synthetic Dye and Pigment Manufacturing	1,000 employees
325180	Other Basic Inorganic Chemical Manufacturing	1,000 employees
325193	Ethyl Alcohol Manufacturing	1,000 employees
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	1,250 employees
325199	All Other Basic Organic Chemical Manufacturing	1,250 employees
325211	Plastics Material and Resin Manufacturing	1,250 employees
325212	Synthetic Rubber Manufacturing	1,000 employees
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1,000 employees
325311	Nitrogenous Fertilizer Manufacturing	1,000 employees
325320	Pesticide and Other Agricultural Chemical Manufacturing	1,000 employees
325411	Medicinal and Botanical Manufacturing	1,000 employees
325412	Pharmaceutical Preparation Manufacturing	1,250 employees

NAICS	NAICS description	SBA Size Standard
325510	Paint and Coating Manufacturing	1,000 employees
325520	Adhesive Manufacturing	500 employees
325611	Soap and Other Detergent Manufacturing	1,000 employees
325612	Polish and Other Sanitation Good Manufacturing	750 employees
325613	Surface Active Agent Manufacturing	750 employees
325910	Printing Ink Manufacturing	500 employees
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1,500 employees
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 employees
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	750 employees
326122	Plastics Pipe, Pipe Fitting, and Unlaminated Profile Shape Manufacturing	750 employees
326140	Polystyrene Foam Product Manufacturing	1,000 employees
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	750 employees
326199	All Other Plastics Product Manufacturing	750 employees
326211	Tire Manufacturing (except Retreading)	1,500 employees
326212	Tire Retreading	500 employees
326220	Rubber and Plastics Hoses and Belting Manufacturing	750 employees
326299	All Other Rubber Product Manufacturing	500 employees
327310	Cement Manufacturing	1,000 employees
327320	Ready-Mix Concrete Manufacturing	500 employees
327390	Other Concrete Product Manufacturing	500 employees
327420	Gypsum Product Manufacturing	1,500 employees

NAICS	NAICS description	SBA Size Standard
331110	Iron and Steel Mills and Ferroalloy Manufacturing	1,500 employees
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	1,000 employees
331221	Rolled Steel Shape Manufacturing	1,000 employees
331222	Steel Wire Drawing	1,000 employees
331315	Aluminum Sheet, Plate, and Foil Manufacturing	1,250 employees
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	1,000 employees
331420	Copper Rolling, Drawing, Extruding, and Alloying	1,000 employees
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing and Extruding	750 employees
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	750 employees
331511	Iron Foundries	1,000 employees
331513	Steel Foundries (except Investment)	500 employees
331523	Nonferrous Metal Die-Casting Foundries	500 employees
332111	Iron and Steel Forging	750 employees
332112	Nonferrous Forging	750 employees
332114	Custom Roll Forming	500 employees
332117	Powder Metallurgy Part Manufacturing	500 employees
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	500 employees
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	750 employees
332216	Saw Blade and Handtool Manufacturing	750 employees
332321	Metal Window and Door Manufacturing	750 employees

NAICS	NAICS description	SBA Size Standard
332322	Sheet Metal Work Manufacturing	500 employees
332323	Ornamental and Architectural Metal Work Manufacturing	500 employees
332410	Power Boiler and Heat Exchanger Manufacturing	750 employees
332420	Metal Tank (Heavy Gauge) Manufacturing	750 employees
332431	Metal Can Manufacturing	1,500 employees
332439	Other Metal Container Manufacturing	500 employees
332510	Hardware Manufacturing	750 employees
332613	Spring Manufacturing	500 employees
332618	Other Fabricated Wire Product Manufacturing	500 employees
332710	Machine Shops	500 employees
332721	Precision Turned Product Manufacturing	500 employees
332722	Bolt, Nut, Screw, Rivet, and Washer Manufacturing	500 employees
332811	Metal Heat Treating	750 employees
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	500 employees
332813	Electroplating, Plating, Polishing, Anodizing and Coloring	500 employees
332911	Industrial Valve Manufacturing	750 employees
332912	Fluid Power Valve and Hose Fitting Manufacturing	1,000 employees
332913	Plumbing Fixture Fitting and Trim Manufacturing	1,000 employees
332919	Other Metal Valve and Pipe Fitting Manufacturing	750 employees
332991	Ball and Roller Bearing Manufacturing	1,250 employees
332992	Small Arms Ammunition Manufacturing	1,250 employees
332993	Ammunition (except Small Arms) Manufacturing	1,500 employees

NAICS	NAICS description	SBA Size Standard
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing	1,000 employees
332996	Fabricated Pipe and Pipe Fitting Manufacturing	500 employees
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	750 employees
333111	Farm Machinery and Equipment Manufacturing	1,250 employees
333112	Lawn and Garden Tractor and Home Lawn and Garden Equipment Manufacturing	1,500 employees
333120	Construction Machinery Manufacturing	1,250 employees
333131	Mining Machinery and Equipment Manufacturing	500 employees
333132	Oil and Gas Field Machinery and Equipment Manufacturing	1,250 employees
333241	Food Product Machinery Manufacturing	500 employees
333242	Semiconductor Machinery Manufacturing	1,500 employees
333243	Sawmill, Woodworking, and Paper Machinery Manufacturing	500 employees
333244	Printing Machinery and Equipment Manufacturing	750 employees
333249	Other Industrial Machinery Manufacturing	500 employees
333314	Optical Instrument and Lens Manufacturing	500 employees
333316	Photographic and Photocopying Equipment Manufacturing	1,000 employees
333318	Other Commercial and Service Industry Machinery Manufacturing	1,000 employees
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	500 employees
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	500 employees
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	1,250 employees

NAICS	NAICS description	SBA Size Standard
333511	Industrial Mold Manufacturing	500 employees
333514	Special Die and Tool, Die Set, Jig and Fixture Manufacturing	500 employees
333515	Cutting Tool and Machine Tool Accessory Manufacturing	500 employees
333517	Machine Tool Manufacturing	500 employees
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	500 employees
333611	Turbine and Turbine Generator Set Units Manufacturing	1,500 employees
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	750 employees
333613	Mechanical Power Transmission Equipment Manufacturing	750 employees
333618	Other Engine Equipment Manufacturing	1,500 employees
333911	Pump and Pumping Equipment Manufacturing	500 employees
333912	Air and Gas Compressor Manufacturing	1,000 employees
333913	Measuring, Dispensing, and Other Pumping Equipment Manufacturing	750 employees
333921	Elevator and Moving Stairway Manufacturing	1,000 employees
333922	Conveyor and Conveying Equipment Manufacturing	500 employees
333923	Overhead Traveling Crane, Hoist, and Monorail System Manufacturing	1,250 employees
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	750 employees
333991	Power-Driven Handtool Manufacturing	500 employees
333992	Welding and Soldering Equipment Manufacturing	1,250 employees
333993	Packaging Machinery Manufacturing	500 employees
333994	Industrial Process Furnace and Oven Manufacturing	500 employees
333995	Fluid Power Cylinder and Actuator Manufacturing	750 employees

NAICS	NAICS description	SBA Size Standard
333996	Fluid Power Pump and Motor Manufacturing	1,250 employees
333997	Scale and Balance Manufacturing	500 employees
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	500 employees
334111	Electronic Computer Manufacturing	1,250 employees
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	1,000 employees
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	1,250 employees
334310	Audio and Video Equipment Manufacturing	750 employees
334413	Semiconductor and Related Device Manufacturing	1,250 employees
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	500 employees
334417	Electronic Connector Manufacturing	1,000 employees
334418	Printed Circuit Assembly (Electronic Assembly) Manufacturing	750 employees
334419	Other Electronic Component Manufacturing	750 employees
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing	1,250 employees
334512	Automatic Environmental Control Manufacturing for Residential, Commercial and Appliance Use	500 employees
334513	Instruments and Related Products Manufacturing for Measuring, Displaying, and Controlling Industrial Process Variables	750 employees
334515	Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals	750 employees
335110	Electric Lamp Bulb and Part Manufacturing	1,250 employees
335121	Residential Electric Lighting Fixture Manufacturing	750 employees

NAICS	NAICS description	SBA Size Standard
335122	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing	500 employees
335129	Other Lighting Equipment Manufacturing	500 employees
335220	Major Household Appliance Manufacturing	1,500 employees
335311	Power, Distribution, and Specialty Transformer Manufacturing	750 employees
335312	Motor and Generator Manufacturing	1,250 employees
335313	Switchgear and Switchboard Apparatus Manufacturing	1,250 employees
335314	Relay and Industrial Control Manufacturing	750 employees
335912	Primary Battery Manufacturing	1,000 employees
335921	Fiber Optic Cable Manufacturing	1,000 employees
335931	Current-Carrying Wiring Device Manufacturing	500 employees
335932	Noncurrent-Carrying Wiring Device Manufacturing	1,000 employees
335991	Carbon and Graphite Product Manufacturing	750 employees
336111	Automobile Manufacturing	1,500 employees
336112	Light Truck and Utility Vehicle Manufacturing	1,500 employees
336120	Heavy Duty Truck Manufacturing	1,500 employees
336211	Motor Vehicle Body Manufacturing	1,000 employees
336212	Truck Trailer Manufacturing	1,000 employees
336213	Motor Home Manufacturing	1,250 employees
336214	Travel Trailer and Camper Manufacturing	1,000 employees
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	1,000 employees
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	1,000 employees

NAICS	NAICS description	SBA Size Standard
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	1,000 employees
336340	Motor Vehicle Brake System Manufacturing	1,250 employees
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	1,500 employees
336360	Motor Vehicle Seating and Interior Trim Manufacturing	1,500 employees
336370	Motor Vehicle Metal Stamping	1,000 employees
336390	Other Motor Vehicle Parts Manufacturing	1,000 employees
336411	Aircraft Manufacturing	1,500 employees
336412	Aircraft Engine and Engine Parts Manufacturing	1,500 employees
336413	Other Aircraft Part and Auxiliary Equipment Manufacturing7	1,250 employees
336414	Guided Missile and Space Vehicle Manufacturing	1,250 employees
336415	Guided Missile and Space Vehicle Propulsion Unit and Propulsion Unit Parts Manufacturing	1,250 employees
336419	Other Guided Missile and Space Vehicle Parts and Auxiliary Equipment Manufacturing	1,000 employees
336510	Railroad Rolling Stock Manufacturing	1,500 employees
336611	Ship Building and Repairing	1,250 employees
336612	Boat Building	1,000 employees
336991	Motorcycle, Bicycle, and Parts Manufacturing	1,000 employees
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	1,500 employees
336999	All Other Transportation Equipment Manufacturing	1,000 employees
337110	Wood Kitchen Cabinet and Counter Top Manufacturing	750 employees
337121	Upholstered Household Furniture Manufacturing	1,000 employees

NAICS	NAICS description	SBA Size Standard
337122	Nonupholstered Wood Household Furniture Manufacturing	750 employees
337124	Metal Household Furniture Manufacturing	750 employees
337125	Household Furniture (except Wood and Metal) Manufacturing	750 employees
337127	Institutional Furniture Manufacturing	500 employees
337211	Wood Office Furniture Manufacturing	1,000 employees
337212	Custom Architectural Woodwork and Millwork Manufacturing	500 employees
337215	Showcase, Partition, Shelving, and Locker Manufacturing	500 employees
339112	Surgical and Medical Instrument Manufacturing	1,000 employees
339113	Surgical Appliance and Supplies Manufacturing	750 employees
339114	Dental Equipment and Supplies Manufacturing	750 employees
339910	Jewelry and Silverware Manufacturing	500 employees
339920	Sporting and Athletic Goods Manufacturing	750 employees
339991	Gasket, Packing, and Sealing Device Manufacturing	500 employees
339993	Fastener, Button, Needle and Pin Manufacturing	750 employees
339995	Burial Casket Manufacturing	1,000 employees
339999	All Other Miscellaneous Manufacturing	500 employees
42331	Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers	750 employees
423510	Metal Service Centers and Other Metal Merchant Wholesalers	200 employees
423830	Industrial Machinery and Equipment Merchant Wholesalers	100 employees
423840	Industrial Supplies Merchant Wholesalers	100 employees
423910	Sporting and Recreational Goods and Supplies Merchant Wholesalers	100 employees
423930	Recyclable Material Merchant Wholesalers	100 employees

NAICS	NAICS description	SBA Size Standard
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	100 employees
424690	Other Chemical and Allied Products Merchant Wholesalers	150 employees
424710	Petroleum Bulk Stations and Terminals	200 employees
441110	New Car Dealers	200 employees
441120	Used Car Dealers	$27.0 million
443142	Electronics Stores	$32.5 million
444110	Home Centers	$41.5 million
451110	Sporting Goods Stores	$16.5 million
454310	Fuel Dealers	100 employees
481111	Scheduled Passenger Air Transportation	1,500 employees
484121	General Freight Trucking, Long-Distance, Truckload	$27.5 million
488190	Other Support Activities for Air Transportation	$32.5 million
488210	Support Activities for Rail Transportation	$15.0 million
493110	General Warehousing and Storage	$27.5 million
493190	Other Warehousing and Storage	$27.5 million
512110	Motion Picture and Video Production	$32.5 million
512290	Other Sound Recording Industries	$11.0 million
517311	Wired Telecommunication Carriers	1,500 employees
525990	Other Financial Vehicles	$32.5 million
531120	Lessors of Nonresidential Buildings (except Miniwarehouses)	$30 million
531190	Lessors of Other Real Estate Property	$16.5 million
541330	Engineering Services	$15.0 million
541380	Testing Laboratories	$15.0 million

NAICS	NAICS description	SBA Size Standard
541512	Computer Systems Design Services	$27.5 million
541620	Environmental Consulting Services	$15.0 million
541714	Research and Development in Biotechnology (Except Nanobiotechnology)	1,000 employees
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	1,000 employees
541720	Research and Development in the Social Sciences and Humanities	$20.5 million
541940	Veterinary Services	$7.5 million
551112	Offices of Other Holding Companies	$22 million
561499	All Other Business Support Services	$15.0 million
561599	All Other Travel Arrangement and Reservation Services	$20.5 million
561740	Carpet and Upholstery Cleaning Services	$5.5 million
561790	Other Services to Buildings and Dwellings	$7.5 million
561990	All Other Support Services	$11.0 million
562111	Solid Waste Collection	$38.5 million
562112	Hazardous Waste Collection	$38.5 million
562211	Hazardous Waste Treatment and Disposal	$38.5 million
562212	Solid Waste Landfill	$38.5 million
562213	Solid Waste Combustors and Incinerators	$38.5 million
562219	Other Nonhazardous Waste Treatment and Disposal	$38.5 million
562910	Remediation Services	$20.5 million
562920	Materials Recovery Facilities	$20.5 million
562998	All Other Miscellaneous Waste Management Services	$8 million

NAICS	NAICS description	SBA Size Standard
611110	Elementary and Secondary Schools	$11.0 million
611210	Junior Colleges	$20.5 million
611310	Colleges, Universities, and Professional Schools	$27.5 million
622110	General Medical and Surgical Hospitals	$38.5 million
624110	Child and Youth Services	$11.0 million
721110	Hotels (except Casino Hotels) and Motels	$38.5 million
811111	General Automotive Repair	$7.5 million
811112	Automotive Exhaust System Repair	$7.5 million
811113	Automotive Transmission Repair	$7.5 million
811118	Other Automotive Mechanical and Electrical Repair and Maintenance	$7.5 million
811121	Automotive Body, Paint and Interior Repair and Maintenance	$7.5 million
811122	Automotive Glass Replacement Shops	$11.0 million
811191	Automotive Oil Change and Lubrication Shops	$7.5 million
811198	All Other Automotive Repair and Maintenance	$7.5 million
811211	Consumer Electronics Repair and Maintenance	$7.5 million
811212	Computer and Office Machine Repair and Maintenance	$27.5 million
811213	Communication Equipment Repair and Maintenance	$11.0 million
811219	Other Electronic and Precision Equipment Repair and Maintenance	20.5 million
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	$8 million
811411	Home and Garden Equipment Repair and Maintenance	$7.5 million
811412	Appliance Repair and Maintenance	$15.0 million

<table>
<tr><th>NAICS</th><th>NAICS description</th><th>SBA Size Standard</th></tr>
<tr><td>811430</td><td>Footwear and Leather Goods Repair</td><td>$7.5 million</td></tr>
<tr><td>811490</td><td>Other Personal and Household Goods Repair and Maintenance</td><td>$7.5 million</td></tr>
<tr><td>812210</td><td>Funeral Homes and Funeral Services</td><td>$7.5 million</td></tr>
<tr><td>812220</td><td>Cemeteries and Crematories</td><td>$20.5 million</td></tr>
<tr><td>812310</td><td>Coin-Operated Laundries and Drycleaners</td><td>$7.5 million</td></tr>
<tr><td>812320</td><td>Drycleaning and Laundry Services (except Coin-Operated)</td><td>$5.5 million</td></tr>
<tr><td>812332</td><td>Industrial Launderers</td><td>$32.5 million</td></tr>
<tr><td>812910</td><td>Pet Care (except Veterinary) Services</td><td>$7.5 million</td></tr>
<tr><td>921110</td><td>Executive Offices</td><td rowspan="10">Small business size standards are not established for these Sectors. Establishments in the Public Administration Sectors are Federal, state, and local government agencies which administer and oversee government programs and activities that are not performed by private establishments.</td></tr>
<tr><td>921120</td><td>Legislative Bodies</td></tr>
<tr><td>921190</td><td>Other General Government Support</td></tr>
<tr><td>922140</td><td>Correctional Institutions</td></tr>
<tr><td>922190</td><td>Other Justice, Public Order, and Safety Activities</td></tr>
<tr><td>924110</td><td>Administration of Air and Water Resource and Solid Waste Management Programs</td></tr>
<tr><td>924120</td><td>Administration of Conservation Programs</td></tr>
<tr><td>926120</td><td>Regulation and Administration of Transportation Programs</td></tr>
<tr><td>927110</td><td>Space Research and Technology</td></tr>
<tr><td>928110</td><td>National Security</td></tr>
<tr><td colspan="3">Source: U.S. Small Business Administration Table of Small Business Size Standards, available at: https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf</td></tr>
</table>

The First TCE Existing Chemical Exposure Limit (ECEL) for Occupational Use

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SUBJECT: Existing Chemical Exposure Limit (ECEL) for Occupational Use of Trichloroethylene

FROM: Yvette Selby-Mohamadu Yvette Selby-Mohamadu
Branch Chief, Existing Chemicals Risk Assessment Division

THRU: Andrew J. R. Gillespie, Ph. D Andrew JR Gillespie
Acting Director, Existing Chemicals Risk Assessment Division

TO: Joel Wolf
Branch Chief, Existing Chemicals Risk Management Division

DATE: February 22, 2021

EPA has developed an 8-hour existing chemical exposure limit (ECEL) in support of risk management efforts on trichloroethylene under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the ECEL to be 4.0 ppb (0.021 mg/m3) for inhalation exposures to trichloroethylene as an 8-hour time-weighted average (TWA) and for use in workplace settings (see Appendix A) based on the chronic non-cancer occupational human equivalent concentration (HEC99) for autoimmunity. EPA has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk in the Risk Evaluation for Trichloroethylene (U.S. EPA, 2020) under TSCA.

EPA expects that at the chronic non-cancer ECEL of 4.0 ppb (0.021 mg/m3), a worker or occupational non-user (ONU) is also protected against mortality due to immunosuppression resulting from acute occupational exposure. In addition, this ECEL protects against excess risk of cancer above the $1x10^{-4}$ benchmark resulting from lifetime exposure if ambient exposures are kept below this ECEL.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as both an 8-hour TWA and an acceptable ceiling concentration for trichloroethylene (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1000TABLEZ2). However, as noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970 and have not been updated since that time." EPA's ECEL is a lower value and is based on newer information and analysis, from the 2020 Risk Evaluation for Trichloroethylene.

Published NIOSH/OSHA/EPA methods were identified and the ECEL is within the limit of detection (LOD) of some of the methods identified in Appendix B.

Appendix A: ECEL and Other Exposure Limit Calculations

This appendix presents the calculations used to estimate the ECEL and other exposure limits used for comparison. The resulting ECEL value was rounded. The values used in the equations are included in the Final Risk Evaluation for Trichloroethylene (U.S. EPA, 2020).

Chronic Non-Cancer ECEL

The 8-hour ECEL is the concentration that EPA determined would indicate no unreasonable risk of injury to human health from chronic inhalation exposures in an occupational setting for the endpoints that are the basis for the TSCA unreasonable risk determination. The ECEL was calculated for (the chronic non-cancer occupational human equivalent concentration (HEC99) for autoimmunity) as the concentration at which the chronic MOE would equal the benchmark MOE for chronic occupational exposures with the following equation:

$$\mathrm{ECEL}_{\mathrm{inhal,occupational}} = \frac{\mathrm{HEC}_{\mathrm{chronic,occupational}}}{Benchmark\ MOE_{chronic}} * \frac{\mathrm{AT}_{\mathrm{POD\ chronic}}}{ED * EF * WY} =$$

$$\frac{0.083\ \mathrm{ppm}}{30} * \frac{8h/d * 365d/y * 40\ y}{8h/d * 250d/y * 40\ y} = 0.0040\ \mathrm{ppm} = 4.0\ \mathrm{ppb}$$

$$ECEL\left(\frac{\mathrm{mg}}{\mathrm{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume} = \frac{0.0040\ \mathrm{ppm} * 131.39\frac{g}{mol}}{24.45\frac{L}{mol}} = 0.021\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

Molar Volume = 24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C

MW = Molecular weight of TCE (131.39 g/mole)

Acute Non-Cancer Exposure Limit

The acute occupational exposure limit (EL_{acute}) was calculated as the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures using the following equation:

$$\mathrm{EL}_{\mathrm{acute}} = \frac{\mathrm{HEC}_{\mathrm{acute,occupational}}}{Benchmark\ MOE_{acute}} * \frac{\mathrm{AT}_{\mathrm{PODacute}}}{ED} = \frac{2.34\ \mathrm{ppm}}{10} * \frac{8h/d}{8h/d} = 0.23\ \mathrm{ppm} = 1.2\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Lifetime Cancer Exposure Limit

The EL_{cancer} is the concentration at which the extra cancer risk is equivalent to the benchmark cancer risk of 1×10^{-4}:

$$\mathrm{EL}_{\mathrm{cancer}} = \frac{Benchmark_{Cancer}}{IUR} * \frac{AT_{IUR}}{ED * EF * WY} = \frac{1X10^{-4}}{2.2 \times 10^{-2}\ per\ ppm} * \frac{24h/d * 365d/y * 78y}{8h/d * 250d/y * 40y} =$$

$$0.039\ \mathrm{ppm} = 0.21\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

$AT_{PODchronic}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, chronic occupational risk, based on study conditions and/or HEC adjustments (8 hrs/day for 365 days/yr) and assuming the number of years matches the high-end working years (WY, 40 yrs) for a worker (RE Section 2.3.1.2.4 and Table 2-17).
$AT_{PODacute}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, acute occupational risk, based on study conditions and/or any HEC adjustments (8hrs/day)
AT_{IUR}	=	Averaging time for the cancer IUR, based on study conditions and any adjustments (24 hrs/day for 365 days/yr) and averaged over a lifetime (78 yrs) (RE Section 2.3.1.2.4 and Table 2-17)
Benchmark MOE_{acute}	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 10 (RE Table 3-16)
Benchmark $MOE_{chronic}$	=	Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 30 (RE Table 3-16)
$Benchmark_{Cancer}$	=	Benchmark for excess lifetime cancer risk ($1x10^{-4}$)
ECEL	=	Existing chemical exposure limit (mg/m^3 or ppm)
EL_{acute}	=	Exposure limit based on acute immunosuppression
EL_{cancer}	=	Exposure limit based on excess cancer risk
ED	=	Exposure duration (8 hrs/day), (RE Table 2-17 and Appendix M)
EF	=	Exposure frequency (250 days/yr), (RE Table 2-17 and Appendix M)
$HEC_{acute\ or\ chronic,\ occupational}$	=	Human equivalent concentration for acute or chronic occupational exposure scenarios (RE Table 3-16)
IUR	=	Inhalation unit risk (per ppm) (RE Table 3-15)
WY	=	Working years per lifetime at the 95th percentile (40 yrs) (RE Table 2-17)

Unit conversion:

1 ppm = 5.37 mg/m^3 (based on molecular weight of 131.39.8 g/mol for TCE and molar volume of 24.45 L/mol at 25°C and 1 atm pressure) $ECEL\left(\frac{\text{mg}}{\text{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume}$

References

U.S. Environmental Protection Agency. 2020. Risk Evaluation for Trichloroethylene (TCE) CASRN: 79-01-6. EPA-740-R1-8008. Office of Chemical Safety and Pollution Prevention. November 2020. Available at: EPA-HQ-OPPT-2019-0500-0113.

U.S. Environmental Protection Agency. 2002. A Review of the Reference Dose and Reference Concentration Processes. Final Report. EPA/630/P-02/002F. Prepared for the Risk Assessment Forum. December.

Appendix B: Summary of Air Sampling Analytical Methods Identified

EPA conducted a search to identify relevant NIOSH/OSHA/EPA analytical methods used to monitor for the presence of trichloroethylene in air (see Table 1). The sources used for the search included the following:

1) NIOSH Manual of Analytical Methods (NMAM); 5th Edition
   - URL: https://www.cdc.gov/niosh/nmam/default.html
2) NIOSH NMAM 4th Edition
   - URL: https://www.cdc.gov/niosh/docs/2003-154/default.html
3) OSHA Index of Sampling and Analytical Methods
   - URL: https://www.osha.gov/dts/sltc/methods/
4) EPA Environmental Test Method and Monitoring Information
   - https://www.epa.gov/emc/epa-websites-environmental-test-method-and-monitoring-information

Table 1: Limit of detection (LOD) summary for air sampling analytical methods identified.

