



March 15, 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; Regulation of Certain Uses Under TSCA § 6(a) (Docket ID. EPA–HQ–OPPT–2016–0163)

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; Regulation of Certain Uses Under TSCA § 6(a)."¹ Safe chemical use and prevention of hazardous exposure to chemicals are a priority for small business formulators and users to be able to protect both the consumer and their employees. Small businesses, however, are concerned that the rule does not consider important compliance costs that will be imposed on them. Small businesses have also expressed their disappointment that they were not afforded an opportunity to provide their feedback at the Small Business Advocacy Review panel. Finally, small businesses have also raised concerns with EPA's basis (i.e., risk assessment) for its regulatory proposal for the use of trichloroethylene (TCE) in aerosol degreasing and spot removal in dry cleaning facilities. Advocacy urges EPA to carefully address the small business concerns and carefully reconsider the impact of its proposal on small businesses.

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

¹ 81 Fed. Reg. 91592 (December 16, 2016).

² 5 U.S.C. §601 et seq.



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 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

³ Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

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>.

In June 2015, EPA formally notified Advocacy of its intent to convene a SBREFA panel for a rulemaking to address its 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 its identified risks for TCE but the panel process was limited only to a discussion of regulatory options for TCE use in open-top vapor degreasing.

On December 16, 2016 EPA published its first TSCA Section 6(a) proposal since the passage of the Lautenberg Act, to regulate certain uses of TCE. EPA proposed a determination of unreasonable risk for TCE use in aerosol degreasing and use in spot cleaning by dry cleaning facilities. The proposal includes a prohibition on the manufacture (including import), processing, and distribution of TCE for these uses, and included downstream notification requirements. The proposal also prohibits the commercial use of TCE in aerosol degreasing and spot cleaning in dry cleaning facilities.

Advocacy Involvement in the Rulemaking Process

Throughout the rule development process Advocacy 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. 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 TCE Uses in This Rule 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 was 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. They have also noted that this study has been subject to criticism in published literature and by other regulatory agencies

¹³ See 15 U.S.C. § 2625(l)(4).

¹⁴ 15 U.S.C. § 2605 (b)(2)(a).

¹⁵ 81 Fed. Reg. 91927 (December 19, 2017).

because of data quality concerns.¹⁶ 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.

Moreover, small businesses representatives have also expressed concerns with the use of hypothetical information to model exposure for the use of aerosol degreasing and reliance on a single study to determine exposure for the use of spot cleaning by the dry cleaning industry. Small business representatives are concerned that the agency did not use any emission or monitoring data to determine the exposure for aerosol degreasing. EPA used information from a 2007 study on spotting chemicals to estimate the releases of TCE and associated inhalation exposures to workers from spot cleaning operations in dry cleaning facilities.¹⁷ Small business representatives expressed concerns that the 2007 study was prepared for California and may not be representative of all the U.S. dry cleaning facilities.

Furthermore, small businesses representatives of the dry cleaning industry have expressed concerns with inclusion of TCE use as a spot cleaning agent in dry cleaning facilities as part of the final risk assessment. The final risk assessment, entitled “*Degreasing, Spot Cleaning, and Arts & Crafts Uses*,” estimated non-cancer and cancer risks for workers and occupational bystanders for using TCE-containing spot cleaners in dry cleaning facilities.¹⁸ However, the draft risk assessment, entitled, “*Degreasing and Arts & Crafts Uses*,” did not analyze any risks for the use of TCE-containing spot cleaners used in dry cleaning facilities.¹⁹ The draft risk assessment evaluated commercial and consumer use of TCE as a solvent degreaser and consumer use of TCE as a spray-applied protective coating for arts and crafts.²⁰ EPA explains that it evaluated the commercial use of TCE for spot cleaning at dry cleaning facilities in the final risk assessment in response to comments and information provided by the peer reviewers.²¹ While EPA emphasizes that it used a peer-reviewed approach to do this additional evaluation, it is obvious that the evaluation of this additional use in the final risk assessment was not actually peer reviewed itself. In addition, small business representatives contend that because the use of TCE as a spotting agent was added to the final risk assessment at the last minute, there was no notice that EPA was addressing spot cleaning and consequently the dry cleaning industry did not participate in its review. OMB’s bulletin on “Final Information Quality Bulletin for Peer Review” requires that important scientific information be peer reviewed.²² The TCE risk assessment for the use of spot cleaning is the basis for EPA’s regulatory proposal for that use. As such, it should be peer reviewed. Under the Lautenberg Act, TSCA specifically requires that in carrying out actions under Section 6, EPA must use scientific information in a manner

¹⁶ 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).

¹⁷ 81 Fed. Reg. 91608.

¹⁸ See 81 Fed. Reg. 91598.

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*

²² 70 Fed. Reg. 2664 (January 14, 2005).

consistent with the best available science, and must consider the extent of independent verification or peer review of that information.²³

Small businesses have also expressed concerns with EPA's supplemental analyses. EPA performed supplemental analyses to identify non-cancer risk and cancer risks for the commercial aerosol degreasing use scenario; the 2014 final risk assessment only identified such risks for consumers and residential bystanders.²⁴ EPA also conducted supplemental analysis of various parameters of exposure scenarios on the use of TCE for spot cleaning in dry cleaning facilities.²⁵ EPA completed these analyses after the final risk assessment was issued and after the passage of the Lautenberg Act.²⁶ Furthermore, these analyses have not been peer reviewed, although EPA has stated that they will be peer reviewed before the final rule is issued.²⁷ The requirements of the OMB bulletin on peer review and the TSCA requirement of peer review apply to these analyses as well for the same reason stated above for the spot cleaning use in the final risk assessment.

EPA notes numerous uncertainties in its risk assessment regarding the number of workers exposed and the inputs used in models to estimate exposures.²⁸ EPA admits to using a number of assumptions in both its final TCE risk assessment and the supporting analysis to develop estimates for occupational and consumer exposure scenarios and to develop the hazard/dose response and risk characterization.²⁹ Among these, EPA includes uncertainties in the number of workers exposed to TCE and in the inputs to the models used to estimate exposures.³⁰ EPA also includes uncertainties in the number of workers exposed to TCE for spot cleaning in dry cleaning.³¹ It is not clear why EPA based its analysis on so many assumptions. However, by redoing the assessment, EPA will have the opportunity to address these shortcomings by engaging the public and seeking independent peer review.

Recommendation

Advocacy recommends that EPA should withdraw the proposed rule. Advocacy further recommends that EPA should reevaluate the TCE use in aerosol degreasing and spot cleaning 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 Reassess Its Certification is the Rule

If the agency decides to proceed with its rulemaking, the Office of Advocacy urges EPA to reassess the impacts on small businesses because EPA's RFA certification is incorrect. EPA certifies that the proposed rule will not have a significant impact on a substantial number of

²³ 15 USC § 2625(h)(5).

²⁴ 81 Fed. Reg. 91602.

²⁵ *Id.* at 91599.

²⁶ Risk assessments published after the passage of the Lautenberg Act cannot be the basis of the new regulations.

²⁷ 81 Fed. Reg. at 91599.

²⁸ *Id.* at 91617-18.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

small entities. However, after hearing from small businesses and further analysis of the industry, there is evidence that EPA's certification is not supported. More specifically, EPA's factual basis that alternatives are available to users with similar costs and performance is inaccurate. Therefore, EPA should reevaluate their compliance with the RFA.

In its analysis, EPA predicts only the blenders of TCE spotting and aerosol products will experience a measureable impact from the proposed rule.³² The analysis assumes that the commercial users of TCE products, specifically those in dry cleaning and automotive repair industries, will not experience any cost from the rule because alternative products are available at similar or lower cost.

However, small businesses have noted that EPA's analysis is incomplete. EPA's analysis does not account for additional steps needed when using alternative products nor the feasibility of the alternatives in some processes. Alternatives to TCE for some cleaning processes require additional time and labor to be as effective. This additional labor requirement will add a measurable cost to these industries that are not currently accounted for by EPA. The agency refers to the Dry-cleaning and Laundry Institute as stating that not all dry cleaning facilities use TCE and that other effective alternatives exist.³³ Small business representatives of the dry cleaner industry disagree with EPA's assertion that the available alternatives are similar in performance as the TCE-containing spot cleaners. In particular, small business representatives of the dry cleaning industry stated that alternatives such as mixtures of glycol ethers and other hydrocarbon solvents do not have a high enough KB value³⁴ to be able to dissolve nonwater stains as effectively and as a result, their use will increase the time it takes to clean nonwater stains. The small businesses representatives also reported that the individual responsible for spot cleaning is often the highest paid employee.

