Comments of the Chemical Users Coalition

Chemical Users Coalition ("CUC") 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 Methylene Chloride 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

In July 2017, EPA published a scope for the risk evaluation of methylene chloride. After receiving public comments, EPA published the problem formulation in June 2018. In October 2019, EPA published a draft risk evaluation, and after public comment and peer review by the Science Advisory Committee on Chemicals, EPA issued a final risk evaluation for methylene chloride in June 2020. In June 2021, EPA announced policy changes surrounding TSCA risk evaluations, which included no longer assuming that personal protective equipment ("PPE") was used in occupational settings and making a single determination of risk for a chemical substance (the "whole chemical approach") instead of making risk determinations on a condition-of-use basis. Applying these new policy directives, EPA issued a draft revised TSCA risk determination for methylene chloride (the "Draft Revision") in July 2022¹ and, after public notice and receipt of comments, published a final revised risk determination for methylene chloride in November

¹ As discussed in the comments submitted by CUC on the Draft Revision, CUC believes the revised approach EPA took fails to provide an accurate picture of the risks presented by methylene chloride under the substance's actual conditions of use. CUC believes that EPA should have included reasonable assumptions regarding the use of PPE when making the risk determinations and should have made condition-of-use-specific risk determinations for methylene chloride, as such an approach is grounded in the statute and regulations, and supported by sound science. CUC believes that the approach taken is at odds with the structure created by Congress in the 2016 TSCA amendments and the regulations establishing the process for conducting risk evaluations.

2022. EPA determined that methylene chloride presents an unreasonable risk of injury to human health under the conditions of use based on acute and chronic non-cancer risks and chronic cancer risks.

In the Proposed Rule, EPA is proposing to: prohibit the manufacture/ import, processing, and distribution in commerce of methylene chloride for consumer use; prohibit most industrial and commercial uses of methylene chloride; require a workplace chemical protection program ("WCPP"), which would include requirements to meet inhalation exposure concentration limits and for exposure monitoring for certain continued conditions of use of methylene chloride; require recordkeeping and downstream notification requirements for several conditions of use of methylene chloride; and provide certain time-limited exemptions from requirements for uses of methylene chloride that purportedly would otherwise significantly disrupt national security and critical infrastructure.

CUC believes that EPA has taken an overly restrictive approach to risk management in the Proposed Rule. As discussed below, the option of implementing a WCPP should be extended to many other conditions of use which the proposed rule would otherwise ban. EPA failed to identify many other critical aerospace and defense ("A&D") applications that must utilize methylene chlorine and should be permitted to continue with the use of a WCPP otherwise they will be subject to the ban. Lastly, there are elements of the WCPP construct that are simply not implementable in real-world operating conditions within certain industries. Practical modifications to the terms of the WCPP will be needed.

Risk Management Measures and Use of a WCPP

Methylene chloride, and formulated products containing methylene chloride, are manufactured, imported, processed, distributed in commerce, used, and disposed of as part of many industrial, commercial, and consumer conditions of use. It is a widely used solvent in a variety of applications, including, but not limited to, adhesives and sealants, automotive products, and paint and coating removers. Many of the uses of methylene chloride are essential for a variety of functions in different commercial and A&D applications. Certain of these essential uses, due to their specific characteristics and functionalities, do not currently have viable and available alternatives.

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 manufacture (including import), distribution, and use of methylene chloride for most EPA-"identified" conditions of use and (2) a requirement for a workplace chemical protection program, which would include requirements to meet specific inhalation exposure concentration limits and for exposure monitoring. The vast majority of conditions of use would be subject to the proposed ban. A smaller subset of conditions of use could continue under a WCPP. 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. EPA is granting the exemption under 6(g) in cases where the Agency has found that the specific conditions of use are critical or essential uses for which no technically and economically feasible safe alternative is available, taking into consideration hazard and exposure and that compliance with the ban would significantly disrupt the national economy, national security, or critical infrastructure.

CUC believes that EPA has selected an overly aggressive approach that goes beyond regulating "to the extent necessary" its identified unreasonable risks. EPA has stated that it has restricted the allowance for use of methylene chloride under a WCPP because of concerns about the feasibility of many facilities implementing a WCPP successfully to meet EPA's proposed Existing Chemical Exposure Limit ("ECEL"). As EPA did not have sufficient information to confidently conclude that facilities engaged in most conditions of use could meet the ECEL for methylene chloride, use of methylene chloride under those conditions of use was simply prohibited.

the Agency's proposal is inconsistent and not in keeping with the risk management approach Congress intended under Section 6 of the amended statute. Specifically, 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 continued use of methylene chloride. If a WCPP cannot be effectively implemented, then such an entity would not be able to continue use of methylene chloride. EPA simply eliminated such an option for most uses because EPA apparently did not want to invest the effort to fully evaluate whether a WCPP could successfully address risk in the numerous uses EPA will otherwise be prohibiting. EPA should allow the implementation of the WCPP for industrial uses of methylene chloride, and if a facility cannot meet the regulatory requirements, the facility will not be able to use methylene chloride. It is not appropriate for EPA to presume whether compliance is achievable within a condition of use, particularly in the absence of information to support such a presumption.

Consideration of Alternatives

TSCA §6(c) provides that if a regulation would operate "in a manner that substantially prevents a specific condition of use of a chemical," EPA must consider "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." EPA has stated that the requirements in this proposal would prohibit uses that account for approximately

one-third of the total annual production volume of methylene chloride (TSCA and non-TSCA uses). EPA did not perform an analysis of the impact of reducing that production volume on the manufacturers of methylene chloride and whether it could lead to a significant economic impact due to price increases and diminished production, and thus limited availability even for exempted uses. Furthermore, EPA should have analyzed these factors in the context of the impact it would have on the sectors of the economy where methylene chloride can continue to be used, either under this rule or pursuant to other statutes. As such an analysis was not done, EPA has failed to consider the statutory factors in section 6. EPA must do so before finalizing an absolute ban that impacts such a significant customer base of the substance.

De Minimis, By-products, Impurities, and Articles

The proposed risk management measures would apply regardless of the quantity or concentration of methylene chloride . CUC believes that, again, this is regulation beyond what is necessary to address the risk. To aid the regulated community's compliance with the restrictions on methylene chloride under those conditions of use when it has been banned, EPA should provide for a permissible de minimis level of methylene chlorine in a product. CUC supports the proposed level of 0.1% as the de minimis level.

EPA should clarify that the presence of methylene chloride 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 CDR reporting), EPA should explicitly exclude trace amounts of methylene chloride as an impurity or by-product from the prohibitions.

Similarly, EPA should explicitly exclude methylene chloride in articles from the restrictions. There are substantial constraints on the ability of entities who import articles that may contain methylene chloride to determine whether such articles do in fact contain trace amounts of methylene chloride. Such entities assemble, manufacture, and distribute exceptionally complex products; some can be minute, while others are of immense scale and have incredible levels of intricacy. These articles are used in the aerospace and defense industries, commercial equipment, transportation products, IT equipment, and other industrial uses. The articles may require and contain thousands of components and parts acquired and assembled by potentially thousands of global suppliers, each of whom may never have a direct business relationship or contact with the manufacturer of the finished good. Given the potentially thousands of suppliers involved in the production of components in any single article or end-use product, and in light of the fact that no risk from exposure to methylene chloride in articles has been identified, the final rule should explicitly state that articles containing methylene chloride are exempt from restrictions.

Industrial and Commercial Use as a Processing Aid

The uses of methylene chloride as a processing aid vary widely based on the very general description included in the proposed rule and the discussion in the Preamble. Consequently, as the use and exposure patterns for these processing aid uses can significantly differ from one another, it is not possible for EPA to have conduct a comprehensive assessment for all the disparate uses, nor did the agency seek and review available monitoring data and/or detailed process descriptions to determine the potential for compliance with the WCPP. Additionally, it is likely impossible for EPA to assess the availability of chemical alternatives across the diverse applications or to evaluate how many of these applications impact critical infrastructure or national security. EPA has recognized that at least some of these industrial operations may be able to implement a WCPP to eliminate unreasonable risk, however, and has received data for one processing application (*i.e.*, use as a heat transfer fluid) supporting the ability to comply.²

Consequently, the proposal to prohibit all uses within the broad category of "Use as a Processing Aid" is not supported by the available data and appears inconsistent with the EPA's characterization of the condition of use. Rather than prohibit the use of methylene chloride as a processing aid, EPA should require facilities within the application to implement a WCPP to eliminate unreasonable risk.

Use as a Laboratory Chemical, Research and Development

One condition of use that is permitted when subject to a WCPP is industrial and commercial use as a laboratory chemical. EPA describes this condition of use as "the industrial or commercial use of methylene chloride in a laboratory process or in specialized laboratory equipment for instrument calibration/maintenance chemical analysis, chemical synthesis, extracting and purifying other chemicals, dissolving other substances, executing research, development, test and evaluation methods, and similar activities." CUC believes that as laboratory uses of methylene chloride vary, the use of methylene chloride specifically for use in research and development activities should be listed separately.

Rather than attempting to describe and to regulate laboratory uses of methylene chloride, EPA could specific in the proposed rule that it intends such laboratories to meeting OSHA's standard for Chemical Hygiene in Laboratories (See <u>1910.1450 - Occupational exposure to hazardous chemicals in laboratories.</u> | <u>Occupational Safety and Health Administration (osha.gov)</u> If the agency is intend on codifying a TSAC standard for the responsible use of Methylene chloride in laboratory settings, it could simply cross reference the existing TSCA regulation concerning the use of R&D substances. See 0 CFR § 720.26, which sets forth specific criteria for a chemical substance used for research and development). These criteria also should suffice to address any

² Final Report of the Small Business Advocacy Review Panel on EPA's Proposed Rule for Methylene Chloride under TSCA Section 6(a) (2021). (SBAR Report) Appendix B1: Written Comments Submitted by Potential Small Entity Representatives following the November 4, 2020 Pre-Panel Outreach Meeting. Comments from Halocarbon (Items 3, 8-10).

risk posed during R&D when properly supervised by a technically qualified individual. EPA should elect to broadly exempt all uses of methylene chloride in a laboratory of in research and development generally. R&D and lab uses should be exempt from regulation and not subject to a WCPP. It is extremely important to be able to conduct research and development freely in the United States. Researchers must be able to include methylene chloride in such research and development exercises for purposes of finding substitutes and comparing performance with the items being phased down/out.

Scope of Distribution in Commerce

EPA is proposing to restrict the distribution in commerce of methylene chloride-containing products. CUC believes that EPA must add additional details as to the parameters of this prohibition so that compliance is possible. There are significant complexities associated with the distribution in commerce of methylene chloride-containing products. Inventory control must be taken into consideration, and manufacturers do not have control over how and when downstream retailers sell inventory. New restrictions may also lead to contractual issues between upstream and downstream entities. To avoid such complications, CUC requests that the restrictions be based on the manufacture date or import date, meaning that products manufactured after or imported after a certain date could not be sold. However, products that were manufacture of such products.

CUC also requests that products that were previously sold/or supplied should be excluded from the prohibition on distribution in commerce. To allow for the continued required servicing or repair of existing products, CUC requests that replacement and repair parts for products manufactured or imported prior to the effective date be exempt from the prohibitions as well. This would provide for continued use of older equipment and prevent unnecessary generation of waste.

Scope of Critical Uses

As discussed above, CUC believes that EPA's primary risk management measure for industrial conditions of use should be full compliance with a simplified WCPP. This is true as well for those conditions of use for which EPA made findings under section 6(g) that such uses warranted a "critical use exemption." The proposal for a 10-year time limit for such uses is completely unfounded. Given that 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 not all of these facilities may be able to implement a protection program, many likely can and should be permitted to continue to use methylene chloride in these critical applications indefinitely while continuing to comply with the original WCPP requirements.

CUC believes that the scope of conditions of use for which a 6(g) finding was made is far too narrow. EPA's proposal focuses solely on paint and coating removal from safety-critical, corrosion-sensitive components of (only) aircraft and spacecraft that are owned or operated by the U.S. Department of Defense, the National Aeronautics and Space Administration, the U.S. Department of Homeland Security, and the Federal Aviation Administration where the removal is performed by the agency or the agency's contractor at locations controlled by the agency or the agency's contractor.

The paint and coating removal substances mentioned tend to be nearly pure methylene chloride as it is the only substance that actually works for coatings typically used in coatings in aerospace and defense application. However, there are numerous other applications of methylene chloride, at generally lower concentrations, which are constituent components of other "critical use" applications such as high-strength adhesives and sealants (including surface preparation for such applications) for unique product-based applications and solvent bonding of plastic components (including other plastics than polycarbonates). For example, secure rubber bonding, which is accomplished using a methylene chloride product, is critical for the operation of pneumatic deicing boots used on smaller aircraft. To date, no substitute has been found for the methylene chloride in that particular end-use product that is also flight-safety critical.

Further, there are safety-critical, corrosion-sensitive components of ground- and marine-based defense products. It is unclear why EPA focused solely 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 ground- and marine-based critical defense applications (not just paint removal). While, as discussed, CUC believes that such critical conditions of use for methylene chloride 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 believes 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 civil aviation.³

New Critical Uses

CUC also recommends that EPA develop a process to deal with emergent critical uses that are realized after the rule 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 believes it would be more efficient if the EPA process allowed any entity, private or public, to petition EPA. Indeed, as the Agency indicated it expects the submission of

³ CUC suggests that the following definition from the US AIM Act could assist EPA in establishing a scope for critical sectors: Mission Critical Military End Use (or MCMEU) which reads as follows: *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.

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 comment 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).

Aerospace and Defense Operations and the WCPP

CUC believes that EPA needs to better understand how entities operate in the aerospace and defense sectors, particularly under government contracts. The Proposed Rule contains provisions that would make it difficult or impossible to comply both with the methylene chloride restrictions and with federal contracting requirements.

The Proposed Rule provides that the permitted paint removal activities must be performed in specific locations. For aircraft owned or operated by air carriers, it must be done on the premises of maintenance or repair facilities operated by air carriers or commercial operators certificated under 14 CFR part 119 or at repair stations certificated under 14 CFR part 145, if their primary business is performing maintenance, preventive maintenance, rebuilding, or alteration of aircraft operated by air carriers and commercial operators certificated under 14 CFR part 119. For aircraft intended for air carriers, it must be performed at locations owned or operated by the manufacturer of the aircraft. For spacecraft, the activities must be performed at locations owned or operated by the manufacturer of the spacecraft or payload or similar hardware.

The Proposed Rule provides that the permitted activities can take place only at specifically designated facilities that differ in each scenario. CUC believes that not only is there no need for the differentiation, but the provisions do not reflect common practice. A typical repair/maintenance scenario is that certain parts are taken off the aircraft and sent to a facility owned and operated by the part/component manufacturer. Accordingly, the provision in the Proposed Rule needs to be changed to include "other" types of repair/maintenance facilities that are not necessarily owned/operated by an aircraft manufacturer or by an entity that primarily performs maintenance.

This same situation may also apply to all defense related products, whether or not they be aviation or aerospace related, and their serviceability. Service for these products can be done by the Department of Defense ("DOD") itself, by a contractor, by a sub-contractor, by the original equipment producer under contract, or even by the original equipment manufacturer at a customer location. As discussed above, CUC believes that other non-aviation/aerospace uses for methylene chloride are critical uses and should therefore be permitted to the same extent as the proposed uses. Therefore CUC also believes that enabling service activities for these defense-related products needs to be appropriately addressed as discussed. If the broader scope of "safety critical" conditions of use is not adopted, CUC believes that significant disruption will occur at many federal agency industrial base suppliers, which will result in the removal from the marketplace of needed commercial and defense-related products.

Another operational aspect of the WCPP that CUC believes needs to be addressed concerns the responsible entity. The term "owner/operator" for the entity responsible for implementation of the WCPP at a facility is much more broadly defined than what is currently used under OSHA. This language change means that employers or "owners/operators" are now responsible for providing respiratory protection and other personal protective equipment to more than their direct employees. The Proposed Rule states that owners or operators must provide respiratory protection to all potentially exposed persons in the regulated area, and in fact must provide air-supplied respirators, as air-purifying respirators do not provide adequate respiratory protection against methylene chloride. Previously under 29 CFR 1910.134, "employers" were required to provide protection to "all potentially exposed persons." This change is impractical for a couple of reasons:

- In certain DOD contracts, the Defense Contract Management Agency ("DCMA") has a right to inspect all aspects of their products meaning that they can go anywhere their product is and inspect it at any time. As DCMA's access to their products cannot be restricted, the "owner/operator" would be required to provide respiratory protection to DOD employees. This is problematic because in order to receive respiratory protection, one must be trained to use a respirator and undergo a "fit test" and a medical evaluation in order to be approved for respirator use. With this language change, the "owner/operator" would be required to ensure DOD employees meet these requirements before potentially being allowed into the regulated area which contradicts their contractual right to immediate access.
- Traditionally, service providers (as "employers") are responsible for providing a respiratory protection program to their direct employees rather than that responsibility falling to the "owner/operator." Again, with this language change the "owner/operator" is now responsible for providing and documenting training, a fit test, and a medical evaluation to those outside of their direct employment. This would require owner/operators to have access to sensitive medical information for those not within their direct employ and make them responsible for storing such information.

CUC therefore recommends that EPA adopt the approach of employers being responsible for providing respiratory protection to their employees and modify the proposed rule to say: § 751.109 (e)(3) "Respirator requirements. The owner or operator must supply *ensure* a respirator" and update § 751.109 (f)(1) in a similar manner as this more closely aligns with the requirements under OSHA.

Conclusion

With the Proposed Rule, EPA has started the process of issuing comprehensive risk management rules for the substances selected for the first risk evaluations pursuant to TSCA amendments of 2016. EPA has the opportunity to demonstrate its ability to issue rules that impose risk management measures that are necessary to address identified unreasonable risks for the evaluated conditions of use. Unfortunately, CUC believes that EPA has more work to do to

ensure that the Proposed Rule meets the legal requirements for a risk management rule. The realworld 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 real 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 pleased to meet with EPA personnel to discuss these comments and related issues as the Agency continues its efforts to address identified risks associated with the use of methylene chloride.