Air Sampling Analytical Methods	Year Published	LOD[a]	Notes	Source
NIOSH Method 8300 https://www.cdc.gov/niosh/docs/2014-151/pdfs/methods/3800.pdf	2016	0.43 ppm	Method reports approximate LOD for an absorption length of 10 m.	NIOSH Manual of Analytical Methods (NMAM); 5th Edition https://www.cdc.gov/niosh/nmam/default.html
NIOSH Method 1022, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/1022.pdf	1994	60 ppb	Method reports estimated LOD as 0.01 mg per sample, with a maximum sample of 30 L.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
NIOSH Method 3701, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/3701.pdf	1994	0.1 ppm	Method reports estimated LOD as 0.1 ppm for a 1 mL injection.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
OSHA Method 1001 https://www.osha.gov/dts/sltc/methods/mdt/mdt1001/1001.html	1999	3.7 or 18 ppb	Method reports LOD of overall procedure as 3.7 ppb for charcoal tubes and 18 ppb for SKC 575-002 Samplers.	OSHA Index of Sampling and Analytical Methods https://www.osha.gov/dts/sltc/methods/
EPA Method TO-14A https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-14ar.pdf	1999	14 ppb	Estimated LOD based on 1 microliter sample volume (Table B-1).	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html
EPA Method TO-15 https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-15r.pdf	1999	≤0.5 ppb	To qualify under Compendium Method TO-15, the method detection limit must ≤0.5 ppbv. This method uses ppbv, but LODs for other methods listed here are also understood to be on a volume basis. For	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html

Air Sampling Analytical Methods	Year Published	LOD[a]	Notes	Source
			consistency, the LOD for this method is listed as ≤0.5 ppb.	
EPA Method TO-17	1999	≤0.5 ppb	To qualify under Compendium Method TO-17, the method detection limit must be ≤0.5 ppb.	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html
ppm = parts per million; ppb = parts per billion; ppt = parts per trillion **[a] EPA has included all relevant NIOSH/OSHA/EPA methods that it identified, including those methods with an LOD above the ECEL.**				

The Second TCE ECEL (Developmental Toxicity) for Occupational Use

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SUBJECT: Second Existing Chemical Exposure Limit (ECEL) (Developmental Toxicity) for Occupational Use of Trichloroethylene

FROM: Keith Jacobs
Team Lead, Risk Assessment Branch 5, Existing Chemicals Risk Assessment Division

THRU: Sheila Healy, Ph.D
Chief, Risk Assessment Branch 5, Existing Chemicals Risk Assessment Division

Jeff Morris
Director, Existing Chemicals Risk Assessment Division

TO: Joel Wolf
Chief, Risk Management Branch 1, Existing Chemicals Risk Management Division

DATE: March 31, 2022

On February 22, 2021, EPA developed an 8-hour existing chemical exposure limit (ECEL) for trichloroethylene based on the immunotoxicity endpoint (4.0 ppb (0.021 mg/m^3)) characterized in the November 2020 TSCA Risk Evaluation for Trichloroethylene. In addition, EPA has developed an 8-hour ECEL for the most sensitive acute and chronic non-cancer health endpoint (developmental toxicity) in support of risk management efforts on trichloroethylene under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the ECEL to be 1.1 ppb (0.0059 mg/m^3) for inhalation exposures to trichloroethylene as an 8-hour time-weighted average (TWA) and for use in workplace settings (see Appendix A) based on the acute non-cancer occupational human equivalent concentration (HEC99) for congenital heart defects.

EPA expects that at the acute non-cancer ECEL of 1.1 ppb (0.0059 mg/m^3) a worker or occupational non-user (ONU) is also protected against congenital heart defects resulting from chronic occupational exposure. In addition, this ECEL protects against excess risk of cancer above the 1x10^{-4} benchmark resulting from lifetime exposure if ambient exposures are kept below this ECEL.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as both an 8-hour TWA and an acceptable ceiling concentration for trichloroethylene (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1000TABLEZ2). However, as noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970 and have not been updated since that time." EPA's ECEL is a lower value and is based on newer information and analysis, from the 2020 Risk Evaluation for Trichloroethylene.

Published NIOSH/OSHA/EPA methods were identified and the ECEL is within the limit of detection (LOD) of some of the methods identified in Appendix B.

Appendix A: ECEL and Other Exposure Limit Calculations

This appendix presents the calculations used to estimate the ECEL and other exposure limits used for comparison. The resulting ECEL value was rounded. The values used in the equations are included in the Final Risk Evaluation for Trichloroethylene (U.S. EPA, 2020).

Acute Non-Cancer ECEL

This 8-hour ECEL is the concentration that EPA calculated for (the acute non-cancer occupational human equivalent concentration (HEC99) for congenital heart defects) the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures with the following equation:

$$\mathrm{EL}_{\mathrm{acute}} = \frac{\mathrm{HEC}_{\mathrm{acute,occupational}}}{Benchmark\ MOE_{acute}} * \frac{\mathrm{AT}_{\mathrm{PODacute}}}{ED} = \frac{0.0037\ \mathrm{ppm}}{10} * \frac{\frac{24h}{d}}{\frac{8h}{d}} = 0.0011\ \mathrm{ppm} = 1.1\ \mathrm{ppb}$$

$$ECEL\ \left(\frac{\mathrm{mg}}{\mathrm{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume} = \frac{0.0011\ \mathrm{ppm} * 131.39 \frac{g}{mol}}{24.45 \frac{L}{mol}} = 0.0059\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

Molar Volume	=	24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C
MW	=	Molecular weight of TCE (131.39 g/mole)

Chronic Non-Cancer Exposure Limit

The chronic occupational exposure limit ($\mathrm{EL}_{\mathrm{chronic}}$) was calculated as the concentration at which the chronic MOE would equal the benchmark MOE for chronic occupational exposures using the following equation:

$$\mathrm{ECEL}_{\mathrm{inhal,occupational}} = \frac{\mathrm{HEC}_{\mathrm{chronic,occupational}}}{Benchmark\ MOE_{chronic}} * \frac{\mathrm{AT}_{\mathrm{POD\ chronic}}}{ED * EF * WY} =$$

$$\frac{0.0037\ \mathrm{ppm}}{10} * \frac{24h/d * 365d/y * 40\ y}{8h/d * 250d/y * 40\ y} = 0.0016\ \mathrm{ppm} = 1.6\ \mathrm{ppb} = 0.0086\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Lifetime Cancer Exposure Limit

The $\mathrm{EL}_{\mathrm{cancer}}$ is the concentration at which the extra cancer risk is equivalent to the benchmark cancer risk of $1\mathrm{x}10^{-4}$:

$$\mathrm{EL}_{\mathrm{cancer}} = \frac{Benchmark_{Cancer}}{IUR} * \frac{AT_{IUR}}{ED * EF * WY} = \frac{1X10^{-4}}{2.2 \times 10^{-2}\ per\ ppm} * \frac{24h/d * 365d/y * 78y}{8h/d * 250d/y * 40y} =$$

$$0.039\ \mathrm{ppm} = 0.21\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

$AT_{PODacute}$ = Averaging time for the POD/HEC used for evaluating non-cancer, acute occupational risk, based on study conditions and/or any HEC adjustments (24hrs/day)

$AT_{PODchronic}$ = Averaging time for the POD/HEC used for evaluating non-cancer, chronic occupational risk, based on study conditions and/or HEC adjustments (24 hrs/day for 365 days/yr) and assuming the number of years matches the high-end working years (WY, 40 yrs) for a worker (RE Section 2.3.1.2.4 and Table 2-17).

AT_{IUR} = Averaging time for the cancer IUR, based on study conditions and any adjustments (24 hrs/day for 365 days/yr) and averaged over a lifetime (78 yrs) (RE Section 2.3.1.2.4 and Table 2-17)

Benchmark MOE_{acute} = Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 10 (RE Table 3-13)

Benchmark $MOE_{chronic}$ = Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 10 (RE Table 3-14)

$Benchmark_{Cancer}$ = Benchmark for excess lifetime cancer risk ($1x10^{-4}$)

ECEL = Existing chemical exposure limit (mg/m^3 or ppm)

$EL_{chronic}$ = Exposure limit based on congenital heart defects from chronic exposure

EL_{cancer} = Exposure limit based on excess cancer risk

ED = Exposure duration (8 hrs/day), (RE Table 2-17 and Appendix M)

EF = Exposure frequency (250 days/yr), (RE Table 2-17 and Appendix M)

$HEC_{acute\ or\ chronic,\ occupational}$ = Human equivalent concentration for acute or chronic occupational exposure scenarios (RE Table 3-13 and 3-14)

IUR = Inhalation unit risk (per ppm) (RE Table 3-15)

WY = Working years per lifetime at the 95^{th} percentile (40 yrs) (RE Table 2-17)

Unit conversion:

1 ppm = 5.37 mg/m^3 (based on molecular weight of 131.39.8 g/mol for TCE and molar volume of 24.45 L/mol at 25°C and 1 atm pressure) $ECEL\left(\frac{\text{mg}}{\text{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume}$

References

U.S. Environmental Protection Agency. 2020. Risk Evaluation for Trichloroethylene (TCE) CASRN: 79-01-6. EPA-740-R1-8008. Office of Chemical Safety and Pollution Prevention. November 2020. Available at: EPA-HQ-OPPT-2019-0500-0113.

U.S. Environmental Protection Agency. 2002. A Review of the Reference Dose and Reference Concentration Processes. Final Report. EPA/630/P-02/002F. Prepared for the Risk Assessment Forum. December.

Appendix B: Summary of Air Sampling Analytical Methods Identified

EPA conducted a search to identify relevant NIOSH/OSHA/EPA analytical methods used to monitor for the presence of trichloroethylene in air (see Table 1). The sources used for the search included the following:

1) NIOSH Manual of Analytical Methods (NMAM); 5th Edition
   - URL: https://www.cdc.gov/niosh/nmam/default.html
2) NIOSH NMAM 4th Edition
   - URL: https://www.cdc.gov/niosh/docs/2003-154/default.html
3) OSHA Index of Sampling and Analytical Methods
   - URL: https://www.osha.gov/dts/sltc/methods/
4) EPA Environmental Test Method and Monitoring Information
   - https://www.epa.gov/emc/epa-websites-environmental-test-method-and-monitoring-information

Table 1: Limit of detection (LOD) summary for air sampling analytical methods identified.

Air Sampling Analytical Methods	Year Published	LOD[a]	Notes	Source
NIOSH Method 8300 https://www.cdc.gov/niosh/docs/2014-151/pdfs/methods/3800.pdf	2016	0.43 ppm	Method reports approximate LOD for an absorption length of 10 m.	NIOSH Manual of Analytical Methods (NMAM); 5th Edition https://www.cdc.gov/niosh/nmam/default.html
NIOSH Method 1022, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/1022.pdf	1994	60 ppb	Method reports estimated LOD as 0.01 mg per sample, with a maximum sample of 30 L.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
NIOSH Method 3701, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/3701.pdf	1994	0.1 ppm	Method reports estimated LOD as 0.1 ppm for a 1 mL injection.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
OSHA Method 1001 https://www.osha.gov/dts/sltc/methods/mdt/mdt1001/1001.html	1999	3.7 or 18 ppb	Method reports LOD of overall procedure as 3.7 ppb for charcoal tubes and 18 ppb for SKC 575-002 Samplers.	OSHA Index of Sampling and Analytical Methods https://www.osha.gov/dts/sltc/methods/
EPA Method TO-14A https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-14ar.pdf	1999	14 ppb	Estimated LOD based on 1 microliter sample volume (Table B-1).	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html
EPA Method TO-15 https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-15r.pdf	1999	≤0.5 ppb	To qualify under Compendium Method TO-15, the method detection limit must ≤0.5 ppbv. This method uses ppbv, but LODs for other methods listed here are also understood to be on a volume basis. For consistency, the LOD	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html

Air Sampling Analytical Methods	Year Published	LOD[a]	Notes	Source
			for this method is listed as ≤0.5 ppb.	
EPA Method TO-17	1999	≤0.5 ppb	To qualify under Compendium Method TO-17, the method detection limit must be ≤0.5 ppb.	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html
ppm = parts per million; ppb = parts per billion; ppt = parts per trillion **[a] EPA has included all relevant NIOSH/OSHA/EPA methods that it identified, including those methods with an LOD above the ECEL.**				

Appendix A2: Materials Shared with Small Entity Representatives for the Panel Outreach Meeting, January 23, 2023

Table of Contents

Agenda

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Trichloroethylene (TCE) under TSCA Section 6(a)

January 31, 2023, 12:00 – 3:00 pm, Eastern time zone

Agenda

10:00 Welcome and Opening Remarks

- Bill Nickerson (EPA Small Business Advocacy Chair / Office of Policy)
- Brian Symmes (Acting Director, Existing Chemicals Risk Management Division, EPA Office of Chemical Safety and Pollution Prevention)
- Tayyaba Zeb (Small Business Administration, Office of Advocacy)
- Austin Mudd (Office of Management and Budget, Office of Information and Regulatory Affairs)

10:15 SER Introductions

10:30 Presentation on proposed rulemaking for TCE under TSCA section 6(a) (Office of Chemical Safety and Pollution Prevention)

- Consultations with Small Entity Representatives (SERs)
- Overview of the unreasonable risk determinations and the risk management requirements under TSCA
- Overview of conditions of use in the rulemaking and basis for unreasonable risk determination
- Section 6 risk management overview: EPA's authority to regulate occupational and consumer risks, key "tools in the toolbox" for managing unreasonable risks
- Potential regulatory options

11:00 Discussion on conditions of use (COU) within the scope of the regulation (*See list at end for all conditions of use by group*).

- Detailed description of TCE use
- Your experience with exposure control and risk reduction
- Possible risk management actions
- Cost associated with implementations
- Available alternatives
- Other implementation considerations

TCE COU Group 1: Manufacturers, Processors, and Disposal
TCE COU Group 2a: Industrial Vapor Degreasing and Cold Cleaning Uses
TCE Group 2b: Industrial and Commercial Aerosol Uses

11:50 Break

12:00 Discussion (continued)

TCE COU Group 2c: Other Industrial and Commercial Uses – Industrial and Large Commercial
TCE COU Group 2d: Other Industrial and Commercial Uses – Small Commercial
TCE COU Group 3: Consumer Uses

12:45 Closing session

- Closing remarks from EPA, SBA, and OMB
- Wrap up and next steps (what to expect next)

1:00 Adjourn

Condition of Use Discussion Groups

Group 1: Manufacturers, processors, and disposal

- Includes the following conditions of use:
  - Manufacturing (domestic manufacturing)
  - Manufacturing (import)
  - Processing: repackaging
  - Processing as a reactant/intermediate
  - Processing: incorporation into formulation, mixture or reaction product
  - Processing: incorporation into articles
  - Processing: recycling
  - Disposal

TCE Group 2a: Industrial Vapor Degreasing and Cold Cleaning Uses

- Includes the following conditions of use:
  - 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 penetrating lubricant
  - Industrial and commercial use in automotive care products in brake parts cleaner

TCE Group 2b: Industrial and Commercial Aerosol Uses

- Includes the following conditions of use:
  - 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 penetrating lubricant
  - Industrial and commercial use in automotive care products in brake parts cleaner

TCE Group 2c: Other Industrial and Commercial Uses – Industrial and Large Commercial

- Includes the following conditions of use:
  - Industrial and commercial use as a lubricant and grease in tap and die fluid
  - 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 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

TCE Group 2d: Other Industrial and Commercial Uses – Small Commercial

- Includes the following conditions of use:
  - Industrial and commercial use in laundry and dishwashing products in spot remover
  - Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning
  - Industrial and commercial use as ink, toner and colorant products in toner aid
  - Industrial and commercial use in apparel and footwear care products in shoe polish
  - Industrial and commercial use in hoof polish, gun scrubber, and pepper spray

TCE Group 3: Consumer Uses

- Includes the following conditions of use:
  - 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 adhesive and sealant
  - 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

Rulemaking Presentation

Trichloroethylene (TCE) Small Entity Consultation on Proposed Rulemaking under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Small Business Representative Panel Outreach Meeting
January 31, 2022

Overview

- SERs and the regulatory process
- Key takeaways from the Pre-Panel Outreach Meeting
- Findings from the risk evaluation for TCE
- Overview of conditions of use (COU) in the rulemaking
- Basis for unreasonable risk determination
- Risk management requirements under TSCA
- EPA's authority and “tools in the toolbox”
- Potential regulatory options
- Potential regulatory alternatives
- Additional discussion with Small Entity Representatives
- Closing remarks

Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)

- EPA will use this information to inform the agency's decision on potential regulatory options and to develop a regulatory flexibility analysis, which becomes part of the record for the potential regulation

Consultation with Small Entity Representatives

- Key elements in this regulatory flexibility analysis:
  - Number of small entities to which the potential rule would apply
  - Projected compliance requirements of the potential rule
  - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the potential rule
  - Any significant alternatives to the potential rule which accomplish the stated objectives, and which minimize significant economic impact of the potential rule on small entities

Potentially Affected Entities

- The potential affected industries/sectors for this proposed rule are identified by its NAICS code, SBA thresholds and U.S. Census Bureau Statistics of U.S. Business datasets, published annually
- A list of these industries/sectors potentially affected by the proposed rule is included as a handout
- 349 industries/sectors and their associated NAICS code have been identified although not all of the small firms indicated in the attachment are necessarily expected to be impacted by the proposed rule
- SBA size standards vary greatly by NAICS code and range from $0.75-$41.5 million and 100-1,500 employees
- The attachment “Industry Sectors with Small Entities Potentially Affected by the Rulemaking” provides small firm statistics (number of and employee size) for each industry/sector
- EPA estimates 44,619 small entities may be impacted by the proposed rule
- As more specific information about each entity is identified, it is possible that some entities could be dropped from the list

SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
  - Provide specific examples of impacts
  - Provide cost data, if available
  - Please see detailed questions in a separate handout

SERs and the Regulatory Process

- We are also seeking alternative methods of regulating these risks
  - Suggest other relevant options, including data costs and information on how to ensure compliance
  - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions

- We would like to minimize duplication
  - Provide information on any duplicative or contradictory federal, state, county, or city regulations you are aware of
  - For a list of existing regulations, please see summary of Federal regulations

Key Takeaways from Pre-Panel Outreach Meeting

- Participants: 5 SERs participated and one SER submitted written comments
- SERs discussed: Number and types of small entities affected
  - Included how their products are used and identified uses of TCE
  - Specifically, SERs described degreasing (degreaser and parts cleaner before surface finishing and degreasing for aerospace applications), retail operations, and dry cleaning
  - A trade organization SER explained that TCE is used to degrease aerospace and automotive parts, noting that the industry has transitioned away from it as much as possible, and current users need TCE for its degreasing ability and low flammability
  - In written comments, a consulting SER described that its aerospace clients use approximately 325 gallons of TCE per year as well as their vapor degreaser maintenance process. They also described that their equipment maintenance is performed regularly, and that their degreasing machine is 10 years old, highly maintained, and has been upgraded for solvent recovery and to lower vapor emissions

Key Takeaways from Pre-Panel Outreach Meeting

- SERs discussed: Number and types of small entities affected – dry cleaning
  - Dry cleaning SERs expressed that many cleaners have closed or sold during the COVID-19 pandemic, and that the business volume has not yet returned to pre-pandemic levels
  - SERs stated that TCE is used at “full service” dry cleaners for spot cleaning and is preferred to other cleaners for its low flammability and high efficacy
  - SERs stated that any additional costs to small dry cleaners would result in them going out of business

Key Takeaways from Pre-Panel Outreach Meeting

- SERs discussed: potential reporting, recordkeeping and compliance requirements
  - SERs discussed their experience with:
    - Engineering controls (closed-loop vapor degreasing systems)
    - Exposure limits (EPA should consider that the current ECEL is difficult to meet considering current levels of detection for air monitoring tests)
    - Exposure controls, as required by OSHA (labels, PPE, engineering controls, ventilation systems) or industrial hygiene
    - Substitute chemicals (more expensive, some have safety concerns with use (flammable/explosive), or have other environmental impacts), are currently subject to EPA’s risk evaluation or are being examined by the Agency in other contexts (e.g., fluorinated chemicals)

Key Takeaways from Pre-Panel Outreach Meeting

- SERs discussed: potential reporting, recordkeeping and compliance requirements
  - SERs discussed their experience with:
    - Prohibitions (in degreasing and drycleaning operations, prohibition would lead to significant costs to switch to alternatives; in degreasing and drycleaning operations, alternatives are not as efficacious as TCE)
  - A SER mentioned that in niche applications where TCE is used as a cleaning agent, reformulation is less likely to occur due to lack of viable alternatives
  - In written comments, a consulting SER stated that in the aerospace industry, Military Specifications may specifically require use of TCE or perchloroethylene, and that the inability to use TCE would prevent them from producing parts for clients, including the Department of Defense
  - This SER also mentioned that in the automotive industry, if the concentration of TCE is limited in a brake cleaning and parts degreasing product, the product would most likely not be compliant with the specifications, which are driving its use

Key Takeaways from Pre-Panel Outreach Meeting

- SERs discussed: Related Federal rules
  - Various exposure and risk reduction techniques required by OSHA (labeling, PPE, engineering controls, administrative controls via limiting workspaces to train employees)
  - Compliance with the American Innovation and Manufacturing Act (AIM Act)
    - A trade organization SER stated that some hydrofluorocarbons, which TCE is used as a feedstock to manufacture, will be restricted in some applications under the AIM Act
  - A trade organization SER also mentioned that some chlorinated alternatives to TCE are under increased regulatory scrutiny, especially at state levels, because they may be subject to state PFAS laws based on their chemical structure and properties
  - Compliance with the Clean Air Act, due to TCE classification as a hazardous air pollutant (HAP) and volatile organic compound (VOC)
    - In written comments, SERs also mentioned that in metal manufacturing facilities, TCE usage and emissions are controlled using VOC destruction technologies and require continuous monitoring as defined in site specific permit requirements

Key Takeaways from Pre-Panel Outreach Meeting

- SERs discussed: Regulatory flexibility alternatives
  - SERs described increased costs (material acquisition, storage, and disposal) associated with use of alternatives, especially in the case of modified alcohols and water for use in degreasing
  - SERs also discussed the challenges of identifying feasible alternatives and concern for future regulations on those alternatives
  - Dry cleaning SERs expressed that any changes to anything regarding TCE usage would increase garment cleaning times and decrease customer satisfaction as a result. SERs also stated that a prohibition of TCE usage, assuming a greater number of garments would not be able to be fully cleaned with alternatives, would lead to larger amounts of textile waste

Overview of the Risk Evaluation for TCE

- Risk evaluation published November 24, 2020:
  - 54 conditions of use were evaluated
  - Risk evaluation follows a series of opportunities for public input into EPA's TCE risk evaluation activities
  - TCE draft risk evaluation: February 2020; TCE problem formulation: June 2018; TCE scope document: June 2017

Overview of the Risk Evaluation for TCE

- Public comments and external scientific peer review informed the final risk evaluation
  - 70 public comments received on the draft risk evaluation (comment period closed April 27, 2020)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (March 2020)

- The 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

Determination of Unreasonable Risk

- In the November 2020 risk evaluation, EPA determined that TCE presented unreasonable risk to health and the environment. In that risk evaluation, EPA determined that 52 of the 54 conditions of use (COU) of TCE presented unreasonable risk.

- With EPA's policy change to a whole chemical approach, EPA has issued a revised whole chemical unreasonable risk determination without presuming use of PPE. The changes from that revised determination are included in this presentation and are available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-trichloroethylene.

- There may be some conditions of use in the final risk evaluation that EPA has determined do not drive the unreasonable risk but may still be subject to regulation due to uses elsewhere in the supply chain that drive the unreasonable risk.

