



December 15, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Washington, DC 20460

**Re: Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA),
(Docket ID: EPA–HQ–OPPT–2020–0642; FRL–8317–01–OCSP)**

Dear Administrator Regan:

On October 31, 2023, the Environmental Protection Agency (EPA) published a proposed rule entitled “Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA).”¹ This letter constitutes the Office of Advocacy’s (Advocacy) public comments on the proposed rule.

Advocacy has significant concerns with the EPA’s proposal, most of which are similar to those expressed in Advocacy’s public comments on the agency’s proposal to regulate methylene chloride and perchloroethylene under TSCA.² These concerns include: the agency’s proposal exceeding its statutory authority; the absence of regulatory flexibilities for small entities; and the failure to avoid duplicative and overlapping requirements. Further, Advocacy strongly encourages the EPA to consider all potential adverse impacts of the rule, specifically the proposed requirements for existing chemical exposure level (ECEL) and corresponding action level.

¹ 88 Fed. Reg. 74712 (Oct 31, 2023).

² U.S. Small Bus. Admin., Off. of Advocacy, Comment Letter on Proposed Rule for Methylene Chloride; Regulation Under the Toxic Substances Control Act (TSCA) (July 3, 2023), <https://advocacy.sba.gov/2023/07/03/advocacy-provides-public-comment-on-epas-proposed-risk-management-for-methylene-chloride-under-the-toxic-substance-control-act/>; U.S. Small Bus. Admin., Off. Of Advocacy, Comment Letter on Proposed Rule for Perchloroethylene; Regulation Under the Toxic Substances Control Act (TSCA) (Aug 15, 2023), <https://advocacy.sba.gov/2023/08/15/advocacy-provides-public-comment-on-epas-proposed-risk-management-for-perchloroethylene-under-the-toxic-substance-control-act/>.

I. Background

A. The Office of Advocacy

Congress established the Office of 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) that seeks to ensure small business concerns are heard in the federal regulatory process. Advocacy also works to ensure that regulations do not unduly inhibit the ability of small entities to compete, innovate, or comply with federal laws. The views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration.

The Regulatory Flexibility Act (RFA),³ as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),⁴ 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, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.⁵ Additionally, section 609 of the RFA requires the Consumer Financial Protection Bureau, the Occupational Safety and Health Administration, and the Environmental Protection Agency to conduct special outreach efforts through a review panel.⁶ The panel must carefully consider the views of the impacted small entities, assess the impact of the proposed rule on small entities, and consider less burdensome alternatives for small entities.⁷ If a rule will not have a significant economic impact on a substantial number of small entities, agencies may certify the rule.⁸ The agency must provide a statement of factual basis that adequately supports its certification.⁹

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.¹⁰ The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the Federal Register, unless the agency certifies that the public interest is not served by doing so.¹¹

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."¹²

B. The Proposed Rule

³ Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

⁴ Pub. L. No. 104-121, tit. II, 110 Stat. 857 (1996) (codified in scattered sections of 5 U.S.C. §§601-612).

⁵ 5 U.S.C. § 603.

⁶ *Id.* § 609.

⁷ *Id.*

⁸ *Id.* § 605(b).

⁹ *Id.*

¹⁰ Small Business Jobs Act of 2010, Pub. L. No. 111-240, §1601, 214 Stat. 2551 (codified at 5 U.S.C. § 604).

¹¹ *Id.*

¹² Regulatory Flexibility Act, Pub. L. No. 96-354, 94 Stat. 1164 (1980) (codified at 5 U.S.C. §§ 601-612).

On October 31, 2023, the EPA published a proposed rule to restrict the use of TCE under TSCA. TCE is used as a solvent in a variety of industrial, commercial, and consumer applications including for hydrofluorocarbon (HFC) production, vapor and aerosol degreasing, and in lubricants, greases, adhesives, sealants, and dry cleaning. TSCA requires that the EPA address any unreasonable risk of injury to health or the environment identified in a TSCA risk evaluation to the extent necessary so that the chemical no longer presents an unreasonable risk.¹³

Based on this risk evaluation, the EPA is proposing to prohibit most industrial and commercial uses of TCE, including its use in vapor degreasing and dry cleaning. The EPA is also proposing to ban TCE for consumer use. Out of 54 identified conditions of use, the EPA found that only distribution in commerce and as consumer use in pepper spray were permissible uses. For any permissible use, the EPA is proposing to require the workplace chemical protection program (WCPP). The program includes a requirement to meet an existing chemical exposure limit (ECEL) set by the EPA, as well as exposure monitoring and training. The EPA is proposing an ECEL of 0.0011 ppm for exposures as an 8-hour time-weighted average (TWA) and an action level of half that amount (0.00055 ppm).

