

FINAL REPORT
of the
Small Business Advocacy Review Panel on
EPA's Planned Proposed Rule under Section 6(a) of the
Toxic Substances Control Act (TSCA) as amended by the Frank R. Lautenberg
Chemical Safety for the 21st Century Act for Use of Trichloroethylene (TCE) in
Vapor Degreasing

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Final Report
Small Business Advocacy Review Panel
Proposed Rulemaking: Toxic Substances Control Act (TSCA) as amended by the
Frank R. Lautenberg Chemical Safety for the 21st Century Act Section 6(a) for
Trichloroethylene (TCE) in Vapor Degreasing

1. INTRODUCTION

This report is presented to 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 as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA) to regulate the use of trichloroethylene (TCE) in vapor degreasing. Section 6 provides EPA the authority to address unreasonable risks resulting from the manufacture (including import), processing, distribution in commerce, and use of chemicals, as well as any manner or method of disposal of chemicals. Under section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), a Panel is required to be convened prior to publication of the initial regulatory flexibility analysis (IRFA) that an agency may be required to prepare under the RFA. In addition to EPA's Small Business Advocacy Chairperson, the Panel consists of a representative of the Chemical Control Division of the EPA Office of Pollution Prevention and Toxics, a representative of the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and a representative from 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 would be subject to the proposed rule;
- A description of efforts made to obtain the advice and recommendations of representatives of those small entities;
- A summary of the comments that have been received to date from those representatives; and
- Panel findings and discussion, as required by the statute and described below.

Section 609(b) of the RFA directs the Panel to report on the comments of small entity representatives 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;
- 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 requirements and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all other relevant federal rules which may duplicate, overlap, or conflict with the proposed rule; and

- An initial regulatory flexibility analysis with 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.

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 will be based on the information available at the time the final Panel report is drafted. EPA will continue 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

2.1. Regulatory History

Because of its potential health effects, TCE is subject to state, federal, and international regulations restricting and regulating its use. The federal regulations are described in this section.

EPA has issued several final rules and notices pertaining to TCE under EPA's various authorities:

- *Safe Drinking Water Act*: EPA issued drinking water standards for TCE pursuant to section 1412 of the Safe Drinking Water Act. EPA promulgated the National Primary Drinking Water Regulation (NPDWR) for TCE in 1987 (52 FR 25690, July 8, 1987). The NPDWR established a non-enforceable maximum contaminant level (MCL) goal of zero mg/L based on classification as a probable human carcinogen. The NPDWR also established an enforceable MCL of 0.005 mg/L based on analytical feasibility. EPA is evaluating revising the TCE drinking water standard as part of a group of carcinogenic volatile organic compounds.
- *Clean Water Act*: EPA identified TCE as a toxic pollutant under section 307(a)(1) of the Clean Water Act (33 U.S.C. 1317(a)(1)) in 1979 (44 FR 44502, July 30, 1979) (FRL-1260-5)). In addition, EPA developed a TCE ambient water quality criterion for the protection of human health pursuant to section 304(a) of the Clean Water Act.
- *Clean Air Act*: TCE is designated a hazardous air pollutant (HAP) under the Clean Air Act (42 U.S.C. 7412(b)(1)). In 1994, EPA promulgated national emission standards for halogenated solvent cleaning machines (59 FR 61801) (1994 NESHAP), to control emissions of several halogenated solvents, including TCE, from halogenated solvent cleaning machines, pursuant to Section 112(d) of the CAA. The standards, which can be found in 40 CFR Subpart T, include multiple alternatives that allow maximum compliance flexibility. In May 2007, EPA

promulgated the Halogenated Solvent cleaning rule (72 FR 25138), which established revised standards that further limit emissions of TCE (and other solvents) in halogenated solvent cleaning, pursuant to CAA section 112(f). Specifically, EPA promulgated a facility-wide emission limit of 60,000 kilograms per year (kg/year) methylene chloride equivalent that applied to all halogenated solvent cleaning machines with the exception of halogenated solvent cleaning machines used by the following industries: facilities that manufacture narrow tubing, facilities that use continuous web cleaning machines, aerospace manufacturing and maintenance facilities, and military maintenance and depot facilities. EPA also promulgated a facility-wide emission limit of 100,000 kg/year methylene chloride equivalent for halogenated solvent cleaning machines used at military maintenance and depot facilities. EPA required existing facilities to comply with the revised standards by May 3, 2010, which is three years after the effective date of the Halogenated Solvent Cleaning rule. Further, with regard to halogenated solvent cleaning machines used by facilities that manufacture narrow tubing, facilities that use continuous web cleaning machines, and aerospace manufacturing and maintenance facilities EPA found, after considering risks, associated compliance costs and the availability of control measures, that the 1994 NESHAP reduces risk to acceptable levels, provides an ample margin of safety to protect public health, and prevents adverse environmental effects. The May 2007 rule also included a review of the 1994 NESHAP as required by CAA section 112(d)(6). (73 FR 62387-62388).

- *Resource Conservation and Recovery Act (RCRA)*: EPA classifies certain wastes containing TCE as hazardous waste subject to Subtitle C of RCRA pursuant to the toxicity characteristics or as a listed waste. RCRA also provides authority to require cleanup of hazardous wastes containing TCE at RCRA facilities.
- *Comprehensive Environmental Response, Compensation and Liability Act (CERCLA)*: EPA designated TCE as a hazardous substance with a reportable quantity pursuant to section 102(a) of CERCLA and EPA is actively overseeing cleanup of sites contaminated with TCE pursuant to the National Contingency Plan (NCP).

The Occupational Safety and Health Administration (OSHA), which also regulates TCE, established a permissible exposure limit (PEL) for TCE in 1971. The PEL is an 8-hour time-weighted average (TWA) TCE concentration of 100 ppm. In addition, the TCE PEL requires that exposures to TCE not exceed 200 ppm (ceiling) at any time during an eight hour work shift with the following exception: exposures may exceed 200 ppm, but not more than 300 ppm (peak), for a single time period up to 5 minutes in any 2 hours. OSHA has acknowledged that its TCE PEL is not sufficiently protective of worker health. Most of OSHA's PELs, like the TCE PEL, were established in 1971 under expedited procedures shortly after adoption of the Occupational Safety and Health Act (29 U.S.C. 651 et seq.) in 1970, and have not been updated since that time (79 FR 621384, October, 10, 2014).

2.2. TSCA Work Plan Chemical Risk Assessment for TCE

The Office of Pollution Prevention and Toxics (OPPT) identified and selected TCE for risk evaluation as part of its Work Plan for Chemical Assessment under TSCA. TCE is a volatile organic compound (VOC) and hazardous air pollutant (HAP) that is classified as a human carcinogen. Its

consumption in the United States is 255 million pounds (lbs.) per year. TCE is widely used in industrial and commercial processes, and also has some limited uses in consumer products. The majority (~83.6%) of TCE is used as an intermediate for manufacturing refrigerant chemicals. Much of the remainder (~14.7%) is used as a solvent for metal degreasing, leaving a relatively small percentage (~1.7%) to account for all other uses, including use in consumer products¹.

The final *TSCA Work Plan Chemical Risk Assessment for TCE* was completed and issued in June of 2014. This risk assessment evaluated human health risks to consumers and workers, including occupational bystanders, from inhalation exposures. Single (acute) or short-term exposure can potentially affect the developing fetus. High acute concentrations of TCE vapors can irritate the respiratory system and skin and induce central nervous system (CNS) effects such as light-headedness, drowsiness, and headaches. Repeated (chronic) or prolonged exposure to TCE has been associated with adverse effects in the liver, kidneys, immune system, reproductive system, and central nervous system. EPA has also concerns for effects in the developing fetus from chronic exposure. Chronic TCE exposure is carcinogenic to humans by all routes of exposure.

OPPT's risk assessment identified risks for occupational and consumer exposure scenarios involving the use of TCE-containing degreasers, spot cleaners in dry cleaning and clear protective coating spray in arts/crafts. One of the exposure scenarios evaluated was for commercial facilities conducting vapor degreasing. The populations of interest were workers with direct exposure (users) or indirect (bystanders) exposure to TCE. Only the inhalation route of exposure was considered in this risk assessment.

EPA organized an expert workshop on July 29-30, 2014, to discuss the use of TCE as a degreaser, availability and efficacy of safer alternatives, and possible risk reduction approaches². Users, including the Department of Defense, identified efforts to switch out of TCE commercial degreasing uses. As a result of the workshop, EPA obtained additional data on the uses under consideration for the rulemaking and potential substitutes.