Recent Changes to the Risk Determination

- EPA released for public comment a draft revision to the unreasonable risk determination for TCE on July 7, 2022
- EPA published the final revised risk determination on January 9, 2023
- Incorporates policy changes announced in June 2021
- Specifically, EPA has determined that:
  - Making an unreasonable risk determination for TCE as a whole chemical substance, rather than unreasonable risk determinations separately on each individual condition of use in the risk evaluation, is the most appropriate approach to TCE under the statute and implementing regulations
  - The risk determination does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce workers' exposures; rather, the use of PPE would be considered during risk management as appropriate

Recent Changes to the Risk Determination

- Removing the assumption that workers always and appropriately wear PPE in making the whole chemical risk determination for TCE does:
  - Not alter the conditions of use that drive the unreasonable risk determination for TCE
  - Result is additional risks for acute non-cancer and cancer effects from inhalation and dermal exposures that also drive the unreasonable risk in many of those conditions of use (where previously those conditions of use were identified as presenting unreasonable risk from chronic non-cancer effects and cancer).
- Overall, 52 conditions of use out of 54 EPA evaluated drive the TCE whole chemical unreasonable risk determination
- EPA has not conducted new scientific analysis on TCE; the risk evaluation continues to characterize risks associated with individual conditions of use
- The risk determination is in docket EPA-HQ-OPPT-2016-0737 at regulations.gov

Recent Changes to the Risk Determination

- Separately, EPA is conducting a screening approach to assess potential risks from the air and water pathways for several of the first 10 chemicals, including TCE
  - This screening analysis was presented to the SACC in March and EPA is currently incorporating comments from the SACC and public commenters on revisions to the analysis
- Exposure pathways that were or could be regulated under another EPA-administered statute were excluded from the 2020 TCE risk evaluation, resulting in certain air and water pathways not being fully assessed
- EPA's screening approach will identify if there are risks that were unaccounted for in the risk evaluation for TCE
- If the results suggest there is additional risk, EPA will determine if the risk management approach being contemplated for TCE will protect against these risks or if the risk evaluation will need to be formally supplemented or revised

TCE Manufacturing, Processing, Industrial, and Commercial Uses that Drive the Unreasonable Risk

- Manufacturing (domestic manufacturing)
- Manufacturing (import)
- 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 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

TCE Industrial and Commercial Uses that Drive the Unreasonable Risk

- Industrial and commercial use as a functional fluid in heat exchange fluid
- 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 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

TCE Industrial and Commercial Uses and Disposal that Drive the Unreasonable Risk

- 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
- Disposal

TCE Consumer Uses that Drive the 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 adhesive and sealant

TCE Consumer Uses that Drive the Unreasonable Risk

- 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

Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures to TCE:
  - Immunosuppression effects from acute inhalation and dermal exposures
  - Autoimmunity effects from chronic inhalation and dermal exposures
  - Cancer effects (kidney) from chronic inhalation and dermal exposures
- Consideration of Personal Protective Equipment (PPE):
  - The OSHA permissible exposure limit (PEL) for TCE is set at 100 ppm as an 8-hr time-weighted average
  - EPA does not assume that workers are always provided or appropriately wear PPE, for the purposes of unreasonable risk determination
  - EPA does not assume that it is a standard industry practice that workers in some small commercial facilities (e.g., those performing spot cleaning, wipe cleaning, shoe polishing, hoof polishing, or commercial printing and copying) have a respiratory protection program or regularly employ dermal protection; therefore, the use of respirators and gloves is unlikely for workers in these facilities
  - When no PPE is assumed to be in place, 52 of the 54 COUs drive the unreasonable risk
  - As previously noted, this assumption did not result in additional COUs driving the unreasonable risk determination

Basis for Unreasonable Risk Determination: Consumers and Bystanders

- The unreasonable risk determinations for consumers and bystanders are based on the following health hazards during consumer exposures to TCE:
  - Immunosuppression effects from acute inhalation and dermal exposure

- EPA does not assume dermal exposure to TCE for bystanders

- The unreasonable risk determinations were based on the high intensity risk estimates for consumers and bystanders; unreasonable risk was also presented for moderate intensity use risk estimates for many COUs

- EPA did not evaluate chronic exposures to TCE for consumer users and bystanders because EPA considered the frequency of consumer product use to be too low to create chronic risk concerns

Related Regulations and TSCA Section 6 Authority

- TCE is subject to numerous federal laws and regulations in the United States and is also subject to regulatory actions by states
  - For example, OSHA established a PEL for TCE at 100 ppm as an 8-hour TWA. Most states have set PELs identical to OSHA. Nine states have PELs of 50 ppm. California's PEL of 25 ppm is the most stringent (CCR, Title 8, Table AC-1).
  - As an additional example, TCE is being used in the manufacture of HFCs that will be restricted under the AIM Act
  - See separate document "Related Regulations (EPA, other Federal, State, and International)" for more information on the regulatory history of TCE
- EPA determined that TCE presents an unreasonable risk to workers, ONUs, consumers, and bystanders in the TSCA risk evaluation even though the chemical substance is currently regulated under other statutes (e.g., CERCLA, CAA (NESHAPs))
- Therefore, EPA is required to develop risk management actions under TSCA to address the unreasonable risk
- TSCA Section 9 allows EPA to use statutory authorities other than TSCA to reduce or eliminate identified risk to health or the environment

Risk Management Requirements

- Under TSCA, EPA is required to take action, to the extent necessary, to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process and EPA is seeking stakeholder input now during the SBAR process and during the public comment period following the proposed rule

TSCA Section 6(a)

- TSCA provides EPA with authority to address unreasonable risks, and to regulate entities including:
  - Manufacturers (including importers) and processors (e.g., formulators)
  - Distributors
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
  - Under TSCA, EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
  - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

Availability of Alternatives: TSCA Section 6(c)(2)(C)

- TSCA section 6(c)(2)(C) requires EPA "…in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action…to the extent practicable, 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 when the proposed prohibition or other restriction takes effect"
  - Substitute products and methods vary by condition of use
  - For example, alternatives to TCE in in vapor degreasing include solvent-based alternatives like 1,2-trans-dichloroethylene and aqueous systems which use detergents and other additives to clean, while alternatives for cleaning and furniture care might include different solvents such as glycol ethers.

Effective Dates: TSCA Section 6(d)

- TSCA section 6(d) describes effective dates and compliance dates for TSCA section 6(a) rules
- In these rules, EPA must specify an effective date, which must be as soon as practicable
- Except for uses exempted under TSCA section 6(g), EPA must:
  - Specify mandatory compliance dates for all rule requirements, no later than five years after promulgation of the rule, or, in the case of a ban or phase-out:
    - Specify mandatory compliance dates for the start of a ban or phase-out requirements, which shall be as soon as practicable and no later than five years after promulgation of the rule, and
    - Specify mandatory compliance dates for full implementation of a ban or phase-out requirements, which shall be as soon as practicable
- EPA must also provide for a reasonable transition period

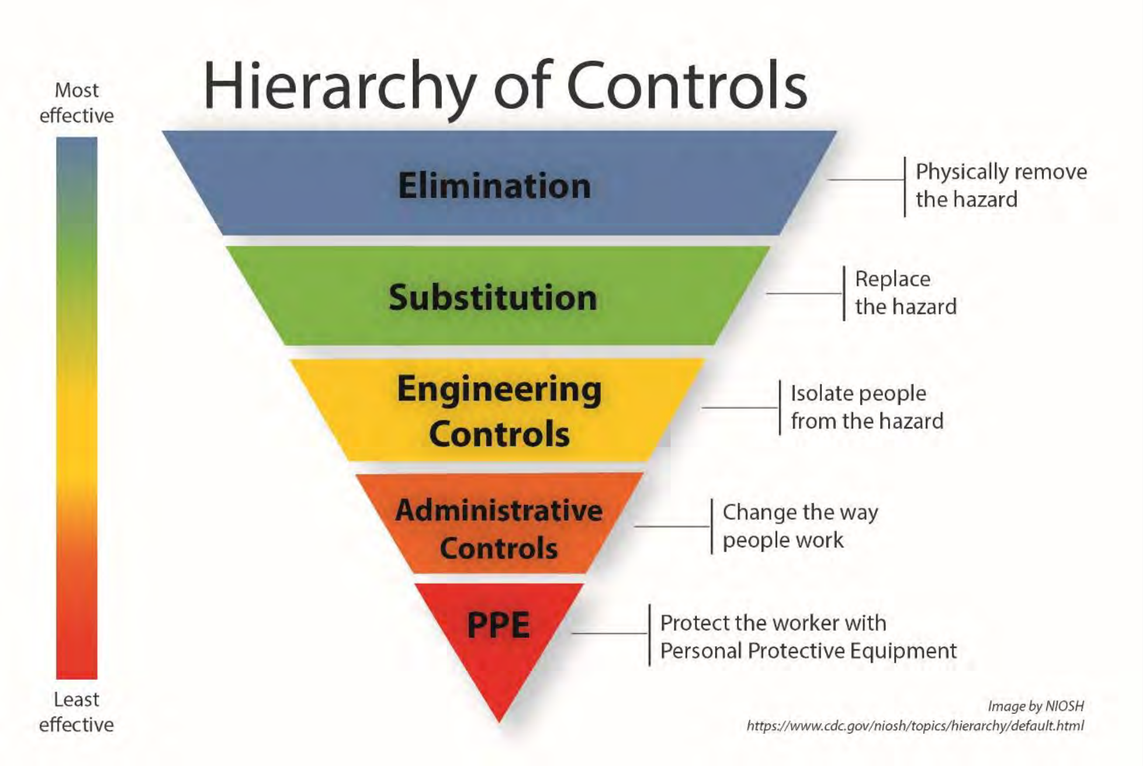
Critical or Essential Uses: TSCA Section 6(g)

TSCA section 6(g) allows EPA to grant, by rule, a time-limited exemption from a section 6(a) rule for a specific condition of use

- To provide an exemption, EPA must find that:
  - The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available;
  - Compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or
  - The specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety
- In granting an exemption, EPA must:
  - Provide a time limit for the exemption
  - Analyze the need for the exemption and make the analysis public
  - Include conditions, such as recordkeeping, monitoring, and reporting requirements, to the extent EPA determines they are necessary to protect health and the environment while achieving the purposes of the exemption
- EPA appreciates any information to inform whether it would be appropriate to propose an exemption under section 6(g), such as:
  - How the exemption request for a COU would meet one or more of the criteria under section 6(g) and information on specific impacts if the chemical were not available
  - Whether the chemical is used to meet requirements or specifications from other regulations, and information on the process, timeline, and challenges for obtaining necessary industry/government approval for use of an alternative substance or method
  - Description of how long a potential section 6(g) exemption would be needed and why

Hierarchy of Controls

- EPA is considering the NIOSH/OSHA hierarchy of controls when developing risk management actions
  - As described by NIOSH (https://www.cdc.gov/niosh/topics/hierarchy/default.html), the hierarchy of controls can be used to implement feasible and effective controls to protect workers
  - It typically includes elimination, substitution, engineering controls, administrative controls, and PPE on a scale of most to least protective
- Any regulatory requirement can be used alone or in combination to the extent necessary so that TCE no longer presents an unreasonable risk under its conditions of use



Potential Regulatory Options

- EPA has considered several regulatory options under TSCA section 6(a), and a wide range of risk reduction practices and options
- Through Agency review and stakeholder input, the following potential options have been identified as reducing exposures, so TCE no longer presents an unreasonable risk of injury to health
- These options are currently being considered and evaluated by EPA, and are not final at this time. EPA has not made a decision at this point about what regulatory options to propose
- Regulatory requirements could be used alone or in combination to the extent necessary so that TCE no longer presents an unreasonable risk under its conditions of use
  - Additionally, under TSCA section 6(g), EPA may propose a time-limited exemption for a specific condition of use for which EPA finds that: 1) The specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; 2) Compliance with the requirement would significantly disrupt the national economy, national security, or critical infrastructure; or 3) The specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety

Potential Regulatory Options

- Prohibit or restrict manufacturing, processing, and distribution
- Prohibit or restrict manufacturing, processing, and distribution for a particular use
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive PPE controls
- Prescriptive administrative controls
- Prescriptive engineering controls
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Potential Regulatory Options: ECEL

- EPA has not decided on the primary regulatory options to propose in the rule
- EPA is considering the following regulatory options and is seeking feedback on the impacts of applying one or more of the following regulatory options to the conditions of use of TCE that drive the unreasonable risk
- For processing, industrial, and commercial uses (occupational exposures):
  - Existing Chemical Exposure Limit (ECEL)
    - Establishes a performance-based airborne concentration limit and is non-prescriptive, enabling users to determine how to most effectively meet the ECEL based on what works best for their workplace and the ability to combine prescriptive controls
    - Industries are already familiar with PELs, and methods of compliance. EPA and OHSA have ongoing dialogue in reference to risk management requirements under TSCA
    - The TCE ECEL(I) based on the immunotoxicity endpoint would be 4.0 ppb (0.021 mg/m3) for an 8-hour time-weighted average (TWA)
    - EPA is also considering occupational safety measures to be based on a different, more sensitive endpoint (fetal cardiac defects), which would result in an ECEL(F) of 1.1ppb (0.0059 mg/m^3) for an 8-hour TWA

Potential Regulatory Options: ECEL, cont.

- The value is based on the chronic non-cancer human equivalent concentration (HEC) for autoimmunity
- If ambient exposures are kept below the 8-hour ECEL(I) of 4.0 ppb, EPA expects that a worker or occupational non-user (ONU) are also protected against
  - mortality due to immunosuppression resulting from an acute (8-hour) exposure
  - excess risk of cancer above the 1×10^{-4} benchmark resulting from lifetime exposure
- If ambient exposures are kept below the 8-hour ECEL(F) of 1.1ppb, EPA expects that children will be protected from maternal exposure by workers or ONUs, in addition to the effects listed above
  - In the 2020 Risk Evaluation for TCE, EPA discussed both the immunotoxicity and fetal heart defects endpoints although the unreasonable risk is based on the immunotoxicity endpoint
  - In the interest of transparency, EPA is providing ECEL values for both endpoints since EPA had previously provided the ECEL for the fetal heart defects with the 2016 proposed TCE rules although the proposals were subsequently withdrawn
  - EPA is interested in hearing from SERs about the feasibility of either ECEL value since both are in the ppb
- Each ECEL is above the limits of detection or quantification, which generally range from about ≤0.5 ppb to 0.43 ppm. Monitoring methods are described in the ECEL memo attachments.
- EPA has determined as a matter of risk management policy that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk
- EPA is seeking feedback from the SERs on what current recordkeeping and monitoring is applied to the OSHA PEL and feedback on how to apply ECEL recordkeeping and monitoring based on current protocol (see attached ECEL memos for more information)

Potential Regulatory Options, cont.

- Prescriptive Controls: Engineering Controls
  - Would reduce worker or ONU exposure by requiring specific physical changes to the workplace
  - Examples: Require use of closed-loop vapor degreasers, require specific ventilation rates, require spraying booths or laboratory hoods for laboratory applications, or isolate the work area where the TCE is present
- Prescriptive Controls: Administrative Controls
  - Would reduce worker or ONU exposure by requiring processes or procedures in the workplace
  - Examples: Limit access to work areas

Potential Regulatory Options, cont.

- Prescriptive Controls: PPE Controls
  - Examples of potential regulatory option: Require use of respirators or/and highly chemical resistant gloves for use with TCE
    - As an example, EPA could require the use of respirators to address unreasonable risks driven by inhalation exposures. For TCE, only a respirator with APF 10,000 may be able to mitigate such risk; EPA recognizes the challenges associated with using such respirators and is interested in SER feedback on this type of PPE
  - See attached memo on “Personal Protective Equipment Respirator System per Worker Unit Cost Breakdown” for more information on respirator costs and Assigned Protection Factors (APFs)
- Prohibition
  - For conditions of use where ECEL or prescriptive controls are not sufficient to address the unreasonable risk

Potential Regulatory Options, cont.

- For consumer uses:
  - Regulation at key points in the supply chain (manufacturing, processing, and/or distribution) to address unreasonable risks to consumers or bystanders
    - Example: March 2019 rule to address unreasonable risks to consumers from methylene chloride in paint and coating removal prohibited manufacture (including import), processing, and distribution in commerce of methylene chloride for this use (including distribution to and by retailers)
  - Potential regulatory options:
    - Prohibition

Potential Regulatory Options, cont.

- Regulatory options applied broadly with other restrictions
  - Recordkeeping – example: ordinary business records to demonstrate compliance (for example not selling products to consumers)
  - Downstream notification – example: modify the SDS to indicate that the product should not be used in consumer products or indicate other regulatory requirements
  - Monitoring – example: of air concentration to demonstrate compliance with ECEL
  - Labeling – example: labeling products to indicate that they should not be used by consumers or to describe other regulatory requirements
  - Limited access program – example: access only to those users with certain equipment, for example product only sold to facilities with close-loop vapor degreasers

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Prohibition of manufacturing, processing, and distribution	Varies by condition of use.	Costs will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), shutting down the operation, and more. Requires input from potentially regulated entities.
Prohibition of Use	Varies by condition of use.	Costs will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), shutting down the operation, and more. Requires input from potentially regulated entities.

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Existing Chemical Exposure Limit (ECEL)	$400 per facility ($70-$1,600 annualized per facility) + $220 per worker. ($40-$800 annualized per worker) for monitoring $400 per facility ($60 annualized per facility) + $20-$100 per worker for recordkeeping Costs of engineering controls or PPE to achieve the ECEL level varies by control type and needs of user	ECEL costs will vary based on the complexity of the site and how many times the site will require monitoring to demonstrate compliance. Costs of engineering controls or PPE to achieve the ECEL level are not captured in these estimates. Potential costs of changes in worker productivity resulting from respirator use or changes to worker compensation for those wearing respirators are unquantified. Requires input from potentially regulated entities.
Engineering/Administrative Controls	Varies by control type and needs of user	Requires input from potentially regulated entities.
Reformulation of product to reduce or eliminate TCE concentration	$60,000 - $100,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities. Setting a concentration limit could impact the efficacy of a product or the feasibility of a process.

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Product Label or Warnings	$750 - $8,000 per product	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor. Due to uncertainties and variations in product types, does not include potential impacts on sales.
Personal Protective Equipment (PPE) – (e.g., respirators)	APF 25: $660-$970 APF 50: $750-$1,100 APF 1,000: $780-$1,150 APF 10,000: $1,800-$2,500	Costs are per employee and include purchase of equipment, routine cleaning of equipment, training, fit-testing, and medical clearance and account for estimated baseline PPE use.
Personal Protective Equipment (PPE) (dermal)	$4 per pair (50 pairs per year, $130-$180 annualized cost)	Costs are per pair of PVA gloves. Requires input from potentially regulated entities regarding which glove material type would be used.

Cost of Regulatory Options

Option/Type of Cost	Estimated Compliance Cost	Notes
Substitute Products	Varies with condition of use	The costs of switching products includes both the costs of the substitute products and differences in efficacy of these products. Costs of differences in efficacy are not quantified. Some applications may need to undergo safety reviews before they could replace TCE products. These costs are unquantified.
Substitute Methods	Varies by job labor rate. For vapor degreasing, initial transition costs are estimated as $100,000 to $500,000 and initial capital costs as $30,000 to $500,000	This will primarily be labor cost and cost of alternative equipment. There may be some safety-critical applications where alternatives would need to undergo extensive safety reviews and testing before they could replace the TCE products. These costs are unquantified.
Recordkeeping	$200 - $325 per firm	Annual labor and material costs associated with documentation of ordinary business records.
Downstream Notification	$112 - $125 per product	Costs are per product and include labor and material costs to update the product's safety data sheet (SDS).

In-Depth Discussion on Conditions of Use for TCE

1. Manufacturers, processors, and disposal

2. Industrial and commercial uses
   a) Vapor degreasing and cold cleaning uses
   b) Aerosol uses
   c) Other industrial and large commercial uses
   d) Other small commercial uses

3. Consumer uses

TCE Group 1: Manufacturers, Processors, and Disposal

- Relevant conditions of use:
  - Manufacturing (domestic manufacturing)
  - Manufacturing (import)
  - Processing: repackaging
  - Processing as a reactant/intermediate
  - Processing: incorporation into formulation, mixture or reaction product
  - Processing: incorporation into articles
  - Processing: recycling
  - Disposal

- What is TCE used for? How is it applied?
  - TCE is domestically manufactured, imported, and repackaged from bulk containers to smaller containers for resale
  - TCE is commonly used as a feedstock in the production of refrigerants, specifically HCFCs
  - TCE may also be incorporated at varying concentrations into products such as adhesives, coatings, inks, aerosols, and other products
  - Each of the conditions of use of TCE may generate waste streams of the chemical that are collected and transported to third-party sites for disposal, treatment, or recycling

Potential Regulatory Options (TCE Group 1: Manufacturers, Processors, and Disposal)

As noted previously EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that TCE no longer presents an unreasonable risk under its conditions of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available or technically/economically feasible alternatives?

Discussion – Formulators of Products Containing TCE

- Product reformulation
  - How often do you reformulate your products?
  - What is the typical cost of reformulating your products?
  - What might reformulation costs be if you needed to reformulate your products without TCE? (For example, costs might include R&D, testing, capital costs of production changes, packaging, labeling)
- Product relabeling
  - How often do you relabel your products?
  - What is the typical cost of relabeling?

Discussion – Formulators of Products Containing TCE (Cont.)

- Alternatives
  - Do you sell another product that does not contain TCE that is designed for the same use or application as the TCE product?
    - If yes, what solvent replaces TCE in the alternative product? How does the alternative product compare in terms of safety, efficacy, and cost?
    - If no, if you needed to reformulate this product with a lower concentration of TCE, what would the implications be for the product in terms of cost and efficacy? What solvent would replace TCE? How do you think the alternative would compare in terms of efficacy and cost?
  - Is there a subset of uses for your product where using a product formulated without TCE would be problematic?

Discussion – Distributors and Retailers

- What is your experience with exposure control and risk reduction?
- If you could no longer sell products containing TCE, how would this impact your business?
- Are there particular challenges to small business doing distribution of products containing TCE that are different from large distributors?
- What is your preferred method of downstream notification?
- If you were required to limit sales of TCE containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

TCE Group 2a: Industrial Vapor Degreasing and Cold Cleaning Uses

- Relevant conditions of use
  - 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

- What is TCE used for? How is it applied?
  - TCE is used as a degreasing solvent to remove drawing compounds, cutting fluids, coolants, and lubricants from metal parts
  - Cold cleaning operations include spraying, brushing, flushing, and immersion

Potential Regulatory Options (TCE Group 2: Industrial and Commercial Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that TCE no longer presents an unreasonable risk under its conditions of use:

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available or technically/economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to TCE, and for how long (days/years and hours/day)?
- What is the concentration of TCE in the product you use?
- What routine worker activities result in worker exposure to TCE and what type of exposure?
- What engineering controls are used to minimize exposure to TCE? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to TCE?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to TCE?

Discussion – Degreasing Operations

- What type of degreasing operation do you use: vapor degreasing, cold cleaning, aerosol/spray degreasing?
- What is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity?
- How old is the cleaning equipment? When did you last update your degreasing system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc.)? What prompted this update?
- What are the most important factors in degreasing for you (in order): e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify)?
- Are there any restrictions or other limitations that prescribe the use of TCE to perform your services (e.g., for aerospace or DOD customers)?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

TCE Group 2b: Industrial and Commercial Aerosol Uses

- Relevant conditions of use:
  - 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 penetrating lubricant
  - Industrial and commercial use in automotive care products in brake parts cleaner
- What is TCE used for? How is it applied?
  - Aerosol-based degreasing products containing TCE include degreasers for applications such as brake cleaning, mold cleaning, and other metal product cleaning
  - Additional aerosol products include film cleaners, coil cleaners, and various lubricants
  - Aerosol degreasing is a process that uses an aerosolized solvent spray, typically applied from a pressurized can, to remove residual contaminants from fabricated parts
  - Aerosol lubricant products use an aerosolized spray to help free frozen parts by dissolving rust and leave behind a residue to protect surfaces against rust and corrosion

Potential Regulatory Options (TCE Group 2: Industrial and Commercial Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that TCE no longer presents an unreasonable risk under its conditions of use :

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available or technically/economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to TCE, and for how long (days/years and hours/day)?
- What is the concentration of TCE in the product you use?
- What routine worker activities result in worker exposure to TCE and what type of exposure?
- What engineering controls are used to minimize exposure to TCE? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to TCE?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to TCE?

Discussion – Users of Products Containing TCE

- What chemicals or processes have you considered as an alternative to using TCE or a product containing TCE?
- Do you currently use any alternatives to TCE or products containing TCE?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?
- Are there any restrictions or other limitations that prescribe the use of TCE containing products as part of your services (e.g., for aerospace or DOD customers)?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

TCE Group 2c: Other Industrial and Commercial Uses – Industrial and Large Commercial

- Relevant conditions of use:
  - Industrial and commercial use as a lubricant and grease in tap and die fluid
  - 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 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

TCE Group 2c: Other Industrial and Commercial Uses – Industrial and Large Commercial (cont.)

- What is TCE used for? How is it applied?
  - TCE is used in various industrial and large commercial settings in adhesives and sealants, lubricants and greases, functional fluids, paints and coatings, and in a variety of cleaning products
  - As a functional fluid, it is used in industrial settings in closed systems, such as to aid with heat exchange
  - It is used as a processing aid that is added to a reaction mixture to aid in the manufacture or synthesis of another chemical substance but does not remain in the product, such as in plastics manufacturing
  - TCE is used in metalworking fluids that are used for the machining of internal and external threads using cutting tools like taps and thread-mills

Potential Regulatory Options (TCE Group 2: Industrial and Commercial Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that TCE no longer presents an unreasonable risk under its conditions of use :

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available or technically/economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to TCE, and for how long (days/years and hours/day)?
- What is the concentration of TCE in the product you use?
- What routine worker activities result in worker exposure to TCE and what type of exposure?
- What engineering controls are used to minimize exposure to TCE? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to TCE?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to TCE?

Discussion – Users of Products Containing TCE

- What chemicals or processes have you considered as an alternative to using TCE or a product containing TCE?
- Do you currently use any alternatives to TCE or products containing TCE?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?
- Are there any restrictions or other limitations that prescribe the use of TCE containing products as part of your services (e.g., for aerospace or DOD customers)?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

TCE Group 2d: Small Commercial Uses

- Relevant conditions of use:
  - Industrial and commercial use in laundry and dishwashing products in spot remover
  - Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning
  - Industrial and commercial use as ink, toner and colorant products in toner aid
  - Industrial and commercial use in apparel and footwear care products in shoe polish
  - Industrial and commercial use in hoof polish, gun scrubber, and pepper spray

TCE Group 2d: Small Commercial Uses (cont.)

- What is TCE used for? How is it applied?
  - Examples of these uses include, but are not limited to, mold cleaning products, shoe polish, hoof polish, pepper spray, and gun scrubber
  - For many of these uses, TCE is expected to act similarly to a cleaning solvent used to remove dirt or other contaminates from substrates
  - In dry cleaning and carpet cleaning settings, spot cleaning can involve the use of a spotting agent containing TCE that can be applied from squeeze bottles, hand-held spray bottles, or spray guns connected to pressurized tanks
  - Once applied, the cleaning person may come into further contact with TCE when using a brush, spatula, pressurized air or steam, or their fingers to scrape or flush away the stain

Potential Regulatory Options (TCE Group 2: Industrial and Commercial Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that TCE no longer presents an unreasonable risk under its conditions of use :

- Prohibition
- Existing Chemical Exposure Limit (ECEL)
- Prescriptive controls (PPE, engineering and administrative controls)
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Your Business and TCE

- How does your organization use TCE?
- Can you describe the specific use, as well as the workplace and workplace setting where it is used?
- What is the trend of TCE use in your organization?
- How important to your business is the function that TCE provides?
- Are there potential critical or essential uses?
- Are there uses for which there are no available or technically/economically feasible alternatives?

Discussion – Workplace Exposure

- What is your experience with exposure control and risk reduction?
- How many employees are exposed to TCE, and for how long (days/years and hours/day)?
- What is the concentration of TCE in the product you use?
- What routine worker activities result in worker exposure to TCE and what type of exposure?
- What engineering controls are used to minimize exposure to TCE? Are additional controls feasible?
- What administrative controls and training do you use to minimize exposure to TCE?
- What respiratory and dermal PPE is regularly worn by workers to minimize exposure to TCE?

Discussion – Users of Products Containing TCE

- What chemicals or processes have you considered as an alternative to using TCE or a product containing TCE?
- Do you currently use any alternatives to TCE or products containing TCE?
- Did you try to switch to another chemical, process, or product, only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
- What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including in terms of exposure, cost, and hazard?
- Are there any restrictions or other limitations that prescribe the use of TCE containing products as part of your services (e.g., for aerospace or DOD customers)?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

TCE Group 3: Consumer Uses

- Relevant conditions of use:
  - 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 adhesive and sealant
  - 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

Potential Regulatory Options (TCE Group 3: Consumer Uses)

As noted previously, EPA is considering the following regulatory options and is seeking your feedback. Any regulatory requirement could be used alone or in combination to the extent necessary so that TCE no longer presents an unreasonable risk under its conditions of use :

- Prohibition of manufacturing, processing or distribution of products for consumer use
- Regulatory options applied broadly with other restrictions
  - Recordkeeping and downstream notification
  - Monitoring and labeling
  - Training, certification, and limited access program

Discussion with Small Entity Representatives

Please provide your comments or questions regarding:

- Number and types of small entities affected
- Potential reporting, recordkeeping and compliance requirements
- Related Federal rules
- Regulatory flexibility alternatives

Discussion – Formulators of Products Containing TCE

- Product reformulation
  - How often do you reformulate your products?
  - What is the typical cost of reformulating your products?
  - What might reformulation costs be if you needed to reformulate your products without TCE? (For example, costs might include R&D, testing, capital costs of production changes, packaging, labeling)
- Product relabeling
  - How often do you relabel your products?
  - What is the typical cost of relabeling?

Discussion – Formulators of Products Containing TCE (Cont.)

- Alternatives
  - Do you sell another product that does not contain TCE that is designed for the same use or application as the TCE product?
    - If yes, what solvent replaces TCE in the alternative product? How does the alternative product compare in terms of safety, efficacy, and cost?
    - If no, if you needed to reformulate this product with a lower concentration of TCE, what would the implications be for the product in terms of cost and efficacy? What solvent would replace TCE? How do you think the alternative would compare in terms of efficacy and cost?
  - Is there a subset of uses for your product where using a product formulated without TCE would be problematic?

Discussion – Distributors and Retailers

- What is your experience with exposure control and risk reduction?
- If you could no longer sell products containing TCE, how would this impact your business?
- Are there particular challenges to small business doing distribution of products containing TCE that are different from large distributors?
- What is your preferred method of downstream notification?
- If you were required to limit sales of TCE containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency?

Discussion – Regulatory Options

- What regulatory approach should EPA take?
- Are there concerns about the ability to comply with any of the potential regulatory options, such as an ECEL?
- What advice do you have for reducing impacts on small businesses?
- What timeframe would your business need to comply with potential new regulations or restrictions?

Closing Session

- Closing remarks from EPA, SBA, and OMB
- Next steps
  - Written comments by February 14, 2023
  - The risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0500, with additional materials supporting the risk evaluation process and the draft revised unreasonable risk determination in docket EPA-HQ-OPPT-2016-0737, on www.regulations.gov

Additional Information

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- TCE Risk Management: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-trichloroethylene-tce
- June 2021 Policy Changes: https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations
- TCE: Katelan McNamara (McNamara.Katelan@epa.gov, 202-564-4361)

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Appendix

- Pre-Panel Outreach SER Questions for Discussion (separate document)
- Related regulations (EPA, other Federal, state, and international) (separate document)
- Industry Sectors with Small Entities Potentially Affected by the Rulemaking (separate document)
- Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown (separate document)
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- Example: OSHA Respiratory Protection Table (Slide 97)
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Example: OSHA Respiratory Protection Table

Minimum Requirements for Respiratory Protection for Airborne Methylene Chloride	
Methylene Chloride Airborne Concentration (ppm) or Condition of Use	Minimum Respirator Required
Up to 625 ppm (25 X PEL)	Continuous flow supplied-air respirator, hood, or helmet
Up to 1,250 ppm (50 X PEL)	(1) Full facepiece supplied-air respirator operated in negative-pressure (demand) mode (2) Full facepiece self-contained breathing apparatus (SCBA) operated in negative-pressure (demand) mode
Up to 5,000 ppm (200 X PEL)	(1) Continuous flow supplied-air respirator, full facepiece (2) Pressure demand supplied-air respirator, full facepiece (3) Positive-pressure full facepiece SCBA
Unknown concentration, or above 5,000 ppm (Greater than 200 X PEL)	(1) Positive-pressure full facepiece SCBA (2) Full facepiece pressure (demand) supplied-air respirator with an auxiliary self-contained air supply
Firefighting	Positive-pressure full facepiece SCBA
Emergency Escape	(1) Any continuous flow or pressure-demand SCBA (2) Gas mask with organic vapor canister

https://www.osha.gov/Publications/osha3144.html

Personal Protective Equipment Glove Unit Cost Breakdown

Product Name	Glove Material Type	Notes	Prices
Ansell Chemical Resistant Glove	Laminate Film	Has a liner material, so appears to be made to wear alone as opposed to as a liner	$7.03 per pair
Ansell Size Knit Lined PVA Gloves	PVA	Has a liner material, so appears to be made to wear alone as opposed to as a liner	$$33.93, $30.08, and $42.25 per pair on different web sites.33.93
Silver Shield gloves	Laminate Film	Says it can be worn as a liner.	$11.60 per pair
Ansell Chemical Resistant	Butyl Viton	Abrasion resistant	$132 per pair

TCE Pre-Panel Key Takeaways

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Trichloroethylene (TCE) under TSCA Section 6(a)

Key Takeaways from Pre-Panel Outreach Meeting

On October 28, 2022, EPA conducted a Pre-Panel outreach meeting with potential small entity representatives (SERs). A total of 5 potential SERs participated in the meeting. Representatives from the Small Business Administration (SBA) Office of Advocacy and Office of Management and Budget (OMB) also participated. EPA presented an overview of the Small Business Advocacy Review (SBAR) Panel process and Section 6 of the Toxic Substances Control Act (TSCA), an explanation of the forthcoming rulemaking, potential regulatory approaches, and cost estimates. EPA also provided opportunities for questions and feedback. EPA asked the potential SERs to provide written comments by November 14, 2022. One SER provided a written comment.

At the Pre-Panel outreach meeting, SERs provided information on the number and type of entities that would be affected (including descriptions of their processing or use of TCE, their customer base, and how their products are used; potential compliance requirements (including exposure and monitoring reduction, anticipated changes due to future requirements, and considerations for substitute chemicals); related Federal rules; and potential regulatory flexibility alternatives (including descriptions of challenges for small businesses and questions for EPA regarding the regulatory approach)). Discussion from SERs focused on several conditions of use (degreasing and dry cleaning), with no concerns expressed by SERs regarding potential EPA restrictions or prohibitions for most industrial and commercial uses and consumer uses of TCE. SERs emphasized that the feasibility of testing for the exposure levels for TCE under TSCA would be a primary concern when considering to potential impacts to their businesses.

Summary of Comments from Potential Small Entity Representatives

Number and Types of Entities Affected

SERs discussed their use of TCE, the workplace setting where it is processed/formulated or used, their customer base, and how their products are used. Specifically:

- A trade association SER described how members use TCE in several niche applications as a cleaning agent. For these niche applications, the SER stated that, in their experience, reformulation is less likely to occur due to lack of viable alternatives from a technology standpoint.
    - For TCE use in electrical cleaning applications, SERs explained that use of a nonflammable solvent is critical. SERs noted that potential alternatives include fluorinated compounds, but manufacturers would require additional testing to ensure proper cleaning, especially to avoid damaging the energized equipment (e.g., circuit board).
- SERs provided additional examples where TCE use as a degreaser may be essential, such as to remove grease where there has been significant buildup overtime (e.g., oil wells).
- For uses where TCE has likely been phased out, SERs suggested that TCE is being slowly phased out and replaced in paints and coatings.

- SERs were not aware of any specific oils or greases where TCE is specifically required.
- For TCE use in vapor degreasing, a SER noted the efforts of one small business deciding to invest in a closed system to continue use of TCE or to phaseout the use of TCE by implementing an aqueous cleaning process.
- One SER explained that TCE is used in the dry-cleaning industry on a limited but necessary basis. Specifically, TCE is used as a spot cleaner, separate from the garment cleaning process in which perchloroethylene or other cleaning reagents are used.
    - The SER noted that spot cleaning products containing TCE are typically used on 8-10 garments in an 8-hour workday.
    - SER estimated that a "full service" dry cleaner might use 1-3 gallons per year, as a small amount of TCE is useful for removal of "oxidized stains" remaining on a garment after the initial cleaning and drying cycle.
    - The SER characterized dry cleaning facilities as generally well ventilated. In addition, the SER noted that approximately 70-80% of "full service" dry cleaning entities use TCE as a spot cleaner.
    - The dry cleaning SER also noted that TCE use for spot cleaning is sporadic and estimated that an employee may be exposed to TCE for about an hour a day over the course of a year.
- In written comments, a consulting SER stated that a typical vapor degreasing operation consumes about 325 gallons of TCE a year.
    - This SER also stated that one client's vapor degreaser is 20 years old and has several modifications made to it, including solvent recovery and additional emission controls, with the last upgrade made in 2016. The SER mentioned that the unit could be expected to be operational for an additional 10 years or more if properly maintained.

Potential Reporting, Recordkeeping, and Compliance Requirements

SERs described their exposure monitoring and reduction practices, anticipated changes due to potential requirements from EPA, and considerations for substitute chemicals or processes. Specifically, for themselves or their customers:

- One SER explained that in industrial settings, industrial hygienists typically ensure that exposure is limited to the extent possible.
- One SER commented that dry cleaners have "good" ventilation (*i.e.,* at least 1 workspace air change every 5 minutes) including local exhaust ventilation in the spotting board area, in addition to the general ventilation and monitoring.
- One SER discussed generally the potential to implement a breathing zone monitoring badge, suggesting a cost of $60 to $70 per sample. The SER noted that the suggested cost accounted for the labor to place and pay for the order, take the sample, send it back, and receive the monitoring information.
- In written comments, a consulting SER stated that TCE is specifically required in the aerospace industry within specifications for acceptable solvent degreasers. They also

stated that phasing out TCE use is not possible without changes to specifications from customers, commonly the Department of Defense.

  - This SER also mentioned how employee exposure to TCE is controlled in the aerospace industry in regard to protections during vapor degreasing operations.
  - This SER also stated that TCE is used for brake cleaning and parts degreasing in the industrial and commercial automotive industry and cautioned that if the concentration of TCE was limited in one of these types of products, the product would most likely not be compliant with the specifications, which are driving its use.
  - This SER also mentioned that TCE exposure is brief in industrial and commercial automotive repair, as it is applied via aerosol spray in short bursts. Additionally, the SER cautioned that an air supplied respirator would impose unreasonable costs on facilities by requiring them to implement a respiratory protection program and that this type of respirator would restrict the movement of mechanics in and around the equipment they are working on.
  - The SER also stated that worker exposure is not applicable in the industrial and commercial automotive materials warehousing and distribution industry, as the materials are stored in closed containers as consumer commodities. They also state that TCE exposure to a consumer would be based on how the materials is used.

- SERs noted that for several uses (e.g., brake and parts cleaners, as a lubricant for spray applications) TCE is preferred due to certain characteristics (non-flammable, degreasing performance, rapid evaporation).
  - SERs noted that perchloroethylene is the primary chemical in most of the degreasing market, and that chlorinated solvents are preferred for quick evaporation for aerosol applications and application by the user (e.g., mechanic).
  - SERs also noted that chlorinated brake and parts cleaners are preferred among alternative chemicals, and explained that to comply with lower volatile organic compound (VOC) limits, companies tend to put in one or two exempt compounds (e.g., acetone or methyl acetate), which have less preferred cleaning or degreasing ability.
- A SER noted that available alternatives for lubricants in spray applications are mostly fluorinated organic compounds, although non-fluorinated options may exist, however there are concerns based on future potential regulatory activity.
- A consulting SER also gave examples of several replacement chemicals that are currently being marketed as drop-in replacements for TCE as a degreaser, such as proprietary fluorinated compounds, >70% by weight trans-1,2-dichloroethylene, and other organic solvents such as isopropyl alcohol or acetone. The SER noted potential concerns with some of these alternatives, namely that trans-1,2-dichloroethylene is currently undergoing risk evaluation within EPA as required by TSCA, and that isopropyl alcohol is labeled a "severe fire hazard" by the National Fire Protection Association.

  - This SER also mentioned that in the automotive industry, alternatives that have been tested have increased cycle times and tend to have their own hazard profile, which can include flammability and toxicity.

Related Federal Rules

When discussing related Federal rules:

- A SER mentioned that restrictions on the use of TCE for open-top and closed-loop vapor degreasing may present implications for cleaning and degreasing of parts where Federal Aviation Administration and Department of Defense specifications need to be met.
- A SER stated that industry works to minimize exposure to TCE to meet OSHA or other recommended requirements by implementing: PPE, administrative controls (e.g., isolating the work area so that only trained employee can enter), and engineering controls.
- A trade organization SER mentioned the American Innovation and Manufacturing Act (AIM Act), and stated that some hydrofluorocarbons, which TCE is used as a feedstock to manufacture, will be restricted in some applications under the AIM Act.
- Additionally, a trade organization SER mentioned that some chlorinated alternatives to TCE are under increased regulatory scrutiny, especially at state levels, because they may be subject to state PFAS laws based on their chemical structure and properties.
- In written comments, a consulting SER expressed concern that many of the alternatives to TCE are also chemicals that have been identified by the Agency as part of the TSCA risk evaluation process as having unreasonable risk to health and/or the environment. They mention that the Hazard Communication Standard was implemented because chemicals are inherently used as part of manufacturing processes, and that manufacturing employers are responsible for ensuring the safety of their employees and properly educating them on the hazards pertaining to each chemical they use as part of their work. They also mention the expense and time invested into infrastructure, education, and disposal for use of chemicals such as TCE, and state that forthcoming rule under TSCA creates the appearance that these companies are being asked to start this process again with a different chemical.
- This SER also stated that TCE is regulated under the Clean Air Act and that metal manufacturing facilities must account for their TCE usage and emissions from any process using TCE due to its classification as a Hazardous Air Pollutant (HAP), or volatile organic compound (VOC). They also mention that TCE usage and emissions are controlled using VOC destruction technologies and require continuous monitoring as defined in site specific permit requirements.

Regulatory Flexibility Alternatives

SERs identified several potential regulatory flexibility alternatives, challenges for small businesses, questions for EPA regarding the Agency's regulatory approach, and provided recommendations:

- One SER noted that small businesses are primarily concerned about viability of TCE alternatives, especially chlorinated chemicals, due to regulatory scrutiny.
- Several SERs discussed certification programs:
  - In cases of niche or critical uses of TCE where alternatives were not considered by SERs to be feasible, several SERs noted that small businesses would appreciate the potential regulatory option of a training and certification program in which a small entity would have to be certified to purchase a TCE-containing product from a retailer, such as industrial supply stores or online retailers.
  - A paint and coating SER stated that there would be inventory issues with stocking products formulated with TCE if regulations limited where they could be bought and if certification was required to purchase them, unless there was a rollout period allowing for stock to be depleted and for the supply chain to adjust to the change.
- A trade organization SER described how many of its members anticipate future TCE regulations and are looking at transitioning away from the chemical but find the commercial viability of potential alternatives challenging. The SER also stated that companies are reluctant to be the first on the market to produce a product using alternatives, which would be at a higher cost than TCE, because they do not wish to see their businesses suffer as a result passing on the cost increases of production to end users.
- In the case of a ban, SERs requested that the potential regulatory option include a de minimis level in the case of an impurity or trace amounts of TCE in products.
- Regarding dry cleaning:
  - One dry cleaning SER discussed how prohibiting TCE use for dry cleaners would cause higher costs in thousands of dollars compared to current conditions in additional labor and running time and would also cause adverse effects to production.
  - A dry cleaning SER mentioned that using an alternative spot removing product may take 5-15 min longer to try and remove a stain, while TCE's high efficacy helps to remove stains without much abrasive action, which increases a garment's useful life and prevents excess textile waste. The SER further noted that the transition to a substitute is a question of time and utility – adding an hour a day to stain removal also adds an hour a day to processing time, compressor time, and labor, and decreases customer satisfaction because of the increased time required to process a garment.
- In written comments, a consulting SER stated that TCE is being replaced with alternatives in the metals manufacturing industry due to regulatory pressure and a reduction in supply, with viable alternatives already in place and reformulated coatings created to exclude chlorinated compounds.
  - The consulting SER also stated that there are some potential alternatives to TCE for use in the aerospace industry as a solvent degreaser, but that these alternatives are currently very expensive and have additional hazards, such as flammability and toxicity.

   - Additionally, this SER mentioned that a ban on TCE for use in the aerospace industry would have major implications, including the inability to operate, because, as they described, TCE is required to meet many specifications for production which take great effort, expense and time to modify and/or change.

TCE Panel Questions for SERs

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Trichloroethylene (TCE) under TSCA Section 6(a)

Panel Outreach Small Entity Representative (SER) Questions for Discussion on TCE

For rules that may have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act (RFA) requires agencies to evaluate regulatory alternatives that may minimize the burden on small entities expected to be regulated. The RFA notes that the regulatory alternatives must be consistent with the stated objectives of applicable statutes (i.e., TSCA), and suggests significant alternatives such as:

- the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;
- the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;
- the use of performance rather than design standards; and
- an exemption from coverage of the rule, or any part thereof, for such small entities.

To that end, these informal questions on your work practices and your experiences with trichloroethylene (TCE) are aimed at guiding our discussion today, and your later written feedback, towards ideas for minimizing the economic impact on your business while remaining within the constraints of TSCA. We are not seeking a structured response on each question; rather, we are interested in any feedback or details you can provide, and hope that these questions let you know what type of information would be most useful as we consider advice from the small entity representatives concerning TSCA regulation of TCE.

If you are interested in providing this or other information in writing, please see the contact information below.

We ask that you refrain from providing Confidential Business information (CBI) during the discussion or in email to EPA. If you choose to provide CBI, we will provide special instructions.

Contact Information:

Lanelle Wiggins
Office of Regulatory Policy and Management
Office of Policy
Phone: (202) 566-2372
E-mail: wiggins.lanelle@epa.gov

1) Your business *(All SERs)*

a. How does your organization use TCE? How much TCE does your organization use?
b. Does your organization still use TCE? What is the trend of use? For example, has your organization increased use of TCE? Has use remained constant? Is use decreasing? Is your organization phasing out the use of TCE?
c. Can you describe the specific use, as well as the workplace and workplace setting where TCE is used?
d. Why does your organization use TCE? What function does TCE provide?

e. Where is your organization in the supply chain? (e.g., are you a processor – formulating another product with TCE, a distributor, or final user of TCE in an application?). Do you provide finished product to another small entity or to a large entity?
f. For what industries or applications do you provide products or services for? (e.g., aerospace, electronics, military, automotive, optics, museums/art restorations, academic, commercial laboratory, consumers, other) Can you provide a NAICs code for the products/services you provide?
g. For what process are you using TCE? (can be more than one, such as cleaning, drying, inspection, etc.)
h. If TCE were not available, how would you adjust and what would the impacts be on your business? What specific barriers would your business face in switching to an alternative?
i. If the concentration of TCE in a product was limited, would this impact the efficacy of the product and/or increase the duration of use or exposure. For which particular uses?
j. What are the benefits to your business of TCE? Are there specific benefits for small businesses using TCE as compared to benefits for larger businesses?

2) Workplace exposure *(All SERs)*

a. How many employees, and what fraction of your employees, are exposed to TCE, and for how long (days/year and hours/day)?
b. If you use a product containing TCE, what product do you use and what is the concentration of TCE in the product?
c. What work activities result in worker exposure to TCE? And what type of exposure (dermal, inhalation)?
d. For each activity, in what physical state and concentration is TCE?
e. Have you taken industrial hygiene monitoring data? If so, what was typical and high-end exposure to TCE?
f. What engineering controls are used to minimize exposure to TCE? How effective are those controls?
    i. Would it be feasible to use additional engineering controls to minimize exposure to TCE? If so, what might those engineering controls be?
    ii. What is your experience with:
        - Installing or updating ventilation and local exhaust, or
        - Equipment changes to reduce exposure or cross-contamination?
g. What administrative controls and training do you use to minimize exposure to TCE? Do you use training to minimize exposure to TCE?
h. Is personal protective equipment (PPE) regularly worn by workers to minimize exposure to TCE?
    i. If yes, could you provide more information regarding the type of PPE that is used? And would it be feasible to use PPE that provided a level of protection beyond what you are already using? Do you have experience with air supplied respirators? Do you have experience with other PPE?

   ii. If no, would it be feasible to have workers wear PPE to minimize their exposure to TCE? And what PPE would be feasible for workers to wear? Are their workers or processes where the use of PPE would be impractical?

i. How many employees are located in the same room where the work activities related to TCE are taking place but not necessarily handling TCE or TCE-containing products?

j. What do you do to comply with OSHA standards for TCE?

3) Regulatory options *(All SERs)*

a. Which of the regulatory options presented today would you recommend?
b. Cost estimates: In your experience, are the cost estimates reasonably representative? Do you have additional information to improve the cost estimates?
c. What indirect costs to your organization do you estimate would occur as a result of this regulation?
d. Recognizing that the cost estimates are only partial unit costs, can you provide any additional information on potential costs or cost considerations the Agency should consider when evaluating the costs of complying with potential regulatory options?
e. Can you think of ways to add flexibility to this rulemaking for your small businesses?
f. Are there other alternative regulatory options that the agency should consider to manage the unreasonable risks identified for TCE?
g. How do you learn about EPA regulations and what you should do to comply?
h. What kind of additional information or resources would help you understand the regulations and steps necessary to comply?
i. What is the best way for EPA to reach out to members of your industry?

4) Additional questions for users of products containing TCE: substitutes and alternatives

a. What chemicals or processes have you considered as an alternative to using TCE or a product containing TCE? Why? How do these chemicals or processes compare to current use containing TCE? More specifically:
   i. Do you currently use any alternatives to TCE (or product)?
   ii. Did you try to switch to another chemical, product, or process only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?
   iii. What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including of exposure, effectiveness, cost, and hazard?
   iv. Provide specific information related to each substitute chemical, product, or process related to the use of alternative chemicals/products and compare to TCE:
      - Identification of alternative chemical/product/process
      - How much of the alternative product/chemical would be needed to perform the same activity
      - Capital costs including new equipment, retrofitting of old equipment, etc. of using the alternative chemical/process, loss of use of existing equipment
      - Number of workers required, amount of worker time required

- Number of workers exposed
- Costs associated with transitioning to the alternative chemical (e.g., identifying, designing, and testing the alternative chemical/process, certifying or otherwise ensuring customer or other required production standards are met, production downtime during the transition, lost productivity while learning how to use the alternative efficiently)
- Process changes required (e.g., additional time to complete task, additional steps, etc.)
- Energy and other resource (e.g., water) usage
- Other operation and maintenance costs (e.g., filters, tank cleanings, etc.)
- Changes in production or output of operation
- Releases of alternative chemicals/products
- Waste and disposal costs associated with alternative chemical/process
- Changes in your product/service quality
- Training, medical surveillance, or other employee-related costs
- Recordkeeping burden/costs
- Monitoring and testing costs
- Potential barriers/concerns with switching to alternatives

5) Additional questions for distributors and retailers (for consumer uses)

a. How much of your business is supplying products containing TCE to consumers? How much of your business is supplying products containing TCE to commercial or industrial users?
b. If you could no longer sell products containing TCE, how would this impact your business?
c. Do you also sell products designed for the same application or use that do not contain TCE?
    i. If yes, what is the relative share of sales for the product(s) containing TCE compared to the products that do not contain TCE?
d. Are there particular challenges to a small business doing distribution of products containing TCE that are different from large distributors?
e. What is your preferred method of downstream notification?
f. If you were required to limit sales of TCE containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency? Please identify any challenges you see with such a limitation.
g. If restrictions (e.g., prohibition or limit to concentration of TCE in products or articles) were placed on TCE in products or articles, how long would you need to notify downstream users? How long would it take to clear channels or trade?

6) **Additional questions for formulators of products containing TCE: substitutes and alternatives**
   a. Product reformulation:
      i. How often do you reformulate your products?
      ii. What is the typical cost of reformulating your products?
      iii. What might reformulation costs be if you needed to reformulate your products without TCE? (e.g., costs associated with research and development, testing, capital costs of production changes, packaging, labeling)
   b. Product relabeling:
      i. How often do you relabel your products?
      ii. What is the typical cost of relabeling?
   c. Alternatives:
      i. Do you sell another product that does not contain TCE that is designed for the same use or application as the TCE product?
         - If yes:
            - What solvent replaces TCE in the alternative product? Can you provide an SDS or the formulation for the alternative product?
            - How does the alternative product compare in terms of safety, efficacy, and cost to use including whether the alternative product would require more time (and how much)?

         - If no:
            - If you need to reformulate this product with a lower concentration of TCE, what would be the implications for the product in terms of cost and efficacy?
            - If you need to reformulate this product without TCE, what solvent would replace TCE in the alternative product? How do you think the alternative product would compare in terms of efficacy and cost to use including whether the alternative product would require more time (and how much)?
      ii. Is there a subset of uses for your product where using a product formulated without TCE would be problematic?