In advance of this proposed rule, the EPA convened a small business advocacy review panel under SBREFA to consult with small entity representatives (SERs). The report issued by that panel is available in the docket.¹⁴ A roundtable was held on November 17, 2023 to discuss the rules' potential impacts on small businesses.

II. Advocacy's Small Business Concerns

Advocacy has several concerns with the rule. First, Advocacy is concerned that the EPA is exceeding its statutory authority under TSCA by proposing to ban uses of TCE for entities that can demonstrate compliance with the ECEL. Second, Advocacy is concerned that the agency did not provide available regulatory flexibilities for the use of TCE by small entities. Third, Advocacy is concerned that the EPA does not satisfy the statutory requirement to consult and coordinate with other federal agencies, particularly OSHA, to avoid duplicative and overlapping requirements. Advocacy recommends the EPA address concerns with the proposed ECEL and action level requirements and consider all potential adverse impacts of the proposed rule.

A. Advocacy is concerned that the EPA is exceeding its statutory authority under TSCA by proposing to ban uses of TCE for entities that can demonstrate compliance with the ECEL.

As expressed in Advocacy's public comments on the proposed risk management rules for methylene chloride and perchloroethylene,¹⁵ Advocacy remains and reiterates its concerns about

¹³ 15 U.S.C. §2605(a).

¹⁴ ENV'T PROT. AGENCY, FINAL REPORT OF THE SMALL BUSINESS ADVOCACY REVIEW PANEL ON EPA'S PLANNED PROPOSED RULE TOXIC SUBSTANCES CONTROL ACT (TSCA) SECTION 6(A) FOR TRICHLOROETHYLENE (TCE) (Apr. 4, 2023), <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0642-0054>.

¹⁵ *Supra* note 2.

the EPA's policy of prohibiting uses based on its independent determination about a business' compliance capability with the WCPP.

According to TSCA, once EPA determines that a chemical substance presents an unreasonable risk of injury to health or the environment, it must apply one or more requirements listed in section 6(a) "*to the extent necessary* so that the chemical substance or mixture no longer presents such risk."¹⁶

If a WCPP with an ECEL is indeed protective of health and the environment in certain uses, as the EPA claims, then banning those uses that can demonstrate compliance with the ECEL go beyond the "extent necessary." If a workplace can document and demonstrate compliance with a WCPP, such a use should be allowed to continue. Imposing regulations on a use that can meet the ECEL exceeds the agency's statutory authority under TSCA. Therefore, the EPA should not propose banning the use of TCE for entities that can demonstrate compliance with the ECEL in the WCPP.

B. Advocacy is concerned that the agency did not provide available regulatory flexibilities for the use of TCE by small entities.

1. Advocacy recommends that EPA allow the continued industrial and commercial use of TCE as a solvent for aerosol spray degreasers and cleaners.

Advocacy is concerned about the lack of availability of safer and technically feasible available alternatives for the industrial and commercial use of TCE, particularly as a solvent for aerosol spray degreasers and cleaners. TCE is commonly used to remove oil and grease, which is necessary during the production process, to create medical devices that are critical to human health. Namely, TCE is used in removing lubricants and other foreign matter from products with small tubes with medical device applications (i.e., pacemakers and heart valves). Small businesses noted that if TCE is no longer available for use, then production of medical devices would be exported out of the U.S., due to a lack of an alternative to remove lubricant from the devices without TCE.

A small business representing small tube producers noted that producers of medical devices (i.e., heart valves and pacemakers) would be unable to use any alternative to continue production. When producing medical devices, lubricant is used during the manufacturing process and other degreasers (including aqueous processes) are unable to remove lubricants from narrow tubes.

SERs from the small business advocacy review panel noted that TCE has niche applications due to its nonflammable properties. One SER estimated that reformulating a degreasing product would cost over \$100,000 through development, testing, certification, and labeling. Another SER representing degreaser system providers estimated that an aqueous cleaning process can cost over \$3,000,000 and requires more time to be as effective as TCE. Further, SERs noted it would take considerable time to create alternatives.

¹⁶ 15 U.S.C. § 2605(a) (emphasis added).

In the dry-cleaning industry, a SER described TCE as the most efficient method of spot cleaning. Using alternatives would increase costs per hour through labor, supply, and utility increases for the average dry-cleaning business. The SER estimated an increase in average labor costs per week going from \$77.00 to \$327.50 if this rule is implemented as proposed.

