U.S. SMALL BUSINESS ADMINISTRATION

OFFICE OF ADVOCACY

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April 17, 2017

VIA REGULATIONS.GOV

The Honorable Scott Pruitt
Administrator
United States Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: Trichloroethylene(TCE); Regulation of Use in Vapor Degreasing Under TSCA § 6(a) (Docket ID. EPA–HQ–OPPT–2016–0387)

Dear Administrator Pruitt:

The U.S. Small Business Administration's (SBA) Office of Advocacy (Advocacy) submits the following comments in response to the Environmental Protection Agency's (EPA) proposed rule, "Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing Under TSCA § 6(a)."[1] Safe chemical use and prevention of hazardous exposure to chemicals are a priority for small business users to be able to protect themselves and their employees. Small businesses, however, have raised concerns with EPA's basis (i.e., risk assessment) for its regulatory proposal for the use of trichloroethylene (TCE) in vapor degreasing. Small businesses are also concerned that the EPA's risk analysis does not support the ban of TCE use in all vapor degreasing machines. In addition, small businesses have expressed concerns with the agency's consideration of the feasibility of alternatives and substitute solvents for TCE. Finally, small businesses have also raised concerns with the short transition period provided by the agency to ban the use of TCE in vapor degreasers. Advocacy urges EPA to carefully address the small business concerns and carefully consider providing regulatory flexibilities to small businesses while still accomplishing the agency's regulatory objective.

The Office of Advocacy

Congress established Advocacy under Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),[2] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[3] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives. EPA is required by the RFA to conduct a SBREFA

[1] 82 Fed. Reg. 7432 (January 19, 2017).
[2] 5 U.S.C. §601 et seq.
[3] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

panel to assess the impact of the proposed rule on small entities,[4] and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[5] The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.[6]

Background

Under Section 6 of the Toxic Substances Control Act (TSCA),[7] if EPA determines after completing a risk evaluation that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA must impose one or more specific requirements so that the chemical substance no longer presents such a risk.[8] TSCA provides EPA the authority to address the 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.[9]

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act),[10] which recently amended TSCA, allows EPA to publish a proposed rule for a chemical listed in the 2014 update to the TSCA Work Plan for Chemical Assessments, as long as EPA published a completed risk assessment prior to June 22, 2016, the date of enactment of the Lautenberg Act.[11] TCE is among the chemicals listed in the 2014 update to the TSCA Work Plan for Chemical Risk Assessments. EPA completed the final risk assessment for TCE uses in June 2014, well before the enactment of the Lautenberg Act.[12]

In June 2015, EPA formally notified Advocacy of its intent to convene a SBREFA panel for a rulemaking to address the identified risks for TCE use in spot cleaning by dry cleaners, in commercial and consumer use in aerosol spray degreasers and in use for open-top vapor degreasing. Subsequently, in June 2016, EPA convened a SBREFA panel for a potential rulemaking to address the identified risks for TCE use in open-top vapor degreasing.

On January 19, 2017, EPA published its proposed rule to regulate certain uses of TCE. EPA is proposing a determination of unreasonable risk for TCE use in vapor degreasing. The proposal includes a prohibition on the manufacture (including import), processing, and distribution of TCE for use in vapor degreasing, and includes downstream notification requirements. The proposal also prohibits the commercial use of TCE in vapor degreasing.

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[4] Under the RFA, small entities are defined as (1) a "small business" under section 3 of the Small Business Act and under size standards issued by the SBA in 13 C.F.C. § 121.201, or (2) a "small organization" that is a not-for-profit enterprise which is independently owned and operated and is not dominant in its field, or (3) a "small governmental jurisdiction" that is the government of a city, county, town, township, village, school district or special district with a population of less than 50,000 persons. 5 U.S.C. § 601.
[5] Small Business Jobs Act of 2010 (PL. 111-240) §1601.
[6] *Id.*
[7] 15 U.S.C. § 2601 et seq. (1976)
[8] See 15 U.S.C. § 2605(a).
[9] *Id.*
[10] Pub. L. 114–182 (June 22, 2016).
[11] See 15 U.S.C. § 2625(l)(4).
[12] EPA. 2014. TSCA Work Plan Chemical Risk Assessment. Trichloroethylene: Degreasing, Spot Cleaning and Arts & Crafts Uses. CASRN: 79–01–6. EPA/740/ R1/4002. Office of Chemical Safety and Pollution Prevention, Washington, DC. https://www.epa.gov/assessing-andmanaging-chemicals-under-tsca/tscawork-plan-chemical-risk-assessment-0.