7) **Additional questions for degreasing operations:**
   a. What type of degreasing operation do you use: vapor degreasing, cold cleaning, aerosol/spray degreasing? Is TCE used in a degreaser? In a tank? As an aerosol? In a small dispenser such as a squirt bottle?
      i. What items do you degrease with for each of the types listed?
      ii. If you use vapor degreasing, what type of system do you use (open-top, closed-loop, in-line, etc.)? How many separate units of each do you have? If multiple units, are all routinely in operation or do you use one or more units for backup?
      iii. What size system do you use?
      iv. How significant is degreasing to your business overall?

v. Do any particular items or grease/oils present special challenges?

b. Current work practices related to degreasing operations:
    i. In your experience, what is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity?
    ii. Do the types of vapor degreasers we are considering (open-top, closed-loop, continuous/in-line vapor degreasers) seem representative of those currently in use for small businesses?
    iii. Is there any difference in terms of operation time for the different types of vapor degreasers or cold cleaners or aerosol degreasers (in terms of hours per day or days per year)?

c. How old is the cleaning equipment? When did you last update your degreasing system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc.)? What prompted this update? What is the remaining life of the current system you have?

d. What are the most important factors in degreasing for you (in order): (e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify))?

e. Why do you use TCE rather than somewhat similar solvents like 1-bromopropane (1-BP), perchloroethylene (PCE), other? Or a blend with *trans*-1,2-dichloroethylene (DCE)? Can you name specific factors that drive your decision to continue to use TCE? Did you consider using another non-halogenated solvent or aqueous process?
    i. When do you use TCE in the process flow in your facility, are you using other cleaning processes as well?
    ii. For example, do you do aqueous cleaning in addition to cleaning with TCE? Does aqueous cleaning happen before or after TCE?
    iii. Are you using TCE on some but not all products?
    iv. If you use one or the other, (aqueous or TCE but not both), how did you decide which to use?

f. One possibility is that TCE might have to be used in a closed-loop/airless system. Have you looked into such systems? Why or why not?
    i. Are you considering purchasing such equipment?
    ii. If not, what are the constraints?
    iii. Would you use TCE in such a system or would you use a different solvent?

g. Have you looked at any alternative processes? Any alternative solvents? Have you looked at product literature?

h. Have you tried using alternative chemicals or methods for degreasing? What were the results?
    i. Please discuss alternative methods for degreasing as well as alternative solvents or equipment in your degreasing process.
    ii. Are you aware of alternative processes or solvents that could be used to achieve similar degreasing results in your operation?
    iii. If you have tried or switched to alternative chemicals or methods, how did they do? how long did that process take? Did it require equipment modifications or new equipment purchases?

i. If TCE could no longer be used for degreasing, would the mix of alternative cleaning methods be different for you as a small businesses compared to larger businesses? For example, are there particular alternatives that are more suitable for small businesses?
j. If there is no technically and economically feasible alternative for TCE available for your use, what are some consequences/impacts that your business may experience?
k. What would be the cost to your business if your use of TCE was prohibited?
l. If you had to change your cleaning process to another somewhat similar solvent like a *trans*-DCE blend, can you give an estimate of costs while considering the following?
    i. Cleaning agent
    ii. Cleaning equipment
    iii. Process development
    iv. Process verification and validation (including lab testing and/or third-party verification), i.e., proving to yourself that the process works
    v. Customer certification
    vi. Training
    vii. Insurance
    viii. Permitting
    ix. Cleaning agent management (including removal of used cleaning agent)
    x. Facilities changes
    xi. Documentation
    xii. PPE requirements
m. What if you needed to move your cleaning process to a different process like aqueous or another non-similar solvent (modified alcohols, hydrocarbons, alcohols, other blends)? Can you give an estimate of costs while considering the following?
    i. Cleaning agent
    ii. Cleaning equipment
    iii. Process development
    iv. Process verification and validation (including lab testing and/or third-party verification) (i.e., proving to yourself that the process works))
    v. Customer certification
    vi. Training
    vii. Insurance
    viii. Permitting
    ix. Cleaning agent management (including removal of used cleaning agent)
    x. Facilities changes
    xi. Documentation
    xii. PPE requirements
n. Do you have an estimate on how many vapor degreasers in the U.S. use TCE?
o. Do you have an estimate on how much TCE is used in the U.S. for vapor degreasing every year?
p. Out of all the vapor degreasers in the U.S., do you have an estimate on what percentage of those vapor degreasers use TCE versus other solvents (methylene chloride, PCE, 1-BP, *trans*-DCE blends, other designer solvents)?
q. How much TCE does a typical vapor degreasing operation consume in a year?

TCE Potential Regulatory Options and Costs

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Trichloroethylene (TCE) under TSCA Section 6(a)

Potential Regulatory Options and Estimated Costs

Any regulatory requirement could be used alone or in combination to the extent necessary so that TCE no longer presents an unreasonable risk under its condition of use. Additionally, under TSCA section 6(g), EPA may propose a time-limited exemption for specific conditions of use provided certain criteria are met.[1]

When considering practicability and a reasonable transition period, EPA works to account for various factors such as supply chains, availability of alternatives, and time needed for recertification, testing, and retrofitting. Any information on historical timelines from industry on replacing chemicals in the past are especially helpful in determining a reasonable transition period, along with the information mentioned in the previous sentence.

Existing Chemical Exposure Limit (ECEL)

- What is an ECEL?
  - A risk management option similar to a permissible exposure limit (PEL), for industrial and most commercial conditions of use. Establishes a performance-based standard and is non-prescriptive, thus providing flexibility to users to determine how to most effectively meet the ECEL based on what works best for their workplace. Industries are already familiar with PELs, and methods of compliance.
  - An ECEL is calculated based on the identified hazard of the chemical, such as the human equivalent concentration or the inhalation unit risk determined in the risk evaluation and considers the most sensitive endpoint.
  - The ECEL is the air concentration at or below which EPA has determined as a matter of policy would address unreasonable risk resulting from inhalation exposures in an occupational setting to workers or occupational non-users (ONUs,) including susceptible subpopulations.
    - The TCE ECEL(I) based on the immunotoxicity endpoint would be 4.0 ppb (0.021 mg/m3) for an 8-hour time-weighted average (TWA).
    - EPA is also considering occupational safety measures based on a different, more sensitive endpoint (fetal cardiac defects) which would result in an ECEL(F) of 1.1 ppb (0.0059 mg/m^3) for an 8-hour TWA.
    - In the 2020 Risk Evaluation for TCE, EPA discussed both the immunotoxicity and fetal heart defects endpoints although the unreasonable risk is based on the immunotoxicity endpoint.

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[1] In order to propose an exemption under TSCA section 6(g), EPA must find that the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available; compliance with the rule would significantly disrupt the national economy, national security, or critical infrastructure; or the specific condition of use, as compared to alternatives, provides a substantial benefit to health, the environment, or public safety. In proposing the exemption, EPA must provide a time limit for the exemption; analyze the need for the exemption and make the analysis public; and include interim conditions to protect health and the environment.

    - In the interest of transparency, EPA is providing ECEL values for both endpoints since EPA had previously provided the ECEL for the fetal heart defects with the 2016 proposed TCE rules although the proposals were subsequently withdrawn.
    - EPA is interested in hearing from SERs about the feasibility of either ECEL value since both are in the ppb.
- How could it be applied?
  - If EPA sets an ECEL, businesses could meet the ECEL by changing their process or formula, using different equipment, using personal protective equipment (PPE), substituting the chemical, or some combination.
  - The decision on how to meet the ECEL is up to the business; however, an ECEL might require monitoring and recordkeeping to demonstrate compliance.

Prescriptive PPE Controls

- A risk management option that would require use of specific PPE to minimize exposure. This may limit flexibility for the regulated entity. PPE may include respirators or gloves.
  - For example, EPA could require the use of specific gloves or gloves that meet certain standards such as providing an impervious barrier to the chemical during expected durations and normal conditions of exposure.
  - As an additional example, EPA could require the use of respirators to address unreasonable risks driven by inhalation exposures. For TCE, only a respirator with APF 10,000 may be able to mitigate such risk; EPA recognizes the challenges associated with using such respirators and is interested in SER feedback on this type of PPE.

Prescriptive Administrative Controls

- A risk management option that would prescribe administrative controls to reduce exposure.
- Example: Prohibit ONU access to the work area where the chemical is being handled.

Prescriptive Engineering Controls

- A risk management option that would prescribe engineering controls, such as removing a hazardous substance through air ventilation with a specific air exchange rate or to a specific air concentration limit.
- Examples:
  - Install additional or different equipment, such as enclosed transfer liquid lines, closed loop container systems or a laboratory type fume hood, to reduce the exposure to the chemical.
  - Install or upgrade ventilation systems to help control and/or eliminate air contaminants.
  - Enclose or confine operations to avoid or reduce employee exposure.

Regulate the Manufacturing, Processing, and/or Distribution

- A risk management option for industrial, commercial, and consumer conditions of use. These authorities allow EPA to regulate at key points, including the manufacturing, processing, and distribution in commerce of a chemical or product in the supply chain.

Prohibition

- EPA could include prohibition on manufacturing, processing, distribution, use, or disposal for specific conditions of use or the chemical as a whole.
    - For example, the Toxics Use Reduction Institute identified alternatives to TCE in vapor degreasing, including 1,2-trans-dichloroethylene[2], 1-bromopropane[3], and hydrocarbon solvents, such as terpenes, alcohols, acetone, ketones, and acetates. (https://www.turi.org/TURI_Publications/TURI_Chemical_Fact_Sheets/Trichloroethylene_TCE_Fact_Sheet/TCE_Facts/Alternatives). EPA is interested in SER feedback on these identified alternatives as well as SER recommendations for alternatives related to the other TCE conditions of use.

Examples of combinations of regulatory options

- A risk management option that would prescribe engineering and PPE to reduce exposure.
    - For example, EPA could mandate use of specific ventilation rate to reduce exposure as much as possible and then require a respirator to ensure exposures are below a set level that would eliminate unreasonable risk.
- A risk management option that would require prescriptive engineering, PPE, and administrative controls to reduce exposure.
    - For example, EPA could require use of specific equipment and PPE to reduce exposure to workers and then limit access to the work area to eliminate the unreasonable risk to ONUs.
- A risk management option that would set a maximum concentration limit and also require engineering controls.
    - For example, require no more than a set percentage concentration of the chemical in the product and then require use of a specific ventilation system to eliminate unreasonable risk.

[2] Currently undergoing risk evaluation within EPA (see docket number EPA-HQ-OPPT-2018-0465).
[3] Currently undergoing risk management within EPA (see docket numbers EPA-HQ-OPPT-2020-0471, EPA-HQ-OPPT-2019-0235, and EPA-HQ-OPPT-2016-0741); the risk evaluation is complete (see docket numbers EPA-HQ-OPPT-2016-0741 and EPA-HQ-OPPT-2019-0235).

Regulatory options applied broadly with other restrictions

- Recordkeeping and downstream notification – Require manufacturers, processors, and distributors to maintain ordinary business records.
  - For example, EPA could require manufacturers, processors, and distributors to provide downstream notification to help ensure regulatory information reaches all users in the supply chain.
- Monitoring and labeling – Require initial or periodic monitoring of occupational exposure.
  - For example, EPA could require that a prominent label be securely attached to each container with specific directions and precautions, or that describes the health endpoints.
- Limited access program
  - For example, restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification.

Cost of Regulatory Options

Type of Cost	Estimated Compliance Cost	Notes
Prohibition of manufacturing, processing, and distribution	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives[4], reformulation (see below), shutting down the operation, and more. Requires input from potentially regulated entities.
Prohibition of Use	Varies with condition of use	Cost will vary by condition of use. Potential activities could include changes in process and equipment, costs of alternatives, reformulation (see below), shutting down the operation, and more. Requires input from potentially regulated entities.
Existing Chemical Exposure Limit (ECEL)	$400 per facility ($70-$1,600 annualized per facility) + $220 per worker ($40-$800 annualized per worker) for monitoring $400 per facility ($60 annualized per facility) + $20-$100 per worker for recordkeeping Costs of engineering controls or PPE to achieve the ECEL level varies by control type and needs of user	ECEL costs will vary based on the complexity of the site and how many times the site will require monitoring to demonstrate compliance. Costs of engineering controls or PPE to achieve the ECEL level are not captured in these estimates. Potential costs of changes in worker productivity resulting from respirator use or changes to worker compensation for those wearing respirators are unquantified. Requires input from potentially regulated entities.
Engineering/Administrative Controls	Varies by control type and needs of user	Requires input from potentially regulated entities.
Reformulation of product to reduce or eliminate TCE concentration	$60,000 - $100,000 per product	Costs will vary by condition of use and will be dependent on reformulation approach. Requires input from potentially regulated entities. Setting a concentration limit could impact the

[4] TSCA section 6(c)(2)(C) requires EPA "…in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action…to the extent practicable, 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 when the proposed prohibition or other restriction takes effect."

Type of Cost	Estimated Compliance Cost	Notes
		efficacy of a product or the feasibility of a process.
Product Label or Warnings	$750 - $8,000 per product	Costs will vary by condition of use. Potential activities may include graphic design changes, plate changes, discarded inventory, and labor. Due to uncertainties and variations in product types, does not include potential impacts on sales.
Personal Protective Equipment (PPE) – (e.g., respirators)	APF 25: $660-$970 APF 50: $750-$1,100 APF 1000: $780-$1,150 APF 10000: $1,800 - $2,500	Costs are per employee and include purchase of equipment, routine cleaning of equipment, training, fit-testing, and medical clearance and account for estimated baseline PPE use.
Personal Protective Equipment (PPE) (dermal)	$4 per pair (50 pairs per year, $130-$180 annualized cost)	Costs are per pair of PVA gloves. Requires input from potentially regulated entities regarding which glove material type would be used.
Substitute Products	Varies with condition of use	The costs of switching products includes both the costs of the substitute products and differences in efficacy of these products. Costs of differences in efficacy are not quantified. Some applications may need to undergo safety reviews before they could replace TCE products. These costs are unquantified.
Substitute Methods	Varies by job labor rate. For vapor degreasing, initial transition costs are estimated as $100,000 to $500,000 and initial capital costs as $30,000 to $500,000	This will primarily be labor cost and cost of alternative equipment. There may be some safety-critical applications where alternatives would need to undergo extensive safety reviews and testing before they could replace the TCE products. These costs are unquantified.
Recordkeeping	$200 - $325 per firm	Annual labor and material costs associated with documentation of ordinary business records.
Downstream Notification	$112 - $125 per product	Costs are per product and include labor and material costs to update the product's safety data sheet (SDS).

TCE Existing Related Regulations

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Trichloroethylene (CASRN 79-01-6) under TSCA Section 6(a)

Related Regulations (EPA, Federal, State, and International)

Table 1 – EPA Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
Toxics Substances Control Act (TSCA) - Section 6(a)	Provides EPA with the authority to prohibit or limit the manufacture (including import), processing, distribution in commerce, use or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment.	Proposed rule under section 6 of TSCA to address the unreasonable risks presented by TCE use in vapor degreasing (82 FR 7432; January 19, 2017). This proposed rule was withdrawn in 2021 (86 FR 3932, January 15, 2021).
TSCA - Section 6(a)	Provides EPA with the authority to prohibit or limit the manufacture (including import), processing, distribution in commerce, use or disposal of a chemical if EPA evaluates the risk and concludes that the chemical presents an unreasonable risk to human health or the environment	Proposed rule under section 6 of TSCA to address the unreasonable risks presented by TCE use in commercial and consumer aerosol degreasing and for spot cleaning at dry cleaning facilities (81 FR 91592; December 16, 2016). This proposed rule was withdrawn in 2021 (86 FR 3932, January 15, 2021).
TSCA - Section 6(b)	Directs EPA to promulgate regulations to establish processes for prioritizing chemicals and conducting Risk Evaluations on priority chemicals. In the meantime, EPA is directed to identify and begin Risk Evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	TCE is on the initial list of chemicals evaluated for unreasonable risks under TSCA (81 FR 91927, December 19, 2016). Commercial and consumer degreasing uses, consumer arts and crafts uses, and commercial use as a spotting agent at dry-cleaning facilities were assessed in 2014, with an assessment narrower in scope than the 2020 TCE Risk Evaluation.
TSCA - Section 5(a)	Once EPA determines that a use of a chemical substance is a significant new use under TSCA section 5(a), persons are required to submit a significant new use notice (SNUN) to EPA at least 90 days before they	Significant New Use Rule (SNUR) (81 FR 20535; April 8, 2016). TCE is subject to reporting under the SNUR for manufacture (including import) or processing of TCE for use in a consumer product

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	manufacture (including import) or process the chemical substance for that use.	except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants and pepper spray. This SNUR ensures that EPA will have the opportunity to review any new consumer uses of TCE and, if appropriate, take action to prohibit or limit those uses.
TSCA - Section 8(a)	The TSCA section 8(a) CDR rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	TCE manufacturing (including importing), processing and use information is reported under the CDR rule (76 FR 50816, August 16, 2011).
TSCA - Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed or imported in the United States.	TCE was on the initial TSCA Inventory and was therefore not subject to EPA's new chemicals review process (60 FR 16309, March 29, 1995).
TSCA - Section 8(e)	Manufacturers (including importers), processors and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	26 substantial risk notifications received for TCE (U.S. EPA, ChemView. Accessed September 27, 2022).
TSCA - Section 4	Provides EPA with authority to issue rules and orders requiring manufacturers (including importers) and processors to test chemical substances and mixtures.	Seven studies received for TCE (U.S. EPA, ChemView. Accessed September 27, 2022).
Emergency Planning and Community Right-to-Know Act (EPCRA) - Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full time equivalent employees and that manufacture, process, or otherwise use a Toxics Release Inventory	TCE is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	(TRI)-listed chemical in quantities above threshold levels. A facility that meets reporting requirements must submit a reporting form for each chemical for which it triggered reporting, providing data across a variety of categories, including activities and uses of the chemical, releases and other waste management (*e.g.,* quantities recycled, treated, combusted) and pollution prevention activities (under section 6607 of the Pollution Prevention Act). These data include on- and off-site data as well as multimedia data (*i.e.,* air, land and water).	
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) – Sections 3 and 6	FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. Pesticides may only be registered if, among other things, they do not cause "unreasonable adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either: (1) the pesticide, labeling, or other material does not comply with FIFRA or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	TCE is no longer used as an inert ingredient in pesticide products.
Clean Air Act (CAA) - Section 112(b)	Defines the original list of CAA hazardous air pollutants (HAPs). Under 112(c) of the CAA, EPA must identify and list source categories that emit HAPs and then set emission standards for those listed	Lists TCE as a HAP (42 U.S.C. 7412(b)(1)).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	source categories under CAA section 112(d). CAA section 112(b)(3)(A) specifies that any person may petition the Administrator to modify the list of HAPs by adding or deleting a substance.	
CAA - Section 112(d)	Directs EPA to establish, by rule, National Emission Standards for Hazardous Air Pollutants (NESHAP) for each category or subcategory of listed major sources and area sources of HAPs (listed pursuant to Section 112(c)). The standards must require the maximum degree of emission reduction that the EPA determines to be achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT). For area sources, the standards must require generally achievable control technology (GACT) though may require MACT.	EPA has promulgated a number of NESHAP regulating industrial source categories that emit trichloroethylene and other HAPs. These include, for example, the NESHAP for Halogenated Solvent Cleaning (59 FR 61801; December 2, 1994), among others.
CAA - Sections 112(d) and 112 (f)	Risk and technology review (RTR) of section 112(d) MACT standards. Section 112(f)(2) requires EPA to conduct risk assessments for each source category subject to section 112(d) MACT standards, and to determine if additional standards are needed to reduce remaining risks. Section 112(d)(6) requires EPA to review and revise the MACT standards, as necessary, taking into account developments in practices, processes and control technologies.	EPA has promulgated a number of RTR NESHAP (*e.g.,* the RTR NESHAP for Halogenated Solvent Cleaning (72 FR 25138; May 3, 2007) and will do so, as required, for the remaining source categories with NESHAP.
Clean Water Act (CWA) – Sections 301(b), 304(b), 306, and 307(b)	Requires establishment of Effluent Limitations Guidelines and Standards for conventional, toxic, and non-conventional pollutants. For toxic and non-conventional pollutants, EPA identifies the best	

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology. Regulations apply to existing and new sources.	TCE is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such, is subject to effluent limitations.
CWA - Section 307(a)	Establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in 40 CFR 401.15. The "priority pollutants" specified by those families are listed in 40 CFR part 423, Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules (Section 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in National Pollutant Discharge Elimination System (NPDES) permits, see Section 4029a)(1)(B).	
Safe Drinking Water Act (SDWA) - Section 1412	Requires EPA to publish a non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgement of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a	TCE is subject to NPDWR under the SDWA with a MCLG of zero and an enforceable MCL of 0.005 mg/L (52 FR 25690, July 8, 1987).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	
Resource Conservation and Recovery Act (RCRA) - Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	TCE is included on the list of commercial chemical products, manufacturing chemical intermediates or off-specification commercial chemical products or manufacturing chemical intermediates that, when disposed (or when formulations containing any one of these as a sole active ingredient are disposed) unused, become hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Status: D040 at 0.5 mg/L; F001, F002; U228
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) - Section 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they have knowledge of a release of a hazardous substance above the reportable quantity threshold.	TCE is a hazardous substance with a reportable quantity pursuant to section 102(a) of CERCLA (40 CFR 302.4) and EPA is actively overseeing cleanup of sites contaminated with TCE pursuant to the National Contingency Plan (NCP) (40 CFR 751).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
American Innovation and Manufacturing (AIM) Act	Directs EPA to address hydrofluorocarbons (HFCs) by phasing down production and consumption by 85 percent over a period ending in 2036, maximizing reclamation and minimizing releases from equipment, and facilitating the transition to next-generation technologies through sector-based restriction.	In 2021, EPA set HFC production and consumption baseline levels from which reductions will be made (86 FR 55116, October 5, 2021). The rule also establishes an initial methodology for allocating and trading HFC allowances for 2022 and 2023. TCE is identified as a feedstock chemical for HFC production.

Table 2 – Other Federal Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Other Federal Regulations		
Occupational Safety and Health Act (OSH Act)	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress or unsanitary conditions (29 U.S.C. section 651 et seq.). Under the Act, OSHA can issue occupational safety and health standards including such provisions as Permissible Exposure Limits (PELs), exposure monitoring, engineering and administrative controls, and respiratory protection.	In 1971, OSHA issued occupational safety and health standards for TCE that included a PEL of 100 ppm as an 8-hr TWA with an acceptable ceiling concentration of 200 ppm. An acceptable maximum peak above the acceptable ceiling concentration for an 8 hour shift is 300 ppm, based on the maximum duration of 5 minutes in any 2 hours (29 CFR 1910.1000). While OSHA has established a PEL for TCE, OSHA has recognized that many of its PELs are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time. Section 6(a) of the OSH Act granted the Agency the authority

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		to adopt existing Federal standards or national consensus standards as enforceable OSHA standards. "OSHA recommends that employers consider using the alternative occupational exposure limits because the Agency believes that exposures above some of these alternative occupational exposure levels are in compliance with the relevant PELS." For TCE, the alternative occupational exposure limits are the NIOSH REL of 2 ppm (as a 60-minute ceiling) during the usage of TCE as an anesthetic agent and 25 ppm (as a 10-hour TWA) during all other exposures. https://www.osha.gov/dsg/annotated-pels/
Atomic Energy Act	The Atomic Energy Act authorizes the Department of Energy to regulate the health and safety of its contractor employees	10 CFR 851.23, Worker Safety and Health Program, requires the use of the ACGIH TLVs if they are more protective than the OSHA PEL. The 2012 TLV for TCE is 10 ppm and the short-term limit is 25 ppm (ATSDR, 2019).
Federal Food, Drug, and Cosmetic Act (FFDCA)	Provides the FDA with authority to oversee the safety of food, drugs and cosmetics.	Tolerances are established for residues of TCE resulting from its use as a solvent in the manufacture of decaffeinated ground coffee, decaffeinated soluble (instant) coffee extract, and spice oleoresins (25 ppm, 10 ppm and 30 ppm, respectively; 21 CFR 173.290).
Federal Hazardous Material Transportation Act	Section 5103 of the Act directs the Secretary of Transportation to: Designate material (including an explosive, radioactive material, infectious substance, flammable or combustible liquid, solid or gas, toxic, oxidizing or corrosive material	The Department of Transportation (DOT) has designated TCE as a hazardous material, and there are special requirements for marking, labeling and transporting it (49 CFR Part 171, 49 CFR 172, 40

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	and compressed gas) as hazardous when the Secretary determines that transporting the material in commerce may pose an unreasonable risk to health and safety or property. Issue regulations for the safe transportation, including security, of hazardous material in intrastate, interstate and foreign commerce.	CFR § 173.202 and 40 CFR § 173.242).

Table 3 – State Laws and Regulations

State Actions	Description of Action
State Actions	
California Code of Regulations (CCR), Title 17, Section 94509(a)	Lists standards for VOCs for consumer products sold, supplied, offered for sale or manufactured for use in California. As part of that regulation, use of consumer general purpose degreaser products that contain TCE are banned in California and safer substitutes are in use (17 CCR, Section 94509(a)).
State Permissible Exposure Limits (PELs)	Nine states (Alaska, Connecticut, Hawaii, Michigan, New York, Oregon, Tennessee, Vermont, and Washington) have PELs of 50 ppm. California has a PEL of 25 ppm (CCR, Title 8, Table AC-1). Minnesota has banned TCE (see below), and its interim limit is 0.002 ppb. Other than these states, other states have set PELs identical to the OSHA 100 ppm 8hour TWA PEL
VOC regulations for consumer products	Many states regulate TCE as a VOC. These regulations may set VOC limits for consumer products and/or ban the sale of certain consumer products as an ingredient and/or impurity. Regulated products vary from state to state, and could include contact and aerosol adhesives, aerosols, electronic cleaners, footwear or leather care products and general degreasers, among other products. California (Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.5, Articles 1, 2, 3 and 4), Connecticut (R.C.S.A Sections 22a-174-40, 22a-174-41, and 22a-174-44), Delaware (Adm. Code Title 7, 1141), District of Columbia (Rules 20-720, 20-721, 20-735, 20-736, 20-737), Illinois (35 Adm Code 223), Indiana (326 IAC 8-15), Maine (Chapter 152 of the Maine Department of Environmental Protection Regulations), Maryland (COMAR 26.11.32.00 to 26.11.32.26), Michigan (R 336.1660 and R 336. 1661), New Hampshire (Env-A 4100) New Jersey (Title 7, Chapter 27, Subchapter 24), New York (6 CRR-NY III A 235), Rhode Island (Air Pollution Control Regulation No. 31) and Virginia

State Actions	Description of Action
	(9VAC5 Chapter 45) all have VOC regulations or limits for consumer products. Some of these states also require emissions reporting.
Bans	Beginning June 1, 2022, in Minnesota, an owner or operator of a facility required to have an air emissions permit issued by the Pollution Control Agency may not use TCE at its permitted facility, including in any manufacturing, processing, or cleaning processes, except for few uses (Minn. Stat. 116.385). Beginning December 1, 2022, New York State prohibits the use of TCE as a vapor degreaser, an intermediate chemical to produce other chemicals, a refrigerant, or an extraction solvent or in any other manufacturing or industrial cleaning process or use (NY. Section 37-0119).