Following the TCE risk assessment, EPA conducted additional analyses to inform risk management. These analyses were based on the peer-reviewed methodology used in the TCE risk assessment and included potential exposure scenarios associated with the use of TCE in commercial vapor degreasing facilities by estimating the likelihood of occurrence of a particular inhalation exposure concentration using Monte Carlo simulation. EPA also analyzed occupational exposure assessment of various exposure reduction scenarios, human health risk characterization based on the exposure scenarios, and uncertainties and data limitations. Results from these analyses were presented to the SERs to inform their advice to EPA; however, the complete analyses were not provided to the SERs. These analyses will be available in the docket for the proposed rule (EPA-HQ-OPPT-2016-0231).

2.3. Estimates of Exposed Populations

Populations exposed to TCE in vapor degreasing include workers and occupational bystanders in facilities where vapor degreasing is conducted with open top, closed, and in-line machines. EPA

¹ Available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemical-risk-assessment>

² EPA. Meetings: Expert Public Workshop on Alternatives and Risk Reduction Approaches to Trichloroethylene. **Federal Register** (79 FR 38024, July 3, 2014)(FRL-9913-17).

estimates that there are approximately 2,600 to 6,200 machines for TCE vapor degreasing in the U.S. Of these, 150 machines are classified as in-line, 120 are closed systems, and 2,400 to 6,000 are open top. These estimates are derived from the Economic Analysis for the proposed rule. While it was not available for the SERs to review at the time of the Panel, when the rule publishes it will be available in the rule docket (EPA-HQ-OPPT-2016-0231).

EPA estimates that there are approximately 5 – 12 workers per machine, yielding an estimated exposed population of 13,000 to 74,400 workers annually.

2.4. Description of the Rule and Scope

By the time the Small Business Advocacy Review Panel met, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (P.L. 114-182) had been passed by Congress. The President subsequently signed the bill into law on June 22, 2016.

The law preserves EPA's ability to address risks presented by the manufacture, processing, distribution in commerce, or use of TCE that were identified in the 2014 TSCA Work Plan Chemical Risk Assessment for TCE. Also, the options available to EPA under TSCA §6(a) for addressing these unreasonable risks have not been changed by the law.

To promulgate a rule under TSCA §6(a), TSCA §6(c)(2)(C) of the new law requires EPA to consider, 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. Additionally, under TSCA §26(h) EPA must use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science. It is important to note that, per TSCA §26(l), because the TCE risk assessment was completed prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA may publish proposed and final rules under §6(a) that are consistent with the scope of the completed risk assessment for this chemical substance and consistent with other applicable requirements of §6.

2.5. Description of the Rule and Scope

Given the risks identified by EPA in the *TSCA Work Plan Chemical Assessment for TCE*, EPA is proposing to regulate the commercial use of TCE in vapor degreasing under TSCA §6(a).

Under TSCA §6(a), if the Administrator determines that 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 Agency's risk evaluation, under the conditions of use, EPA must by rule apply one or more requirements to the extent necessary so that the chemical substance no longer presents such risk.

The table below summarizes the regulatory requirements EPA can utilize, separately or in combination, under TSCA § 6(a).

The options under consideration would not duplicate other federal regulations, and current federal regulations discussed previously in Section 2.1 do not protect adequately against the risks that EPA has identified with use of TCE in vapor degreasing.

Table 1. Regulatory Requirements Available under TSCA § 6(a).

TSCA §	Requirement
6(a)(1)	A requirement (A) prohibiting or otherwise restricting 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 or otherwise restricting 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 minimum 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 minimum 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 or 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. (B) 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.
6(a)(7)	A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such determination 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 determination, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

3. OVERVIEW OF OPTIONS UNDER CONSIDERATION

EPA has considered a number of regulatory options under section 6(a). In assessing these options, EPA considered a wide range of exposure scenarios and risk reduction practices and options. Through Agency review and stakeholder input, two options have been identified as reducing exposures sufficiently that acute, chronic, and cancer risks are reduced to the extent necessary so that TCE no longer presents an unreasonable risk with respect to this use. These options are currently being considered and evaluated by EPA, and are not final at this time.

3.1. Prohibit the manufacturing (including import), processing, distribution in commerce, and use of TCE in vapor degreasing, and require downstream notification

- Prohibit manufacturing (including import), processing, and distribution in commerce of TCE for vapor degreasing,
- Prohibit the commercial use of TCE in vapor degreasing,
- Require downstream notification of the prohibitions and recordkeeping by manufacturers, processors and distributors (but not retailers) of TCE.

3.2. Allow use of TCE with appropriate personal protective equipment (supplied air respirator with assigned protection factor of 10,000) in certain closed vapor degreasing systems

Specifically, this option would:

- Restrict the use of TCE in vapor degreasing to certain closed vapor degreasing systems and with appropriate personal protective equipment (self-contained breathing apparatus with an assigned protection factor (APF) of 10,000) or equivalent air exposure limit in certain closed vapor degreasing systems.
- Require downstream notification of the restriction and recordkeeping by manufacturers, processors and distributors (but not retailers) of TCE.

4. 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 regulatory revisions being considered by EPA for this rulemakings are expected to affect a variety of small businesses, small governments, and small organizations. 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 2 in Section 5, below.

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

The following table lists industries/sectors potentially affected by the regulation.

Table 2: Industry Sectors and Small Entities Potentially Affected by EPA’s Planned Action

NAICS CODE	NAICS Description
339	Miscellaneous Manufacturing
3399	Other Miscellaneous Manufacturing
32799	All Other Nonmetallic Mineral Product Manufacturing
33299	All Other Fabricated Metal Product Manufacturing
33634	Motor Vehicle Brake System Manufacturing
33641	Aerospace Product and Parts Manufacturing
33999	All Other Miscellaneous Manufacturing
81131	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance
311812	Commercial Bakeries
323111	Commercial Printing (except Screen and Books)
325199	All Other Basic Organic Chemical Manufacturing
325220	Artificial and Synthetic Fibers and Filaments Manufacturing
325611	Soap and Other Detergent Manufacturing
325612	Polish and Other Sanitation Good Manufacturing
325998	All Other Miscellaneous Chemical Product and Preparation Manufacturing
326299	All Other Rubber Product Manufacturing
331210	Iron and Steel Pipe and Tube Manufacturing from Purchased Steel
331410	Nonferrous Metal (except Aluminum) Smelting and Refining
331512	Steel Investment Foundries
332111	Iron and Steel Forging
332119	Metal Crown, Closure, and Other Metal Stamping (except Automotive)
332215	Metal Kitchen Cookware, Utensil, Cutlery, and Flatware (except Precious) Manufacturing
332216	Saw Blade and Handtool Manufacturing
332313	Plate Work Manufacturing
332431	Metal Can Manufacturing
332618	Other Fabricated Wire Product Manufacturing
332721	Precision Turned Product Manufacturing
332722	Bolt, Nut, Screw, Rivet, and Washer Manufacturing
332811	Metal Heat Treating
332812	Metal Coating, Engraving (except Jewelry and Silverware), and Allied Services to Manufacturers
332813	Electroplating, Plating, Polishing, Anodizing, and Coloring

NAICS CODE	NAICS Description
332912	Fluid Power Valve and Hose Fitting Manufacturing
332913	Plumbing Fixture Fitting and Trim Manufacturing
332994	Small Arms, Ordnance, and Ordnance Accessories Manufacturing
332999	All Other Miscellaneous Fabricated Metal Product Manufacturing
333249	Other Industrial Machinery Manufacturing
333249	Other Industrial Machinery Manufacturing
333318	Other Commercial and Service Industry Machinery Manufacturing
333413	Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing
333511	Industrial Mold Manufacturing
333999	All Other Miscellaneous General Purpose Machinery Manufacturing
334416	Capacitor, Resistor, Coil, Transformer, and Other Inductor Manufacturing
334419	Other Electronic Component Manufacturing
334511	Search, Detection, Navigation, Guidance, Aeronautical, and Nautical System and Instrument Manufacturing
334512	Automatic Environmental Control Manufacturing for Residential, Commercial, and Appliance Use
334515	Instrument Manufacturing for Measuring and Testing Electricity and Electrical Signals
334519	Other Measuring and Controlling Device Manufacturing
335312	Motor and Generator Manufacturing
336310	Motor Vehicle Gasoline Engine and Engine Parts Manufacturing
336411	Aircraft Manufacturing
336413	Other Aircraft Parts and Auxiliary Equipment Manufacturing
337127	Institutional Furniture Manufacturing
339112	Surgical and Medical Instrument Manufacturing
339114	Dental Equipment and Supplies Manufacturing
339910	Jewelry and Silverware Manufacturing
339999	All Other Miscellaneous Manufacturing
424690	Other Chemical and Allied Products Merchant Wholesalers
811310	Commercial and Industrial Machinery and Equipment (except Automotive and Electronic) Repair and Maintenance
812310	Coin-Operated Laundries and Drycleaners
812320	Dry cleaning and Laundry Services (except Coin-Operated)
928110	National Security

6. SUMMARY OF SMALL ENTITY OUTREACH

EPA conducted an online solicitation to identify small businesses and trade associations interested in participating in the Small Business Advocacy Review (SBAR) Panel process by serving as

Small Entity Representatives (SERs). EPA issued a press release inviting self-nominations by affected small entities to serve as SERs. The press release directed interested small entities to a web page where they could indicate their interest. EPA launched the website on March 30, 2015, and accepted self-nominations until April 10, 2015. EPA also contacted potential SERs directly throughout 2015 to generate additional interest.