A small chemical manufacturer further explained that there is no comparable alternative for TCE-based spot cleaners because these cleaners do not leave any residue behind on the garment. The small chemical manufacturer added that in comparison to other products, TCE dries invisibly whereas others often leave a ring or a water mark and as a result the garment is required to be reprocessed and repressed. EPA relies on a series of reports by Dr. Kathleen Wolf, director of the Institute for Research and Technical Assistance, to support its claim for spot cleaning alternatives being just as effective or similar in performance as TCE-based spot cleaners.³⁵ The Wolf studies used by EPA state that the products are effective and of similar costs, but the reports are vague on the details and do not specifically evaluate the time it takes to use the products or alternative methods needed.

EPA also estimates that costs to users of aerosol degreasers to be negligible because of alternative products being available and similarly priced.³⁶ Small business representatives also

³² See, EPA (US Environmental Protection Agency). 2016. Economic Assessment for Trichloroethylene (TCE) under TSCA Section 6. Office of Chemical Safety and Pollution Prevention, Washington, DC. [hereinafter Economic Analysis].

³³ 81 Fed. Reg. at 91611.

³⁴ The Kauri-butanol value ("Kb value") is an international, standardized measure of solvent power for a hydrocarbon solvent, and is governed by an ASTM standardized test, ASTM D1133.

³⁵ See, Economic Analysis, *supra* note 27.

³⁶ 81 Fed. Reg. at 91616.

expressed disagreement with EPA’s assertion that alternative products for TCE-based aerosol degreasers are as effective. In particular, for end users that use TCE-based aerosol degreasing products to clean intricate electronic parts, there are concerns that using a water-based degreaser will add a step to the normal process because it will require the addition of a coating product to protect against water damage. Small business representatives also explained that for aerosol degreasing, products are used for specific purposes; the alternatives with lower flash points and those that are water-based pose fire and electrocution hazards for the users.

Due to the characteristics of the industries affected by this rule, an apparently small added cost, like that of additional labor, can produce a significant impact (see Table below). Based on EPA’s guidance, to determine whether there is a significant economic impact, the agency describes defined lower threshold as compliance costs of one percent of sales and the higher threshold as compliance costs of three percent of sales.³⁷ The agency states that the upper threshold defines a level of economic impact that would be unquestionably significant for a small entity.³⁸ In the dry cleaning industry, which has a high concentration of very small businesses, a cost as small as \$2,500 annually can be a significant impact for almost 90 percent of small businesses in that industry. Commenters in this industry have indicated that an annual cost of \$8,000 could be a conservative estimate for the added costs they face by switching from TCE. For the automotive repair industry, a similar cost of \$8,000 would also be significant for the majority of the small business community.

Industry (NAICS) <i>Size (Annual Revenue)</i>	Percent of All Small Businesses	Average Revenue per Firm	Needed Cost to Reach % of Revenue	
			1%	3%
Coin-Operated Laundries and Drycleaners (812310)				
<i>Micro (<\$100,000)</i>	29%	\$57,609	\$576	\$1,728
<i>Very Small (\$100,000-\$499,999)</i>	62%	\$214,638	\$2,146	\$6,439
Drycleaning and Laundry Services (except Coin-Operated) (812320)				
<i>Micro (<\$100,000)</i>	23%	\$53,564	\$536	\$1,607
<i>Very Small (\$100,000-\$499,999)</i>	61%	\$241,620	\$2,416	\$7,249
General Automotive Repair (811111)				
<i>Micro (<\$100,000)</i>	16%	\$51,988	\$520	\$1,560
<i>Very Small (\$100,000-\$499,999)</i>	54%	\$271,323	\$2,713	\$8,140

Data from the Census Bureau’s Statistics of US Businesses (2012). Terms Micro and Very Small are for descriptive reasons only.

Recommendation

Advocacy recommends that EPA reassess its certification under the RFA and include the additional compliance costs to the users in its analysis.

³⁷ EPA (US Environmental Protection Agency). November 2006. EPA’s Action Development Process. Final Guidance for EPA Rulewriters: Regulatory Flexibility Act as amended by SBREFA. Office of Policy, Economic and Innovation, Washington, DC. Pg. 25. [hereinafter EPA RFA Guidance].

³⁸ *Id.*

III. EPA should Convene a SBREFA Panel to Learn about Small Business Impacts

EPA must and should convene a SBREFA panel. The RFA requires covered agencies like EPA to conduct special outreach efforts to ensure that small entity views are carefully considered prior to the issuance of proposed rule through the work of the SBREFA panel.³⁹ EPA has recognized in its guidance that such procedural requirements are intended to ensure that small entities have a voice when EPA makes policy determinations in shaping its rules.⁴⁰ Moreover, TSCA also directs the agency to consider “reasonably ascertainable economic consequences of the rule, including the likely effect of the rule on...small businesses...”⁴¹ Experience has shown that the panel process results in better rules, better compliance, and reduced litigation. There are threefold benefits of a SBREFA panel: first, the process ensures that small entities that would be affected by a regulatory proposal are consulted about the pending action and offered an opportunity to provide information on its potential effects; second, a panel can develop, consider and recommend less burdensome alternatives if warranted; and finally, the agency benefits from the input from both real-world small entities and the panel’s report and analysis prior to publication.

Based on the gaps in information and data and coupled with the concerns conveyed by small businesses, it appears that EPA did not engage in adequate outreach to small entities. Even if the agency ultimately certifies under the RFA, EPA’s own guidance on the RFA states that as a matter of agency policy, “to the extent that you foresee that your rule will have an adverse economic impact on small entities, you should assess those impacts and make efforts to minimize them through consultation with the small entities likely to be regulated, while remaining consistent with applicable statutory requirements.”⁴²

EPA originally planned to convene a SBREFA panel for these uses, as noted in its formal notification to Advocacy, and the agency had solicited names for SERs to participate in such a panel. However, since EPA certified the rule, it did not follow through in convening the SBREFA panel. EPA would have benefited from the feedback of small businesses through the SBREFA panel process for these uses, especially since EPA has included various assumptions on a number of identified uncertainties. More importantly, because EPA’s certification is not supported, the agency must convene a SBREFA panel to comply with the RFA.

Through a SBREFA panel, small entity representatives (SERs) help the panel (including the rulemaking agency) better understand the ramifications of the proposed rule. The participation of SERs provides extremely valuable information on the real-world impacts and compliance costs of agency proposals. For instance, as mentioned in the above section, EPA would have been informed about and would be able to account for the additional compliance costs identified by small businesses by convening a SBREFA panel for this rule. In addition, EPA could have obtained information to provide regulatory flexibilities for any potential critical or essential

³⁹ 5 USC § 609(d)(2).

⁴⁰ See EPA RFA Guidance, *supra* note 33, at 1.

⁴¹ 15U.S.C. 2605§ (c)(2)(B).

⁴² See EPA RFA Guidance, *supra* note 33, at 10-11.

uses.⁴³ EPA concluded that there are no specific aerosol degreasing uses for which TCE is critical because the agency has determined that the “a wide variety of effective substitutes are available.”⁴⁴ Based on Advocacy’s outreach efforts this may or may not be accurate as many small businesses and their representatives have expressed disagreement with the agency’s conclusion that the available substitutes are as effective for their designed uses.

In the preamble, EPA has outlined a specific section on uncertainties which include uncertainties of costs for alternatives and reblending.⁴⁵ EPA admitted to additional uncertainties in benefit calculations due to its reliance on professional judgment to estimate the alternatives that users might choose to adopt and the potential risks for adverse health effects that the alternatives may pose.⁴⁶ EPA states that only a small percentage will switch to aqueous-cleaners, a quarter of users will switch to perchloretheyle and 1-bromopropane and that the majority will switch to other alternatives for spot cleaning.⁴⁷ Small businesses have reported an unwillingness to invest in switching to perchlorehttyele and 1-bromopropane-based cleaners because of the ongoing review and potential regulatory actions by EPA regarding these chemicals. EPA should have engaged SERs to seek feedback on what alternatives users might realistically consider.

