

September 26, 2016

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator McCarthy:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened for EPA's planned proposed rulemaking entitled "Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing under TSCA §6(a)." This notice of proposed rulemaking is being developed by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA).

Under section 6(a) of TSCA (15 U.S.C. § 2605(a)), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, if EPA determines after risk evaluation 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 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 or mixture no longer presents such risk. Based on EPA's risk assessment of TCE, published on June 25, 2014, EPA has determined that the use of TCE in vapor degreasers presents an unreasonable risk of injury to health. Accordingly, EPA has identified two regulatory approaches that may reduce these risks to the extent that those risks are no longer unreasonable. As described in section 3 of the Panel Report, these approaches are to 1) Prohibit the manufacturing (including import), processing, distribution in commerce, and use of TCE in vapor degreasing, and require downstream notification, or 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. These options are currently being considered and evaluated by EPA, and are not final at this time.

On June 1, 2016, EPA's Small Business Advocacy Chairperson convened this Panel under section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). In addition to its Chairperson, the Panel consists of a representative from 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 of the Chief Counsel for Advocacy of the Small Business Administration. It is important to note that the Panel's findings and discussion are based on the information available at the time the report was drafted. EPA is continuing 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.

THE FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

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 section 6(a) for addressing these unreasonable risks have not been changed by the law.

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 of the Panel report), 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 of the Panel Report. 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 of the Panel Report.

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 of the Panel Report. 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.

PANEL FINDINGS AND DISCUSSION

Under section 609(b) of the RFA, the Panel is to report its findings related to these four items:

- 1) A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.
- 2) A description of the projected reporting, recordkeeping 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.
- 3) Identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap or conflict with the proposed rule.
- 4) An initial regulatory flexibility analysis with a description of any significant alternatives to the planned proposed rule which would minimize any significant economic impact of the proposed rule on small entities consistent with the stated objectives of the authorizing statute.

The Panel's most significant findings and discussion with respect to each of these items are summarized below. Section 9 of the Panel report has the full description of the Panel findings and recommendations.

A. Number and Types of Entities Affected

The proposed rule potentially affects small manufacturers (including importers), processors, distributors, and retailers of TCE for use in vapor degreasing and small entities that are commercial users of TCE in vapor degreasing equipment. EPA 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. Sections 4, 5 and 7 of the Panel report include a complete description of the small entities to which the proposed rule may apply.

B. Recordkeeping, Reporting, and Other 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. The Panel agrees that reporting and recordkeeping requirements should be streamlined to the extent practicable.

C. Related Federal Rules

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 recommended TCE ambient water quality criteria 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 amendments to the NESHAP “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).

D. 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 recommendations

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.

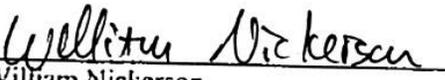
The SBA Office of Advocacy recommends that EPA conduct peer review for the supplemental analyses completed after EPA's final TCE risk assessment and specifically seek public comments on the supplemental analysis especially since the SERs did not review these analyses during the panel process.

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.

Sincerely,


William Nickerson
Acting Small Business Advocacy Chair
Office of Policy
U.S. Environmental Protection Agency


Howard Shelanski
Administrator
Office of Information and Regulatory Affairs
U.S. Office of Management and Budget


Darryl L. DePriest
Chief Counsel
Office of Advocacy
U.S. Small Business Administration


Jeffery I. Morris, Ph.D.
Deputy Director for Programs
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Enclosure