Advocacy Involvement in the Rulemaking Process

Throughout the rule development process Advocacy was engaged with EPA and the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) as well as with small businesses and small business representatives, including during the SBREFA Panel process. In addition, following the publication of the proposed rule, Advocacy held a roundtable on March 10, 2017 at which EPA presented its proposal. Advocacy has had extensive contact with various small businesses and small businesses representatives regarding their concerns with the proposal.

Advocacy's comments

I. EPA Should Withdraw the Proposed Rule and Reassess the Use of TCE in Vapor Degreasing as Part of its Ongoing Risk Evaluation of TCE.

The Office of Advocacy urges EPA to withdraw this proposed rule. There is no statutory mandate for this regulation at this time. While it is true that under the Lautenberg Act, the agency *may* regulate TCE use based on the existing final risk assessment,[13] Congress did not *require* the agency to issue rules based on that risk assessment. Moreover, as required by the Lautenberg Act,[14] EPA recently identified a list of ten high-priority chemicals for which it will begin chemical risk evaluations, and TCE is among those high-priority chemicals.[15] As a result, in the next three years, EPA will be working to complete a new risk assessment for all uses of TCE.

Small business representatives have expressed several concerns with EPA's existing final risk assessment. Specifically, they have pointed to concerns with EPA's reliance on a single study that is unreproducible and was used to estimate the non-cancer risks.[16] They have also noted that this study has been subject to criticism in published literature and by other regulatory agencies because of data quality concerns.[17] Small business representatives highlighted criticism by peer reviewers of the risk assessment, who also expressed similar concerns with the study and the quality of the risk assessment overall.[18]

Moreover, small business representatives have also criticized the agency's use of an incorrect baseline for exposure to TCE from vapor degreasing. For instance, small business representatives explained that the exposure data used in the final risk assessment for TCE were collected before the May 2010 compliance date established in the 2007 National Emission Standards for Hazardous Air Pollutants (NESHAP) for Halogenated Solvent Cleaning.[19] EPA currently regulates TCE as a hazardous air pollutant (HAP) under the Clean Air Act.[20] The halogenated solvent cleaning NESHAP includes controls for emissions of TCE from halogenated solvent cleaning machines such as vapor degreasers.[21] In 2007, EPA revised its TCE standards to further limit emissions, to be effective May 2010.[22] EPA also included other controls that are used to comply with the NESHAP, including two-part covers, extended freeboard (area above the vapor

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[13] See 15 U.S.C. § 2625(l)(4).
[14] *Id.* § 2605 (b)(2)(a).
[15] 81 Fed. Reg. 91927 (December 19, 2017).
[16] See, TCE Developmental Cardiac Toxicity Assessment Update, pg. 7-8 and pg. 11-12 (available at http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2012-0723-0045).
[17] See, for example, Hardin, B, *et al.*, Trichloroethylene and cardiac malformations, Environ. Health Perspect. 112: A607-8 (2004); Watson, R., *et al.*, Trichloroethylene-contaminated drinking water and congenital heart defects: a critical analysis of the literature, Repro. Toxicol. 21: 117-47 (2006); and California EPA Public Health Goal for Trichloroethylene in Drinking Water (July 2009).
[18] See, OPPT Trichloroethylene (TCE) Draft Risk Assessment Final Comments of 9 Member Peer Review Panel September 5, 2013, available at https://www.epa.gov/sites/production/files/2015-09/documents/tce_consolidated_peer_review_comments_september_5_2013.pdf.
[19] 72 Fed. Reg. 25138 (May 3, 2007).
[20] 42 U.S.C. § 7412(b)(1).
[21] See 40 C.F.R. subpart T.
[22] 72 Fed. Reg. 25138 (May 3, 2007).

zone), freeboard refrigeration devices, and holding cleaned parts in the freeboard to allow draining.[23] These enclosed vapor degreasing systems are either vented directly to the atmosphere or first vented to an external carbon filter and then to the atmosphere.[24] As a result, all open-top degreasers now have covers and other controls required to comply with the 2007 NESHAP.[25] According to small businesses and their representatives, the 2007 NESHAP's TCE emission limit from vapor degreasers changed work practices and reduced both in-facility exposure and fenceline emissions.[26]

Furthermore, small business representatives have expressed concerns that the agency's regulation of all vapor degreasers is not supported by its final risk assessment of TCE because the scope of EPA's final risk assessment is limited to open-top vapor degreasing machines.[27] The agency conducted additional analysis to evaluate the use of TCE in other types of vapor degreasing machines, which include closed-loop systems and in-line systems.[28] EPA completed these analyses after the final 2014 risk assessment was issued and after the passage of the Lautenberg Act.[29] Additionally, these analyses have not been peer reviewed, although EPA has stated that they will be peer reviewed before the final rule is issued.[30] OMB's bulletin on "Final Information Quality Bulletin for Peer Review" requires that important scientific information be peer reviewed.[31] In addition, under the Lautenberg Act, TSCA specifically requires that in carrying out actions under Section 6, EPA must use scientific information in a manner consistent with the best available science, and must consider the extent of independent verification or peer review of that information.[32]

Recommendation

Advocacy recommends that EPA withdraw the proposed rule. In light of the concerns regarding the hazard and exposure assessments, Advocacy further recommends that EPA reevaluate the TCE use in vapor degreasing as part of the ongoing risk evaluation of TCE uses. Advocacy also recommends that EPA seek peer review on all scientific analyses prior to their use as a basis for any future regulations.

II. EPA Should Not Ban the Use of TCE in All Vapor Degreasers.

If the agency moves forward with the regulation of TCE use in vapor degreasing, Advocacy encourages EPA to allow the use of TCE in closed-loop systems. EPA identified two regulatory options that address the identified unreasonable risks of TCE use in vapor degreasing. EPA proposed the first option, which is to ban the use of TCE for vapor degreasing.[33] However, EPA evaluated an alternative which exempts airless vacuum-to-vacuum closed-loop systems or enclosed vapor degreasers (EVDs) while still banning all other use of TCE for vapor degreasing.[34] Under this option, TCE use would be allowed in EVDs with specific personal protective equipment (PPE) coupled with an alternative air exposure limit.[35]

According to EPA's economic analysis the benefits from banning EVDs do not justify the added costs. EPA estimates the worker exposure to TCE from the use of EVDs to be about fifty times less than with

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[23] 82 Fed. Reg. at 7441.
[24] *Id.*
[25] EPA states that "[n]early all open top vapor degreasing systems regulated by the 2007 NESHAP have a cover because that is a more common compliance strategy than complying with the overall emission limit." *Id.*
[26] *Id.*
[27] 82 Fed. Reg. at 7438.
[28] EPA. Supplemental Occupational Exposure and Risk Reduction Technical Report in Support of Risk Management Options for Trichloroethylene (TCE) Use in Vapor Degreasing. Office of Chemical Safety and Pollution Prevention. Washington, D.C. 2016.
[29] Risk assessments published after the passage of the Lautenberg Act cannot be the basis of the new regulations.
[30] 82 Fed. Reg. at 7443.
[31] 70 Fed. Reg. 2664 (January 14, 2005).
[32] 15 USC § 2625(h)(5).
[33] 82 Fed. Reg. at 7444.
[34] *Id.*
[35] *Id.* at 7444-7445.

other degreasers. Small businesses confirm that the exposure to TCE is minimal when using EVDs as compared to older versions of open-top degreasers. In their Economic Analysis, EPA estimates the benefits of reducing this risk could be as small as $28 per degreaser annually.[36] These small potential benefits are dwarfed by the large costs of a ban. The Economic Analysis estimates that banning TCE in EVDs would cost $8,400 to $18,400 per degreasing unit annually (see Table below). Overall, banning the use of TCE in EVDs could cost businesses upwards of $2.2 million annually with very few benefits.[37] It would also eliminate the ability for businesses with older, higher emitting degreasers to retrofit or replace their existing systems with safer EVDs.

	Cost		**Benefits**	
	Low Estimate	High Estimate	Low Estimate	High Estimate
Annualized Cost Per EVD of Proposed EPA Action	$8,363	$18,380	$28	$759

Source: EPA's Economic Analysis, Table 7-2; Annualized using 7% discount; Low and High Cost estimates used in lieu of # of OTVDs for the purpose of clarity.

Also, in their analysis, EPA believes only a small number of businesses use EVDs. However, due to other EPA regulations, such as those stemming from the NESHAP, small business owners have told Advocacy that EVDs are more prevalent than EPA believes. If EVDs are in greater use, then exempting them from the rulemaking could dramatically lower the burden on small businesses while still achieving EPA's regulatory goal.

EPA states it is not proposing the less restrictive option because substitutes are commercially available and because the implementation of a respiratory protection program is likely to be difficult for many facilities.[38] Many small businesses have noted specific degreasing services that require the use of TCE. While many solvents can be used in vapor degreasing, TCE has specific properties that can make its use necessary. Banning TCE's use in vapor degreasing would eliminate entire product lines for some small businesses and lead to very significant costs. Exempting the relatively safe EVDs would allow these product lines to continue, while the risks are managed in a responsible way. Small business representatives contend that a company should have the ability to decide for itself whether to use a closed-loop system coupled with an air exposure limit, including the use of PPE. Exempting EVDs will allow specific business services and product lines with no substitutes to continue.

Finally, it is unclear why, among the different types of closed-loop systems, EPA chose the most restrictive, airless vacuum-to-vacuum, closed-loop system. It is especially unclear since EPA states that the data available on TCE emissions from closed-loop systems is not sufficient to enable EPA to distinguish between the three types of closed-loop systems (airtight, airless and airless vacuum-to-vacuum) with respect to employee exposures.[39] Advocacy is concerned with the agency's understanding and characterization of the various types of vapor degreasers in use today.

[36] EPA (US Environmental Protection Agency). 2016. Economic Assessment for Trichloroethylene (TCE) under TSCA Section 6. Office of Chemical Safety and Pollution Prevention, Washington, DC., 6-29 [hereinafter Economic Analysis]
[37] *Id.* at 7-9, Table 7-4.
[38] 82 Fed. Reg. at 7445.
[39] *Id.* at 7443.

Recommendation

Advocacy recommends that EPA not regulate the use of TCE in all vapor degreasers. More specifically, Advocacy recommends that the agency not ban the use of TCE in closed-loop systems, where the identified unreasonable risk can be eliminated with the use of engineering controls, personal protective equipment or other means.

III. EPA Should Reassess the Alternatives and Solvent Substitutes for Availability and for Safe and Effective Use.

Small businesses contend that the vast majority of the cleaning substitutes for TCE do not clean as well as TCE, are more expensive to purchase and require a large capital investment for a cleaning process that is less efficacious. EPA has identified several kinds of alternatives to TCE, including drop-in solvents, non-drop-in solvents, aqueous cleaning systems, other cleaning solvents, (glycol ethers, soy-based cleaners, etc.), and cold cleaning with TCE.[40] Drop-in solvents include methylene chloride, 1-bromopropoane, and perchloroethylene; these can be used in existing vapor degreasing systems with some modification.[41] EPA clarifies that all three drop-in replacements for TCE in vapor degreasing have significant hazards associated with them, but assume in their economic analysis that some businesses would switch to them.[42] Small businesses have expressed concerns with the agency's consideration of the alternatives and substitute solvents for TCE use in vapor degreasing. Specifically, small businesses have noted significant issues associated with the possible alternatives such as potential health hazards, availability for safe use, related (and prohibitive) equipment costs, low boiling points and uncertainty with cleaning effectiveness. Under the amended TSCA, EPA is required to consider 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.[43]

Small businesses have expressed significant concerns with the agency's suggested use of drop-in solvents as alternative to TCE because they do not consider them to be viable alternatives in vapor degreasing. Moreover, drop-in solvents are currently undergoing risk assessment review by EPA. In addition, small businesses have noted that these substitutes operate at temparatures incompatible with their current process and are less stable compared to TCE. For example, a small business that switched to one of the identified drop-in alternatives, 1-bromopropane (nPB), incurred significant costs to upgrade their equipment ($60K). This small business estimates that it costs twice as much as TCE on annual basis to use nPB. The small business added that due to compatibility issues with aluminum castings additional cleaning solutions are required. The small business also noted that they had to refuse defense and aerospace work that specified the use of TCE.[44]

As for non-drop-in solvents, small businesses point out that these products boil at much lower temperatures and as a result are harder to keep in the machine which increases worker exposure. In addition, cleaning these chemicals requires an addition of a chlorinated derivative, which is flammable. Finally, small businesses identify that these products are ten times more expensive per pound and significantly more product is used because of the lower boiling point.

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[40] 82 Fed. Reg. at 7449-50.
[41] *Id.* at 7450.
[42] *Id.*
[43] 15 U.S.C. § 2605(c)(2)(C).
[44] Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule under Section 6(a) of the Toxic Substance 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 (September 26, 2016). U.S. Environmental Protection Agency, Office of Policy, Washington, D.C., Appendix B at B-24. [hereinafter Panel Report].

Small businesses also expressed several concerns with the use of aqueous cleaning systems including expense, increased water use (triggering water permit requirements), increased energy use, increased delay (multiple stages required to reach the same cleaning) and the need for additional facility space.

The SBREFA Panel recommended that EPA provide exemptions under section 6(g)[45] for 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 policy.[46] However, rather than proposing to obtain the adequate documentation to provide a critical use exemption, the agency provides a lengthy petition process to qualify for a critical use exemption.[47] During the SBREFA Panel process, many small businesses provided the agency with information on several critical uses for TCE in vapor degreasing. The small businesses emphasized that while TCE use in vapor degreasing has declined rapidly over the years in certain sectors, it is still the method of choice for cleaning of some parts and substrates.

Recommendation

Advocacy recommends that EPA reassess the alternatives and solvent substitutes for availability and for safe and effective use. Advocacy also recommends that the agency follow the recommendation of the SBREFA Panel in providing critical use exemptions.

IV. EPA Should Allow Five Years to Comply with Any Regulations of TCE Use for Vapor Degreasing Under TSCA 6(a).

Small businesses also provided feedback on the agency's compliance timelines suggesting that a longer phase-out period is necessary to research and test effective alternatives. EPA has proposed to make the ban on manufacturing, processing, or distributing in commerce TCE for vapor degreasing uses, including the downstream notification and recordkeeping requirements, effective eighteen months after the publication of the final rule.[48] As for the ban on the use of TCE in commercial vapor degreasing, EPA set an effective date two years after the publication of the final rule.[49] During the SBREFA Panel, many small businesses noted that the conversion process may take longer.[50] Small businesses emphasized that "TCE clean" is an industry standard. To change this, a new cleaning specification must be developed. A small chemistry distributor and vapor degreaser manufacturer noted that developing such a cleaning specification can take anywhere from six months to four years. Specifically small businesses noted that medical devices, aerospace, and electronics for military defense have very stringent cleaning specifications that are subject to governmental approval through the appropriate agencies. The small business further estimated that after the approval of a cleaning specification, equipment design, build, installation, building modification if necessary and local permits can take an additional two years. The Panel recommendation for EPA to provide regulatory flexibility such as delayed compliance or a phase-out option for small businesses reflects those concerns.[51] In setting an appropriate transition period, the agency must consider whether technically and economically feasible alternatives will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.[52] EPA can

[45] Under TSCA Section 6(g), EPA has the authority to grant exemptions for a critical use for which no technically and economically feasible safer alternative is available. See,15 U.S.C. § 2605(g).
[46] Panel Report at 30.
[47] 82 Fed. Reg. 7451.
[48] *Id.* at 7456.
[49] *Id.*
[50] *Id.*
[51] Panel Report at 31.
[52] 15 U.S.C. § 2605(c)(2)(C).

consider a phase-out or a longer staggered compliance period to assist with a reasonable transition period under TSCA[53] and provide adequate time for innovation by considering a phase-out instead of a full ban.[54] TSCA allows EPA up to five years to require compliance.[55]

Recommendation

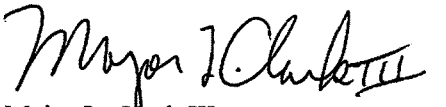
Advocacy recommends that the agency also provide the full five years as the transition period to allow for planning, research and testing of alternatives.

Conclusion

Advocacy suggests that EPA withdraw the proposed rule and reassess the TCE use in this rule as part of its ongoing risk evaluation of TCE uses. Alternatively, if the agency decides to go forward based on the existing risk assessment, Advocacy suggests that EPA refrain from regulating the use of TCE in vapor degreasers where the risk can be eliminated with the use of engineering controls and personal protective equipment. The agency should also reassess the alternatives and solvent substitutes for availability and for safe and effective use. Finally, the agency should also provide a longer compliance or phase-out period. Advocacy urges EPA to give full consideration to the above issues and recommendations. We look forward to working with you to reduce the regulatory burden on small businesses.

If you have any questions or require additional information please contact me or Assistant Chief Counsel Tayyaba Waqar at (202) 205-6970 or by email at twaqar@sba.gov.

Sincerely,



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[53] 15 U.S.C. § 2605(d)(1)(E).
[54] *Id.* at 2605(d)(1).
[55] *Id.*

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