On February 4 and 10, 2016, EPA held kick-off meetings with representatives from the Office of Advocacy of the Small Business Administration (SBA) and the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB). At those meetings, EPA gave a presentation, answered questions on the options being considered for the rule, and provided follow-up information.

After identifying a list of potential SERs (shown in Section 7), EPA conducted a Pre-Panel outreach meeting with potential SERs on March 17, 2016. To help them prepare for the meeting, EPA sent materials to each of the potential SERs via email. The materials shared with the potential SERs during the Pre-panel outreach meeting are included in Appendix A. For the March 17, 2016, Pre-Panel outreach meeting with the potential SERs, EPA also invited representatives from SBA and OMB. A total of 7 potential SERs participated in the meeting. EPA presented an overview of the SBAR Panel process, an explanation of the planned rulemaking, and technical background.

This outreach meeting was held to solicit feedback from the potential SERs on their suggestions for the upcoming proposed rulemaking. EPA asked the potential SERs to provide written comments by March 31, 2016. Comments made during the March 17, 2016, Pre-Panel outreach meeting and written comments submitted by the potential SERS are summarized in section 8 of this document. Written comments appear in Appendix B.

On June 1, 2016, EPA’s Small Business Advocacy Chairperson convened this Panel. The Panel outreach meeting was held on June 15, 2016 with eight SERs in attendance. As with the Pre-Panel outreach meeting, EPA sent materials to each of the SERs via email. For the Panel outreach meeting, EPA invited representatives from SBA and OMB. The materials shared with the potential SERs during Panel outreach meeting are included in Appendix A. EPA presented similar materials at the Pre-Panel meeting with an overview of the SBAR Panel process, an explanation of the planned rulemaking, and technical background.

7. LIST OF SMALL ENTITY REPRESENTATIVES

A list of potential SERs was identified at the time of the Pre-panel meeting/teleconference. Prior to the SBAR Panel meeting, a final list of SERs was developed. Table 3 below lists the SERs providing input to this Panel.

Table 3. TCE Panel Potential SERs

ENTITY
Able Electropolishing Company, Inc. (IL)
Casting Impregnators Inc. (IL)
Chem Processing (IL)

E. C. Styberg Engineering Company (WI)
East - Lind Heat Treat, Inc. (MI)
Emporium Specialties Company Inc. (PA)
Globe Engineering Co., Inc (KS)
Kearflex Engineering Co. (RI)
Marquette Tool and Die Company (MO)
McMillan Electric Company (WI)
Nobert Plating Co.(IL)
Parts Cleaning Technologies, LLC
Plano Metal Specialties Inc. (IL)
Precision Machined Products Association (OH)
Viking Drill & Tool (MN)
Whittet-Higgins Company (RI)

8. SUMMARY OF COMMENTS FROM SMALL ENTITY REPRESENTATIVES

8.1. Summary of Oral Comments and Pre-Panel Outreach Meeting, March 17, 2016

The following is a summary of the oral comments from the Pre-Panel outreach meeting discussion from the potential SERs, either made by phone or in person.

- One potential SER discussed how TCE is a solvent with a good knowledge base built for removing adhesives from certain components and substrates. Some substitute solvents are not compatible with the degreasing operations.
- Several vapor degreasers said it is common for customers to require solvent degreasing and to provide degreasing facilities with a specific list of suggested or required degreasing solvents. Therefore, in these cases, a degreasing facility will use a solvent from the customer's list and not search on their own for suitable alternative solvents.
- Alternatives to TCE appear on some of these customer lists for certain industries for degreasing operations.
- Open-top vapor degreaser operations were discussed, as the solvent bath comes into contact with the indoor air at some point during the degreasing process.
- Changing operations from TCE-based vapor degreaser machines to updated systems that use other solvents is often cost-prohibitive.
- The substitute solvent discussed by several potential SERs was 1-bromopropane (1-BP), but it has a higher cost (2-3 times more) than TCE.
- None of the potential SERs had performed exposure monitoring in their workplace or on their workers, one had experience using PPE, and none described using engineering controls.

8.2. Summary of Written Comments from potential SERs following the Pre-Panel Outreach Meeting, March 17, 2016

The following is a summary of the written comments submitted by the potential SERs. A copy of each of the comments submitted by the potential SERs is included in Appendix B.

- One potential SER said their company switched away from using TCE in vapor degreasing due to health concerns and now use a 1-BP containing solvent. They discussed how 1-BP may not be a long-term solution as an alternative to TCE, and other alternatives should be researched for various industries.
- One potential SER said vapor degreasing using an open-top degreaser is an integral part of their operations; workers use it daily. PPE, training, ventilation, and monitoring are utilized on a regular basis (i.e. daily, weekly, or monthly).
- Air-supplied respirators are not in daily use, but are used for periodic cleaning in the confined space of the tank.
- One potential SER described an updated system that was implemented to include a steam valve that auto-modulates the control of the vapor and steam level for better control and safety because it can be shut down if there is any sort of problem.
- If TCE were not available for degreasing, one potential SER said they would have to shut down until an alternative solution was found. This potential SER said that their customers require TCE be used as a solvent in their specifications.
- A potential SER indicated a new industry standard is needed to be able to get away from TCE.
- A potential SER indicated that the rule should include a defined time frame to gather information and testing of new solvents (what we use is not really up to us, customer driven).
- Another potential SER suggested that efforts should be made to vet some real and viable alternatives to give to the end users, such as airplane/aerospace manufacturers, government defense contractors, weapons designers, Medical equipment manufacturers etc.

8.3. Summary of Oral Comments and Panel Outreach Meeting, June 15, 2016

The following is a summary of the oral comments from the Panel outreach meeting discussion from the SERs, either made by phone or in person.

Description of the degreasing operations of the SERs

- The primary business sectors of the SERs include:
 - Aerospace parts (e.g., landing gear, tubing “down to 1/8 inch”);
 - Automobile parts (e.g., glass to metal seals);
 - Razor blades;
 - Medical equipment (e.g., batteries for pacemakers);
 - Precision machine products industry (NAICS 33721); and,
 - Field electronics for Department of Defense applications (e.g., ceramics for electronic field radios).
- SERs noted that the use of TCE vapor degreasing is declining very rapidly in certain sectors, but is still the method of choice for some; predominantly for small, intricate parts and substrates

(e.g., small tubes). The industry is phasing out TCE due to economic considerations as well as pending environmental regulations.

- A SER that manufactures and sells vapor degreasing equipment and degreasing chemicals (including TCE and alternatives) stated: “I have not made a new one in ten years”, referring to TCE degreasers. Furthermore, he estimated that more than 90% of vapor degreasing systems are open top with the majority of TCE releases from these systems associated with carry out (drag out).
- A SER indicated that larger facilities use dedicated rooms for vapor degreasing operations where emissions are captured in carbon adsorbers with 98% efficiency and ventilated to other rooms. Examples of parts cleaned in these large operations include large tubes and aircraft parts. The SER stated that larger degreasing industries were “carved out” of the 2007 revisions to the NESHAP for Halogenated Solvent Cleaning, including the narrow tube industry, aircraft/aerospace industry, and razor blade industry (for which this SER stated there is no suitable replacement for TCE). The narrow tube industry utilizes an enclosed system where one or two bundles of tubes or loads are degreased per hour. As the tubes (smaller than 1/64 inch diameter) are removed from the degreaser they are allowed to cool and then placed in a draft box where air is blown through the tubes for drying. The SER stated that the NESHAP revisions in 2007 significantly changed the industry and continues to do so, further stating that information more than five to ten years old is no longer applicable to describe the industry today.
- Throughout the meeting, SERs referred to the NESHAP as limiting the use rate of TCE because of the associated emission limit (ten tons of TCE emitted per site, per year). Based on this limit on the use rate and the overall domestic production of TCE, one SER estimated there are no more than 650 degreasers currently in operation with systems operating approximately four hours per day and typically with only one operator exposed during degreasing operations, not three workers over eight hours as EPA has estimated. Another SER indicated they have multiple operators exposed for an entire work day during degreasing operations.
- A SER indicated that many companies in the industry comply with the American Council of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 10 ppm rather than the OSHA PEL of 100 ppm.
- Another SER indicated that respondents to a survey indicated they typically use less than 1,000 gallons TCE per year (one indicated 291 gallons/year, another 145 gallons/year, and a third only 45 gallons/year; however, one shop indicated the use of 2,000 gallons per year). These survey respondents indicated that investment for new (non-TCE) systems would require approximately two to three years of budgeted capital expenditures. The respondents did not indicate the type of replacement system they would utilize.
- The use of alternative chemicals with lower boiling points poses problems because the chemicals vaporize too rapidly at typical operating temperatures of current systems. Multiple SERs commented that none of the currently available chemical alternatives can fully replace TCE due to: associated health hazards, potential regulations that introduce uncertainty regarding the future availability and possible use restrictions, use rate based on compliance with NESHAP limitations

that are even lower than that for TCE, and cost (some substitute chemicals cost approximately ten times that of TCE).