EPA also expresses uncertainty concerns with the estimate for the cost of reblending products and the time required to reblend those products.⁴⁸ EPA based its estimates on an automotive aftermarket parts products industry study and feedback received from a few blenders of aerosol degreasing products.⁴⁹ EPA, however, admittedly received no information from the dry cleaning spot cleaning product blender.⁵⁰ Through outreach and a SBREFA panel, EPA could have obtained that specific information from small businesses for dry cleaners and additional information for aerosol degreasing. EPA also assumes that it will take about six months for companies to reblend products but expressed uncertainty about whether there would be additional costs if the product is not available within that time.⁵¹ The assumption for a six month time period to reblend products appears to be arbitrary as EPA does not provide a basis for this estimate. Specifically, EPA claims that the staggered compliance dates it has provided to implement the prohibition on manufacturing, processing, distribution in commerce (within 180 days after the date of the publication of the final rule) and commercial use (within 270 days after the date of publication of the final rule) will avoid undue impacts on the businesses involved.⁵²

A small business formulator for an aerosol degreaser product relayed that it can take over a year to reblend and successfully test a replacement product. He also added that any alternative product may cost more either because of the chemical being used or the amount being used and the additional cost will likely have to be passed on to their customers. The small business formulator described that its degreaser is designed to clean a specific surface for a specific

⁴³ 15 U.S.C. § 2606(g) authorizes EPA to provide exemptions for critical and essential use.

⁴⁴ 81 Fed. Reg. at 91606.

⁴⁵ *Id.* at 91617-91618.

⁴⁶ 81 Fed. Reg. at 91602 and 91607.

⁴⁷ *Id.* at 91608.

⁴⁸ *Id.* at 91618.

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.* at 91624 and 91605 (aerosol degreasing) and 91610 (spot cleaning).

product and therefore serves a particular end user. It is a fair assumption that an unavailability of this degreaser may result in a loss of business from that end user. To provide a reasonable and a justifiable compliance time period, EPA would have been able to get feedback through the SBREFA panel and further examine any relevant regulatory flexibilities. For example, EPA could have considered a phase-out or a longer staggered compliance period to assist with a reasonable transition period under TSCA⁵³ 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

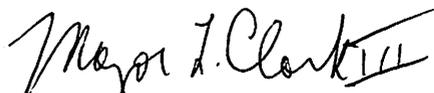
Advocacy recommends that to comply with the RFA, EPA convene a SBREFA panel to seek feedback from small businesses on the impacts of its proposed regulation of TCE use in aerosol degreasers and use in spot cleaners in dry cleaning facilities. Advocacy also recommends that EPA prepare an Initial Regulatory Flexibility Analysis after convening the SBREFA panel as required by the RFA.⁵⁶

Conclusion

Small businesses have expressed concerns with the agency's risk assessment used to support the unreasonable risk determination for these TCE uses. Advocacy suggests that EPA withdraw the proposed rule and reassess the TCE uses in this rule as part of its ongoing risk evaluation of TCE uses. Small businesses have also identified additional costs that were not considered by the agency in determining the compliance costs for these businesses. Advocacy suggests that the agency reassess its compliance with the RFA to include these additional costs. Small businesses have also expressed concerns with the agency's decision not to convene a SBREFA panel for these uses. Advocacy suggests that EPA convene a SBREFA panel to learn about small business impacts of regulatory proposal, and to develop significant alternatives to the rule. Advocacy urges EPA to give full consideration to the above issues and recommendations. We look forward to working with you.

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,



Major D. Clark III
Acting Chief Counsel
Office of Advocacy
U.S. Small Business Administration

⁵³ 15 U.S.C. § 2605(d)(1)(E).

⁵⁴ *Id.* at 2605(d)(1).

⁵⁵ *Id.*

⁵⁶ See 5 U.S.C. § 603.



Tayyaba Waqar
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: Dominic J. Mancini
Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget