U.S. Chamber of Commerce

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Via Electronic Filing

Ms. Kelly Summers
Existing Chemicals Risk Management Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: U.S. Environmental Protection Agency Proposed Rule: Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 39652 (June 16, 2023)

Dear. Ms. Summers:

The U.S. Chamber of Commerce (Chamber) appreciates the opportunity to comment on the U.S. Environmental Protection Agency's (EPA's or Agency's) proposed rule on "Perchloroethylene (PCE); Regulation Under the Toxic Substances Control Act (TSCA)."[1]

The Chamber's members include companies across all sectors that are impacted by TSCA—chemicals, coatings, refining, petrochemicals, petroleum, forestry, wood products, batteries, electronics, energy, and electricity, among many others. These companies, which manufacture and use chemicals subject to regulation under TSCA, deliver products and innovation that are integral not only to the health and well-being of the American people, but also to the domestic economy and supply chain. Chemical technologies improve our quality of life in numerous ways by providing new solutions to problems in health, materials, transportation, agriculture, and energy usage. Protecting the health of workers and surrounding communities is a priority for our members.

It is also a priority to ensure the availability of critical chemicals, including industrial solvents such as PCE, by avoiding unnecessary overregulation. In addition, overregulating PCE could impede the achievement of Administration priorities, such as rebuilding U.S. infrastructure and incentivizing U.S. manufacturing. PCE is a solvent widely used in a variety of occupational and consumer applications including petroleum manufacturing, dry cleaning, and aerosol degreasing.[2] Chamber members include manufacturers of PCE as well as companies that rely on the availability of PCE for industrial, commercial, and consumer uses including adhesives, paints and coatings, aerosol degreasers, brake cleaners, aerosol lubricants, sealants, stone polish, stainless steel polish, and wipe cleaners.

[1] 88 Fed. Reg. 39652 (June 16, 2023).
[2] *Id*.

The Chamber urges EPA to consider the important issues raised in our comments and make appropriate modifications before finalizing its risk management requirements for PCE. Several comments addressing EPA's general approach to risk management were raised previously in the Chamber's comments on the methylene chloride proposed risk management rule.[3] We reiterate here that this proposal exceeds what is required under TSCA to prevent unreasonable risks based in part on EPA's incorrect interpretation of what is required under TSCA.

Additionally, EPA's approach to developing the Existing Chemical Exposure Limit (ECEL) for PCE is flawed and must undergo peer review, and EPA has not consulted with other relevant agencies, most notably OSHA, as TSCA requires. EPA should also consider certification and training as an alternative to an ECEL and worker protection program. Finally, EPA should consider including important flexibilities in the final rule to avoid significant economic disruptions for PCE manufacturers and users.

I. EPA's Approach to Risk Management is Inconsistent with TSCA Requirements

A. The proposed rule is not consistent with TSCA, which requires that risk management be applied only to the extent necessary to prevent unreasonable risk

TSCA Section 6(a) requires that EPA prevent "unreasonable" risks of injury to health or the environment to the extent necessary so that the chemical substance or mixture no longer presents such risks.[4] In the proposed rule, EPA has not demonstrated that it has followed this statutory requirement because its prohibition is not limited to unreasonable risks. Instead, EPA proposes to ban most uses of PCE that it determines cannot meet its proposed ECEL without sufficiently analyzing alternatives. EPA's default approach to banning numerous conditions of use of PCE even though workplaces can reduce exposures below the ECEL, is inconsistent with TSCA's requirement to impose risk management restrictions "to the extent necessary" to prevent "unreasonable risk."[5] EPA describes the proposed ECEL for PCE as a level below which the adult human would be unlikely to suffer "adverse effects" if exposed for a working lifetime.[6] EPA also states that, as a matter of risk management policy, ensuring exposures remain at or below the ECEL will eliminate any unreasonable risk.[7] Therefore, EPA is setting the unreasonable risk standard at the ECEL—a level which prevents likelihood of *any adverse effect*—rather than proposing a risk-based ECEL as required by TSCA. TSCA does not direct EPA to eliminate *any* adverse effect of a chemical; it requires EPA to prevent *unreasonable risks* to the extent necessary. As discussed further below, setting an ECEL at a level to eliminate all risk, as the proposed rule

[3] 88 Fed. Reg. 28284 (May 3, 2023). See the Chamber's methylene chloride comments at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0465-0279.
[4] 15 U.S.C. § 2605(a).
[5] *Id*.
[6] "The ECEL represents the concentration at which an adult human, including a member of a PESS, would be unlikely to suffer adverse effects if exposed for a working lifetime." 88 Fed. Reg. at 39659. See also EPA Memorandum on the ECEL For Occupational Use of Perchloroethylene (Apr. 15, 2021) available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0023.
[7] 88 Fed. Reg. at 39659.

suggests, would impose broad, sweeping restrictions on the use of PCE that would be inconsistent with the statute and its purpose to allow important chemicals to continue to be used without causing unreasonable risk of injury to health or the environment.

B. EPA has not provided sufficient rationale for why other regulatory authorities cannot prevent unreasonable risks of PCE

Section 9 of TSCA was enacted to prevent duplicative regulation and to reinforce TSCA's original "gap filling" purpose. Sections 9(a), 9(b), and 9(d) direct EPA to coordinate with other federal agencies when those agencies can take or have already taken action under their own authorities to address identified risks.[8] If EPA determines that risks associated with a substance can be eliminated or reduced to a sufficient extent by actions taken under another EPA-administered federal law, EPA must use such authorities to protect against such risk. Similarly, if EPA determines that unreasonable risks of a substance can be prevented or reduced to a sufficient extent by action taken under another federal agency, such as OSHA, EPA must allow that agency to take action on the identified risks. In the proposed rule, EPA failed to do the robust analysis required under Section 9 of TSCA to explain how it coordinated with other agencies and other federal laws, and determined that they cannot sufficiently mitigate the identified unreasonable risks of PCE.

Specifically, EPA is required to properly consult and coordinate with OSHA as it carries out its obligations under TSCA Section 6(a) to mitigate the identified unreasonable risks to workers, as OSHA has the primary responsibility and experience in regulating chemical risks in the workplace. EPA's requirement to mitigate risks to workers "to the extent necessary" does not broadly confer upon EPA the authority to take over the role of OSHA and ban some conditions of use. EPA's proposed approach to mitigating worker risks would make OSHA's regulatory authority and practices irrelevant, which is not what Congress intended. EPA should appropriately defer to OSHA to address worker risks.

Section 9(a) of TSCA requires that if, at EPA's discretion, it determines that an unreasonable risk associated with a chemical substance or mixture may be prevented or reduced to a "sufficient extent" by action taken by another federal agency, EPA must submit a report to that agency describing such risk and must request that the agency determine if the risk may be prevented or reduced to a sufficient extent under its authority.[9] The other agency must respond to EPA's report. If the other agency either determines that the activity discussed in EPA's report does not present an unreasonable risk or initiates agency action to protect against such risk, then EPA may not take risk management action on that substance under TSCA. If the other agency fails to respond to EPA's report in accordance with Section 9(a), EPA may initiate TSCA risk management, and the other agency must consult with EPA before taking any action under its own authority "for the purpose of avoiding duplication of Federal laws against such risk."[10] Congress intended EPA to "defer to other agencies that have relevant responsibility such as the Department of Labor in

[8] See also the Chamber's Asbestos Part 1 comments at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0057-0389.
[9] 15 U.S.C. § 2608(a)(1).
[10] 15 U.S.C. § 2608(a)(6).

cases involving occupational safety" and did not intend for TSCA to conflict with or disregard OSHA standards.[11]

Section 9(b) of TSCA also requires that EPA coordinate actions taken under TSCA with actions taken under other federal laws administered by EPA.[12] If EPA determines that a risk to health or the environment associated with a chemical substance can be eliminated or reduced to a sufficient extent by actions taken under other federal laws, EPA must use those authorities unless it is in the public interest to take actions under TSCA. This language is intended to focus EPA's exercise of discretion regarding which statute to apply and to "encourage decisions that avoid confusion, complication, and duplication."[13]

In the proposed rule, EPA has chosen not to undertake the report that is contemplated in Section 9(a) or to do an analysis of other laws implemented by EPA under Section 9(b). EPA's decision is based on the presumption that other authorities would not mitigate the unreasonable risk to a sufficient extent. Yet, EPA provides no analysis to support this presumption. EPA merely speculates that, if OSHA initiated a new action to lower the existing permissible exposure limit (PEL) for PCE, it "*may well* result in the OSHA PEL being set at a higher level than the exposure limit that EPA determined would be sufficient to address unreasonable risk under TSCA."[14] Further, EPA acknowledges that the Consumer Product Safety Commission (CPSC) has authority to regulate PCE in consumer products but not in the industrial or commercial setting.[15] Yet EPA does not explain why OSHA and CPSC together do not have adequate authority to regulate uses of PCE that present an unreasonable risk.

EPA also concludes that actions taken under other EPA authorities cannot sufficiently prevent unreasonable risk because other statutes such as the Clean Air Act, the Clean Water Act, and the Resource Conservation and Recovery Act address environmental releases and not occupational or consumer exposures to PCE, and that TSCA is "the most appropriate regulatory authority able to prevent or reduce risks of PCE to a sufficient extent across the range of conditions of use, exposures, and populations of concern."[16] While EPA identifies routes of exposure that are not covered by these particular environmental statutes under its authority, it does not do what is called for under TSCA—look at all existing authority, including OSHA or CPSC authority, to determine whether those tools can be used to sufficiently prevent unreasonable risks.

EPA's attempt to avoid a reasonable analysis of other federal regulatory approaches is inconsistent not only with TSCA's text, but also with its effort to avoid unnecessary duplication of regulatory burden, and does not adequately support EPA's alleged choice in favor of dual regulation over a tailored approach under which TSCA should supplement but not supplant existing statutory schemes that are protective. EPA's "statutory gap"

[11] H. Rept. 114-176 TSCA Modernization Act of 2015 at 28-29.
[12] 15 U.S.C. § 2608(b).
[13] H. Rept. 114-176 TSCA Modernization Act of 2015 at 28.
[14] *Id*. at 39704 (emphasis added).
[15] *Id*. at 39704.
[16] *Id*. at 39705.

explanation is not a sufficient, nonarbitrary basis for forgoing a complete analysis of its sister agencies' authority. EPA appears to be applying this generic rationale about OSHA standards in a number of risk management rules, which is contrary to the intent, text, and structure of TSCA Section 9 and would improperly circumvent EPA's obligation to coordinate its regulatory activity with OSHA (and other agencies) pursuant to the statute. At bottom, EPA makes no serious attempt in this proposed rule to determine why OSHA's (or other federal agencies') current authorities to address chemical risks cannot sufficiently address the risks for the conditions of use of PCE.

EPA's view that a single statute should be used to address all risks is contrary to the plain language of TSCA and should not be a substitute for an analysis of existing law and regulation. EPA incorrectly presumes, without supporting analysis, that, because other statutes have differing balancing factors (e.g., OSHA requires consideration of technical and economic feasibility), these statutes cannot address unreasonable risks to a "sufficient extent." EPA has provided no data or information to show that other statutes would not have the authority to mitigate unreasonable risk under TSCA. This is simply an assumption, and EPA has not given other agencies, in this case OSHA and CPSC, the opportunity to address the identified risks.

Further, EPA does not explain how cost and practicability under TSCA risk management rules promulgated under Section 6 may differ significantly from considerations under other federal risk management approaches. As discussed above, TSCA also requires that, in selecting risk management requirements for conditions of use that present an unreasonable risk, EPA consider the economic consequences of the rule, including consideration of the costs and benefits of the regulatory action and the likely effect of the rule on the economy and technological innovation.

EPA should first conduct a reasonable analysis to support a determination as to whether other statutory authorities cannot be used to address risk. EPA must explain why it cannot take action under its other statutory authorities to mitigate risks to workers and consumers. As required by law, EPA should follow the Section 9(a) procedures by submitting a report to OSHA and CPSC that describes the risk and the activities that present such risk. In addition, EPA should also conduct an analysis of the duplicative burdens that it would be imposing by requiring new obligations in areas already regulated by OSHA and CPSC.

C. EPA should not ban important uses of PCE when there are effective approaches to mitigate risk, such as applying performance standards (ECEL and WCPP)

EPA's proposed bans for most uses of PCE goes beyond the "extent necessary" to prevent unreasonable risk. EPA has determined "as a matter of risk management policy, that ensuring exposures remain at or below the ECEL will eliminate the unreasonable risk of injury to health from occupational inhalation exposures."[17] EPA concluded that "[t]he

[17] 88 Fed. Reg. at 39659.

uncertainties related to whether users under certain conditions of use could comply with the requirements of a PCE WCPP, combined with the severity of the risks of PCE, the prevalence of alternative processes and products (Unit V.B), and in some cases reasonably available information indicating a use is no longer ongoing (Refs. 56, 3), has led EPA to propose prohibitions for most industrial and commercial uses of PCE, as well as for the upstream manufacturing, processing, and distribution in commerce for those uses."[18]

Because EPA has identified the ECEL as a clear performance standard to prevent unreasonable risk, it should not propose to ban any conditions of use. To do so with incomplete data or with speculation about whether a particular facility is capable of meeting the ECEL or the requirements of the WCPP is inappropriate and unnecessary. Workplaces must have the opportunity to comply with the proposed standard. The burden should be on regulated entities to ensure they meet the WCPP requirements rather than EPA eliminating any compliance option for these users.

EPA has provided no explanation for why a company that can comply with the WCPP could not continue to use PCE. It is improper for EPA to decide who can and who cannot comply with the WCPP to minimize exposures simply because it lacks certainty based upon a lack of data. Many companies lack the data that EPA deems necessary to prove compliance with the ECEL is achievable, but this does not mean that they would be unable to meet the ECEL if they were given the opportunity. Companies have been monitoring and collecting data to ensure compliance with the OSHA PEL for PCE, which is less stringent than EPA's proposed ECEL. Therefore, monitoring at exposure levels well below the OSHA PEL is not common, and it is unrealistic for EPA to expect that data currently exist for companies to show that they are in compliance with the ECEL. Yet, without describing exactly what data it seeks and without describing what constitutes acceptable data, EPA has suggested that these unidentified and undescribed data are necessary for EPA to allow for a WCPP in place of a prohibition.[19]

OSHA does not require that employers provide data to OSHA proving with certainty that they are capable of complying with an OSHA standard (a PEL or other worker protection requirement) before being subject to the standard. Instead, OSHA issues a standard applicable to employers (general industry, construction industry, or shipyard industry), and the regulated employers must comply with the standard; otherwise, they could be in violation of the standard and face enforcement. Pre-approval from OSHA before being subject to a standard is not a requirement from OSHA, nor should it be a requirement from EPA.

Consistent with the OSHA approach, EPA should allow all workplaces the opportunity to meet the WCPP. If EPA believes data are necessary to show compliance, EPA should allow all employers to continue using PCE while the required data are collected. EPA also must provide sufficient time for companies to conduct the exposure monitoring necessary to

[18] 88 Fed. Reg. at 39691-92.

[19] EPA "also requests monitoring data and detailed descriptions of PCE involving activities for these conditions of use to determine whether these additional conditions of use could comply with the WCPP such that risks are no longer unreasonable." 88 Fed. Reg. at 39708.

collect these data. Because the WCPP will require capital expenditures, including engineering and administrative controls consistent with the hierarchy of controls, EPA should allow companies a reasonable timeframe to demonstrate compliance with the WCPP. Companies that are willing to undertake engineering and process control modifications will not be able to make these changes within 9 months of finalization of the rule, and EPA must ensure that a fair opportunity is provided for those companies that choose to invest in modifying their processes. If compliance cannot be demonstrated to mitigate unreasonable risks after a reasonable timeframe for necessary modifications, then prohibitions would be appropriate.

Further, EPA should develop a consistent framework for all TSCA risk management rules that allows for a chemical's continued use under a WCPP. For example, EPA's proposed methylene chloride rule and PCE proposed rule would, if finalized, require different, inconsistent approaches to a WCPP. It is not practical for EPA to impose multiple differing WCPPs on facilities that may use more than one chemical that EPA is regulating under TSCA. EPA should consider developing an overarching WCPP framework that provides a harmonized approach for all chemicals regulated under Section 6 of TSCA. This framework, which should undergo notice and comment, coordinated inter-agency review, and peer review by subject matter experts with experience in occupational and industrial hygiene, should be put in place before EPA finalizes TSCA Section 6 risk management rules.

D. EPA's application of the "whole chemical" approach in its revised risk determination for PCE is inconsistent with TSCA

Under TSCA Section 6(b), EPA is required to evaluate risks of chemical substances "under the conditions of use"[20] which requires use-by-use risk determinations. EPA's use of the "whole chemical" approach to risk evaluations and risk determinations, as newly implemented by this Administration, is inconsistent with TSCA Section 6(b). Under this improper approach, EPA decides whether the "whole chemical," at the broadest (and arguably most abstract) level, poses an "unreasonable risk" to human health or the environment "when it is clear the majority of the conditions of use warrant one determination," rather than making determinations of unreasonable risk based on individual conditions of use.[21]

EPA revised its risk determination for PCE to implement the whole chemical approach in December 2022, long after the release of the PCE risk evaluation.[22] EPA also revised its risk determination to remove the assumption that workers wear PPE. The Chamber believes that the revised risk determination is inconsistent with TSCA. EPA's "whole chemical" approach and "no PPE" assumption have led EPA to require more stringent risk mitigations

[20] 15 U.S.C. § 2605(b)(4)(A).
[21] See EPA announcement "EPA Announces Path Forward for TSCA Chemical Rick Evaluations" on June 30, 2021: https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations ("EPA will continue to assess and analyze each condition of use, but then the agency plans to make the determination of unreasonable risk just once for the whole chemical when it is clear the majority of the conditions of use warrant one determination").
[22] See EPA's Final Revised Risk Determination for PCE available at: https://www.epa.gov/system/files/documents/2022-12/PCE_Final%20Revised%20RD_12-5-22.pdf.

than necessary. EPA's decision to change the risk determination for PCE to the "whole chemical" approach after the PCE risk evaluation was completed undermines the careful risk evaluation process that is required by TSCA. This statutory process involved opportunities for public comment and collection of data from stakeholders. EPA's new approach effectively ignores exposure data provided for certain conditions of use that demonstrated no unreasonable risks and makes a single global determination that the chemical presents an unreasonable risk based on only some conditions of use. Stakeholders and peer reviewers were not informed during the risk evaluation peer review process that EPA would be applying this novel approach to making the risk determinations and subsequent risk management decisions. In fact, this approach did not even undergo peer review or any scientific review. EPA must revert to its prior approach to issuing risk determinations based on individual conditions of use.

II. EPA's ECEL for PCE is Not Fit for Purpose

A. EPA's ECELs must undergo peer review to improve EPA's process for developing scientifically sound ECELs

The EPA did not conduct a peer review for important aspects of the ECEL, leading to a number of substantive concerns with the science underpinning the ECEL. The 2016 TSCA Amendments require that EPA consult with the Science Advisory Committee for Chemicals (SACC) "with respect to the scientific and technical aspects of issues relating to implementation of this title."[23] EPA should use the SACC to review its overarching approach to the ECEL, as well as the specific choices made for deriving the PCE ECELs before finalizing this rule.

EPA proposes an ECEL for airborne concentrations of PCE in excess of 0.14 ppm based on an 8-hour time-weighted average (TWA) and a short-term exposure limit (STEL) of 0.07 ppm over a period of 15 minutes. EPA released these derived values through a memorandum that was added to the docket after the risk evaluation for PCE was complete.[24] This memorandum was not part of the information that underwent peer review by the SACC. While the ECEL derivation uses information that is in the PCE risk evaluation, there are many science and policy choices that are part of the derivation. Considering the concerns from the EPA peer reviewers on the draft risk evaluation,[25] and the analyses by the German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area using the same data, which set its occupational standard at 10 ppm,[26] EPA has not sufficiently justified its ECEL set at 0.14 ppm. EPA's ECEL document does not directly identify the studies used and the reasoning for choosing

[23] 15 U.S.C. § 2625(o).
[24] The Risk Evaluation for PCE was finalized in December 2020, and the memorandum setting the ECEL was signed on April 15, 2021.
[25] Transmittal of Meeting Minutes and Final Report for the TSCA Science Advisory Committee on Chemicals Meeting via Phone and Webcast held May 26-29, 2020, at page 18, available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0502-0055.
[26] The MAK Collection for Occupational Health and Safety 2019, Vol 4, No 4; also available at: https://onlinelibrary.wiley.com/doi/full/10.1002/3527600418.mb12718e6319.

them; it simply points back to the risk evaluation without providing any additional justification.

Additionally, EPA also does not explain why it has assumed workers are exposed to PCE for eight hours each day and whether this assumption is appropriate for all the conditions of use EPA evaluated. For instance, data show that a brake cleaning task, using PCE, can be conducted in under 3 hours, and that, on average, an auto repair worker will only conduct 1-2 brake jobs per week.[27] These omissions are not acceptable considering the importance of the new values EPA is setting.

EPA has proposed the novel ECEL approach in its recent proposals for asbestos part 1 and methylene chloride, and now PCE, none of which have been finalized. EPA must ensure that the approach it is proposing across all risk management rules under TSCA is consistent with best available science as required by TSCA Section 26. While EPA uses values that were evaluated in the risk assessment for PCE, it has an obligation to ensure that these same values are fit for purpose when setting workplace standards. It is inconsistent with sound scientific practice to begin implementing a program to limit workplace exposures without ever seeking peer review of the approach—including the choice of data, the exposure periods used, and the adjustment factors that are applied when setting a workplace standard. Industrial hygiene and workplace exposure experts should be part of a peer review panel that provides guidance to EPA on how to appropriately derive and apply these values for the hundreds of diverse occupational uses to which EPA intends them to apply. This is also why consulting with OSHA is so imperative; employers need one unified set of well validated requirements regarding workplace exposures with which they must comply.

B. The proposed ECEL cannot be easily measured or easily implemented

EPA's proposed ECEL for PCE of 0.14 ppm (as an 8-hour TWA) is three orders of magnitude lower than the existing OSHA PEL for PCE of 100 ppm (as an 8-hour TWA). EPA must consider that when it establishes an ECEL at such low levels, it will not have utility if it cannot be easily measured or even implemented by businesses subject to the WCPP. An overprotective ECEL will not be a useful part of a WCPP, and as discussed earlier in these comments, EPA must address important scientific issues. To measure at this level, active sampling with a pump will be needed and passive sampling will be ineffective. Additionally, samples must be sent to an external laboratory for analysis, and results will not be available instantaneously. The proposed action level is even more problematic, as it is half of the proposed ECEL. EPA must consider whether the ECEL is feasible for employers to detect in workplaces when, prior to this rulemaking, employers typically only measured PCE at levels to comply with the OSHA PEL or other exposure limits such as the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) of 25 ppm.

[27] See *Usage of Chemical Brake Cleaners in Automotive Repair Facilities*, J. Norton, George Mason University, 1996, at page 5, available at: https://hsia.org/wp-content/uploads/2018/07/Perc-Exhibit-1Chemical-Brake-Cleaners.pdf.

OSHA's statutory requirement to consider technological feasibility encompasses the ability to test at prescribed levels. Inability to test down to the level of an ECEL would make that testing requirement technologically infeasible. EPA ought not impose a requirement that would not be acceptable under OSHA limitations.

C. EPA should consider training and certification as an alternative to the ECEL and WCPP for PCE

EPA acknowledges in the proposed rule that it considered but did not propose point-of-sale self-certification in order to purchase and use PCE. A robust point-of-sale self-certification approach would ensure that only facilities able to implement a WCPP or prescriptive controls can purchase PCE, and the self-certification would be submitted to the distributor or retailer at the time of purchase.[28] EPA decided not to propose this as a risk management option:

> [B]ecause of the number and types of entities where users can obtain PCE or PCE-containing products, EPA does not believe the added requirement and subsequent burden of a point-of-sale self-certification requirement for the use of PCE would be an effective tool for preventing facilities that may be unable to comply with the WCPP or prescriptive controls of this proposed rulemaking from accessing PCE or PCE-containing products.[29]

The Chamber disagrees with this conclusion. EPA should consider training and certification as a risk management approach to mitigate unreasonable risks for professional users of PCE. Under TSCA Section 6(a), risk management requirements can restrict how a substance is distributed in commerce for a particular use[30] and regulate any manner or method for use of the substance commercially.[31] EPA has recognized in previous Section 6 rulemakings that TSCA provides EPA ample authority to require certification and training as a risk management approach.[32]

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[28] 88 Fed. Reg. at 39697.
[29] *Id*.
[30] 15 U.S.C. § 2605(a)(2).
[31] 15 U.S.C. § 2605(a)(5).
[32] In 2017, EPA acknowledged that a certification and training program could be a regulatory option for methylene chloride used in paint and coating removal. See Methylene chloride and N-Methylpyrrolidone; Regulation of Certain Uses under TSCA Section 6(a), 82 Fed. Reg. 7,464 (Jan. 19, 2017). In 2019, EPA solicited further public comment on training, certification, and limited access requirements for methylene chloride when used for commercial paint and coating removal, specifically citing TSCA Sections 6(a)(2) and (5) as providing authority for such requirements. See Methylene chloride; Commercial Paint and Coating Removal Training, Certification and Limited Access Program, 84 Fed. Reg. 11467 (Mar. 27, 2019) ("TSCA sections 6(a)(2) and (5) authorize EPA to regulate the distribution in commerce for a particular use and any manner or method of commercial use, respectively, of a chemical found to present unreasonable risk. Potential training, certification, and limited access program requirements could be promulgated under those authorities as part of rulemaking under the authority of TSCA section 6(a)").

A recent analysis which included a systematic literature review identified 56 studies which evaluated whether training programs were effective.[33] The studies used diverse endpoints to evaluate efficacy, including improvements that remained post-intervention, declines in unsafe practices, improvements in workers' knowledge, improvements in safety performance, reduced incidence of injury, decreased cultural and linguistic barriers, and reduction in injury claims. The overwhelming majority of studies showed that training is effective.

We are aware of uses of PCE, including the use of PCE in energized electrical cleaning, where trained contractors go to differing facilities to conduct this work. Energized electrical cleaning is the cleaning of equipment where there is an electrical current running through it.[34] Many industrial and commercial facilities that don't necessarily use PCE have equipment such as motors and generators that require energized electrical cleaning. Despite EPA's flawed alternatives analysis (as discussed below), there are no safe and effective non-flammable alternatives to PCE-containing energized electrical cleaners. This is why many states have continued to allow uses of energized electrical cleaners.[35] Facilities that require energized electrical cleaning may not have WCPP programs in place because the PCE use may only occur when the contractor brings the product to the facility to conduct the EEC. They will rely on highly trained and skilled technicians to conduct this cleaning work, some of which is conducted outdoors and some indoors. For example, in the electrical utility industry, some of this cleaning is conducted underground in confined spaces where respirators are used. These technicians undergo extensive training before conducting this work. A WCPP is impractical, and EPA must allow for these essential uses to continue. Therefore, EPA should use training and certification as a tool to ensure safety.

While training programs already exist for certain skilled users of PCE, as discussed above, EPA is well equipped to administer training and certification programs for chemicals regulated under TSCA Section 6. EPA has substantial experience with such programs, including the Lead-Based Paint Renovation, Repair, and Painting (RRP) and Abatement Programs,[36] the Asbestos Certification Program under the Asbestos Hazard Emergency Response Act,[37] the regulation of restricted use pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[38] and the Refrigerants Certification under the Clean Air Act.[39]

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[33] See comments and analysis submitted by the American Chemistry Council (ACC) to Denise Keehner, May 26, 2023, regarding the systematic literature review on training and certification. ACC states "[a]s reflected in this analysis, the majority of the available literature supports the beneficial impacts of training on worker health and safety." Available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0465-0182

[34] 88 Fed. Reg. at 39664.

[35] As we will discuss in greater detail, California, Connecticut, Delaware, DC, Maryland, New York, Rhode Island, New Jersey, Illinois, Indiana, Maine, and Massachusetts all exempt energized electrical cleaners from the definitions of general purpose degreasers, electrical cleaners and electronic cleaners, which are products that are prohibited from being manufactured or sold in the state with PCE (other than present as an impurity).

[36] 40 C.F.R. § 745.81(a)(2), (3).

[37] See https://www.epa.gov/asbestos/asbestos-training#law.

[38] 40 C.F.R. §§ 171.101, 171.103, 171.105.

[39] 40 C.F.R. § 82.161.

All of these programs demonstrate that EPA has the ability to develop programs that effectively eliminate risk associated with hazardous chemicals by limiting use to trained, qualified professionals. These programs would protect workers, mitigate unreasonable risk, and impose fewer costs than the prohibitions in the proposed rule. A training and certification program and limited use program represent a reasonable approach that would allow EPA to mitigate risks "to the extent necessary." EPA should develop a proposal for implementing a program for PCE and release a draft for notice and comment before finalizing the current proposal.

III. EPA Should Modify its WCPP Requirements

EPA is requesting comment on whether owners and operators should be required to attest to whether and why the exposure controls they have selected would not result in increased air releases of PCE from the workplace, and keep records of that statement as part of the WCPP exposure control plan.[40] This is another overly burdensome requirement Rather than requiring attestation, this information should be documented through the results of the sampling for when the processes change. Such documentation is adequate, and EPA offers no persuasive reason why attestation is required.

EPA also proposes to require that owners and operators must re-monitor within 15 working days after receipt of any exposure monitoring when results indicate non-detect or air monitoring equipment malfunction, unless an Environmental Professional as defined at 40 C.F.R. § 312.10 or a Certified Industrial Hygienist reviews the monitoring results and determines re-monitoring is not necessary.[41] EPA's requirement for re-monitoring is overly burdensome. Additionally, EPA's requirement for a certified Industrial Hygienist or Environmental Professional may require smaller companies to hire outside contractors to conduct this work. This aspect of the proposal also appears to be inconsistent with OSHA rules and the proposed methylene chloride rule. There are qualified industrial hygienists that for various reasons are not certified and adding this requirement could be costly because either additional training or hiring new personnel to meet this requirement may be required.

EPA has also proposed that the owner or operator must directly provide information and training to employees assigned to a job involving potential exposure to PCE. EPA should change this language to state that the owner or operator must ensure that training is completed and should not unnecessarily restrict the manner in which the training is provided.[42] This change would be consistent with current OSHA practice and would ensure protections are in place and compliance is achieved while not being overly burdensome.

EPA is proposing to require recurring 5-year initial exposure monitoring. If initial monitoring demonstrates that PCE is not detected, and if there are no changes to the process or controls in place, further monitoring should not be required. At minimum, there should be a mechanism to allow for less frequent monitoring. If the process hasn't changed,

[40] 88 Fed. Reg. at 39701.
[41] *Id*. at 39718.
[42] *Id*. at 39720.

and the WCPP is in place and is effective, continued monitoring will not change the exposure and will unnecessarily divert resources from other activities that will ensure that health and safety are protected

EPA is also requesting comments on owners' or operators' ability to conduct initial monitoring within six months after date of publication of the final rule and anticipated timelines for any procedural adjustments needed to comply with the requirements outlined in this section of the proposal, including establishment of a respiratory protection program and development of an exposure control plan. As discussed later in these comments, lengthening these compliance timeframes including conducting the initial monitoring would make it easier to achieve compliance with this new rule (assuming a more appropriate ECEL is finalized). Large corporations, as well as small businesses, with different types of processes would need time to work through how this new rule impacts their companies and how and where the various products using PCE apply to the rule.

IV. EPA's Analysis Fails to Address Important Issues

A. EPA's alternatives assessment for PCE is insufficient and potentially dangerous

In deciding whether to prohibit or substantially restrict a condition of use, EPA must consider whether "technically and economically feasible alternatives" are available as a substitute.[43] EPA needs to ensure that technically and economically feasible alternatives exist for uses the Agency intends to prohibit. EPA's current alternatives assessment does not meaningfully assess alternatives available for PCE that will be effective or reasonably available, yet EPA still proposes to ban most industrial, commercial, and consumer uses of PCE. And, for the few remaining uses allowed to continue, they must comply with an ECEL that is significantly lower than the OSHA PEL and any other restriction on PCE in the world.

An example of EPA's flawed alternatives assessment is EPA's treatment of flammability. As noted in section 2 of the Economic Analysis,[44] EPA is aware that other states, including California, recognize that non-flammable alternatives to PCE do not exist for energized electrical cleaning. Yet, in the alternatives analysis, EPA states that "[t]his review did not find any barriers related to fire safety that could be caused by restricting use of PCE in this product category, as energized electrical degreasers are formulated to have non-flammable properties."[45] EPA acknowledges that there were no reviews for the supposed alternatives. These alternatives contain trans-DCE (also known as trans 1,2-dichloroethylene). Trans-DCE is a chemical known well to EPA, yet EPA has not incorporated available information on trans-DCE in this evaluation. In December 2019, EPA listed trans-DCE as a high-priority chemical that was listed for risk evaluation under TSCA Section 6.[46] In September 2020,

[43] 15 U.S.C. § 2605(c)(2)(C).
[44] See EPA's "*Economic Analysis of the Proposed Regulation of Perchloroethylene Under TSCA Section 6(a)*" (Economic Analysis) (June 2023) available at https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0125, at chapter 2.
[45] Economic Analysis at page 5-47.
[46] See information on trans-DCE available at: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under.

EPA finalized its scoping document for trans-DCE.[47] On page 11 of the scoping document, EPA states that "trans-1, 2-Dichloroethylene (CASRN 156-60-5) is a highly flammable, colorless liquid with a sharp, harsh odor."[48] EPA should have incorporated that information into this assessment of alternatives. It is well known in industrial circles that trans-DCE can be flammable and is not recommended for energized electrical cleaning, which is why EPA was unable to find any relevant reviews for products containing trans-DCE.

Another area where EPA's analysis is lacking is its evaluation of brake cleaning uses. EPA inappropriately assumes that alternative products can provide a replacement for PCE for this purpose, and that the same volumes of product would be used. This is an oversimplification that leads to an underestimate of replacement costs. To estimate removal time, for some conditions of use, EPA used the Hansen Solubility Parameters (HSP) theory to quantify solvent efficiency. However, EPA does not provide sufficient details to understand how this theory was applied. Appendix B of the economic analysis provides calculations for only a very limited set of products for only one condition of use[49] and provides no example of how the theory was applied to other products. EPA should have its implementation of the HSP theory peer-reviewed before it is used to support analyses for final regulations.

EPA must provide adequate justifications for its conclusory statements (or otherwise withdraw them). Also, it should array the use and alternatives analysis in tables, as was done in the alternatives screen, so that stakeholders can do a side-by-side comparison of all the elements in the use and alternatives analysis. Improving transparency in this way, will allow stakeholders to better follow and understand EPA's logic in reaching its conclusions. It appears that, at least for the brake cleaning example, there is not one product that meets all the criteria EPA evaluates. A more transparent analysis is needed for each of the conditions of use that EPA seeks to regulate.

B. EPA should consider alternatives for each condition of use, not just some conditions of use

In Appendix C to the alternatives analysis, EPA lists the conditions of use not analyzed further (which includes conditions of use proposed to be prohibited) due to the "complexity" of the analysis or due to EPA's inability to identify alternatives.[50] In addition, as is shown in tables 1-1 and 5-1 of the Economic Analysis, EPA lumps multiple conditions of use into a far more limited set of use categories and does not evaluate some conditions of use.[51] The technological and economic feasibility analysis is not sufficient to cover all the uses that EPA seeks to regulate. EPA should conduct the required alternatives analyses for

[47] EPA, *Final Scope of the Risk Evaluation for trans-1,2-Dichloroethylene*, Sept. 2020, available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0465-0042.
[48] *Id*. at 11.
[49] *Id*. at B-1.
[50] "Due to the lack of reasonably available information, this analysis did not assess alternatives for every individual COU EPA is proposing to prohibit or significantly restrict." EPA's "An Alternatives Assessment for Use of Perchloroethylene" (Jan. 2023) at 8. See also Appendix C: https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0720-0104.
[51] Economic Analysis at chapter 5.

all the conditions of use that EPA seeks to regulate or should explain its rationale for not doing so. TSCA requires such a review of alternatives whenever EPA proposes to prohibit or substantially restrict a condition of use.[52] If such evaluation is not possible for EPA, or if it could not find information on alternatives, then EPA should *not* prohibit or substantially restrict that condition of use given the lack of technically and economically feasible alternatives available.

C. EPA's definition for retailers is unworkable and fails to consider professional users

EPA defines retailer as "a person who distributes in commerce or makes available a chemical substance or mixture to consumer end users, including e-commerce internet sales or distribution. Any distributor with at least one consumer end user customer is considered a retailer. A person who distributes in commerce or makes available a chemical substance or mixture solely to commercial or industrial end users or solely to commercial or industrial businesses is not considered a retailer."[53] In the proposed rule, retailers would be prohibited from distributing PCE products, and all persons would be prohibited from distributing PCE products to retailers for any use (other than commercial dry cleaning or consumer use of clothing and articles that have been commercial dry cleaned).[54]

Many professionals in diverse sectors are small businesses or operate independently. EPA's proposed definition of "retailer" would inappropriately limit the ability of many of these small businesses and professional users to use PCE, even if they can meet the ECEL and WCPP. These professional users would not be able to purchase the PCE products they need. EPA should allow retailers to sell PCE to any user that can meet the ECEL and WCPP. EPA should consider training and certification programs to more appropriately limit distribution to small business and professional users.

D. The economic analysis does not appropriately consider reasonably ascertainable economic consequences

EPA must factor in the reasonably ascertainable economic consequences of its risk management rule.[55] EPA's cost analysis[56] is not sufficient to justify the extensive prohibitions that will result from implementing the proposed rule. In this case, many important costs have gone unquantified.[57] These include costs associated with the hazards of PCE alternatives; costs associated with alternatives that are not exact product replacements for products containing PCE; costs associated with the inability to use PCE or PCE-containing products; costs associated with firm closures; costs associated with the changes in the supply chain and availability of PCE for uses that will continue; and costs

[52] 15 U.S.C. 2605(c)(2)(C)
[53] 88 Fed. Reg. at 39717.
[54] *Id*.
[55] 15 U.S.C. § 2605(c)(2)(B).
[56] Economic Analysis at chapter 7.
[57] *Id*. at 26.

associated with unemployment impacts. EPA offers no persuasive rationale as to why it has failed to quantify these costs.

Notwithstanding EPA's insufficient cost analysis and flawed alternatives analysis, EPA still finds that for many conditions of use, the benefits of the rule do not outweigh the costs.[58] EPA has not explained why these economic consequences justify the sweeping prohibitions that go beyond the extent necessary to mitigate unreasonable risk. EPA must remedy the defects in its cost analysis and must also reconsider, and better explain, its approach to mitigating unreasonable risks beyond those required by the statute.

V. EPA Should Include Other Key Flexibilities to Avoid Economic Disruptions

A. The Chamber supports EPA's proposed *de minimis* threshold

EPA seeks comment on whether a *de minimis* level of PCE should be allowed to account for impurities.[59] The Chamber and its members support the inclusion of a *de minimis* level of 0.1% for PCE. This level is consistent with reporting requirements under the Globally Harmonized System (GHS) and OSHA Safety Data Sheets (SDSs) for carcinogens. Levels below 0.1% are typically considered to be impurities, are unlikely to impact toxicity, and are not associated with unreasonable risks. Additionally, because levels below 0.1% are not required to be reported on SDSs, there is not an awareness of products that contain PCE below these levels. Requiring reporting for impurities below this level would be impractical and would require modifications of potentially thousands of SDSs. EPA has not conducted the required cost analysis to determine the impacts of finalizing a regulation that does not include a *de minimis* value.

B. The WCPP should accommodate existing effective risk mitigation measures

EPA's proposed WCPP should include flexibilities to accommodate existing, effective risk mitigation measures consistent with OSHA standards. For instance, where tasks are completed in a closed system and/or only infrequently, there should be a mechanism to allow these tasks to continue when appropriate PPE is used, without triggering automatic and unnecessary reoccurring monitoring requirements. Additionally, as noted above, for some uses of PCE, including energized electrical cleaning, trained contractors travel to different facilities to conduct this important work. The WCPP is not designed to travel with the worker, and facilities that need energized electrical cleaning may not otherwise use or purchase PCE. It would not be feasible for these facilities to have a WCPP, yet this essential work will need to be conducted. As described previously, and as recognized by other states, there are no safe alternatives to PCE for energized electrical cleaning. EPA must allow these uses, and a worker protection program must be appropriately tailored to the type of work required. As proposed, the WCPP does not address these needs. A training and certification

[58] *Id*. at 32-36.
[59] 88 Fed. Reg. at 39671.

program for workers would be consistent with a fit-for-purpose approach, and EPA should consider an appropriate training program in lieu of a WCPP.

C. All industry sectors should be permitted to petition for critical use exemptions

EPA proposes a time-limited exemption under TSCA Section 6(g) for certain emergency uses of PCE in furtherance of NASA's mission.[60] EPA allows for such a critical use exemption if it finds that the condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available.[61] EPA recognizes that there may be instances where an ongoing use of PCE that has implications for national security or critical infrastructure, as it relates to Federal agencies, may be identified after the proposed rule is finalized, and EPA requests comments on an appropriate process to expedite reconsideration of such uses.[62] EPA proposes that Federal agencies could petition EPA, and it would make a decision within 30 days regarding whether to allow the critical use.[63]

As with the methylene chloride proposed rule, the Chamber supports the concept of a petition process.[64] However, EPA provides no adequate reason why this expedited process is limited to only Federal agencies or their contractors. All users, including those in the private sector, should be allowed to utilize this process and request a TSCA Section 6(g) exemption. EPA states that it expects that Federal and Federal contractor facilities would be subject to a higher level of oversight than non-Federal or contractor facilities. However, EPA provides no facts to support this assumption. Treating private businesses across the board less favorably than their government counterparts, without appropriate data, is inappropriate and unnecessary.

Additionally, EPA describes a petition process that requires the submission of monitoring data to ensure compliance with the WCPP, and EPA also requests "documentation of efforts to identify or qualify substitutes."[65] This latter documentation request is unnecessary and has no practical utility. If there is compliance with the WCPP, unreasonable risk has been mitigated. There is no need for a requirement to identify or qualify substitutes, and there is no need to further mitigate any potential risk. Requirements for unnecessary documentation should not be part of any petition process for a national security or infrastructure exemption.

Finally, EPA should better define what constitutes a contractor and specifically a Federal agency contractor. All contractors of employers (Federal and non-Federal) requiring a TSCA Section 6(g) exemption should be eligible for TSCA Section 6(g) exemptions. It is

[60] 88 Fed. Reg. at 39681.
[61] *Id*.
[62] *Id.* at 39669.
[63] *Id.*
[64] U.S. Chamber of Commerce, Comments on EPA's Proposed Rule; Methylene Chloride Regulation Under the Toxic Substances Control Act (TSCA), submitted to EPA Jul. 3, 2023, at page 13, available at: https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0465-0279.
[65] 88 Fed. Reg. at 39670.

important that EPA provide a clear definition to help identify these contractors so that there is a common understanding of who may apply for the exemption. EPA must also conduct an analysis to ensure that sufficient PCE will be available in the supply chain to support critical uses for infrastructure and national security.

D. A critical use exemption is necessary for energized electrical cleaning

The Chamber requests that EPA include a critical use exemption under TSCA Section 6(g) for uses of PCE in energized electrical cleaning.

Under TSCA Section 6(g), EPA may grant an exemption from a requirement of a TSCA risk management rule for a specific condition of use of a substance if EPA finds that:

> (A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;
>
> (B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or
>
> (C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.[66]

In this case, the use of PCE in energized electrical cleaning meets the criteria. Energized electrical cleaners are for use on energized equipment that cannot be shut off or unplugged before being cleaned. This equipment is common in utilities, the oil industry, and other manufacturing environments. Motorized equipment of this type must be cleaned with non-flammable products. Further, EPA is on notice, and likely aware that the following 12 states already recognize the importance of energized electrical cleaning, because these states' regulations exempt this use from the scope of their restrictions on certain PCE-containing products: California, Connecticut, Delaware, District of Columbia, Maryland, New York, Rhode Island, New Jersey, Illinois, Indiana, Maine, and Massachusetts. These state regulations exempt from prohibitions the use of PCE for energized electrical cleaning because they consider the critical need for a non-flammable product for this use and the lack of viable alternatives. The Chamber urges EPA to adopt a Section 6(g) critical use exemption for PCE in energized electrical cleaning.

E. EPA should not propose to prohibit the manufacture and processing of PCE for export

EPA proposes in the Preamble that "[a]s the manufacture and processing of PCE presents an unreasonable risk to health in the United States, the manufacture and processing of PCE

[66] 15 U.S.C. § 2605(g).

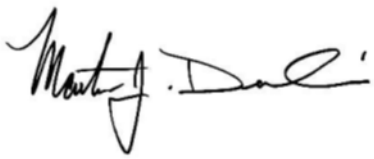
for export would also be prohibited or restricted in accordance with TSCA section 12(a)(2)."[67] However, manufacturers who export products overseas will already be subject to export notification under TSCA Section 12(b), thereby providing notice about PCE in products exported. Further, other countries do not have the same restrictions on PCE in products as EPA proposes here. It is inappropriate and unnecessary to ban products that are exported outside of the U.S. when most other countries have significantly higher exposure limits for PCE in products than the proposed ECEL.[68]

F. Implementation timelines in the proposal should be lengthened (including those for WCPP)

The timelines in the proposed rule are not sufficient to allow employers and users of PCE to ensure compliance with the WCPP and initial sampling requirements. EPA must publish additional guidance on sampling and acceptable test methods before implementation of a final rule that requires a WCPP. Standard test methods should be articulated by EPA and EPA must allow sufficient time for manufacturers and processors to make the necessary changes to ensure compliance. In addition, time is required for the development and validation of direct-read monitoring capabilities. Therefore, after the effective date of the final rule, EPA should allow 36 months for full implementation of the WCPP, including the exposure control plan.[69]

Thank you for the opportunity to provide these comments. The Chamber welcomes further discussion with EPA on this important proposal. Please contact Preston Beard, Director of Policy, at pbeard@uschamber.com with any questions regarding these comments.

Sincerely,



Martin J. Durbin
Senior Vice President, Policy
President, Global Energy Institute
U.S. Chamber of Commerce

[67] *Id*. at 39669.
[68] For example, the EU has an occupational exposure limit of 20 ppm for PCE. See European Chemicals Agency (ECHA) profile on PCE: https://echa.europa.eu/substance-information/-/substanceinfo/100.004.388.
[69] We note that this timeline is consistent with OSHA implementation of its beryllium standard (29 CFR 1019.1024(f), (o)).