**Before the United States**
**Environmental Protection Agency**
**Perchloroethylene; Regulation Under the Toxic Substances Control Act**
**88 Fed. Reg. 39652 (June 16, 2023); Docket EPA-HQ-OPPT-2020-0720**

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**Comments of the Chemical Users Coalition**

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Chemical Users Coalition ("CUC")[1] appreciates the opportunity to provide these comments regarding the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") Proposed Rule for the Regulation of Perchloroethylene under Section 6(a) of the Toxic Substances Control Act ("TSCA") (the "Proposed Rule"). CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances. Our members depend on the availability of certain existing substances for which there are not technically feasible substitutes as well as a reliable pipeline for innovative new chemistries to be able to thrive in a competitive, global economy. Consequently, our members encourage EPA to develop regulatory approaches that encourage innovation and permit sustainability. Thus, CUC supports measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. This is critical in the area of chemical regulatory policy, which necessarily addresses emerging information about health and environmental risk.

## Background

After undertaking its risk evaluation for perchloroethylene ("PCE") in July 2017, the Agency published its draft risk evaluation in April 2020 and completed a final risk evaluation for PCE in December 2020. However, EPA substantially changed its approach for performing risk evaluations commencing in June 2021; including making its determination of unreasonable risk for a chemical substance employing a "whole chemical approach", in contrast to its original method of making risk determinations the basis of each condition-of-use for a chemical substance. Simultaneously, EPA discontinued its practice of assuming that employers would supply, and employees would use, personal protective equipment ("PPE") in occupational settings incoming chemical substances undergoing risk evaluations. In accordance with these new policies, EPA issued a draft revised TSCA risk determination for PCE in June 2022[2] that

[1] The members of CUC are Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, RTX Corporation, Sony Electronics Inc., and TDK U.S.A. Corporation.

[2] As discussed in comments submitted by CUC on the Draft Revised Determinations, CUC finds this revised approach does not provide an accurate picture of the risks presented by PCE under the substance's actual conditions of use. CUC considers it to be appropriate for EPA to reasonably assume PPE will be worn and for the Agency to make risk determinations on the basis of the actual condition-of-use that are specific to each substance, including PCE. CUC considers such an approach to be grounded in the statute and regulations, and supported by sound science. CUC has previously commented, the current approach is at odds the 2016 TSCA amendments and in the existing risk evaluations regulations establishing the process for conducting risk evaluations.

reflected these policy changes. EPA issued the final revised risk determination for PCE in December 2022. EPA determined that PCE presents an unreasonable risk of injury to health due to the significant adverse health effects associated with exposure to PCE, including neurotoxicity effects from acute and chronic inhalation exposures and dermal exposures, and cancer from chronic inhalation exposures.

**Overview of CUC Comments**

CUC believes that the approach EPA has adopted in the Proposed Rule does not recognize that different conditions of use present different risks; it appears EPA is taking a one-size-fits-all approach. Furthermore, EPA is clearly focusing significantly on workplace exposures. However, EPA does not appear to be fully consulting with industrial hygiene experts or recognizing certain best practices and standards followed in the discipline of industrial hygiene. In addition, the exercise of EPA authority in regulating workplace practices presents significant challenges, both for the EPA and for the regulated community. Before EPA finalizes a risk management rule for PCE, it should provide more information to stakeholders and the public about the planned framework for the Agency's compliance and enforcement efforts, and the Agency should consider whether revisions to the Proposed Rule are needed to facilitate more effective implementation and compliance in light of the planned framework. Lastly, EPA needs to be more cognizant of real-world PCE use scenarios and ensure that the phase-in of compliance mandates does not have disruptive or premature impacts on uses that the Proposed Rule allows to continue, including critical and essential uses and other environmentally beneficial uses.

**A More Flexible Approach to TSCA Risk Management Rules Is Needed**

Section 6(a) of TSCA states:

> If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture ***to the extent necessary*** so that the chemical substance or mixture no longer presents such risk …. (emphasis added)

EPA selected two main methods of risk management in the Proposed Rule: (1) a ban on most conditions of use and (2) a requirement for a workplace chemical protection program (WCPP), which would include requirements to meet specific inhalation exposure concentration limits and for exposure monitoring and dermal protection provisions. For some conditions of use, EPA, under the authority of TSCA section 6(g), intends to grant a time-limited exemption and allow the use with a WCPP if possible.

Our Members consider EPA's TSCA Section 6 risk mitigation approach to be overly aggressive in that it goes beyond regulating "to the extent necessary" the identified unreasonable risks. If implementation and compliance with the proposed WCPP can mitigate risks to workers, section

6 of TSCA requires that EPA should allow the use of such risk management measures to permit any continued commercial or industrial use of PCE. If a WCPP cannot be effectively implemented, then such an entity would not be able to continue use of PCE, but EPA should not predetermine whether a WCPP can be effectively implemented for particular uses. EPA should allow facilities to elect to implement the WCPP for any commercial or industrial use of PCE, and if a facility cannot meet the regulatory requirements, the facility should be required to discontinue its use of PCE. Reasonable phase-in periods for facilities to make such determinations should be provided, and the amended statute allows for such a timeline to be established as part of the rulemaking.

Additionally, there appears to be a disconnect from the prohibitions on processing versus prohibitions on distribution and/or use. For example, EPA has proposed that PCE may be processed into a formulation, mixture, or reaction product in paint and coating mixtures, subject to WCPP requirements. However, EPA has also proposed that manufacturing, processing, distribution in commerce, and use of PCE is prohibited for use in solvent-based paints and coatings. Permitting the manufacture of a product that then cannot be used is not logical, and appears to reflect potential drafting errors. In the case of maskants, EPA has proposed that PCE can be used for industrial and commercial use in maskants for chemicals milling. However, EPA has not explicitly permitted the manufacturing or processing of PCE for use in maskants. In this situation, the maskants containing PCE can be used, but it will be impossible to obtain them as manufacture for use in a maskant is prohibited. CUC requests that EPA review and correct and issue a revised proposal in which such drafting errors have been corrected and/or clarified, or to explain the prohibitions clearly throughout all steps in the value chain for each particular condition of use, to prevent these incongruities and confusing, illogical outcomes.

There are additional conditions of use, primarily within the aerospace and defense sector (A&D), that EPA has not addressed. CUC therefore suggests that the following conditions of use be added, and permitted to continue pursuant to compliance with streamlined WCPP requirements: processing into polishing formulations (mainly for metals); commercial and industrial use of polishing formulations in the production of A&D products; commercial and industrial use as a cold, immersion cleaner; processing into solvent-based polyurethanes formulations and industrial use in production of A&D products; and processing into lubricants (aerosol or otherwise) and industrial use for A&D products.

**The Workplace Chemical Protection Program**

The preference for taking a one-size-fits-all approach is evident within the context of the proposed WCPP requirements. For example, the Proposed Rule requires that baseline monitoring be conducted within six months of the date of the final rule, and that under certain circumstances, periodic monitoring is required. However, there are some conditions of use for which the potential for workplace exposure may occur only annually, for example in certain batch manufacturing operations, or in circumstances in which PCE is used in a completely closed system. In certain enclosed systems scenarios, potential human exposures might occur only during periodic (perhaps only annual) maintenance. The initial monitoring requirements, and the WCPP requirements generally, do not differentiate between different types of workplaces and

operations – they are all presumed to be the same. EPA should make changes to the rule before issuing it in final form to permit flexibility in the WCPP requirements to accommodate the practical realities of a variety of manufacturing operations and practices.

For example, EPA is proposing to require recurring 5-year periodic exposure monitoring. In the alternative, CUC suggests that EPA create a new option for where PCE is present in the product/process, but the initial monitoring demonstrates that PCE was not detected in a statistically significant level. In such circumstances, further periodic monitoring would not be required as long as there has been no change to the process/controls. At minimum, there should be a mechanism to allow for less frequent monitoring. If a process has not changed and the WCPP is in place and working, continued monitoring will not change the (absence of) exposure.

Another operational aspect of the WCPP that CUC recommends be addressed concerns the identification of the responsible entity for WCPP implementation and compliance. The term "owner/operator" for the entity responsible for implementation of the WCPP at a facility is much more broadly defined than terms that are currently used for standards overseen by the Occupational Safety and Health Administration ("OSHA"). This language change means that "owners/operators" – not employers – are now responsible for providing respiratory protection and other personal protective equipment to more than their direct employees. For a facility that may have many contractors present, the new compliance mandate could create enormous complexities. This approach, unless significant changes are implemented, will be confusing and impractical, and will create tensions between EPA rules and OSHA rules and lead to confusion and potential compliance issues. CUC therefore recommends that EPA adopt the approach of requiring "employers" to be the entities responsible for providing respiratory protection and other PPE to their employees. The owner/operator could be the entity responsible for ensuring compliance with the WCPP. For example, the owner/operator could be responsible for ensuring that training of those working in its facilities is completed; however, the employer would be the entity responsible for providing the training. This language change would be consistent with current OSHA practice and ensure protections are in place while not being overly burdensome.

CUC Members generally support EPA's objective as stated in the Proposed Regulation that facilities should implement the WCPP "in accordance with the hierarchy of controls" and to use "pollution prevention to control exposures whenever practicable." Nevertheless, CUC Members do not agree that the terms of the PCE regulation should mandate that companies implementing the WCPP requirements should need to create records or otherwise substantiate that they have "institute[d] one or a combination of elimination, substitution, engineering controls or administrative controls to reduce exposure to or below the ECEL" or to "demonstrate that such controls are not feasible." While industrial hygiene professionals work with their colleagues to implement the hierarchy of controls when determining the most appropriate methods to mitigate workplace exposures to chemical substances, CUC considers it to be unnecessary for EPA (and presumably its enforcement staff) to expect a business to create records reflecting how such determinations were made. This is especially concerning to CUC Members because in many cases where PCE has been in use for decades or more, such analyses would have been made

years ago and newly required records may need to be created (or recreated). This requirement is unworkable, and should be abandoned before the PCE rule is finalized.

Additionally, EPA is requesting comment on whether owners/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 to the atmosphere from the workplace, and keep records of that statement as part of the WCPP exposure control plan. CUC considers such attestation to be unnecessary and should not be required. This is another burdensome documentation requirement that complicates compliance. Rather than attesting, this information should be documented through the results of the sampling done when the process changes.

EPA also has requested comments concerning an owner's/operator's 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 unit, including establishment of a respiratory protection program and development of an exposure control plan. CUC requests that EPA must lengthen these compliance timeframes in order to allow for ease of achieving compliance with the rule. A large corporation with many different types of processes will need time to work through how the new requirements impact company operations and processes, and determine the application of the new requirements to the various products and processes that use PCE.

Under the Proposed Rule, owners/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 CFR 312.10, or a Certified Industrial Hygienist reviews the monitoring results and determines re-monitoring is not necessary. CUC does not think it is appropriate for EPA to require review of non-detect air monitoring samples. This requirement appears to be inconsistent with the OSHA rules and the proposed methylene chloride rule.

A general concern of CUC members is the lack of consistency of WCPP requirements from one risk management rule to the next. EPA needs to create a consistent framework for each rule that allows for a chemical's continued use with a WCPP. The required programs will be easier to comply with when each chemical's risk management rule follows a consistent program outline. CUC acknowledges that there may be circumstances of use of a specific chemical that warrant additional measures under a WCPP. However, the general framework for the WCPP should be the same from one chemical to the next, and that is not the case for methylene chloride, PCE, and carbon tetrachloride. This only creates confusion and significant compliance challenges. EPA should address this issue for PCE and all other similar TSCA section 6 rules that it will be issuing.

**Industrial Hygiene and OSHA**

Industrial hygiene is a multidisciplinary field that combines elements of engineering, chemistry, toxicology, and public health. It is focused on the identification and evaluation of workplace hazards that may affect the health and well-being of employees so that such hazards can be addressed. Any regulation that is directed at occupational hazards must be developed with the

input of industrial hygienists ("IHs"). However, it is evident that such input was lacking in the development of the WCPP and existing chemical exposure limit ("ECEL").

- The EPA established a scientific advisory committee to provide input on the risk assessment and resulting risk management measures. Yet, IHs were not included on that committee.
- While it is true that many OSHA Permissible Exposure Limits have not been updated and may not be reflective of current science, the Threshold Limit Values ("TLVs") developed by the American Conference of Governmental Industrial Hygienists ("ACGIH") are accepted as the standard for workplace exposures throughout industry. It is unclear why EPA disregarded the science of the body dedicated to occupational health and believed that their science that led to the ECEL was somehow "better."
- IHs working in industrial settings commonly encounter numerous occupational exposures to workers (and others – "ONUs") from chemical substances. To accommodate that workload, IHs must determine priorities based on risks and develop those into an exposure assessment strategy. When an exposure assessment is mandated by regulation and not by an assessed exposure risk, it skews the priorities of the assessment strategy, so that higher risk assessments (and any needed risk management) might be delayed in order to meet the regulatory requirements.
- EPA's deviation from using best industrial hygiene practices and standards will lead to confusion and difficulties in risk communication. Employees who are accustomed to working with the understanding that ACGIH TLVs are the best practice may question this as EPA issues values that deviate drastically for specific substances.
- The options that EPA has discussed for WCPP compliance (respirator use and types of dermal testing) are not necessarily the industry accepted practices.
- Having two agencies with concurrent jurisdiction over the exact same setting, albeit with differing standards, will only lead to confusion. To date, EPA has not disclosed how EPA and/or OSHA will (or may?) support and/or enforce workplace safety measures, and whether EPA even has the requisite expertise to do so.

**Scope of Critical Uses**

CUC recommends that EPA's primary risk management measure for addressing workplace exposure concerns to chemical substances in industrial conditions of use should be full compliance with a *substantially simplified* WCPP. This is true as well for conditions of use for which EPA made findings under section 6(g) that such uses warranted a "critical use exemption." Proposed 10-year time limits for such uses are not justified. In situations when EPA has determined that certain facilities can develop a WCPP to comply with the proposed regulation, it is not clear why such programs should cease to be acceptable after a decade of compliance, while other uses are not. CUC recommends EPA develop clear, predictable, and articulated standards (perhaps in a separate rulemaking) for responding to exemption requests and for implementing requirements for exempt uses versus other uses which are allowed to continue without time limitations.

CUC also considers the scope of conditions of use for which EPA has been making 6(g) findings is far too narrow. EPA, in both the methylene chloride and PCE rules, has been focusing almost

exclusively on a narrow sector of the economy. Although CUC members support the determinations for proposed section 6(g) exemptions, it is unclear why EPA appears to have focused on aviation and aerospace uses. Even within those categories, the use of the term "aerospace vehicles," which encompasses airplanes, helicopters, missiles, rockets, and space vehicles, as opposed to aircraft, would be more appropriate in combination with critical ground- and marine-based defense applications. While, as discussed, CUC believes that such critical conditions of use should be authorized for use at all times with a WCPP, to the extent that EPA is compelled to make a "critical use" finding, CUC recommends that such findings should encompass a broader scope of products and services that also meet all the criticalities of the national security and transport sectors collectively, not just aeronautics/aviation.[3]

**New Critical Uses**

In lieu of granting more time to develop needed industry responses, CUC also recommends that EPA develop a process to deal with emergent critical uses that are realized after this rule (and other risk management rules) is finalized. Although EPA suggested an approach in the proposed rule, that process would require a federal agency to petition EPA to exempt new or newly discovered critical uses. CUC suggests it would be more efficient if the EPA process allowed any entity, private or public, to petition EPA. Section 6(g) does not require the involvement of a federal agency. Indeed, as the Agency indicated, it expects the submission of monitoring data to indicate compliance with the WCPP and documentation of efforts to identify or qualify a substitute; the entity responsible for developing this information is better suited to submit it directly to EPA, rather than conveying comments through a federal agency. In that way, parties who may be the first to discover the critical uses can petition EPA right away, rather than having to work through a federal agency, which will involve greater expenditures of time and resources (and possible delays).

CUC Members also encourage EPA to consider the possibility of, and prepare for, circumstances that are likely to arise when there are certain conditions of use for which EPA could make the necessary findings under section 6(g), but which are not amenable to the implementation of a full-fledged WCPP program. CUC Members recommend EPA consider how it would respond quickly if unforeseen, emergency circumstances should arise that would not permit an entity to implement the elaborate measures EPA requires for its WCPP requirements. Certainly, in amending section 6, Congress intended the Agency to have such a capacity to respond swiftly under section 6(g).

**Compliance Timeframe Impacts on Supply Chains for Continuing Uses**

[3] CUC suggests that the following definition of Mission-Critical Military End Use (or "MCMEU") from the regulations implementing the American Innovation and Manufacturing Act of 2020 could assist EPA in establishing a scope for critical sectors: *Mission-critical military end uses means those uses of regulated substances by an agency of the Federal Government responsible for national defense that have a direct impact on mission capability, as determined by the U.S. Department of Defense, including, but not limited to uses necessary for development, testing, production, training, operation, and maintenance of Armed Forces vessels, aircraft, space systems, ground vehicles, amphibious vehicles, deployable/expeditionary support equipment, munitions, and command and control systems.* 40 C.F.R. § 84.3.

EPA should consider longer compliance timeframes for the prohibitions on manufacturing, processing, and distributing of PCE to avoid disruptions in supply chains for continuing uses, including critical and essential and other beneficial uses. The proposed timeframes – and even the primary alternative regulatory action's timeframes, which allow an additional six months – are relatively short and likely not to be practicable at the supply chain level. For some uses, including defense sector uses, making changes to respond to the PCE restrictions is a multiyear process that requires redesign and recertification that a product meets performance standards such as customers' technical requirements, UL and CE marking requirements, military specifications, and specifications from other government agencies such as the Federal Aviation Administration and National Aeronautics and Space Administration. As a practical matter, it can be anticipated that the Proposed Rule, if finalized with its compliance timeframes, will cause certain producers of PCE to leave the market for PCE, potentially cutting off the PCE supply for continuing critical uses, including emergency uses. This is likely to have unforeseen economic impacts which EPA has not accounted for in its regulatory analyses and may increase the possibility of "regrettable substitution" in response. This market reaction also creates a risk of obsolescence for essential equipment that is reliant on PCE.

EPA should include longer phase-out periods for the prohibitions or consider other strategies to ensure that the supply remains available for critical, essential, and other continuing uses of PCE. Additionally, increasing the number of conditions of use that may continue while complying with a WCPP will also help to alleviate market pressures created by restrictions on PCE use.

**De Minimis Levels, By-products, Impurities, and Articles**

CUC supports the proposed level of 0.1% as the de minimis level. EPA should clarify how it is calculating the 0.1% PCE by weight limit. EPA should also clarify that the presence of PCE as an impurity or by-product in a substance would not subject that substance or mixture to the proposed ban. In the same way EPA has excluded impurities and by-products from other regulations under TSCA (such as for purposes of Chemical Data Reporting), EPA should explicitly exclude trace amounts of PCE as an impurity or by-product from the prohibitions. Similarly, EPA should explicitly exclude PCE in articles from the restrictions.

**Conclusion**

CUC supports EPA's efforts to appropriately manage risks presented by high priority substances. However, CUC notes that EPA has more work to do to ensure that the Proposed Rule meets the legal requirements for a TSCA Section 6 risk management rule. The real-world conditions of use must be evaluated. The risks, if any, of such real-world uses must be properly characterized. Any risk management rule that is then proposed to address such risks muse be based on data and information and the best available science, not conjecture or assumptions. Accordingly, CUC asks that EPA take a closer look at the true risks that may be posed by the actual conditions of use, addressing the issues raised above. EPA can then make a determination as to the risk management measures that are *necessary* to address such risks. Only then can EPA issue a draft rule that may meet the statutory requirements of TSCA.

CUC Members would be glad to make themselves available to discuss any questions EPA personnel may have concerning CUC's comments and/or to discuss any issues related to the Agency efforts to evaluate and to mitigate risks associated with the use of high priority substances.