Table 4 – International Laws and Regulations

Country/Organization	Requirements and Restrictions
Canada	TCE is on the Canadian List of Toxic Substances (CEPA 1999 Schedule 1). TCE is also regulated for use and sale for solvent degreasing under *Solvent Degreasing Regulations (SOR/2003-283)* (*Canada Gazette*, Part II on August 13, 2003). The purpose of the regulation is to reduce releases of TCE into the environment from solvent degreasing facilities using more than 1000 kilograms of TCE per year. The regulation includes a market intervention by establishing tradable allowances for the use of TCE in solvent degreasing operations that exceed the 1000 kilograms threshold per year.
European Union	In 2011, TCE was added to Annex XIV (Authorisation list) of regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals). Entities that would like to use TCE needed to apply for authorization by October 2014, and those entities without an authorization must stop using TCE by April 2016. The European Chemicals Agency (ECHA) has received 24 applications for authorization from entities interested in using TCE beyond April 2016. Currently, 22 of these applications have been approved and 2 are currently under review (ECHA, Accessed September 30, 2022). TCE is classified as a carcinogen category 1B, and was added to the EU REACH restriction of substances classified as carcinogen category 1A or 1B under the EU Classification and Labeling regulation (among other characteristics) in 2009. The restriction bans the placing on the market or use of TCE as substance, as constituent of other substances, or, in mixtures for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than 0.1 % w/w (Regulation (EC) No 1907/2006 - REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)).

Country/Organization	Requirements and Restrictions
	Previous regulations, such as the Solvent Emissions Directive (Directive 1999/13/EC) introduced stringent emission controls of TCE.
Australia	In 2000, TCE was assessed (National Industrial Chemicals Notification and Assessment Scheme, NICNAS (2000), *Trichloroethylene*. Accessed April, 18 2017).
Japan Chemical Substances Control Law	TCE is regulated in Japan under the following legislation: -Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law; CSCL) -Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof -Industrial Safety and Health Act (ISHA) -Air Pollution Control Law -Water Pollution Control Law -Soil Contamination Countermeasures Act -Law for the Control of Household Products Containing Harmful Substances (National Institute of Technology and Evaluation (NITE) Chemical Risk Information Platform (CHIRP), Accessed April 18, 2017).
Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Japan, Latvia, New Zealand, People's Republic of China, Poland, Singapore, South Korea, Spain, Sweden, Switzerland, United Kingdom	Occupational exposure limits for TCE (GESTIS International limit values for chemical agents (Occupational exposure limits, OELs) database. Accessed April 18, 2017).

Table 5 – Regulatory and Non-Regulatory Exposure Limits

Both regulatory and non-regulatory worker exposure limits have been established for trichloroethylene (TCE) by OSHA, NIOSH, and the American Conference of Government Industrial Hygienists (ACGIH).

Source	Limit Type	Exposure Limit
OSHA PEL	PEL (8-hr TWA) [a]	100 ppm [b]
	STEL (15-minute TWA)	100 ppm
	Action Level (8-hr TWA)	50 ppm
NIOSH exposure limits	IDLH [c]	150 ppm
	Recommended Exposure Limit	Ca [d]
ACGIH TLV [e]	8-hr TWA	10 ppm

Notes:
[a] PEL= Permissible exposure limit; TWA= Time-weighted average
[b] Airborne concentration conversion factor for TCE is 537 mg/m^3 per ppm and the acceptable ceiling concentration is 200 ppm with an acceptable maximum peak of 300 ppm (with a maximum duration of 5 minutes in any 3-hour period) for an 8-hour shift (NIOSH, 2005).
[c] IDLH = Immediately dangerous to life or health. IDLH values are based on effects that might occur from a 30-minute exposure.
[d] The Recommended Exposure Limit notation "Ca" is for a potential occupational carcinogen. The NIOSH Pocket Guide website has detailed policy recommendations for chemicals with "Ca" notations (NIOSH, 2005).
[e] TLV = Threshold limit value

TCE Personal Protective Equipment Respirator Cost Breakdown

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Trichloroethylene (TCE) under TSCA Section 6(a)

Personal Protective Equipment Respirator System Per Worker Unit Cost Breakdown

OSHA's Respiratory Protection Standard (29 CFR 1910.134)[1] identifies several types of respirators and their Assigned Protection Factors (APFs). The APF denotes the level of respiratory protection that a given respirator is expected to provide employees. Table 1 presents example annualized unit costs estimates for respirators, respirator system components, training, fit testing, and medical clearance. Actual costs will vary for each rule depending on the affected industry and the analytical timeframe. Useful lives define the schedule used to discount each cost component before the estimates are annualized.

Respirators are organized by their corresponding APF. Unit cost estimates for individual respirator system components and kits are based on price data collected from retailer websites. Price data are averaged for component and kit unit cost estimates that incorporate the price of more than one product brand.

Table 1: Example Annualized PPE Unit Costs per Worker, by Respirator System

Respirator System	Component	Unit Cost	Useful Life	Annualized Unit Costs[1]	
				3%	7%
APF Factor 25					
SAR, Loose-Fitting Facepiece	Loose-Fitting Facepiece	$56.60	3	$19	$20
	Breathing Tube	$157.55	3	$54	$56
	Pump	$976.52	7	$152	$169
	Pump Installation	$53.45	7	$8	$9
	Pump Inlet Filter	$8.33	0.48	$16	$16
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Medical Evaluation Costs	$104.19	20	$7	$9
	Training Costs	$245.06	1	$230	$224
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$926	$932
APF Factor 50					
SAR, Continuous Flow Mode, Half Mask	Half Mask	$21.53	3	$7	$8
	Breathing Tube	$157.55	3	$54	$56
	Pump	$976.52	7	$152	$169
	Pump Installation	$53.45	7	$8	$9
	Pump Inlet Filter	$8.33	0.48	$16	$16
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$245.06	1	$230	$224
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$1,049	$1,052

[1] The Respiratory Protection Standard (29 CFR 1910.134), promulgated by OSHA, contains requirements for program administration, procedures for respirator selection, employee training, fit testing, medical evaluation, respirator use, APFs and Maximum Use Concentrations (MUCs), as well as other provisions.

APF Factor 1000					
SAR, Continuous Flow Mode, Full Facepiece	Full Facepiece	$194.14	3	$67	$69
	Pump (1/4 HP)	$976.52	7	$152	$169
	Breathing Tube and Airline Hose	$157.55	3	$54	$56
	Pump Installation	$53.45	7	$8	$9
	Pump Inlet Filter	$8.33	0.48	$16	$16
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$245.06	1	$230	$224
	Cleaning Costs	$395.52	0.008	$371	$361
	Total			$1,109	$1,113
SAR, Continuous Flow Mode, Helmet/Hood	Hood	$96.02	3	$33	$34
	Pump (3/4 HP)	$1,055.77	7	$165	$183
	Breathing Tube and Airline Hose	$157.55	3	$54	$56
	Pump Installation	$53.45	7	$8	$9
	Pump Inlet Filter	$12.53	0.48	$24	$24
	Pump Outlet Filter	$14.07	0.19	$69	$68
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$245.06	1	$230	$224
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$1,096	$1,100
APF Factor 10000					
SCBA, Positive-pressure Mode, Full Facepiece	Positive-pressure SCBA System (includes full facepiece):	$2,431.38	3	$835	$866
	Air Compressor	$5,776.86	16	$591	$667
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$490.12	1	$459	$448
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$2,398	$2,483
SCBA, Positive-pressure Mode, Helmet/Hood	Positive-pressure SCBA system (includes hood)	$2,660.77	3	913	948
	Air Compressor	$5,776.86	16	591	667
	Medical Evaluation Costs	$104.19	20	$7	$9
	Fit Test Costs	$144.44	1	$135	$132
	Training Costs	$490.12	1	$459	$448
	Cleaning Costs	$395.52	0.008	$371	$361
			Total	$2,476	$2,565

[1] Costs are annualized over a 20-year time period

Acronyms

- APF: Assigned Protection Factors
- APR: Air-Purifying Respirator
- OSHA: Occupational Safety and Health Administration
- PARP: Powered Air-Purifying Respirator
- PPE: Personal Protective Equipment
- SAR: Supplied-Air Respirator (SAR) or Airline Respirator
- SCBA: Self-Contained Breathing Apparatus

TCE Industry Sectors Potentially Affected by Rulemaking

EPA's SBAR Panel Outreach Meeting with Small Entity Representatives on Proposed Rulemaking for Trichloroethylene (TCE) under TSCA Section 6(a)

Industry Sectors with Small Entities Potentially Affected by the Rulemaking

Entities potentially regulated by this rulemaking to address the unreasonable risks from TCE include those entities relevant to the conditions of use of TCE that EPA evaluated, including domestic manufacturing, import, processing uses of TCE, repackaging and recycling, industrial and commercial uses of TCE (such as solvents for cleaning and degreasing, adhesives and sealants, lubricants and greases, functional fluids, paints and coatings, and in a variety of cleaning products), all but one consumer use (such as cleaners and degreasers, adhesives and sealants, paints and coatings, lubricants and greases, arts and crafts glue, and other miscellaneous uses), and disposal. Entities may include manufacturers (including importers), processors, formulators, industrial and commercial users, or distributors (such as retailers) of TCE or products containing TCE within the scope of this rulemaking.

Potentially affected entities will include both employer and non-employer firms and establishments identified within these sectors by the U.S. Census for each applicable North American Industry Classification System (NAICS) code. Since the Small Business Administration (SBA) size standard varies by NAICS code, they are also included in the table below. NAICS codes of potentially affected entities may include, but are not limited to:

NAICS	NAICS description	SBA Size Standard
111421	Nursery and Tree Production	$0.75 million
111422	Floriculture Production	$0.75 million
111998	All Other Miscellaneous Crop Farming	$0.75 million
112210	Hog and Pig Farming	$0.75 million
112990	All Other Animal Production	$0.75 million
211120	Crude Petroleum Extraction	1,250 employees
212111	Bituminous Coal and Lignite Surface Mining	1,250 employees
212210	Iron Ore Mining	750 employees
212312	Crushed and Broken Limestone Mining and Quarrying	750 employees
212321	Construction Sand and Gravel Mining	500 employees
212399	All Other Nonmetallic Mineral Mining	500 employees
221112	Fossil Fuel Electric Power Generation	750 employees
221113	Nuclear Electric Power Generation	750 employees
221117	Biomass Electric Power Generation	250 employees
221118	Other Electric Power Generation	250 employees
221121	Electric Bulk Power Transmission and Control	500 employees
221122	Electric Power Distribution	1,000 employees
221210	Natural Gas Distribution	1,000 employees
221310	Water Supply and Irrigation Systems	$27.5 million
221320	Sewage Treatment Facilities	$20.5 million
221330	Steam and Air-Conditioning Supply	$16.5 million
237310	Highway, Street, and Bridge Construction	$36.5 million
2383	Building Finish Contractors	$16.5 million
311119	Other Animal Food Manufacturing	500 employees

NAICS	NAICS description	SBA Size Standard
311211	Flour Milling	1,000 employees
311221	Wet Corn Milling	1,250 employees
311224	Soybean and Other Oilseed Processing	1,000 employees
311423	Dried and Dehydrated Food Manufacturing	750 employees
311611	Animal (except Poultry) Slaughtering	1,000 employees
311615	Poultry Processing	1,250 employees
311812	Commercial Bakeries	1,000 employees
311911	Roasted Nuts and Peanut Butter Manufacturing	750 employees
311919	Other Snack Food Manufacturing	1,250 employees
312120	Breweries	1,250 employees
312130	Wineries	1,000 employees
312140	Distilleries	1,000 employees
312230	Tobacco Manufacturing	1,500 employees
313210	Broadwoven Fabric Mills	1,000 employees
313230	Nonwoven Fabric Mills	750 employees
313310	Textile and Fabric Finishing Mills	1,000 employees
313320	Fabric Coating Mills	1,000 employees
314999	All Other Miscellaneous Textile Product Mills	500 employees
321113	Sawmills	500 employees
321114	Wood Preservation	500 employees
321211	Hardwood Veneer and Plywood Manufacturing	500 employees
321212	Softwood Veneer and Plywood Manufacturing	1,250 employees
321213	Engineered Wood Member (except Truss) Manufacturing	750 employees
321214	Truss Manufacturing	500 employees
321219	Reconstituted Wood Product Manufacturing	750 employees
321911	Wood Window and Door Manufacturing	1,250 employees
321912	Cut Stock, Resawing Lumber, and Planing	500 employees
321918	Other Millwork (including Flooring)	500 employees
321920	Wood Container and Pallet Manufacturing	500 employees
321992	Prefabricated Wood Building Manufacturing	500 employees
321999	All Other Miscellaneous Wood Product Manufacturing	500 employees
322110	Pulp Mills	750 employees
322121	Paper (except Newsprint) Mills	1,250 employees
322122	Newsprint Mills	750 employees
322130	Paperboard Mills	1,250 employees
322211	Corrugated and Solid Fiber Box Manufacturing	1,250 employees
322220	Paper Bag and Coated and Treated Paper Manufacturing	750 employees
323111	Commercial Printing (except Screen and Books)	500 employees
323113	Commercial Screen Printing	500 employees
324110	Petroleum Refineries	1,500 employees

NAICS	NAICS description	SBA Size Standard
324121	Asphalt Paving Mixture and Block Manufacturing	500 employees
324122	Asphalt Shingle and Coating Materials Manufacturing	750 employees
324191	Petroleum Lubricating Oil and Grease Manufacturing	750 employees
324199	All Other Petroleum and Coal Products Manufacturing	500 employees
325110	Petrochemical Manufacturing	1,000 employees
325120	Industrial Gas Manufacturing	1,000 employees
325130	Synthetic Dye and Pigment Manufacturing	1,000 employees
325180	Other Basic Inorganic Chemical Manufacturing	1,000 employees
325193	Ethyl Alcohol Manufacturing	1,000 employees
325194	Cyclic Crude, Intermediate, and Gum and Wood Chemical Manufacturing	1,250 employees
325199	All Other Basic Organic Chemical Manufacturing	1,250 employees
325211	Plastics Material and Resin Manufacturing	1,250 employees
325212	Synthetic Rubber Manufacturing	1,000 employees
325220	Artificial and Synthetic Fibers and Filaments Manufacturing	1,000 employees
325311	Nitrogenous Fertilizer Manufacturing	1,000 employees
325320	Pesticide and Other Agricultural Chemical Manufacturing	1,000 employees
325411	Medicinal and Botanical Manufacturing	1,000 employees
325412	Pharmaceutical Preparation Manufacturing	1,250 employees
325510	Paint and Coating Manufacturing	1,000 employees
325520	Adhesive Manufacturing	500 employees
325611	Soap and Other Detergent Manufacturing	1,000 employees
325612	Polish and Other Sanitation Good Manufacturing	750 employees
325613	Surface Active Agent Manufacturing	750 employees
325910	Printing Ink Manufacturing	500 employees
325992	Photographic Film, Paper, Plate and Chemical Manufacturing	1,500 employees
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing	500 employees
326113	Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing	750 employees
326122	Plastics Pipe, Pipe Fitting, and Unlaminated Profile Shape Manufacturing	750 employees
326140	Polystyrene Foam Product Manufacturing	1,000 employees
326150	Urethane and Other Foam Product (except Polystyrene) Manufacturing	750 employees
326199	All Other Plastics Product Manufacturing	750 employees
326211	Tire Manufacturing (except Retreading)	1,500 employees
326212	Tire Retreading	500 employees
326220	Rubber and Plastics Hoses and Belting Manufacturing	750 employees
326299	All Other Rubber Product Manufacturing	500 employees

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NAICS	NAICS description	SBA Size Standard
327310	Cement Manufacturing	1,000 employees
327320	Ready-Mix Concrete Manufacturing	500 employees
327390	Other Concrete Product Manufacturing	500 employees
327420	Gypsum Product Manufacturing	1,500 employees
331110	Iron and Steel Mills and Ferroalloy Manufacturing	1,500 employees
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel	1,000 employees
331221	Rolled Steel Shape Manufacturing	1,000 employees
331222	Steel Wire Drawing	1,000 employees
331315	Aluminum Sheet, Plate, and Foil Manufacturing	1,250 employees
331410	Nonferrous Metal (except Aluminum) Smelting and Refining	1,000 employees
331420	Copper Rolling, Drawing, Extruding, and Alloying	1,000 employees
331491	Nonferrous Metal (except Copper and Aluminum) Rolling, Drawing and Extruding	750 employees
331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum)	750 employees
331511	Iron Foundries	1,000 employees
331513	Steel Foundries (except Investment)	500 employees
331523	Nonferrous Metal Die-Casting Foundries	500 employees
332111	Iron and Steel Forging	750 employees
332112	Nonferrous Forging	750 employees
332114	Custom Roll Forming	500 employees
332117	Powder Metallurgy Part Manufacturing	500 employees
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)	500 employees
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing	750 employees
332216	Saw Blade and Handtool Manufacturing	750 employees
332321	Metal Window and Door Manufacturing	750 employees
332322	Sheet Metal Work Manufacturing	500 employees
332323	Ornamental and Architectural Metal Work Manufacturing	500 employees
332410	Power Boiler and Heat Exchanger Manufacturing	750 employees
332420	Metal Tank (Heavy Gauge) Manufacturing	750 employees
332431	Metal Can Manufacturing	1,500 employees
332439	Other Metal Container Manufacturing	500 employees
332510	Hardware Manufacturing	750 employees
332613	Spring Manufacturing	500 employees
332618	Other Fabricated Wire Product Manufacturing	500 employees
332710	Machine Shops	500 employees
332721	Precision Turned Product Manufacturing	500 employees

NAICS	NAICS description	SBA Size Standard
332722	Bolt, Nut, Screw, Rivet, and Washer Manufacturing	500 employees
332811	Metal Heat Treating	750 employees
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers	500 employees
332813	Electroplating, Plating, Polishing, Anodizing and Coloring	500 employees
332911	Industrial Valve Manufacturing	750 employees
332912	Fluid Power Valve and Hose Fitting Manufacturing	1,000 employees
332913	Plumbing Fixture Fitting and Trim Manufacturing	1,000 employees
332919	Other Metal Valve and Pipe Fitting Manufacturing	750 employees
332991	Ball and Roller Bearing Manufacturing	1,250 employees
332992	Small Arms Ammunition Manufacturing	1,250 employees
332993	Ammunition (except Small Arms) Manufacturing	1,500 employees
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing	1,000 employees
332996	Fabricated Pipe and Pipe Fitting Manufacturing	500 employees
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	750 employees
333111	Farm Machinery and Equipment Manufacturing	1,250 employees
333112	Lawn and Garden Tractor and Home Lawn and Garden Equipment Manufacturing	1,500 employees
333120	Construction Machinery Manufacturing	1,250 employees
333131	Mining Machinery and Equipment Manufacturing	500 employees
333132	Oil and Gas Field Machinery and Equipment Manufacturing	1,250 employees
333241	Food Product Machinery Manufacturing	500 employees
333242	Semiconductor Machinery Manufacturing	1,500 employees
333243	Sawmill, Woodworking, and Paper Machinery Manufacturing	500 employees
333244	Printing Machinery and Equipment Manufacturing	750 employees
333249	Other Industrial Machinery Manufacturing	500 employees
333314	Optical Instrument and Lens Manufacturing	500 employees
333316	Photographic and Photocopying Equipment Manufacturing	1,000 employees
333318	Other Commercial and Service Industry Machinery Manufacturing	1,000 employees
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing	500 employees
333414	Heating Equipment (except Warm Air Furnaces) Manufacturing	500 employees
333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing	1,250 employees
333511	Industrial Mold Manufacturing	500 employees
333514	Special Die and Tool, Die Set, Jig and Fixture Manufacturing	500 employees

NAICS	NAICS description	SBA Size Standard
333515	Cutting Tool and Machine Tool Accessory Manufacturing	500 employees
333517	Machine Tool Manufacturing	500 employees
333519	Rolling Mill and Other Metalworking Machinery Manufacturing	500 employees
333611	Turbine and Turbine Generator Set Units Manufacturing	1,500 employees
333612	Speed Changer, Industrial High-Speed Drive, and Gear Manufacturing	750 employees
333613	Mechanical Power Transmission Equipment Manufacturing	750 employees
333618	Other Engine Equipment Manufacturing	1,500 employees
333911	Pump and Pumping Equipment Manufacturing	500 employees
333912	Air and Gas Compressor Manufacturing	1,000 employees
333913	Measuring, Dispensing, and Other Pumping Equipment Manufacturing	750 employees
333921	Elevator and Moving Stairway Manufacturing	1,000 employees
333922	Conveyor and Conveying Equipment Manufacturing	500 employees
333923	Overhead Traveling Crane, Hoist, and Monorail System Manufacturing	1,250 employees
333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	750 employees
333991	Power-Driven Handtool Manufacturing	500 employees
333992	Welding and Soldering Equipment Manufacturing	1,250 employees
333993	Packaging Machinery Manufacturing	500 employees
333994	Industrial Process Furnace and Oven Manufacturing	500 employees
333995	Fluid Power Cylinder and Actuator Manufacturing	750 employees
333996	Fluid Power Pump and Motor Manufacturing	1,250 employees
333997	Scale and Balance Manufacturing	500 employees
333999	All Other Miscellaneous General Purpose Machinery Manufacturing	500 employees
334111	Electronic Computer Manufacturing	1,250 employees
334118	Computer Terminal and Other Computer Peripheral Equipment Manufacturing	1,000 employees
334220	Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing	1,250 employees
334310	Audio and Video Equipment Manufacturing	750 employees
334413	Semiconductor and Related Device Manufacturing	1,250 employees
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing	500 employees
334417	Electronic Connector Manufacturing	1,000 employees
334418	Printed Circuit Assembly (Electronic Assembly) Manufacturing	750 employees
334419	Other Electronic Component Manufacturing	750 employees

NAICS	NAICS description	SBA Size Standard
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing	1,250 employees
334512	Automatic Environmental Control Manufacturing for Residential, Commercial and Appliance Use	500 employees
334513	Instruments and Related Products Manufacturing for Measuring, Displaying, and Controlling Industrial Process Variables	750 employees
334515	Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals	750 employees
335110	Electric Lamp Bulb and Part Manufacturing	1,250 employees
335121	Residential Electric Lighting Fixture Manufacturing	750 employees
335122	Commercial, Industrial, and Institutional Electric Lighting Fixture Manufacturing	500 employees
335129	Other Lighting Equipment Manufacturing	500 employees
335220	Major Household Appliance Manufacturing	1,500 employees
335311	Power, Distribution, and Specialty Transformer Manufacturing	750 employees
335312	Motor and Generator Manufacturing	1,250 employees
335313	Switchgear and Switchboard Apparatus Manufacturing	1,250 employees
335314	Relay and Industrial Control Manufacturing	750 employees
335912	Primary Battery Manufacturing	1,000 employees
335921	Fiber Optic Cable Manufacturing	1,000 employees
335931	Current-Carrying Wiring Device Manufacturing	500 employees
335932	Noncurrent-Carrying Wiring Device Manufacturing	1,000 employees
335991	Carbon and Graphite Product Manufacturing	750 employees
336111	Automobile Manufacturing	1,500 employees
336112	Light Truck and Utility Vehicle Manufacturing	1,500 employees
336120	Heavy Duty Truck Manufacturing	1,500 employees
336211	Motor Vehicle Body Manufacturing	1,000 employees
336212	Truck Trailer Manufacturing	1,000 employees
336213	Motor Home Manufacturing	1,250 employees
336214	Travel Trailer and Camper Manufacturing	1,000 employees
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing	1,000 employees
336320	Motor Vehicle Electrical and Electronic Equipment Manufacturing	1,000 employees
336330	Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	1,000 employees
336340	Motor Vehicle Brake System Manufacturing	1,250 employees
336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	1,500 employees
336360	Motor Vehicle Seating and Interior Trim Manufacturing	1,500 employees

NAICS	NAICS description	SBA Size Standard
336370	Motor Vehicle Metal Stamping	1,000 employees
336390	Other Motor Vehicle Parts Manufacturing	1,000 employees
336411	Aircraft Manufacturing	1,500 employees
336412	Aircraft Engine and Engine Parts Manufacturing	1,500 employees
336413	Other Aircraft Part and Auxiliary Equipment Manufacturing7	1,250 employees
336414	Guided Missile and Space Vehicle Manufacturing	1,250 employees
336415	Guided Missile and Space Vehicle Propulsion Unit and Propulsion Unit Parts Manufacturing	1,250 employees
336419	Other Guided Missile and Space Vehicle Parts and Auxiliary Equipment Manufacturing	1,000 employees
336510	Railroad Rolling Stock Manufacturing	1,500 employees
336611	Ship Building and Repairing	1,250 employees
336612	Boat Building	1,000 employees
336991	Motorcycle, Bicycle, and Parts Manufacturing	1,000 employees
336992	Military Armored Vehicle, Tank, and Tank Component Manufacturing	1,500 employees
336999	All Other Transportation Equipment Manufacturing	1,000 employees
337110	Wood Kitchen Cabinet and Counter Top Manufacturing	750 employees
337121	Upholstered Household Furniture Manufacturing	1,000 employees
337122	Nonupholstered Wood Household Furniture Manufacturing	750 employees
337124	Metal Household Furniture Manufacturing	750 employees
337125	Household Furniture (except Wood and Metal) Manufacturing	750 employees
337127	Institutional Furniture Manufacturing	500 employees
337211	Wood Office Furniture Manufacturing	1,000 employees
337212	Custom Architectural Woodwork and Millwork Manufacturing	500 employees
337215	Showcase, Partition, Shelving, and Locker Manufacturing	500 employees
339112	Surgical and Medical Instrument Manufacturing	1,000 employees
339113	Surgical Appliance and Supplies Manufacturing	750 employees
339114	Dental Equipment and Supplies Manufacturing	750 employees
339910	Jewelry and Silverware Manufacturing	500 employees
339920	Sporting and Athletic Goods Manufacturing	750 employees
339991	Gasket, Packing, and Sealing Device Manufacturing	500 employees
339993	Fastener, Button, Needle and Pin Manufacturing	750 employees
339995	Burial Casket Manufacturing	1,000 employees
339999	All Other Miscellaneous Manufacturing	500 employees
42331	Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers	750 employees
423510	Metal Service Centers and Other Metal Merchant Wholesalers	200 employees
423830	Industrial Machinery and Equipment Merchant Wholesalers	100 employees
423840	Industrial Supplies Merchant Wholesalers	100 employees

NAICS	NAICS description	SBA Size Standard
423910	Sporting and Recreational Goods and Supplies Merchant Wholesalers	100 employees
423930	Recyclable Material Merchant Wholesalers	100 employees
423990	Other Miscellaneous Durable Goods Merchant Wholesalers	100 employees
424690	Other Chemical and Allied Products Merchant Wholesalers	150 employees
424710	Petroleum Bulk Stations and Terminals	200 employees
441110	New Car Dealers	200 employees
441120	Used Car Dealers	$27.0 million
443142	Electronics Stores	$32.5 million
444110	Home Centers	$41.5 million
451110	Sporting Goods Stores	$16.5 million
454310	Fuel Dealers	100 employees
481111	Scheduled Passenger Air Transportation	1,500 employees
484121	General Freight Trucking, Long-Distance, Truckload	$27.5 million
488190	Other Support Activities for Air Transportation	$32.5 million
488210	Support Activities for Rail Transportation	$15.0 million
493110	General Warehousing and Storage	$27.5 million
493190	Other Warehousing and Storage	$27.5 million
512110	Motion Picture and Video Production	$32.5 million
512290	Other Sound Recording Industries	$11.0 million
517311	Wired Telecommunication Carriers	1,500 employees
525990	Other Financial Vehicles	$32.5 million
531120	Lessors of Nonresidential Buildings (except Miniwarehouses)	$30 million
531190	Lessors of Other Real Estate Property	$16.5 million
541330	Engineering Services	$15.0 million
541380	Testing Laboratories	$15.0 million
541512	Computer Systems Design Services	$27.5 million
541620	Environmental Consulting Services	$15.0 million
541714	Research and Development in Biotechnology (Except Nanobiotechnology)	1,000 employees
541715	Research and Development in the Physical, Engineering, and Life Sciences (except Nanotechnology and Biotechnology)	1,000 employees
541720	Research and Development in the Social Sciences and Humanities	$20.5 million
541940	Veterinary Services	$7.5 million
551112	Offices of Other Holding Companies	$22 million
561499	All Other Business Support Services	$15.0 million
561599	All Other Travel Arrangement and Reservation Services	$20.5 million
561740	Carpet and Upholstery Cleaning Services	$5.5 million
561790	Other Services to Buildings and Dwellings	$7.5 million

NAICS	NAICS description	SBA Size Standard
561990	All Other Support Services	$11.0 million
562111	Solid Waste Collection	$38.5 million
562112	Hazardous Waste Collection	$38.5 million
562211	Hazardous Waste Treatment and Disposal	$38.5 million
562212	Solid Waste Landfill	$38.5 million
562213	Solid Waste Combustors and Incinerators	$38.5 million
562219	Other Nonhazardous Waste Treatment and Disposal	$38.5 million
562910	Remediation Services	$20.5 million
562920	Materials Recovery Facilities	$20.5 million
562998	All Other Miscellaneous Waste Management Services	$8 million
611110	Elementary and Secondary Schools	$11.0 million
611210	Junior Colleges	$20.5 million
611310	Colleges, Universities, and Professional Schools	$27.5 million
622110	General Medical and Surgical Hospitals	$38.5 million
624110	Child and Youth Services	$11.0 million
721110	Hotels (except Casino Hotels) and Motels	$38.5 million
811111	General Automotive Repair	$7.5 million
811112	Automotive Exhaust System Repair	$7.5 million
811113	Automotive Transmission Repair	$7.5 million
811118	Other Automotive Mechanical and Electrical Repair and Maintenance	$7.5 million
811121	Automotive Body, Paint and Interior Repair and Maintenance	$7.5 million
811122	Automotive Glass Replacement Shops	$11.0 million
811191	Automotive Oil Change and Lubrication Shops	$7.5 million
811198	All Other Automotive Repair and Maintenance	$7.5 million
811211	Consumer Electronics Repair and Maintenance	$7.5 million
811212	Computer and Office Machine Repair and Maintenance	$27.5 million
811213	Communication Equipment Repair and Maintenance	$11.0 million
811219	Other Electronic and Precision Equipment Repair and Maintenance	20.5 million
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance	$8 million
811411	Home and Garden Equipment Repair and Maintenance	$7.5 million
811412	Appliance Repair and Maintenance	$15.0 million
811430	Footwear and Leather Goods Repair	$7.5 million
811490	Other Personal and Household Goods Repair and Maintenance	$7.5 million
812210	Funeral Homes and Funeral Services	$7.5 million
812220	Cemeteries and Crematories	$20.5 million
812310	Coin-Operated Laundries and Drycleaners	$7.5 million
812320	Drycleaning and Laundry Services (except Coin-Operated)	$5.5 million

NAICS	NAICS description	SBA Size Standard
812332	Industrial Launderers	$32.5 million
812910	Pet Care (except Veterinary) Services	$7.5 million
921110	Executive Offices	Small business size standards are not established for these Sectors. Establishments in the Public Administration Sectors are Federal, state, and local government agencies which administer and oversee government programs and activities that are not performed by private establishments.
921120	Legislative Bodies	
921190	Other General Government Support	
922140	Correctional Institutions	
922190	Other Justice, Public Order, and Safety Activities	
924110	Administration of Air and Water Resource and Solid Waste Management Programs	
924120	Administration of Conservation Programs	
926120	Regulation and Administration of Transportation Programs	
927110	Space Research and Technology	
928110	National Security	
Source: U.S. Small Business Administration Table of Small Business Size Standards, available at: https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf		

TCE Existing Chemical Exposure Limit (Immunotoxicity) for Occupational Use

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SUBJECT: Existing Chemical Exposure Limit (ECEL) for Occupational Use of Trichloroethylene

FROM: Yvette Selby-Mohamadu *Yvette Selby-Mohamadu*
Branch Chief, Existing Chemicals Risk Assessment Division

THRU: Andrew J. R. Gillespie, Ph. D *Andrew JR Gillespie*
Acting Director, Existing Chemicals Risk Assessment Division

TO: Joel Wolf
Branch Chief, Existing Chemicals Risk Management Division

DATE: February 22, 2021

EPA has developed an 8-hour existing chemical exposure limit (ECEL) in support of risk management efforts on trichloroethylene under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the ECEL to be 4.0 ppb (0.021 mg/m3) for inhalation exposures to trichloroethylene as an 8-hour time-weighted average (TWA) and for use in workplace settings (see Appendix A) based on the chronic non-cancer occupational human equivalent concentration (HEC99) for autoimmunity. EPA has determined, as a matter of risk management policy, that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health resulting from inhalation exposures in an occupational setting for those conditions of use identified as presenting unreasonable risk in the Risk Evaluation for Trichloroethylene (U.S. EPA, 2020) under TSCA.

EPA expects that at the chronic non-cancer ECEL of 4.0 ppb (0.021 mg/m3), a worker or occupational non-user (ONU) is also protected against mortality due to immunosuppression resulting from acute occupational exposure. In addition, this ECEL protects against excess risk of cancer above the 1×10^{-4} benchmark resulting from lifetime exposure if ambient exposures are kept below this ECEL.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as both an 8-hour TWA and an acceptable ceiling concentration for trichloroethylene (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1000TABLEZ2). However, as noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970 and have not been updated since that time." EPA's ECEL is a lower value and is based on newer information and analysis, from the 2020 Risk Evaluation for Trichloroethylene.

Published NIOSH/OSHA/EPA methods were identified and the ECEL is within the limit of detection (LOD) of some of the methods identified in Appendix B.

Appendix A: ECEL and Other Exposure Limit Calculations

This appendix presents the calculations used to estimate the ECEL and other exposure limits used for comparison. The resulting ECEL value was rounded. The values used in the equations are included in the Final Risk Evaluation for Trichloroethylene (U.S. EPA, 2020).

Chronic Non-Cancer ECEL

The 8-hour ECEL is the concentration that EPA determined would indicate no unreasonable risk of injury to human health from chronic inhalation exposures in an occupational setting for the endpoints that are the basis for the TSCA unreasonable risk determination. The ECEL was calculated for (the chronic non-cancer occupational human equivalent concentration (HEC99) for autoimmunity) as the concentration at which the chronic MOE would equal the benchmark MOE for chronic occupational exposures with the following equation:

$$\mathrm{ECEL}_{\mathrm{inhal,occupational}} = \frac{\mathrm{HEC}_{\mathrm{chronic,occupational}}}{Benchmark\ MOE_{chronic}} * \frac{\mathrm{AT}_{\mathrm{POD\ chronic}}}{ED * EF * WY} =$$

$$\frac{0.083\ \mathrm{ppm}}{30} * \frac{8h/d * 365d/y * 40\ y}{8h/d * 250d/y * 40\ y} = 0.0040\ \mathrm{ppm} = 4.0\ \mathrm{ppb}$$

$$ECEL\ \left(\frac{\mathrm{mg}}{\mathrm{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume} = \frac{0.0040\ \mathrm{ppm} * 131.39 \frac{g}{mol}}{24.45 \frac{L}{mol}} = 0.021\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

Molar Volume	=	24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C
MW	=	Molecular weight of TCE (131.39 g/mole)

Acute Non-Cancer Exposure Limit

The acute occupational exposure limit (EL_{acute}) was calculated as the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures using the following equation:

$$\mathrm{EL}_{\mathrm{acute}} = \frac{\mathrm{HEC}_{\mathrm{acute,occupational}}}{Benchmark\ MOE_{acute}} * \frac{\mathrm{AT}_{\mathrm{PODacute}}}{ED} = \frac{2.34\ \mathrm{ppm}}{10} * \frac{8h/d}{8h/d} = 0.23\ \mathrm{ppm} = 1.2\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Lifetime Cancer Exposure Limit

The EL_{cancer} is the concentration at which the extra cancer risk is equivalent to the benchmark cancer risk of 1×10^{-4}:

$$\mathrm{EL}_{\mathrm{cancer}} = \frac{Benchmark_{Cancer}}{IUR} * \frac{AT_{IUR}}{ED * EF * WY} = \frac{1X10^{-4}}{2.2 \times 10^{-2}\ per\ ppm} * \frac{24h/d * 365d/y * 78y}{8h/d * 250d/y * 40y} =$$

$$0.039\ \mathrm{ppm} = 0.21\ \frac{\mathrm{mg}}{\mathrm{m}^3}$$

Where:

$AT_{PODchronic}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, chronic occupational risk, based on study conditions and/or HEC adjustments (8 hrs/day for 365 days/yr) and assuming the number of years matches the high-end working years (WY, 40 yrs) for a worker (RE Section 2.3.1.2.4 and Table 2-17).
$AT_{PODacute}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, acute occupational risk, based on study conditions and/or any HEC adjustments (8hrs/day)
AT_{IUR}	=	Averaging time for the cancer IUR, based on study conditions and any adjustments (24 hrs/day for 365 days/yr) and averaged over a lifetime (78 yrs) (RE Section 2.3.1.2.4 and Table 2-17)
Benchmark MOE_{acute}	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 10 (RE Table 3-16)
Benchmark $MOE_{chronic}$	=	Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 30 (RE Table 3-16)
$Benchmark_{Cancer}$	=	Benchmark for excess lifetime cancer risk ($1x10^{-4}$)
ECEL	=	Existing chemical exposure limit (mg/m^3 or ppm)
EL_{acute}	=	Exposure limit based on acute immunosuppression
EL_{cancer}	=	Exposure limit based on excess cancer risk
ED	=	Exposure duration (8 hrs/day), (RE Table 2-17 and Appendix M)
EF	=	Exposure frequency (250 days/yr), (RE Table 2-17 and Appendix M)
$HEC_{acute\ or\ chronic,\ occupational}$	=	Human equivalent concentration for acute or chronic occupational exposure scenarios (RE Table 3-16)
IUR	=	Inhalation unit risk (per ppm) (RE Table 3-15)
WY	=	Working years per lifetime at the 95th percentile (40 yrs) (RE Table 2-17)

Unit conversion:

1 ppm = 5.37 mg/m^3 (based on molecular weight of 131.39.8 g/mol for TCE and molar volume of 24.45 L/mol at 25^{o}C and 1 atm pressure) $ECEL\left(\frac{\text{mg}}{\text{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume}$

References

U.S. Environmental Protection Agency. 2020. Risk Evaluation for Trichloroethylene (TCE) CASRN: 79-01-6. EPA-740-R1-8008. Office of Chemical Safety and Pollution Prevention. November 2020. Available at: EPA-HQ-OPPT-2019-0500-0113.

U.S. Environmental Protection Agency. 2002. A Review of the Reference Dose and Reference Concentration Processes. Final Report. EPA/630/P-02/002F. Prepared for the Risk Assessment Forum. December.

Appendix B: Summary of Air Sampling Analytical Methods Identified

EPA conducted a search to identify relevant NIOSH/OSHA/EPA analytical methods used to monitor for the presence of trichloroethylene in air (see Table 1). The sources used for the search included the following:

1) NIOSH Manual of Analytical Methods (NMAM); 5th Edition
   - URL: https://www.cdc.gov/niosh/nmam/default.html
2) NIOSH NMAM 4th Edition
   - URL: https://www.cdc.gov/niosh/docs/2003-154/default.html
3) OSHA Index of Sampling and Analytical Methods
   - URL: https://www.osha.gov/dts/sltc/methods/
4) EPA Environmental Test Method and Monitoring Information
   - https://www.epa.gov/emc/epa-websites-environmental-test-method-and-monitoring-information

Table 1: Limit of detection (LOD) summary for air sampling analytical methods identified.

Air Sampling Analytical Methods	Year Published	LOD[a]	Notes	Source
NIOSH Method 8300 https://www.cdc.gov/niosh/docs/2014-151/pdfs/methods/3800.pdf	2016	0.43 ppm	Method reports approximate LOD for an absorption length of 10 m.	NIOSH Manual of Analytical Methods (NMAM); 5th Edition https://www.cdc.gov/niosh/nmam/default.html
NIOSH Method 1022, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/1022.pdf	1994	60 ppb	Method reports estimated LOD as 0.01 mg per sample, with a maximum sample of 30 L.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
NIOSH Method 3701, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/3701.pdf	1994	0.1 ppm	Method reports estimated LOD as 0.1 ppm for a 1 mL injection.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
OSHA Method 1001 https://www.osha.gov/dts/sltc/methods/mdt/mdt1001/1001.html	1999	3.7 or 18 ppb	Method reports LOD of overall procedure as 3.7 ppb for charcoal tubes and 18 ppb for SKC 575-002 Samplers.	OSHA Index of Sampling and Analytical Methods https://www.osha.gov/dts/sltc/methods/
EPA Method TO-14A https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-14ar.pdf	1999	14 ppb	Estimated LOD based on 1 microliter sample volume (Table B-1).	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html
EPA Method TO-15 https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-15r.pdf	1999	≤0.5 ppb	To qualify under Compendium Method TO-15, the method detection limit must ≤0.5 ppbv. This method uses ppbv, but LODs for other methods listed here are also understood to be on a volume basis. For	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html

Air Sampling Analytical Methods	Year Published	LOD[a]	Notes	Source
			consistency, the LOD for this method is listed as ≤0.5 ppb.	
EPA Method TO-17	1999	≤0.5 ppb	To qualify under Compendium Method TO-17, the method detection limit must be ≤0.5 ppb.	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html

ppm = parts per million; ppb = parts per billion; ppt = parts per trillion
[a] EPA has included all relevant NIOSH/OSHA/EPA methods that it identified, including those methods with an LOD above the ECEL.

TCE Existing Chemical Exposure Limit (Developmental Toxicity) for Occupational Use

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SUBJECT: Second Existing Chemical Exposure Limit (ECEL) (Developmental Toxicity) for Occupational Use of Trichloroethylene

FROM: Keith Jacobs
Team Lead, Risk Assessment Branch 5, Existing Chemicals Risk Assessment Division

THRU: Sheila Healy, Ph.D
Chief, Risk Assessment Branch 5, Existing Chemicals Risk Assessment Division

Jeff Morris
Director, Existing Chemicals Risk Assessment Division

TO: Joel Wolf
Chief, Risk Management Branch 1, Existing Chemicals Risk Management Division

DATE: March 31, 2022

On February 22, 2021, EPA developed an 8-hour existing chemical exposure limit (ECEL) for trichloroethylene based on the immunotoxicity endpoint (4.0 ppb (0.021 mg/m^3)) characterized in the November 2020 TSCA Risk Evaluation for Trichloroethylene. In addition, EPA has developed an 8-hour ECEL for the most sensitive acute and chronic non-cancer health endpoint (developmental toxicity) in support of risk management efforts on trichloroethylene under TSCA section 6(a), 15 U.S.C. §2605. EPA calculated the ECEL to be 1.1 ppb (0.0059 mg/m^3) for inhalation exposures to trichloroethylene as an 8-hour time-weighted average (TWA) and for use in workplace settings (see Appendix A) based on the acute non-cancer occupational human equivalent concentration (HEC99) for congenital heart defects.

EPA expects that at the acute non-cancer ECEL of 1.1 ppb (0.0059 mg/m^3) a worker or occupational non-user (ONU) is also protected against congenital heart defects resulting from chronic occupational exposure. In addition, this ECEL protects against excess risk of cancer above the 1×10^{-4} benchmark resulting from lifetime exposure if ambient exposures are kept below this ECEL.

The Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) as both an 8-hour TWA and an acceptable ceiling concentration for trichloroethylene (https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1000TABLEZ2). However, as noted on OSHA's website, "OSHA recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970 and have not been updated since that time." EPA's ECEL is a lower value and is based on newer information and analysis, from the 2020 Risk Evaluation for Trichloroethylene.

Published NIOSH/OSHA/EPA methods were identified and the ECEL is within the limit of detection (LOD) of some of the methods identified in Appendix B.

Appendix A: ECEL and Other Exposure Limit Calculations

This appendix presents the calculations used to estimate the ECEL and other exposure limits used for comparison. The resulting ECEL value was rounded. The values used in the equations are included in the Final Risk Evaluation for Trichloroethylene (U.S. EPA, 2020).

Acute Non-Cancer ECEL

This 8-hour ECEL is the concentration that EPA calculated for (the acute non-cancer occupational human equivalent concentration (HEC99) for congenital heart defects) the concentration at which the acute MOE would equal the benchmark MOE for acute occupational exposures with the following equation:

$$\mathrm{EL_{acute}} = \frac{\mathrm{HEC_{acute,occupational}}}{Benchmark\ MOE_{acute}} * \frac{\mathrm{AT_{PODacute}}}{ED} = \frac{0.0037\ \mathrm{ppm}}{10} * \frac{\frac{24h}{d}}{\frac{8h}{d}} = 0.0011\ \mathrm{ppm} = 1.1\ \mathrm{ppb}$$

$$ECEL\ \left(\frac{\mathrm{mg}}{\mathrm{m^3}}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume} = \frac{0.0011\ \mathrm{ppm} * 131.39 \frac{g}{mol}}{24.45 \frac{L}{mol}} = 0.0059\ \frac{\mathrm{mg}}{\mathrm{m^3}}$$

Where:

Molar Volume	=	24.45 L/mol, the volume of a mole of gas at 1 atm and 25 °C
MW	=	Molecular weight of TCE (131.39 g/mole)

Chronic Non-Cancer Exposure Limit

The chronic occupational exposure limit ($\mathrm{EL_{chronic}}$) was calculated as the concentration at which the chronic MOE would equal the benchmark MOE for chronic occupational exposures using the following equation:

$$\mathrm{ECEL_{inhal,occupational}} = \frac{\mathrm{HEC_{chronic,occupational}}}{Benchmark\ MOE_{chronic}} * \frac{\mathrm{AT_{POD\ chronic}}}{ED * EF * WY} =$$

$$\frac{0.0037\ \mathrm{ppm}}{10} * \frac{24h/d * 365d/y * 40\ y}{8h/d * 250d/y * 40\ y} = 0.0016\ \mathrm{ppm} = 1.6\ \mathrm{ppb} = 0.0086\ \frac{\mathrm{mg}}{\mathrm{m^3}}$$

Lifetime Cancer Exposure Limit

The $\mathrm{EL_{cancer}}$ is the concentration at which the extra cancer risk is equivalent to the benchmark cancer risk of $1\mathrm{x}10^{-4}$:

$$\mathrm{EL_{cancer}} = \frac{Benchmark_{Cancer}}{IUR} * \frac{AT_{IUR}}{ED * EF * WY} = \frac{1X10^{-4}}{2.2 \times 10^{-2}\ per\ ppm} * \frac{24h/d * 365d/y * 78y}{8h/d * 250d/y * 40y} =$$

$$0.039\ \mathrm{ppm} = 0.21\ \frac{\mathrm{mg}}{\mathrm{m^3}}$$

Where:

$AT_{PODacute}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, acute occupational risk, based on study conditions and/or any HEC adjustments (24hrs/day)
$AT_{PODchronic}$	=	Averaging time for the POD/HEC used for evaluating non-cancer, chronic occupational risk, based on study conditions and/or HEC adjustments (24 hrs/day for 365 days/yr) and assuming the number of years matches the high-end working years (WY, 40 yrs) for a worker (RE Section 2.3.1.2.4 and Table 2-17).
AT_{IUR}	=	Averaging time for the cancer IUR, based on study conditions and any adjustments (24 hrs/day for 365 days/yr) and averaged over a lifetime (78 yrs) (RE Section 2.3.1.2.4 and Table 2-17)
Benchmark MOE_{acute}	=	Acute non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 10 (RE Table 3-13)
Benchmark $MOE_{chronic}$	=	Chronic non-cancer benchmark margin of exposure, based on the total uncertainty factor (UF) of 10 (RE Table 3-14)
$Benchmark_{Cancer}$	=	Benchmark for excess lifetime cancer risk ($1x10^{-4}$)
ECEL	=	Existing chemical exposure limit (mg/m^3 or ppm)
$EL_{chronic}$	=	Exposure limit based on congenital heart defects from chronic exposure
EL_{cancer}	=	Exposure limit based on excess cancer risk
ED	=	Exposure duration (8 hrs/day), (RE Table 2-17 and Appendix M)
EF	=	Exposure frequency (250 days/yr), (RE Table 2-17 and Appendix M)
$HEC_{acute\ or\ chronic,\ occupational}$	=	Human equivalent concentration for acute or chronic occupational exposure scenarios (RE Table 3-13 and 3-14)
IUR	=	Inhalation unit risk (per ppm) (RE Table 3-15)
WY	=	Working years per lifetime at the 95th percentile (40 yrs) (RE Table 2-17)

Unit conversion:

1 ppm = 5.37 mg/m^3 (based on molecular weight of 131.39.8 g/mol for TCE and molar volume of 24.45 L/mol at 25°C and 1 atm pressure) $ECEL\left(\frac{\mathrm{mg}}{\mathrm{m}^3}\right) = \frac{ECEL\ ppm * MW}{Molar\ Volume}$

References

U.S. Environmental Protection Agency. 2020. Risk Evaluation for Trichloroethylene (TCE) CASRN: 79-01-6. EPA-740-R1-8008. Office of Chemical Safety and Pollution Prevention. November 2020. Available at: EPA-HQ-OPPT-2019-0500-0113.

U.S. Environmental Protection Agency. 2002. A Review of the Reference Dose and Reference Concentration Processes. Final Report. EPA/630/P-02/002F. Prepared for the Risk Assessment Forum. December.

Appendix B: Summary of Air Sampling Analytical Methods Identified

EPA conducted a search to identify relevant NIOSH/OSHA/EPA analytical methods used to monitor for the presence of trichloroethylene in air (see Table 1). The sources used for the search included the following:

1) NIOSH Manual of Analytical Methods (NMAM); 5th Edition
   - URL: https://www.cdc.gov/niosh/nmam/default.html
2) NIOSH NMAM 4th Edition
   - URL: https://www.cdc.gov/niosh/docs/2003-154/default.html
3) OSHA Index of Sampling and Analytical Methods
   - URL: https://www.osha.gov/dts/sltc/methods/
4) EPA Environmental Test Method and Monitoring Information
   - https://www.epa.gov/emc/epa-websites-environmental-test-method-and-monitoring-information

Table 1: Limit of detection (LOD) summary for air sampling analytical methods identified.

Air Sampling Analytical Methods	Year Published	LOD[a]	Notes	Source
NIOSH Method 8300 https://www.cdc.gov/niosh/docs/2014-151/pdfs/methods/3800.pdf	2016	0.43 ppm	Method reports approximate LOD for an absorption length of 10 m.	NIOSH Manual of Analytical Methods (NMAM); 5th Edition https://www.cdc.gov/niosh/nmam/default.html
NIOSH Method 1022, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/1022.pdf	1994	60 ppb	Method reports estimated LOD as 0.01 mg per sample, with a maximum sample of 30 L.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
NIOSH Method 3701, Issue 2 https://www.cdc.gov/niosh/docs/2003-154/pdfs/3701.pdf	1994	0.1 ppm	Method reports estimated LOD as 0.1 ppm for a 1 mL injection.	NIOSH NMAM 4th Edition https://www.cdc.gov/niosh/docs/2003-154/default.html
OSHA Method 1001 https://www.osha.gov/dts/sltc/methods/mdt/mdt1001/1001.html	1999	3.7 or 18 ppb	Method reports LOD of overall procedure as 3.7 ppb for charcoal tubes and 18 ppb for SKC 575-002 Samplers.	OSHA Index of Sampling and Analytical Methods https://www.osha.gov/dts/sltc/methods/
EPA Method TO-14A https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-14ar.pdf	1999	14 ppb	Estimated LOD based on 1 microliter sample volume (Table B-1).	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html
EPA Method TO-15 https://www3.epa.gov/ttn/amtic/files/ambient/airtox/to-15r.pdf	1999	≤0.5 ppb	To qualify under Compendium Method TO-15, the method detection limit must ≤0.5 ppbv. This method uses ppbv, but LODs for other methods listed here are also understood to be on a volume basis. For consistency, the LOD	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html

Air Sampling Analytical Methods	**Year Published**	**LOD[a]**	**Notes**	**Source**
			for this method is listed as ≤0.5 ppb.	
EPA Method TO-17	1999	≤0.5 ppb	To qualify under Compendium Method TO-17, the method detection limit must be ≤0.5 ppb.	EPA Air Toxics – Monitoring Methods https://www3.epa.gov/ttn/amtic/airtox.html
ppm = parts per million; ppb = parts per billion; ppt = parts per trillion **[a] EPA has included all relevant NIOSH/OSHA/EPA methods that it identified, including those methods with an LOD above the ECEL.**				

APPENDIX B: Written Comments Submitted by Small Entity Representatives following the Pre-Panel and Panel Outreach Meetings

Appendix B1 is a compilation of all written comments submitted by SERs following the Pre-Panel Outreach meeting on October 28, 2022, contained in a separate attachment. One SER submitted written comments: Industrial Compliance Solutions.

Appendix B2 is a compilation of all written comments submitted by SERs following the Panel Outreach meeting on January 31, 2023, contained in a separate attachment. One SER submitted written comments: Industrial Compliance Solutions.

Appendix B1: Written Comments Submitted by Small Entity Representatives following the October 28, 2022 Pre-Panel Outreach Meeting

Table of Contents

ICS represents multiple business sectors including Aerospace, Metal Manufacturing and Metal Finishing and Industrial/Commercial Automotive repair and Industrial/Commercial Automotive materials warehousing and distribution. The answers provide here in have been broken out by business type for clarity. Answers to the questions are presented as bold print.

1) Your business *(All SERs)*

a. How does your organization use TCE? How much TCE does your organization use?
b. Does your organization still use TCE? What is the trend of use? For example, has your organization increased use of TCE? Has use remained constant? Is use decreasing? Is your organization phasing out the use of TCE?
c. Can you describe the specific use, as well as the workplace and workplace setting where TCE is used?
d. Why does your organization use TCE? What function does TCE provide?
e. Where is your organization in the supply chain? (e.g., are you a processor – formulating another product with TCE, a distributor, or final user of TCE in an application?). Do you provide finished product to another small entity or to a large entity?
f. For what industries or applications do you provide products or services for? (e.g., aerospace, electronics, military, automotive, optics, museums/art restorations, academic, commercial laboratory, consumers, other) Can you provide a NAICs code for the products/services you provide?
g. For what process are you using TCE? (can be more than one, such as cleaning, drying, inspection, etc.)
h. If TCE were not available, how would you adjust and what would the impacts be on your business? What specific barriers would your business face in switching to an alternative?
i. If the concentration of TCE in a product was limited, would this impact the efficacy of the product and/or increase the duration of use or exposure. For which particular uses?
j. What are the benefits to your business of TCE? Are there specific benefits for small businesses using TCE as compared to benefits for larger businesses?

Aerospace (SIC 3471)

As a final user of TCE in a manufacturing setting that provides services to Prime aerospace customers, TCE is used in a solvent degreaser. The Aerospace industry is often driven by Mil Specifications which tightly control the means and methods utilized to control the outcome from a process. Many of our customers (Primes) issue their own specification which are directed by, in many cases, the DOD. The Prime specifications specifically state "Degreasing Solvent. Perchloroethylene conforming to ASTM D 4081 or ASTM D 4376 or Trichloroethylene conforming to ASTM D 4080." The process to revise a controlled specification should considered during the regulatory process the specification revisions can take a significant amount of time.

TCE is still in use. While Equipment and Inventory Management methods has decreased usage, a phase out is not possible without changes to specifications from customers. Alternatives have been evaluated and potential via alternatives have been identified however the alternatives are currently very expensive.

If the concentration of TCE in a product was limited the product would most likely not be compliant with the specifications which are driving its use. The reason it is currently being used is because it is so effective at cleaning and degreasing. Alternatives tested have increased cycle times and the replacements come with their own set of hazards including flammability and toxicity.

If TCE was not available it would have major implications to this industry up to and including the inability to operate as many uses are driven be dictated specifications under the control of others which take great effort, expense, and time to modify and/or change.

Metals Manufacturing (3411)

As a final user of TCE in a manufacturing setting that provides services to large packaging entities, TCE is used as an additive to coating, a diluent in the coating application or a cleanup solvent. TCE is regulated under the Clean Air Act and facilities must account for the usage on the material and subsequent emissions from any process using materials designated as Hazardous Air Pollutants or VOCS. The usage and emissions are controlled using VOC destruction technologies and require continuous monitoring as defined in site specific permit requirements.

TCE is being replaced with alternate chemistries by the coating manufacturers in part because of regulatory pressures and the reduction in supply. There are viable alternatives already in place and most of the coatings have been reformulated to exclude the chlorinated compounds.

Industrial/Commercial Automotive repair (7699)

As a final user of TCE in a manufacturing setting that provides services to various sized companies customers, TCE and PCE are found in products used for brake cleaning and parts degreasing. Most of these products are applied using aerosol methods and are used as needed. The products are also offered for purchase to consumers for use in home and garage repair application.

TCE and PCE are found in products used for brake cleaning and parts degreasing. Most of these products are applied using aerosol methods and are used as needed. The chlorinated cleaners and degreasers are more effective than the non-chlorinated options. Use of the chlorinated products has been restricted to applications where alternatives are not working as intended so usage has declined, however, demand remains steady for the chlorinated degreasers.

If the concentration of TCE in a product was limited the product would most likely not be compliant with the specifications which are driving its use. The reason it is currently being used is because it is so effective at cleaning and degreasing. Alternatives tested have increased cycle times and the replacements come with their own set of hazards including flammability and toxicity.

If TCE was not available, it would have moderate implications as it would increase cycle times to process work and could have impacts on the quality of the services provided. It would take time to develop viable alternatives to reduce impacts to process times and quality.

Industrial/Commercial Automotive materials warehousing and distribution (5013)

As a supplier of products that contain chlorinated solvents to consumers, TCE is used in TCE and PCE are found in products used for brake cleaning and parts degreasing. Most of these products are applied using aerosol methods and are used as needed. The products are offered for purchase to consumers for use in home and garage repair application.

TCE and PCE are found in products used for brake cleaning and parts degreasing. Most of these products are applied using aerosol methods and are used as needed. The products are offered for purchase to consumers for use in home and garage repair application. While both chlorinated and non-chlorinated products are offered to consumers, the chlorinated products are chosen more often than the non-chlorinated alternatives.

If the concentration of TCE in a product was limited the product would most likely not be compliant with the specifications which are driving its use. The reason it is currently being used is because it is so effective at cleaning and degreasing. Alternatives tested have increased cycle times and the replacements come with their own set of hazards including flammability and toxicity.

If TCE was not available, it could have moderate to major implications as it would current inventories would need to be either removed (major) from inventory and/or cycled out (moderate) of inventory.

2) Workplace exposure *(All SERs)*

a. How many employees, and what fraction of your employees, are exposed to TCE, and for how long (days/year and hours/day)?
b. If you use a product containing TCE, what product do you use and what is the concentration of TCE in the product?
c. What work activities result in worker exposure to TCE? And what type of exposure (dermal, inhalation)?
d. For each activity, in what physical state and concentration is TCE?
e. Have you taken industrial hygiene monitoring data? If so, what was typical and high-end exposure to TCE?
f. What engineering controls are used to minimize exposure to TCE? How effective are those controls?
    i. Would it be feasible to use additional engineering controls to minimize exposure to TCE? If so, what might those engineering controls be?
    ii. What is your experience with:

- Installing or updating ventilation and local exhaust, or
- Equipment changes to reduce exposure or cross-contamination?

g. What administrative controls and training do you use to minimize exposure to TCE? Do you use training to minimize exposure to TCE?
h. Is personal protective equipment (PPE) regularly worn by workers to minimize exposure to TCE?
    i. If yes, could you provide more information regarding the type of PPE that is used? And would it be feasible to use PPE that provided a level of protection beyond what you are already using? Do you have experience with air supplied respirators? Do you have experience with other PPE?
    ii. If no, would it be feasible to have workers wear PPE to minimize their exposure to TCE? And what PPE would be feasible for workers to wear? Are their workers or processes where the use of PPE would be impractical?
i. How many employees are located in the same room where the work activities related to TCE are taking place but not necessarily handling TCE or TCE-containing products?
j. What do you do to comply with OSHA standards for TCE?

Aerospace (SIC 3471)

Employee exposure is controlled by a combination of access restriction, engineering controls and work practices to minimize emissions and exposure to vapors. Two employees are trained to work degreaser operations which are conducted on an as needed basis based on production. Potential Exposure includes inhalation, and dermal contact both of which are controlled using PPE. The degreaser has an extended free board and is located in a draft free environment. The hoist used to feed the degreaser is maintained at consistent
speed to control draft to the vapor zone. The air permit requires freeboard Refrigerated Chiller Maximum Temperature at Center of Air Blanket 244.53 F and a Superheated Vapor System with a Minimum Temperature at Center of Superheated Vapor Zone (0 f): 198.0 F. Work practices include the cover of the solvent cleaning machine being kept in place during the idling mode, and during the downtime mode unless either the solvent has been removed from the machine or maintenance or monitoring is being performed that requires the cover to not be in place. The parts baskets or the parts being cleaned in an open-top batch vapor cleaning machine not occupying more than 50 percent of the solvent/ air interface area unless the parts baskets or parts are introduced at a speed of 0.9 meters per minute (3 feet per minute) or less. Any spraying operations being done within the vapor zone or within a section of the solvent cleaning machine that is not directly exposed to the ambient air (i.e., a baffled or enclosed area of the solvent cleaning machine). Racking parts to allow complete drainage. Moving parts in and out of the degreasing unit at less than 3.3 meters per minute (11feet per minute); Holding the parts in the vapor zone at least 30 seconds or until condensation ceases, whichever is longer; Tipping out any pools of solvent on the cleaned parts before removal from the vapor zone; and allowing parts to dry within the degreasing unit for at least 1 5 seconds or until visually dry, whichever is longer.

The facility is equipped with ventilation and exhaust associated with the spray

operations which do not use TCE. These systems were recently upgraded and required a significant amount of time and money for engineering the upgrades.

Annual training is conducted for the degreaser operators as required by the NESAP regulations. The facility currently has a respirator protection program and utilizes full and half face respirators with organic vapor cartridges depending on application. Air supplied respirators would restrict movement and create potential safety issues for the degreaser operators when maneuvering large heavy parts. The current method of production would need to be reengineered to eliminate the hazards associated with the introduction of SAR's.

Industrial/Commercial Automotive repair (7699)

TCE exposure is brief, sporadic, and dependent on production. The TCE contained material is applied via aerosol spray in short bursts. No LEV present. The use of an air supplied respirator would impose unreasonable costs on facilities in the form implementing a respiratory protection program, the cost of the ASR and would restrict the movement of the mechanics in and around the equipment they are working on.

Industrial/Commercial Automotive materials warehousing and distribution (5013)

Worker exposure not applicable as materials are stored in closed containers as consumer commodities. Exposure to consumer would be based on how the material is used.

3) **Regulatory options *(All SERs)***
   a. Which of the regulatory options presented today would you recommend?
   A combination of phased regulations with varied options for compliance including administrative methods depending on the complexity of the operations.

   b. Cost estimates: In your experience, are the cost estimates reasonably representative? Do you have additional information to improve the cost estimates?
   The cost estimates for sampling and PPE are low. Analytical fees can be double and triple that depending on the complexity of the sampling methodology and associated detection limits of the analytical process. The costs of respiratory protection appear low as costs associated with the implementation and maintenance of a respiratory protection often include the assistance of outside consultants. The costs can also increase significantly if there is high employee turnover which requires an employer to basically start over to retrain and certify an employee in the program.

   c. What indirect costs to your organization do you estimate would occur as a result of this regulation?
   Costs associated with tracking compliance changes to the regulation and associated updates to plans implemented to comply with the regulations.

d. Recognizing that the cost estimates are only partial unit costs, can you provide any additional information on potential costs or cost considerations the Agency should consider when evaluating the costs of complying with potential regulatory options?

Many small businesses are focused on production and quality and run very lean. The time and expertise required to comply with the myriad of regulations under which they must operate is often beyond onsite resources and often requires the assistance from consultants that specialize in regulatory issues. The costs of EHS consultants can vary but can be significant for heavily regulated entities.

e. Can you think of ways to add flexibility to this rulemaking for your small businesses?
- **Used of a combination of restricted use access to employees based on training and location of use.**
- **Phased approach based on usage – periodic or sporadic usage less regulated than continued prolong usage.**

f. Are there other alternative regulatory options that the agency should consider to manage the unreasonable risks identified for TCE?
- **Used of a combination of restricted use access to employees based on training and location of use.**
- **Phased approach based on usage – periodic or sporadic usage less regulated than continued prolong usage.**

g. How do you learn about EPA regulations and what you should do to comply?
Use of a consultant and participation with various manufacturers associations.

h. What kind of additional information or resources would help you understand the regulations and steps necessary to comply?
Training Webinars, guidance documents, resource lists.

i. What is the best way for EPA to reach out to members of your industry?

4) Additional questions for users of products containing TCE: substitutes and alternatives

a. What chemicals or processes have you considered as an alternative to using TCE or a product containing TCE? Why? How do these chemicals or processes compare to current use containing TCE? More specifically:
   i. Do you currently use any alternatives to TCE (or product)?
   In some cases, viable alternatives are available and already being introduced into the supply chain specifically in the coatings industry. These changes have been implemented over many years as the reformulation/qualification process takes time and resources.
   ii. Did you try to switch to another chemical, product, or process only to switch back? If so, what did you switch to, why did you switch back, and what made you switch in the first place?

Engineering trials for alternatives to TCE use as a degreasing solvent have been conducted and there are alternatives which might work, however, the alternatives tested either require capital expenses for new equipment or the alternative chemicals are extremely expensive and there is no significant data currently regarding how often the alternatives will function as intended before requiring change out which could result in even higher costs if the alternatives use cycle is less than anticipated.

iii. What are the relative advantages and disadvantages of different substitutes and/or processes that you have considered, including of exposure, effectiveness, cost, and hazard?
Advantages – may be less toxic
Disadvantages- alternatives often cost more, have less technical expertise because they are new or the technology is new, many alternatives have their own hazards and exposures and many of process require the purchase of equipment, most of which is newer technology thus limiting the purchasing of use equipment to reduce costs.

iv. Provide specific information related to each substitute chemical, product, or process related to the use of alternative chemicals/products and compare to TCE:

- **There are several replacement chemicals being marketed currently as drop in replacements for TCE as a degreaser, many of them are identified as proprietary fluorinated compound, >70% by weight trans-1,2-dichloroethylene – and some containing IPA or Acetone. EPA designated trans-1,2- dichloroethylene as a high priority chemical in December 2019 and the chemical is currently undergoing risk evaluation. Find other information about other chemicals undergoing risk evaluations under TSCA. IPA is labeled a "severe fire hazard" by the National Fire Protection Association.**

- Identification of alternative chemical/product/process

- **Trials on reportedly direct drop-in replacements, ultrasonic cleaners (replacement technology).**

- How much of the alternative product/chemical would be needed to perform the same activity
- **Engineering trials for alternatives to TCE use as a degreasing solvent have been conducted and there are alternatives which might work, however, the alternatives tested either require capital expenses for new equipment or the alternative chemicals are extremely expensive and there is no significant data currently regarding how often the alternatives will function as intended before requiring change out which could result in even higher costs if the alternatives use cycle is less than anticipated.**

- Capital costs including new equipment, retrofitting of old equipment, etc. of using the alternative chemical/process, loss of use of existing equipment

- Number of workers required, amount of worker time required
- Number of workers exposed
- Costs associated with transitioning to the alternative chemical (e.g., identifying, designing, and testing the alternative chemical/process, certifying or otherwise ensuring customer or other required production standards are met, production downtime during the transition, lost productivity while learning how to use the alternative efficiently)

- Process changes required (e.g., additional time to complete task, additional steps, etc.)
- Energy and other resource (e.g., water) usage
- Other operation and maintenance costs (e.g., filters, tank cleanings, etc.)
- Changes in production or output of operation
- Releases of alternative chemicals/products
- Waste and disposal costs associated with alternative chemical/process
- Changes in your product/service quality
- Training, medical surveillance, or other employee-related costs
- Recordkeeping burden/costs
- Monitoring and testing costs
- Potential barriers/concerns with switching to alternatives

- **Many of the alternatives contain chemicals also included on the TSCA risk assessment which has the potential for repeating finding an alternative when the new alternative is identified as having an unacceptable risk. The use of chemicals is inherent to manufacturing processes which is why the Hazard Communication Standard was implemented. The employers have the responsibility to ensure all employees are informed of the risks associated with the chemicals used while performing their assigned tasks. The employer is also responsible for ensuring the safety of their employees who use these chemicals. The regulatory framework is already in place and widely understood by the manufacturing community. Significant time and expense have been invested in building the required infrastructure to manage the exposures and use and disposal of these chemicals in manufacturing. The appearance of the new proposal is that they are being asked to start over.**

5) **Additional questions for distributors and retailers (for consumer uses)**
   a. How much of your business is supplying products containing TCE to consumers? How much of your business is supplying products containing TCE to commercial or industrial users?
   b. If you could no longer sell products containing TCE, how would this impact your business?

c. Do you also sell products designed for the same application or use that do not contain TCE?
    i. If yes, what is the relative share of sales for the product(s) containing TCE compared to the products that do not contain TCE?
d. Are there particular challenges to a small business doing distribution of products containing TCE that are different from large distributors?
e. What is your preferred method of downstream notification?
f. If you were required to limit sales of TCE containing products to only persons who were certified to purchase it, what activities and costs would be involved? What guidance would be helpful from the Agency? Please identify any challenges you see with such a limitation.
g. If restrictions (e.g., prohibition or limit to concentration of TCE in products or articles) were placed on TCE in products or articles, how long would you need to notify downstream users? How long would it take to clear channels or trade?

6) Additional questions for degreasing operations:

a. What type of degreasing operation do you use: vapor degreasing, cold cleaning, aerosol/spray degreasing? Is TCE used in a degreaser? In a tank? As an aerosol? In a small dispenser such as a squirt bottle?

One Baron Blakeslee DP5-3030 Vapor Degreaser upgraded with a l00% Ultra Cool Freeboard Extension annual purchased 325 gallons.

What items do you degrease with for each of the types listed?

i. If you use vapor degreasing, what type of system do you use (open-top, closed-loop, in-line, etc.)? How many separate units of each do you have? If multiple units, are all routinely in operation or do you use one or more units for backup?
   See above
ii. What size system do you use?
   See above
iii. How significant is degreasing to your business overall?

The degreasing operation is critical to the operation as it begins the coating process. Clean surfaces are critical to the application of subsequent coatings.

iv. Do any particular items or grease/oils present special challenges?
   Yes, processes DOD, MIL or Prime Specification Drive. The Aerospace industry is often driven by Mil Specifications which tightly control the means and methods utilized to control the outcome from a process. Many of our customers (Primes) issue their own specification which are directed by, in many cases, the DOD. The Prime specifications specifically state "Degreasing Solvent. Perchloroethylene conforming to ASTM D 4081 or ASTM D 4376 or Trichloroethylene conforming to ASTM D 4080." The process to revise a controlled specification should considered during the regulatory process the specification revisions can take a significant amount

of time.

b. Current work practices related to degreasing operations:
   i. In your experience, what is the average size of a vapor degreaser used by small businesses, in terms of either solvent air interface or solvent capacity?
   14.82 SAI
   ii. Do the types of vapor degreasers we are considering (open-top, closed-loop, continuous/in-line vapor degreasers) seem representative of those currently in use for small businesses?
   Yes

   iii. Is there any difference in terms of operation time for the different types of vapor degreasers or cold cleaners or aerosol degreasers (in terms of hours per day or days per year)?

c. How old is the cleaning equipment? When did you last update your degreasing system and what was the nature of the update (e.g., new system/machinery, installation of emissions devices, etc.)? What prompted this update? What is the remaining life of the current system you have?

   The degreaser is 20 years old but has several modifications including solvent recovery and additional emission controls added to it. The last upgrade was in 2016. Remaining life on this unit is +10 years or more if properly maintained.

d. What are the most important factors in degreasing for you (in order): (e.g., precision, speed, impact on the item, safety, total job time, price of materials, client preference, or other factors (please identify))?

   Specification driven usage

e. Why do you use TCE rather than somewhat similar solvents like 1-bromopropane (1-BP), perchloroethylene (PCE), other? Or a blend with *trans*-1,2-dichloroethylene (DCE)? Can you name specific factors that drive your decision to continue to use TCE? Did you consider using another non-halogenated solvent or aqueous process?
   Specification driven usage

   i. When do you use TCE in the process flow in your facility, are you using other cleaning processes as well?
   Yes, aqueous cleaners in a different process

   ii. For example, do you do aqueous cleaning in addition to cleaning with TCE?
   No, it is a separate process, again specification driven

   iii. Does aqueous cleaning happen before or after TCE?

No, it is a separate process, again specification driven

iv. Are you using TCE on some but not all products?
Yes Specification driven
v. If you use one or the other, (aqueous or TCE but not both), how did you decide which to use?
Specification driven

f. One possibility is that TCE might have to be used in a closed-loop/airless system. Have you looked into such systems? Why or why not?
   i. Are you considering purchasing such equipment?
   ii. If not, what are the constraints?
   iii. Would you use TCE in such a system or would you use a different solvent?
g. Have you looked at any alternative processes? Any alternative solvents? Have you looked at product literature?
h. Have you tried using alternative chemicals or methods for degreasing? What were the results?
   i. Please discuss alternative methods for degreasing as well as alternative solvents or equipment in your degreasing process.
   ii. Are you aware of alternative processes or solvents that could be used to achieve similar degreasing results in your operation?
   iii. If you have tried or switched to alternative chemicals or methods, how did they do? how long did that process take? Did it require equipment modifications or new equipment purchases?
i. If TCE could no longer be used for degreasing, would the mix of alternative cleaning methods be different for you as a small businesses compared to larger businesses? For example, are there particular alternatives that are more suitable for small businesses?
j. If you had to change your cleaning process to another somewhat similar solvent like a *trans*-DCE blend, can you give an estimate of costs while considering the following?
   i. Cleaning agent
   ii. Cleaning equipment
   iii. Process development
   iv. Process verification and validation (including lab testing and/or third-party verification), i.e., proving to yourself that the process works
   v. Customer certification
   vi. Training
   vii. Insurance
   viii. Permitting
   ix. Cleaning agent management (including removal of used cleaning agent)
   x. Facilities changes
   xi. Documentation
   xii. PPE requirements
k. What if you needed to move your cleaning process to a different process like aqueous or another non-similar solvent (modified alcohols, hydrocarbons, alcohols, other blends)? Can you give an estimate of costs while considering the following?
   i. Cleaning agent
   ii. Cleaning equipment
   iii. Process development

iv. Process verification and validation (including lab testing and/or third-party verification) (i.e., proving to yourself that the process works))
v. Customer certification
vi. Training
vii. Insurance
viii. Permitting
ix. Cleaning agent management (including removal of used cleaning agent)
x. Facilities changes
xi. Documentation
xii. PPE requirements

l. Do you have an estimate on how many vapor degreasers in the U.S. use TCE?
no
m. Do you have an estimate on how much TCE is used in the U.S. for vapor degreasing every year?
no
n. Out of all the vapor degreasers in the U.S., do you have an estimate on what percentage of those vapor degreasers use TCE versus other solvents (methylene chloride, PCE, 1-BP, *trans*-DCE blends, other designer solvents)?
no
o. How much TCE does a typical vapor degreasing operation consume in a year?
Annual purchased 325 gallons.

Appendix B2: Written Comments Submitted by Small Entity Representatives following the January 31, 2023 Panel Outreach Meeting

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February 13, 2023

Mr. Lanelle Wiggins
Office of Regulatory Policy and Management
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: My comments concerning the phaseout of trichloroethylene (TCE) and its impact on the drycleaning industry

Dear Mr. Wiggins,

It is the National Cleaners Association's opinion that a phaseout of TCE would have a negative economic impact on the drycleaning industry. The use of TCE as a stain removal agent is an integral part of the stain removal process. While there may be alternatives to TCE, in my professional opinion, these alternatives are not as effective as TCE when used on the spotting board. Therefore, the use of available alternatives would increase labor, supply, and utility costs by having to repeatedly reprocess stained garments. This would be especially burdensome on small volume "mom and pop" operations that have annual sales of $250,000 - $300,000. These operators work on thin profit margins and represent a major percentage of the drycleaning industry. If the condition of the garment could not be corrected and deemed to be unwearable by the consumer, it would be disposed of in a landfill. This would have a negative environmental impact since many garments contain plastic based synthetic fibers take a lifetime to degrade.

The following information will describe the economic impact that the phaseout of TCE would have on an average small volume drycleaner:

A small volume drycleaner runs 5 loads per day @ 1-1.5 hours per load for 6-7 hours per day

If an average of 2 garments/day require a stain removal treatment with TCE @ 4-10 minutes per garment, the spotter will use 8-20 labor minutes/day with an average of 14 minutes/garment or an average of 28 minutes for the 2 garment average. If the stain cannot be removed on the first run using an alternative to TCE, it may have to be re-spotted and re-run 2-3 times, this would increase the labor minutes to an average of 28 labor minutes/day per garment, or 56 minutes a day for average of 2 garments. If the garment is re-processed 3 times, the labor minutes will increase to 42 minutes/day per garment or 84 minutes/day for the 2 garment average.

On a weekly basis (6 days) this will compute to 168 labor minutes/week or approximately 2½ labor hours when TCE is used on the 2 garments, or up to 504 labor minutes/week (or approximately 8½ labor hours) if the 2 garments are processed 3 times in an alternate to TCE.

The average spotter's salary is $35.00/hour (including payroll expenses) Since the average spotter works 6 days (40 hours straight time and 8 hours overtime), their average salary/week, including overtime and payroll expenses would be $1,840.00. Therefore, their average pay (including overtime) will cost their employer $38.50/hour

If TCE is used, the average labor cost/week for the 2 garments is $77.00. If an alternate to TCE is used, the labor cost/week will be $327.50 (if the 3 garments are processed 3 times) Therefore, the labor costs using an alternate to TCE may more than quadruple the labor costs of servicing the garment using TCE.

I hope that the above-mentioned labor numbers will explain the devastating effect that the phaseout of TCE will have on the drycleaning industry.

Sincerely,

Alan Spielvogel
Director of Technical Services