- Some degreasing applications such as those for military use and automobile manufacturing (e.g. electronics) require highly efficient cleaning, including electronics. An example is glass to metal seals, which must be absolutely free of soil. Additionally, there can be a concern for galvanizing corrosion of these parts from residues. No substitutes for TCE for critical glass to metal seals have been identified.
- According to a SER, many users who need items degreased do not know “how clean they need their product to be or how clean the system gets them.” Previously, customer specifications simply indicated a requirement for open top cleaning using TCE. To move to a different system, testing is needed to determine the required efficiency (how clean to get the part). The SER further stated that figuring out how clean is clean can take six months and changing to a new system could take 12 to 18 months.
- SERs noted that industry is concerned the rule will result in plant closures and losing business to off-shore competitors.

Current work practices regarding the SERs’ degreasing operations

- One SER that sells degreasing systems has evaluated and successfully installed aqueous-based systems, but there are potential drawbacks. Aqueous systems typically require very large quantities of water (citing one example of 30,000 gallons of water per day) and can cause concerns for facilities subject to water restrictions. Also, the water effluent is considered industrial wastewater and must be handled appropriately (one customer could not get a permit because of the need to handle the water as industrial wastewater). In addition the SER said aqueous systems are typically much larger than vapor degreasing systems. Another drawback is that aqueous operations often require multiple stages to reach the same cleaning efficiency as vapor degreasing. He indicated, “Sometimes you have three machines replacing one. One customer put in five different aqueous machines to replace their degreaser.” Another consideration is the increased energy requirement for aqueous systems because heating via a blower oven is needed to dry the parts. In summary, the SER indicated the cost benefit analysis is case-by-case and can be favorable if these barriers can be overcome, acknowledging that water use restrictions in certain regions of the country may prohibit use even with a favorable economic analysis.
- Another SER indicated that a survey respondent moved from a TCE system (the type of new system was not discussed) at a cost of over \$500,000. He further noted that a typical shop in this industry has \$5 to \$8 million in sales per year per NAICS 33271 census.
- Another SER has evaluated new systems but has not identified any that clean as well. He noted that ultrasonic cleaning may be sufficient but the cycle time was too slow and therefore not a feasible option. His business is an aerospace manufacturer, “running a lot of heavily oiled parts ... with a ton of small tubing, down to 1/8”. His company runs degreasers ten hours/day, five days/week, and 6 hours on Saturday. The company cleans 14,000 parts/day. Open top degreasers are used (they don’t actively use the cover for the degreaser). The company uses ventilation, but

one can still “smell fumes.” Operations include pre-clean steps with an alcohol or ketone wipe for “just a few minutes.” The open top vapor degreasing cycle time is approximately 45 minutes to an hour. Parts are then “just a few minutes” in the degreaser. Parts are then rinsed and taken out. The area is ventilated with exhaust out the back wall of the building. A total of five employees, rotating in and out of work areas are involved during all work hours (individual workers do not spend the entire 10 hours in the degreasing work area). The machine is approximately 30 years old, and has been updated over the years. The facility complies with the 10 ton/year NESHAP emissions limit, often approaching this volume (nine tons last year). Due to their high-use rate, closed systems are not feasible because they could not clean the 14,000 parts/day currently cleaned with the open top system, and new machines occupy a longer footprint in the shop.

- Several SERs indicated that minimizing cycle time is important and some systems require long cycle times, making them less attractive options.
- One SER indicated that if it is possible to put parts on a belt washer then aqueous systems can maintain low cycle times. However, if tanks are required, an aqueous system may require significantly more time because multiple machines/tanks may be required (as noted above, three machines may be needed to achieve the efficiency of one vapor degreaser).
- Multiple SERs noted that boiling point is a significant consideration, stating low boiling point chemicals are not viable substitutes because they volatilize during processes involving elevated temperatures, and because they cannot be shipped in standard drums.
- Several SERs suggested that EPA consider evaluating “large” and “small” shops separately.
- In summary, important factors for degreasing operations for the SERs included:
 - Cleaning efficiency;
 - Managing health hazards (for TCE as well as potential alternatives);
 - Client specifications/preferences;
 - Cycle time;
 - Different boiling points;
 - Water use restrictions and regulations;
 - Energy use for alternate process (utility cost);
 - Cost (both type of system such as aqueous vs. vapor, and cost of specific chemical); and
 - Space constraints.

Use of TCE in businesses and exposure reduction

- Multiple SERs indicated there is no viable substitute for TCE and they were not aware of any new chemicals currently being evaluated for degreasing.
- One SER indicated that 50% of the respondents to his survey indicated the cost of alternatives would hit “the tipping point” and they could not stay in business if required to shift from TCE.
- Another SER evaluated alternatives and determined there are no viable substitutes.
- Although not directly related to TCE, one SER indicated that any option requiring more than a \$100K investment would “put us out of business.”

- Multiple SERs indicated engineering controls are used throughout the industry, including carbon adsorption for larger operations and ventilation systems channeling exhaust outside the facility. Further, current practices are such that degreasing operations occur in dedicated rooms or areas.
- Multiple SERs acknowledged the OSHA PEL is 100 ppm; however, industry practice is to abide by the ACGIH TLV which is 10 ppm. Some SERs suggesting consider adopting the ACGIH recommended exposure limit of 10 ppm as a requirement.
- Multiple SERs indicated use of the proposed PPE in general would not be realistic, one cited summer ambient temperatures exceeding 100 degrees Fahrenheit as a reason.
- A suggestion was made from multiple SERs that EPA develop a mechanism for submitting exposure data, showing compliance with the current OSHA PEL.

Substitutes and alternatives

- As noted previously, a SER provided information pertaining to the use of aqueous based systems. He indicated solvent vapor degreasing may be best suited (potentially required) for smaller, intricate parts that require a very high level of cleaning in hard-to-reach areas (e.g. small tubes, items with blind holes); whereas aqueous systems are appropriate for larger parts and substrates. Primary considerations regarding aqueous systems include:
 - Significant water use (one example was 30,000 gallons per day);
 - Used/effluent water is considered industrial wastewater and must be handled/treated appropriately;
 - Significant energy requirements due to the need for drying operations;
 - Potential need for multiple stages (and multiple machines) to accomplish similar cleaning efficiency;
 - Aqueous operations require significantly more space, often due to multi-stage systems; and,
 - Overall cycle times can be higher when multiple stages/tanks are needed to accomplish comparative cleaning levels.
- Multiple SERs indicated that the Department of Defense (DoD) and the Food and Drug Administration (FDA) have certain specifications that use TCE in vapor degreasing, such as parts for electronic field radios and tubing for medical devices. One SER stated that a facility manufacturing tubing for medical devices would need to undergo an FDA approval process, taking up to four years, to approve an alternative for these processes.
- Several SERs indicated that none of the proposed chemical alternatives are realistic options. A summary of reasons include:
 - Potential health hazards associated with possible alternatives;
 - Potential regulations associated with possible alternatives;
 - Low-boiling alternatives result in significant volatilization (and loss) during typical operations; these chemicals also present a shipping concern because they cannot be shipped in typical drums;
 - Uncertainty with cleaning effectiveness; and,

- Significantly higher costs associated with some of the alternative chemicals.

SER concerns with the TCE Risk Assessment

- Several SERs suggested that EPA re-examine the underlying inputs for the calculations and evaluations in the current risk assessment, particularly those associated with:
 - The number of open top vapor degreasing units in the US (SERs estimated <650);
 - The typical use rate of TCE at facilities (SERs estimate significantly lower use rates, based on the NESHAP emission limit of ten tons per year);
 - The number of workers exposed (SERs estimate one worker per machine);
 - The frequency and duration of exposure (SERs provided a range of exposure durations ranging from one to four hours per day).
- Some SERs questioned the basis of the risk evaluation by EPA and cited other evaluation done by the National Academy of Science regarding Camp Lejeune.

Other comments

- Multiple SERs extended invitations for site visits to their facilities to assist EPA staff in understanding operating practices and worker exposure patterns.

8.4. Summary of Written Comments from SERs following the Panel Outreach Meeting, June 15, 2016

EPA received written comments from ten SERs between June 15 and July 1, 2016. The following is a summary of the written comments submitted by the potential SERs, which in some instances repeats what was provided orally at the Panel outreach meeting. A copy of each of the comments submitted by the potential SERs is included in Appendix B.

Description of the degreasing operations of the SERs

- One SER indicated that they manufacture parts for the aerospace industry, and TCE is an integral part of the operations due to the configuration of the sheet metal parts and the small diameter tubing of the systems for the aircraft.
- One SER indicated that they clean small formed parts, machined parts and precision assemblies. Their customers include aerospace, general aviation, military aviation, medical and other critical markets.
- Another SER indicated that they clean parts used in motor case assemblies.
- One SER indicated that they use TCE for degreasing drills and taps that need to be blacken or golden product. Water presents a challenge to the drills because it leaves stain and rust.
- One SER indicated that they manufacture precision, internally threaded retaining components for mechanical power transmission and they are the last manufacturer of these components in the United States.
- One SER indicated that they distribute cleaning chemistries (including TCE) and manufacture parts cleaning equipment (including vapor degreasers using TCE). According to this SER, from

1940's to the early 1990's, chlorinated solvent used to be 90% of the cleaning process industry. The SER stated that TCE has the ability to clean a wide range of lubricants over a wide divergent array of geometric part size and configuration and substrates, with a small footprint and the least amount of indirect costs, such as labor and utilities. According to this SER, the 1994 National Emission Standards for Hazardous Air Pollutants; Halogenated Solvent Cleaning (NESHAP) and the 2007 revisions of the NESHAP have resulted in 95% reduction of TCE consumption and emissions and worker exposure. This SER estimates that the current number of facilities using TCE is less than 800, based on the current volume of TCE used in the United States, the SER's estimated 5% of TCE used in vapor degreasing operations and the limit of TCE emissions allowed per facility under the NESHAP.

Current work practices regarding the SERs' degreasing operations

- One SER currently employs 212 people. Two to four employees directly operate the vapor degreaser and an additional two to four employees are near the system to support the degrease operations. The vapor degreaser was designed by the SER and has been in operation for over 30 years with several upgrades and modifications. The vapor degreaser is operated 10 hours per day Monday to Thursday, 9 hours per day on Friday, and 6 hours per day on Saturday. There are about 165 gallons of TCE in the tank of the degreaser. The SER currently uses 1200 to 1500 gallons of TCE a year.
- One SER indicated that their system holds about 5 gallons of TCE, and uses between 452 and 1120 gallons of TCE per year for all open-top vapor degreasing units. The machine is used for cleaning an average of 3 hours per day and since the process is semi-automatic and timed, the operator is present at the machine an average of 30 minutes per day. The machine can run 4 to 6 cleaning cycles per hour and only requires a few minutes to load and unload.
- One SER indicated that they only use 2.5% of their permitted amount of TCE.
- One SER currently employs 217 people, and one employee is involved in the loading and unloading of the degreaser, nobody is around when the degreaser is in use. The system operates from Monday to Friday, 8 hours a day.
- One SER indicated that they currently employ 150 people, and only one employee is involved in the degreasing operation. Occasionally a forklift driver (3 to 4 times per hour) will be 15 feet from the lip of the free board area of the open top degreaser, and another worker might be about 50 feet away with a wall between their position and the degreaser.
- One SER indicated that six employees over three shifts conduct the degreasing operations. The degreaser operates 24 hours a day, 5 days a week. The solvent capacity is 750 gallons in the degreaser and 185 gallons in the sill.
- One SER indicated that they installed their degreaser in 1997 and updated the system in 2006.
- One SER indicated that their current system has a double tank chamber, a pneumatically sealing cover, a loading robot, and condensing coil chillers. The facility also has an exhaust to eliminate TCE fumes. The operator is within 25 feet of the cleaning system and other employees are within 75 feet of the system. The degreasing system operates less than 19 minutes per day, but only the robot is directly exposed to the TCE fumes. The tanks openings are above the operator's head

and the fumes are exhausted outside of the building. The SER's experience is that operators work just over 12 months loading the system, instead of the 40 years exposure assumed by EPA.

- Two SERs indicated that small degreasers referred to as "open tops" are required by the NESHAP to have covers, extended walls, chillers, engineering controls, operating procedures, and quarterly reporting to minimize emissions.
- According to one SER, in line vapor degreasers are large capacity machines operating in a separate room without operators, and the emissions are captured and run through a carbon absorption system. This SER also indicated that vacuum degreasers have very limited application and are very expensive, have a large footprint with limited production capacity.
- Several SERs provided diagrams of the equipment used.

Use of TCE in businesses and exposure reduction

- One SER indicated that all degreasing operators are provided training and must be certified before they can operate the degreasing machine. Operators are also protected from exposure through the use of engineering controls and standard operating procedures. Periodic testing is performed to monitor exposure levels. The most recent monitoring session included a sample of a full shift, which indicated an exposure of 39.8 ppm, and a second sample for 15 minutes of exposure as the employee lowered and retrieved parts from the tank, which indicated an exposure of 153 ppm.
- One SER purchased a compliant vapor degreasing machine in June of 2008, and at that time procedures were established and training and operator certification was performed. There are weekly and monthly operational test performed and recorded to ensure the unit is functioning correctly. About 12 employees operate the degreaser at random, most of the use would be by five employees with no more than 2 hours in the vicinity of the machine per day for any one person. The area is well ventilated. Gloves and masks are available to handle and transfer the TCE, and the SER conducts OSHA surveys to ensure compliance. The SER has developed work practices that estimate a Time Weighted Average (TWA) for an 8 hour day of 2.5 ppm or less. The air samples taken in April 2008 indicated an operator TWA PEL of 0.09 and the area TWA PEL of 0.21 ppm.
- One SER indicated that they check for compliance with OSHA, monitor the equipment every month, and monitor the solvent every 15 days. The SER hired an industrial hygienist and they conduct quarterly sampling. Results provided by the SER indicate an 8-hour TWA concentration values ranging from 10 ppm to 16 ppm.
- One SER indicated that based on his experience and industry practices the average number of workers per vapor degreaser is one, the number of workers adjacent to the vapor degreaser is one, TWA exposure limits are significantly lower than 190, and the vapor degreaser is operated less than 8 hours per 8 hour shift. Furthermore, most degreasing operations are isolated from the rest of the manufacturing operation.
- According to a SER, industries that work with narrow tube, razor blade and aerospace maintenance comply with the NESHAP, they conduct degreasing operations in a separate room, all vapors are captured and processed thru a carbon absorption process and workers are either

never in the room or enter to engage an automatic loading system and leave – which results in lower worker exposure.

- Based on feedback from 12 shops, the typical annual usage of TCE ranges from 110 gallons to 2,000 gallons per year. All shops reporting running 8 hours per day, with 240 to 250 days per year of operation. Typically all production is cleaned in the TCE vapor degreaser, which includes critical items with blind holes, rigorous cleanliness requirements, and critical metal to glass seal components.
- One SER indicated that their machine was installed in the late 1970's with upgrades before 1998, and no further work is currently planned since it meets the MACT standards. The SER conducts annual vapor degreaser training for all operators, provides procedures to minimize the exposure to vapors, has a plastic curtain enclosures around the immediate degreaser and there is an exhaust fan in an adjacent room. The SER indicates that no worker spends more than 4 hours per day operating the degreaser at a time.
- One SER indicated that the degreaser was installed in 2003 with a new recycler installed in 2015 to increase workflow and extend the life of TCE. The system is enclosed with a dedicated exhaust system, super heater and a cold trap. For personal protection equipment (PPE), the SER mentions they supply air hoods, respirators, chemical suits, gloves, and boots. The SER also has worker training (NESHAP, Right-To-Know, Hazardous Material handling). Monitoring results in February of 2016 indicated a 0.40 ppm for 8 hour TWA.
- A SER indicated that a control option for a lower exposure limit than the current proposed 100 ppm was not currently available. The SER's view is that the engineering controls he uses in conjunction with a well-designed machine should allow compliance with a lower limit without the loss of business. The SER also stated that at a minimum, gradually lowering the exposure limits over time would drive improved workplace safety and allow to the industry to develop practical alternatives. The SER further stated that for his company, implementing the ACGIH limit of 10 ppm over a 10 year period would not require additional investment. The SER is compliant with the current OSHA regulations for vapor degreasers, and expects similar results from other small companies that are using similar equipment.

Substitutes and alternatives

- Several SERs stated that any substitute or alternative method used would have to be tested to ensure that it meets the specifications of their clients. One SER indicated that the update to their existing equipment took 2 years. Another SER indicated that developing cleaning specifications could take from 6 months to 4 years, examples provided by the SER included: medical instruments that come in contact with the human body take four years, aerospace approval on critical parts is four years, and military approval for electronic parts is three years. After the cleaning specification is approved, equipment design, installation, and obtaining local permits could take another two years.
- One SER has determined that it would not be economically feasible to replace the existing machine due to the initial cost, space limitations, and the changes in the cycle time.
- One SER indicated that the vast majority of the industry has already converted to an alternative cleaning process, the majority converted to an aqueous chemistry cleaning process. The change

to aqueous cleaning requires significantly larger space, is more expensive, and are less productive machines. Another SER indicated that the greatest potential issues with aqueous cleaning is water residual, and the potential for corrosion conditions from water to be introduced in an undetectable manner.

- SERs indicated that drop in replacements suggested by EPA (chlorinated and brominated solvents) are not viable alternatives. SERs indicated that the toxicity of the chlorinated and brominated alternatives was equal or higher than TCE and subject to similar exposure limits. SERs also stated that other alternatives such as hydrofluorocarbons, hydrofluoroethers, and hydrofluoroolefins are not viable replacements since they boil at much lower temperatures, they don't clean without adding a chlorinated derivative, they have similar health risks, or require positive pressure air supplied respirators when in use.
- Several SERs mention that replacements are 10 times more expensive. One SER indicated that the cost of 1-bromopropane is twice the cost of TCE.
- One SER indicated that is very expensive to implement a new chemical cleaning process that might be just as hazardous and might be regulated in the future.
- One SER indicated that they switched to a 1-bromopropane system in 2013. The cost to switch over was considerable (about \$60,000 for the degreaser and double the chemical cost on an annual basis to run the degreaser). The SER found out that 1-bromopropane is not a good substitute for working with aluminum castings and they have to turn down defense and aerospace work that specifies TCE.
- One SER considered CO₂ technology, but the equipment cost is about \$0.5 million.
- One SER indicated that the only alternative that would meet the level of cleaning required by their customers, meets the Department of Defense MIL-P-116J, and does not chemically damage their products are modified alcohol cleaning solvents. The investment required would be \$650,000.
- One SER concluded that there are no practical alternatives to TCE available at this time.
- One SER indicated that they would need to use full time protective equipment and replace the degreaser to attempt to achieve the proposed 0.0004 exposure limit, and the SER is not confident that they can achieve such a level. In the opinion of the SER, the proposed exposure limit is equivalent to banning TCE.
- One SER indicated that conversion of a cleaning process from manufacturer is expensive, time consuming and complicated. According to this SER past specifications indicated "cleaned by TCE in a vapor degreaser."
- One SER indicated that based on feedback from 12 shops, the impacts if TCE were prohibited include: no comparable cleanliness alternative method has been found; TCE works for plastics/polymers/engineered materials in conjunction with metallic inserts; several shops already switched to an alternative – although might be struggling meeting the productivity and cleanliness levels; failure to remove oil can affect the reliability of auto and aerospace parts – many end use customers (e.g. aerospace, defense, medical and automotive) demand that the critical machine parts supplied by the shop should be free from oil; the re-approval process for a new cleaning process with their automotive customers would entail between 5 to 10 man-years;

some shops indicate that similar shops in Europe have been exempted from any ban on TCE; their customer orders include the use of TCE in their process; TCE is essential in parts for metal to glass seal and electronic connects applications. Other small business potential impacts of prohibition of TCE include: cost estimates to replace equipment ran from \$350,000 to over \$500,000 (equivalent to 2 to 5 years of planned capital investments), for some shops the estimate was ranged from 25% of net revenue to 100% of annual profit – these investments will leave the shops far behind competitors in South Korea, China, Indonesia, Malaysia, and India who are investing in new technologies and capabilities; the level of investment will lead to customer rejections and rework, and some companies felt that the costs will lead to decisions regarding closing which could impact 12-70 employees per shop. The SER concluded that about 5% of 240 companies could be impacted by the rule.

- A SER suggested that EPA drop its faulty and fictional notion that there exist “drop in replacements” for TCE. According to the SER, TCE remains an unmatched cleaner that is critical to many US high technology and advanced technology manufacturing applications. The SER believes that critical modern transportation, safety, communications, computing, and defense applications require the unmatched performance provided by TCE.
- One SER submitted an analysis of how the Frank R. Lautenberg Chemical Safety for the 21st Century Act would impact the consideration of alternatives:
 - Consideration of alternatives: Multiple SERs expressed concerns regarding the alternatives mentioned by EPA: n-propyl bromide, perchloroethylene, methylene chloride, and other compounds. Several SERs also questioned whether these alternatives would realistically be available given current and future planned EPA regulation. The SER mentioned the new requirement of TSCA Section 6(c)(2)(C) “Consideration of alternatives.” The SER mentioned the “regrettable substitution” of methylene chloride with n-propyl bromide in the foam fabrication, and the SER also stated that n-propyl bromide does not have the long history of safe use in the workplace of TCE.

SER concerns with the TCE Risk Assessment

- One SER recommended EPA cancel this project and enforce rules already in place that were developed by EPA with industry input. According to this SER, rulemaking should not go forward until an accurate baseline assessment of exposure and risk has been developed. The SER stated that the 2014 Work Plan assessment uses worker and bystander exposures based on conditions that predated the NESHAP and thus presents an inaccurate and unduly alarming perspective.
- Another SER requested that EPA reassess its assumptions regarding exposure limits, its assumptions regarding processes and exposures currently found in the industry, and its insistence that there exists a toxic connection between TCE and various cancer and non-cancer health outcomes for which the National Academies found “no causal relationship nor any associated relationship.”
- One SER requested that the EPA consider collecting further case study data at ongoing degreasing operations, producing a risk assessment report based upon observed exposure data

and years employees are exposed, and determine whether workers are actually being exposed to harmful levels of TCE instead of making new rules and policy based upon inaccurate assumptions and no factual data.

- Two SERs provided comments questioning the findings of EPA’s risk evaluation given the findings of the National Academies of Science evaluation of the TCE contamination at Camp Lejeune. The SERs indicated that the National Academies of Science were unable to find “sufficient evidence of a causal relationship” or “sufficient evidence of an association.” Also, the SERs indicated that the National Academies of Science report found “limited/suggested evidence of an association” for PCE or solvent mixtures, in 14 health outcomes, and found inadequate/insufficient evidence to determine whether an association exists on 44 health outcomes – only 4 of which were characterized as potentially thought to be connected to TCE. The SERs indicated that is hard for them to understand how EPA can confidently determine risk to a fraction of a part per billion when the National Academies were unable to find a causal relationship for negative health outcomes.
- One SER questioned the accuracy and validity of the estimates and assumptions made by EPA and the practicality of forcing manufacturers to spend hundreds of thousands of dollars replacing existing safe and functional equipment.
- One SER submitted an analysis of how the Frank R. Lautenberg Chemical Safety for the 21st Century Act would impact the risk evaluation for TCE in vapor degreasing:
 - Risk evaluation for TCE in vapor degreasers: the amended TSCA requires risk evaluations based relevant information and science (Sections 6(b)(4)(F) and 26(h)).
 - Exposure assessment: SERs indicated that EPA/OPPT risk assessment should be updated to take NESHAP emission limits into account. According to the SER, implementing NESHAP requirements resulted in more than 95% reduction and fewer vapor degreasers in operation (600 to 700). The SER also cited a comment from one of the peer reviewers of the TCE risk assessment indicating that more work is needed to tighten up the exposure assessment and provide further justification of the exceedingly low HEC99 values used in the MOE analysis.
 - Hazard assessment: the SER stated that the TCE risk assessment relied on hazard values derived from Johnson *et al.* (2003) to estimate non-cancer risk, and in the SER’s view the study is flawed and should not be the basis for regulation. The SER indicated that other studies have been unable to reproduce the effects seen by Johnson *et al.* (2003). The SER described the initial publication of the data reported by Johnson *et al.* (2003) indicating that the initial publication did not have meaningful dose-response relationship. The SER stated that Johnson *et al.* (2003) has been heavily criticized in the published literature, its predecessor study was rejected by ATSDR in its last TCE Toxicological Profile Update, and the California Office of Environmental Health Hazard Assessment rejected the study as deficient. The SER also points out the opinion of one EPA staff member included in the docket regarding similar concerns with the Johnson *et al.* (2003) study and the opinion of several EPA staff indicating little confidence that the

study supported the dose-response assessment. The SER indicates that the Halogenated Solvents Industry Alliance is sponsoring a guideline study of TCE developmental toxicity focused on cardiac abnormalities that is intended to help understand the different results seen in the earlier studies, the result of this guideline study are expected later this year. The SER also indicated that a peer review panelist of the TCE assessment also raised concerns over the non-cancer dose response. The SER states that instead of accepting the advice of the peer review panel, EPA relied upon an erratum published by the study authors reaffirming the adequacy of Johnson *et al.* (2003).

- Impact of TSCA science provisions: the SER indicates that the risk evaluation that supports a TSCA Section 6 rule must be more robust than the screening level work plan assessment that EPA carried out for TCE. According to the SER, the Chairperson of the peer review panel of the TCE assessment's main concern was that the information is not consistent with any intended use to support regulation and her advice was that there would be little benefit in even revising the assessment, given its inadequacy for regulatory use. As noted by the SER, the Chairperson said "the current draft screening level assessment could then be attached as an appendix to the second-generation assessment, and described, in summary form, in the early chapter(s) of the new assessment." The SER also concluded that the TCE risk evaluation does not meet the requirements of new TSCA Section 26(h). According to the SER, other panelists in the peer review panel of the TCE assessment also raised serious concerns regarding the "best available science" criteria of Section 26(h), including: inappropriate use of default assumptions; ignoring contrary evidence that affects the weight of the scientific evidence; reliance on inapposite exposure data; conclusions inconsistent with the evidence cited; and, most importantly, reliance on a study that is not reproducible. According to the SER using the 2014 assessment for the rulemaking will be inconsistent with the new Section 26(1)(4). The SER also stated that EPA decided that no distinction will be drawn between large and small shops, according to the SER, even small business might operate large degreasing machines which were not covered by the assessment.

Other comments

- A SER suggest that EPA delay any further work on this proposed rule until we have clarity on the version of TSCA that passed the House and Senate and that will become the law of the land upon signature by the president.
- One SER submitted an analysis of how the Frank R. Lautenberg Chemical Safety for the 21st Century Act would impact the replacement parts provision and the gap filling purpose of TSCA:

- Replacement parts: a number of SERs' business consists largely of precision cleaning parts for uses in medical, aviation, aerospace, defense, and automotive applications. The SER indicated that changing federal agency or industry specifications for these parts take years, and many of these parts are replacement parts. According to the SER, NESHAP recognized this fact. The SER also indicated that the new TSCA Section 6(c)(2)(D) includes specific requirements for replacement parts. The SER also mentions other requirements included in TSCA regarding an implementable and robust consideration of cost and benefits and how such consideration influenced the choice of regulatory requirements.
- Gap filling purpose of TSCA: according to the SER, TCE does not appear to present an unreasonable risk of injury to health for purposes of regulation under TSCA. The SER also states that the amended TSCA Section 9 requires EPA to consult and coordinate with other federal agencies and impose the least burdens of duplicative requirements. According to the SER the use of TCE in vapor degreasing is already more than adequately regulated under the Occupational Safety and Health Act as well as by EPA under the Clean Air Act.
 - OSHA Regulation: according to the SER, worker health and safety falls under the jurisdiction of the Occupational Safety and Health Administration (OSHA), which has regulated occupational exposure to TCE for many years. The SER indicates that OSHA should be given an opportunity to consider whether a lower workplace standard would be appropriate. The SER indicates that any EPA regulation has the potential for conflicting and overlapping with OSHA's existing limits, furthermore, the SER states that OSHA's enforcement of its own standards is mandatory, however, OSHA many not enforce an EPA regulation. The SER also indicates that EPA is not authorized to establish ambient concentration limits under TSCA Section 6; therefore, according to the SER, EPA can only control the amount used in a product or prohibiting a particular use of the substance under Section 6. The SER indicates that this approach is potentially much more burdensome economically. The SER also mentions Executive Order 13563 which requires agencies to achieve their objectives using the least costly regulatory alternative.
 - EPA Regulation: the SER described the requirements of the NESHAP. According to the SER, by imposing an annual limit on TCE emissions from vapor degreasers, the NESHAP changed work practices and reduced both in-facility (occupational and bystander) exposure and fence line emissions, estimated by the SERs to be more than 95%, and the NESHAP is a comprehensive regulation of TCE in vapor degreasing.
 - Requirements of TSCA Section 9: the SER cites TSCA Section 9 and the legislative history, including the House Committee Report and several quotes from members of the House of Representatives, to highlight the SER's position on the limitations on EPA's authority. Specifically, the SER quoted report language that "EPA simply has to account for why a new regulation for methylene chloride and TCE under TSCA is necessary since its own existing regulatory framework already appropriately addresses risk to human health. New Section 9(b)(2) will force the Agency to do just that." According to the SER, TSCA is to be used only when other statutes or authorities fail to provide a remedy for unreasonable risks to human health or the environment, and EPA should avoid duplicative regulation under TSCA. The SER indicates that there is no evidence that EPA

submitted to OSHA a report describing the risk and the specific activities that present such risk, as required by TSCA Section 9(a)(1). According to the SER, the non-existent report obviously did not include a statement of the information on which it is based or was published in the Federal Register, as required. The SER indicates that the letter from OSHA dated April 2016 does not meet the requirements of TSCA, and furthermore, does not identify a gap specific to vapor degreasing, rather, the letter states overall limitations of OSHA and therefore seems that EPA is assuming authority over the use of hazardous substances in the workplace. Finally, according to the SER, the NESHAP regulation precludes regulation under TSCA Section 6 unless EPA can make a determination under TSCA Section 9(b) “that it is in the public interest to protect against such risk by actions taken under this Act.”

9. PANEL FINDINGS AND DISCUSSION

9.1. Number and Types of Entities Affected

For a complete description of the small entities to which the proposed rule may apply, see Sections 4, 5 and 7 of this document.

9.2. Potential Reporting, Recordkeeping, and Compliance Requirements

The potential reporting, recordkeeping, and compliance requirements are still under development. However, the Panel anticipates that the requirements will be the minimum necessary to ensure compliance with the regulatory option chosen. Reporting and recordkeeping requirements should be streamlined to the extent practicable.

9.3. Related Federal Rules

See Section 2.1 of this document for a discussion of related federal rules.

TSCA Section 9(a) analysis

Section 9(a) of TSCA provides that, if the Administrator determines in her discretion that an unreasonable risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by EPA, the Administrator must submit a report to the agency administering that other law that describes the risk and the activities that present such risk. If the other agency responds by declaring that the activities described do not present an unreasonable risk or if that agency initiates action under its own law to protect against the risk, EPA is precluded from acting against the risk under sections 6 or 7 of TSCA.

Section 9(d) of TSCA instructs the Administrator to consult and coordinate TSCA activities with other Federal agencies for the purpose of achieving the maximum enforcement of TSCA while imposing the least burden of duplicative requirements. For this proposed rule, EPA has consulted with OSHA. These consultations included numerous meetings at the staff and management level, to discuss technical, legal, and public health issues related to this rulemaking. OSHA supports both EPA’s proposed regulation of TCE use for consumer and commercial aerosol degreasing and spot cleaning under Section

6 of TSCA, which has been submitted for inter-Agency review under Executive Order 12866 and EPA's related proposed regulation of TCE for vapor degreasing under Section 6 of TSCA, and has provided a letter documenting this support (Appendix A).

OSHA assures safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance. OSHA adopted an eight-hour time weighted average PEL of 100 ppm along with a ceiling limit in 1971 shortly after the agency was formed. It was based on the American Conference of Governmental Industrial Hygienists (ACGIH) recommended occupational exposure limit that was in place at that time. OSHA recognizes that the TCE PEL and many other PELs issued shortly after adoption of the OSHA Act in 1970 are outdated and inadequate for ensuring protection of worker health. OSHA recently published a Request for Information on approaches to updating PELs and other strategies to managing chemicals in the workplace. OSHA's current regulatory agenda does not include revision to the TCE PEL or other regulations addressing the risks EPA has identified when TCE is used in vapor degreasing.

EPA has determined that risks from the use of TCE in vapor degreasers, spot cleaning and consumer and commercial aerosol degreasing are best managed by regulations under TSCA rather than referral to OSHA, because of the limitations imposed on OSHA's authority under the OSH Act, namely that OSHA lacks jurisdiction over self-employed workers; military personnel and uniquely military equipment, systems, and operations; certain federal sectors, as well as state and local government workers. State and local government workers are covered only if they work in those states that have OSHA-approved state safety and health programs. In addition, OSHA does not have the authority to bar the manufacture, processing or distribution for these uses and require downstream notification of restrictions as EPA plans to do, and which is likely to be more efficient and effective than regulating on a facility-by-facility basis. Finally, because EPA is also planning to regulate consumer uses of TCE in aerosol degreasing, the risks presented by TCE overall can be addressed in a more coordinated and efficient manner under TSCA than under two or more different laws implemented by different agencies.

TSCA Section 9(b) Analysis

If EPA determines that actions under other Federal authorities administered in whole or in part by EPA may eliminate or sufficiently reduce unreasonable risks, section 9(b) of TSCA instructs EPA to use these other statutes unless the Administrator determines in the Administrator's discretion that it is in the public interest to protect against such risk under TSCA. In making such a public interest finding, section 9(b)(2) of TSCA states: "the Administrator shall consider, based on information reasonably available to the Administrator, all relevant aspects of the risk . . . and a comparison of the estimated costs and efficiencies of the action to be taken under this title and an action to be taken under such other law to protect against such risk."

Although several EPA statutes have been used to limit TCE exposure, as discussed in Section 2.1, regulations under these EPA statutes have limitations because they largely regulate releases. SDWA only applies to drinking water. CAA does not apply directly to worker exposures where TCE is used. Under RCRA, TCE that is discarded may be considered a hazardous waste and subject to requirements designed to reduce exposure from the disposal of TCE to air, land and water. RCRA does not address exposures during use of products containing TCE. Only TSCA provides EPA the authority to regulate

the manufacture (including import), processing, distribution in commerce, and commercial use of chemical substances.

9.4. Regulatory Flexibility Alternatives

Panel recommendations

The Panel recommends that EPA request additional information on critical uses; availability, effectiveness, and costs of alternatives; implementation timelines; and exposure information to provide flexibility to lessen impacts to small entities, as appropriate.

Critical uses

The Panel recommends that EPA provide exemption, in accordance with TSCA section 6(g), for those critical uses for which EPA can obtain adequate documentation that:

- no technically and economically feasible safer alternative is available;
- compliance with the ban would significantly disrupt the national economy, national security, or critical infrastructure; or
- the specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

To that end, the Panel recommends that EPA include in its proposal specific targeted requests for comment directed towards identifying critical uses (such as the aeronautics industry and national security) and obtaining information to justify exemptions.

The Panel also recommends that EPA request public comment on allowing the use of TCE in closed-top vapor degreasing systems with the use of appropriate PPE.

Alternatives

The Panel recommends that EPA ensure that its analysis of the available alternatives to TCE in vapor degreasing complies with the requirements of section 6(c)(2)(C) and includes consideration, to the extent legally permissible and practicable, of whether technically and economically feasible alternatives that benefit health or the environment, compared to the use being prohibited or restricted, will be reasonably available as a substitute when the proposed requirements would take effect. Specifically, the Panel recommends that EPA:

- evaluate the feasibility of using alternatives, including the cost, relative safety, and other barriers (such as space constraints, cleaning efficiency, increased energy use, cycle time, boiling points, and water use restrictions)
- take into consideration the current and future planned regulation of compounds the agency has listed as alternatives.

Implementation timelines

The Panel recommends that EPA provide regulatory flexibility, as applicable, based on additional information, such as delayed compliance or a phase-out option, for small businesses that may be affected by the rule and in its proposal specifically request additional information regarding timelines for transitioning to alternative chemicals or technologies.

Cost information

The Panel also recommends that EPA specifically evaluate the cost to small business degreasing services without a viable alternative to TCE (*i.e.*, the cost of going out of business).

The Panel recommends that EPA request additional information on the cost to achieve reduced exposures in the workplace or to transition to alternative chemicals or technologies.

Exposure information

The Panel recommends that EPA include in its proposal specific requests for additional pertinent exposure data that may be available.

Risk Assessment

The Panel recommends that EPA recognize the concerns that the SERs had on the risk assessment by referring readers to the risk assessment and the Agency's Summary of External Peer Review and Public Comments and Disposition document, which addresses those concerns, in the preamble of the proposed rulemaking.

SBA Office of Advocacy Recommendation

The SBA Office of Advocacy recommends that EPA address the concerns expressed by the SERs on the final risk assessment for TCE in the preamble of the proposal for this rulemaking. Moreover, based on the SER concerns, Advocacy recommends that EPA revise the risk assessment to specifically address the comments from the Chairperson of the peer review panel for EPA's TCE risk assessment, who referred to the assessment as a screening level assessment. Finally, Advocacy recommends that EPA revise the risk assessment to incorporate the supplemental analyses conducted after the final TCE risk assessment. These recommendations are included to ensure that the risk assessment provides sufficient basis for EPA's regulatory action with regard to TCE vapor degreasing in occupational settings.

The SBA Office of Advocacy recommends that EPA conduct peer review for the supplemental analyses completed after EPA's final TCE risk assessment and specifically seek public comments on the supplemental analysis especially since the SERs did not review these analyses during the panel process.

EPA Response

EPA disagrees with the recommendation by Advocacy to revise the risk assessment for TCE and to have the supplemental analysis peer reviewed. The TCE risk assessment was already open for public comment and has been peer reviewed, and that peer-reviewed methodology was used for the

supplemental analysis. The current final risk assessment and supplemental analysis provide the necessary scientific support for the rule. EPA believes that additional comments relating to the completed risk assessment are most appropriately addressed during the public comment period for the proposed rule.

APPENDICES

Appendix A: Materials EPA shared with Small Entity Representatives

The U.S. Environmental Protection Agency (EPA) conducted a Pre-Panel outreach meeting with potential Small Entity Representatives (SERs) on March 17, 2016. EPA, along with Panel partners, Small Business Administration's Office of Advocacy (SBA), and Office of Management and Budget's Office of Information and Regulation Affairs (OMB), hosted a Panel outreach meeting with SERs on June 15, 2016.

Appendix A1. Materials EPA shared with potential SERs before the Pre-Panel outreach meeting, March 17, 2016

- Agenda for Pre-Panel Outreach Meeting, March 17, 2016
- Power Point Presentation: An Overview of the Small Business Advocacy Review Panel Process
- PowerPoint Presentation: Rulemaking for TCE under the Toxic Substances Control Act (TSCA) March 17, 2016
- SBAR Pre-Panel Discussion Questions
- Estimated Incremental Costs for TCE Vapor Degreasing Options

Appendix A2. Materials EPA shared with SERs before the Panel outreach meeting, June 15, 2016

- Agenda for Panel Outreach Meeting, June 15, 2016
- Power Point Presentation: Small Business Advocacy Review Panel Process Recap, June 15, 2016
- Power Point Presentation: Rulemaking under the Toxic Substances Control Act (TSCA) for Use of Trichloroethylene (TCE) in Vapor Degreasing, June 15, 2016.
- Panel Questions for Small Entity Representatives (SERs)
- Regulatory History and International Actions for TCE
- U.S. Department of Labor Letter to EPA in Support of Rulemaking
- Additional Cost Information - Cost of Substitute Materials
- OSHA Assigned Protection Factors for the Revised Respiratory Standard

Appendix B: Written Comments Submitted by Small Entity Representatives

The U.S. Environmental Protection Agency (EPA) conducted a Pre-Panel outreach meeting with potential Small Entity Representatives (SERs) on March 17, 2016. EPA, along with Panel partners, Small Business Administration's Office of Advocacy (SBA), and Office of Management and Budget's Office of Information and Regulation Affairs (OMB), hosted a Panel outreach meeting with SERs on June 15, 2016.

Appendix B1. Written Comments from potential SERs following the March 17, 2016 Pre-Panel outreach meeting

After the March 17, 2016 pre-Panel outreach meeting, potential SERs submitted two sets of written comments, which are provided in this Appendix:

1. Globe Engineering Co., Inc. from Wichita, KS
2. Nobert Plating Co., Rob Sickles, from Chicago, IL

Appendix B2. Written Comments from SERs following the June 15, 2016 Panel outreach meeting

After the June 15, 2016 meeting, the following SER submitted eleven sets of written comments, which are provided in this Appendix:

1. Globe Engineering Co., Inc., Jeff Teague, President and Scott Lauderbaugh, EHS Coordinator, from Wichita, KS
2. Kearflex Engineering, Brian Peskin, VP, from Warwick, RI (6/22/2016 comments)
3. Kearflex Engineering, Brian Peskin, VP, from Warwick, RI (6/28/2016 comments)
4. Marquette Tool & Die Co., Gerry Richardson, from St. Louis, MO
5. McMillan Electric Company, Floyd Ankrum, Plant Engineering Manager, from Woodville, WI
6. Nobert Plating Co., Rob Sickles, C.E.F., from Chicago, IL
7. Parts Cleaning Technologies, David Crandell, President, from Redford, MI
8. Precision Machined Products Association, Miles Free, Director, Industry Research and Technology, from Brecksville, OH
9. E. C. Styberg Engineering Company, from Racine, WI
10. Viking Drill and Tool, Inc., from St. Paul, MN
11. Whittet-Higgins Company, Andrew A.O. Brown, from Central Falls, RI