The EPA's proposal to limit the use of TCE will directly impact small businesses who will be faced with few economically feasible alternatives. Further, some small businesses will be without the ability to find an alternative to continue production in the United States.

2. Advocacy recommends that EPA provide a longer compliance timeframe for small entities.

Advocacy is concerned the EPA's proposal does not provide a practicable compliance timeline for small entities. According to TSCA, when the agency is contemplating a prohibition or a substantial restriction on the use of a chemical, it is required to set an appropriate transition period.¹⁷ To make this determination, "the Administrator shall 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."¹⁸

Advocacy is concerned that the agency did not adequately account for the limited resources available to small entities to ensure timely compliance. The uses subject to prohibition will require additional time and costs for researching alternative processes or substitutes, securing financing for testing such alternative, and implementing the use of an alternative into their process/product. Similarly, other small entities will have to utilize their limited staff and financial resources to implement procedures, equipment, and other necessities to comply with the proposed requirement of the WCPP.

One small business entity that works with small tube producers noted that many products such as medical devices would need to go through extensive testing and certification by the FDA before they could continue producing medical devices without the use of TCE.

Advocacy urges the EPA to consider the amount of time necessary to develop new methods to replace TCE, particularly in industries which require approval and certification from state and federal agencies.

¹⁷ 15 U.S.C. § 2605(c)(2)(C)(2)(a)(iv)(I).

¹⁸ 15 U.S.C. § 2605(a).

C. Advocacy remains concerned that EPA does not satisfy the statutory requirement to consult and coordinate with OSHA to avoid duplicative and conflicting requirements.

As expressed in Advocacy's public comments on the proposed risk management rules for methylene chloride and perchloroethylene,¹⁹ Advocacy remains concerned with the EPA's failure to satisfy the statutory requirements to consult and coordinate with OSHA to avoid duplicative and conflicting requirements. The EPA should not have proposed duplicative, overlapping, and conflicting regulations by issuing a WCPP, including an ECEL, to cover worker exposures subject to OSHA's jurisdiction.

TSCA section 9 requires the EPA to consult and coordinate with other federal agencies, "for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes."²⁰ In the proposed rule, the EPA states that the agency consulted and coordinated TSCA activities with OSHA and other relevant federal agencies, "for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements."²¹

Under the RFA, the sixth element of an initial regulatory flexibility analysis (IRFA) is to identify any duplicative, overlapping, and conflicting federal rules.²² Rules are considered duplicative or overlapping if they are based on the same or similar reasons for the regulation, the same or similar regulatory goals, and if they regulate the same classes of industry. Conflicting rules impose two conflicting regulatory requirements on the same classes of industry. In the IRFA, the EPA must examine the potential conflicting and duplicative rule that can unnecessarily add cumulative regulatory burdens on small entities without any gain in regulatory affairs.

The EPA's proposal is duplicative of OSHA's regulations for TCE because they both aim to protect workers from unsafe exposure to TCE and they apply to the same classes of industry. The EPA's proposal conflicts with OSHA's regulations as it imposes different regulatory requirements on the same classes of industry. In addition to proposing a different, much lower, exposure limit from OSHA, EPA is proposing additional requirements for user notification, recordkeeping, periodic monitoring, and respirator selection criteria as part of the WCPP.²³ The EPA acknowledges that entities currently in compliance with the OSHA standard may have to increase the frequency and scope of their compliance activities, such as through the implementation of engineering, controls to reduce exposures to the extent feasible, periodic exposure monitoring frequency, establishment of regulated areas, use of respiratory protection, and notification of monitoring results.²⁴

¹⁹ *Supra* note 2.

²⁰ 15 U.S.C. § 2608(d).

²¹ 88 Fed. Reg. at 74,720.

²² 5 U.S.C. § 603(b)(5).

²³ 88 Fed. Reg. at 74,736.

²⁴ *Id.* at 74,720

OSHA regulates worker exposure to TCE under a permissible exposure limit (PEL) of 100ppm.²⁵ The EPA's proposal conflicts with OSHA's regulations as it imposes different regulatory requirements on the same classes of industry. Importantly, the EPA's proposed ECEL of 0.001ppm is drastically lower than the OSHA PEL.

TSCA provides the EPA with discretion to avoid such duplicative, overlapping, and conflicting federal requirements. Specifically under TSCA section 9, if the EPA determines that the identified unreasonable risks for TCE:

“May be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such a law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk.”²⁶

In the proposed rule, EPA does not determine that unreasonable risk from TCE can be addressed by action taken under a different federal law.²⁷

Regarding workplace exposures, EPA reasons that an action under TSCA can address occupational unreasonable risk and reach entities that are not subject to OSHA, such as self-employed individuals and public sector workers who are not covered by a state plan.²⁸ The EPA also expressed concerns about the potentially longer timeframe for updating OSHA's standards.²⁹

TSCA should be administered as a gap-filling statute. The EPA should focus its intentions on those workers not currently protected under the Occupational Safety and Health Act.³⁰ The EPA should not attempt to supplant existing regulatory frameworks. Advocacy reiterates from previous comments that EPA should proceed with a rulemaking that covers those entities not subject to OSHA's regulations and allow OSHA to address the identified unreasonable risks within its jurisdiction.

The EPA asserts that unreasonable risk for TCE “can be addressed in a more coordinated, efficient, and effective manner under TSCA than under different laws implemented by different agencies.”³¹ However, the agency directly contradicts this statement by creating another set of requirements from those set by OSHA. The EPA is creating another set of requirements to be implemented by a different agency in addition to OSHA's requirements. Under TSCA section 9, the EPA should have consulted with OSHA to address the risk concerns with its standards and collaborated with OSHA in updating its PEL for TCE, rather than creating an additional regulatory framework for the same entities.

²⁵ *Id.* at 74,719.

²⁶ 15 U.S.C. § 2608(a)(1).

²⁷ 88 Fed. Reg. at 74,712.

²⁸ *Id.* at 74,720.

²⁹ *Id.*

³⁰ 29 U.S.C. §§ 651-678 (1970).

³¹ 88 Fed. Reg. at 74,774.

D. Advocacy recommends EPA address concerns with the proposed ECEL and action level.

Advocacy is concerned that the ECEL and action level are too low and may not be reliably measured in real time. As mentioned earlier, the agency proposes an ECEL level of 0.0011ppm. The agency also proposes an action level of half that at 0.00055ppm.³² The EPA assumes that a regulated entity has the necessary means to detect those levels because the agency understands them to be above the detection limit.³³ However, small business stakeholders have expressed their disagreement with this assumption.

While there may be commercially available methods to detect an exposure at the proposed levels, it may not be instantaneous, and the ability to measure it on-site is not readily available to all potentially regulated entities at this time.

Considering this feedback from small entities, Advocacy recommends that the EPA consider adjusting the ECEL and action level. It is crucial to consider the practical limitations faced by small businesses and ensure that the proposed ECEL and action level are reliably measurable in real-time.

E. Advocacy recommends that EPA consider all important impacts of the proposed rulemaking.

Under TSCA, the EPA is obligated to consider the reasonably ascertainable economic consequences of the rule, including the likely effect of the rule on the national economy, small businesses, technological innovation, the environment, and public health.³⁴ Small entity representatives have pointed out that the EPA's economic analysis does not consider the impact on American manufacturing competitiveness resulting from the proposed prohibition and restriction on the use of TCE.

Advocacy encourages the agency to consider the impacts on these entities and provide burden reducing compliance flexibilities. Advocacy strongly urges the EPA to take these and other related consequences into account when considering the adverse effect on the national economy and on minority populations.

III. Conclusion

Advocacy is concerned that the agency's proposal exceeds its statutory authority by prohibiting a vast majority of the commercial and industrial uses of TCE. Additionally, Advocacy is concerned about the lack of available regulatory flexibilities for the use of TCE by small businesses, particularly in cases where feasible alternatives are not available. Moreover,

³² *Id.* at 74,737.

³³ *Id.*

³⁴ 15 U.S.C. § 2605(C)(2)(A)(iv)(I).

Advocacy is concerned that the EPA does not satisfy the statutory requirement to consult and coordinate with OSHA to avoid duplicative and overlapping requirements. Lastly, Advocacy strongly urges the agency to address concerns with the proposed ECEL and action level and to consider all potential impacts of the proposed rule.

Advocacy recommends EPA reconsider the proposed rule. It is important to protect public health, but it is also important to consider small business impacts when creating expansive regulations.

If you have any questions or require additional information, please contact me or Law Clerk David Mullis at (202) 830-2292 or by email at david.mullis@sba.gov.

Sincerely,

/s/

Major L. Clark, III
Deputy Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/

David Mullis
Law Clerk
Office of Advocacy
U.S. Small Business Administration

Copy to: The Honorable Richard L. Revesz, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget