



July 3, 2023

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Submitted via regulations.gov at EPA-HQ-OPPT-2020-0465-0022

Dear Ms. Feustel:

The American Coatings Association ("ACA")<sup>1</sup> appreciates the opportunity to submit comment regarding EPA's proposed methylene chloride risk mitigation rule. ACA is committed to working with EPA to help ensure an accurate understanding of chemical risk through implementation of the *Lautenberg Amendments*. The Association's membership represents 90% of the paint and coatings industry, including downstream users of chemicals, as well as chemical manufacturers. Our membership includes companies that manufacture a variety of formulated products including paints, coatings, sealants and adhesives and their raw materials.

Due to the precedent setting nature of this rulemaking and the complexities of EPA's novel approach to workplace risk mitigation, ACA had requested an extension of the comment period which EPA denied. ACA is submitting this comment to note issues for further analysis. ACA may supplement this comment with supporting information and analysis.

EPA published its risk mitigation proposal on May 3, 2023, with a 60-day comment period. The rule includes bans for several conditions of use that were initially deemed "no unreasonable risk" under the initial risk evaluation, when EPA considered standard risk mitigation practices. Upon a change in EPA policy, EPA is now proposing to ban those uses after determining companies performing most uses would not be able to comply with its novel Existing Chemical Exposure Limit (ECEL) and Short-term Exposure Limit (STEL). As such, EPA is proposing to ban most industrial and commercial uses, including

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<sup>1</sup> ACA is a voluntary, non-profit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services. ACA's membership represents over 90 percent of the total domestic production of paints and coatings in the country.

industrial paint stripping compounds. EPA's 2020 risk evaluation for methylene chloride evaluated risks associated with 53 identified conditions of use in the following categories: manufacturing (including import); processing; distribution in commerce, industrial and commercial uses; consumer use; and disposal.

**I. Banning uses is not necessary to mitigate workplace risk from methylene chloride.**

Section 6(a) of TSCA indicates that EPA narrowly tailor its risk mitigation strategies "to the extent necessary to protect adequately so that the chemical substance or mixture no longer presents such risk." EPA proposes to ban about 34 uses. EPA notes that several of these uses may be eligible for the WCPP (Workplace Chemical Protection Program) but EPA currently does not have monitoring information to support compliance. In effect, EPA proposes to prohibit use, but seeks additional data from stakeholders, within the 60-day comment period. EPA is requiring sectors, by use, prove ability to comply, or the use will be banned. This is a significant variation from standard regulatory practice, where an agency would issue a requirement, and a company would then discontinue use if it is unable to comply. Additionally, requiring this information within a short, 60-day comment period is not feasible and may rise to the level of a due process violation.

By banning uses, EPA also bans any future uses where an industry sector could comply with the WCPP (Workplace Chemical Protection Program). Changes to technology may also facilitate compliance for currently banned uses in the future. An approach where EPA issues a safety standard rather than selecting industry sectors by use would allow for future uses in compliance with the WCPP. ACA suggests that banning chemical use in this manner is beyond the scope of authority of Section 6(a). ACA further suggests that EPA not finalize proposed bans of chemical uses and issue a revised ECEL and STEL, based on the technical comments below, allowing companies to determine whether compliance is feasible and discontinue use if necessary.

**II. EPA must consult with the community of industrial hygienists regarding the derivation of the ECEL and STEL and its WCPP**

ACA is concerned that EPA has not accurately characterized the risk of methylene chloride for industrial and commercial use, and in effect, the ECEL and STEL may be overly prescriptive. Workplace exposure limits, including OSHA PELs and other reference exposure limits, are developed in communication with the community of industrial hygienists, represented by the ACGIH (American Conference of Government Industrial Hygienists), AIHA (the American Industrial Hygiene Association), NIOSH, OSHA and other organizations. These organizations evaluate and provide valuable insight into workplace exposure analysis, especially when an exposure level must be updated or changed.

ACA recommends developing EPA ECELS and STELS with review and analysis from these organizations. This is standard practice for reference exposure limits, including OSHA PELs, ACGIH TLVs and other exposure reference values. Peer review and consultations of EPA's analysis should not be limited by differences in scope under TSCA compared to the OSH Act. Those differences can be factored into any peer review and consultation, while retaining focus on evaluating exposure analysis to understand the need for a variance from existing exposure limits. Such peer review would strengthen EPA's conclusions by pushing towards consensus within the community of industrial hygienists. Consensus also facilitates implementation, with a clear understanding of the need for lower limits by workers, management and the broader community of industrial hygienists.

EPA has proceeded unilaterally without adequate communication or review from the community of industrial hygienists, who have decades of experience in risk management for methylene chloride. In several parts of the proposed rule, EPA over-states the workplace risk of methylene chloride, further indicating that EPA is acting beyond the scope of Section 6(a). Please consider the following technical comments.

EPA's description of methylene chloride as an "acutely lethal" neurotoxicant is not accurate. Acutely lethal substances typically cause death within 96 hours of exposure. With proper ventilation, methylene chloride exposure does not result in death. Methylene chloride has an IDLH (Immediately Dangerous to Life or Health) level of 2,300 ppm.<sup>2</sup> By comparison, acutely lethal substances have significantly lower IDLHs:

- Sarin gas has an IDLH within 10 minutes of .064
- Phosgene has an IDLH of 2 ppm, and
- Methyl Isocyanate has an IDLH of 3 ppm.

OSHA describes the hazards of methylene chloride:

"MC is classified as a suspect or potential human carcinogen. It is a central nervous system (CNS) depressant and a skin, eye and respiratory tract irritant. At extremely high concentrations, MC has caused liver damage in animals. MC principally affects the CNS, where it acts as a narcotic."

In contrast to acutely lethal substances, with proper ventilation, methylene chloride can be used safely. EPA notes 85 documented workplace fatalities from 1980 to 2018 (28284). EPA, however, does not consider that circumstances resulting in deaths include failure to comply with safety protocol. Acute death from methylene chloride exposure can only occur in a confined space, without adequate ventilation. Death is due to non-compliance, not the allegedly acutely lethal quality of methylene chloride.

EPA also notes that air cartridge respirators are not effective against methylene chloride. This is not true. Air cartridge respirators are an effective control method for methylene chloride exposure. The reason air cartridge respirators are not allowed relates to odor detection, so if methylene chloride enters a mask, the user would not be able to smell methylene chloride until they are over exposed. Methylene chloride has a relatively high odor threshold of 250 ppm.

EPA has not considered existing medical monitoring data in developing the WCPP. An analysis of current medical monitoring under the OSHA methylene chloride standard would assist companies in understanding the need to for a transition to EPA's WCPP, if allowed, and justifying that change to workers. EPA should carefully consider medical monitoring reports and documented health effects prior to changing exposure limits.

EPA has not provided any new data to justify the ECEL of 2 ppm. The ECEL is based on modeling methods of an existing mouse study, considered when OSHA developed its methylene chloride standard. This not

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<sup>2</sup> New Jersey Department of Health Right to Know Fact Sheet for Methylene Chloride, available online at: <https://nj.gov/health/eoh/rtkweb/documents/fs/1255.pdf>

only brings the accuracy of this methodology into question, but also causes problems in communicating risk to workers. Employers must now indicate that they were over-exposing employees to methylene chloride based EPA's new ECEL. Consensus from the community of industrial hygienists through ACGIH, AIHA, etc. would assist with this transition while providing important insight into the derivation of the ECEL.

Notably, regardless of EPA's conservative approach, MOE calculations that were done with PPE in place did not result in unreasonable risk for most conditions of use.<sup>3</sup> EPA performed these calculations prior to the change to the whole chemical approach. With the whole chemical approach, EPA made a policy determination not to consider PPE to have broader perspective on chemical risk. Without consideration of exposure controls, EPA's analysis is akin to a hazard determination and not a risk evaluation. Notably, without consideration of PPE or other exposure controls, EPA determined that all uses must undergo risk mitigation, resulting in a ban of most uses.

ACA recommends that EPA consider the risk mitigation strategies typically used in industry when conducting a risk evaluation. Failure to do so will always result in unreasonable risk for conditions of use and unnecessary bans. When implementing the whole chemical approach, EPA stated that procedurally, EPA would consider PPE during risk mitigation instead of during risk evaluation. However, EPA has not fully considered where PPE resulted in determinations of "no unreasonable risk." Further, ACA recommends consideration of "confidence factors" assigned to risk evaluation conclusions, evaluating the strength of underlying data and conclusions. Lastly, EPA's analysis should be subject to peer review and comment from organizations representing industrial hygienists.

### **III. EPA must further consult with the community of industrial hygienists regarding inadequacy of the existing exposure limits.**

EPA underestimates the importance of OSHA PELs, ACGIH TLVs and other established OELs. EPA dismisses the OSHA PELs as outdated and/or limited by feasibility and economic considerations. ACA recommends that EPA conduct a case-by-case analysis of PELs and other OELs and why a variance is necessary. The current OSHA PEL for methylene chloride is a conservative exposure limit, lower than the ACGIH TLV, STEL and other established OELs. ACGIH also routinely reviews its TLVs to update according to the latest state of the science.

In the preamble of the proposed rule, EPA considers its role and authority in protecting workers, other potentially susceptible subpopulation and the public generally. EPA identifies what it sees as a regulatory gap in OSHA's authority that TSCA is designed to address. As a starting point, EPA notes that OSHA rarely cites violations of the Occupational Safety and Health Act's General Duty Clause for chemical-specific exposure since the clause provides a high threshold for violations:

To prove a violation of the General Duty Clause, OSHA must prove employer or industry recognition of the hazard, that the hazard was causing or likely to cause death or serious physical harm, and a feasible method to eliminate or materially reduce the hazard was available. In rare situations, OSHA has cited employers for violation of the General Duty Clause where exposures were below a chemical-specific permissible exposure limit (PEL). In such situations, OSHA must demonstrate that the employer had actual knowledge that the PEL was inadequate to protect its employees from death or serious

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<sup>3</sup> EPA, *Risk Evaluation for Methylene Chloride* (June 2020, EPA Document# EPA-740-R1-8010), page 34.

physical harm. Because of the heavy evidentiary burden on OSHA to establish violations of the General Duty Clause, it is not frequently used to cite employers for employee exposure to chemical hazards.<sup>4</sup>

EPA explains that not only are OSHA PEL's outdated, but OSHA's requirement to set standards that are technologically and economically feasible prevent it from imposing requirements that ensure no significant risk to workers from chemical exposures. These statements underestimate the effect of existing exposure limits. It is not a "heavy burden" to demonstrate actual knowledge of an exposure value commonly used in industry during an OSHA safety audit. As noted above, industrial hygienists use a variety of references, other than OSHA PELs to develop workplace protection programs that abate risk. These references are commonly updated and available to industry, forming a common set of exposure values and protective measures. Any failure to provide protective measures in compliance with these industry practices risk to the level of an enforceable violation of the OSH Act under the General Duty Clause.

As the body of reference materials generated by industrial hygienists form convenient reference materials, it is not overly burdensome for OSHA to refer to those materials when noting practices that are not adequately protective. EPA may consider further data related to OSHA enforcement practices under the General Duty Clause, but enforcement activity is not informative to establishing a protective exposure limit. EPA should focus on evaluating whether the existing limit is adequately protective and revising it if necessary to abate a clearly defined risk.

To that end, EPA notes that the OSHA PEL for methylene chloride is not adequately protective since it was limited by feasibility considerations when it was set in 1997.<sup>5</sup> In its 1997 methylene chloride exposure rule, OSHA proceeds to explain that it will continue to monitor methylene chloride related exposure to determine if the 25 ppm PEL is adequately protective. EPA is presumably building on OSHA's 1997 standard. ACA suggests further analysis of why the 25 ppm OSHA standard is not protective, considering that the workplace action level is half of the PEL. That is, workers are not exposed at 25 ppm. If a worker is exposed at 12.5 ppm or higher, an employer takes measures to reduce exposure to bring it below 12.5 ppm. ACA also suggests further analysis of workplace medical monitoring records to identify problems with current practices.

#### **IV. EPA must provide further analysis of affected susceptible subpopulations and current safety practices.**

Another consideration in varying from OSHA requirements is the varying scope of TSCA and the OSH Act. Under TSCA, EPA is required to abate risk to "potentially exposed and susceptible subpopulations," meaning:

a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

(TSCA, Section 3(12))

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<sup>4</sup> Preamble to EPA's Proposed Risk Mitigation Rule at Section II(C)(1)(a) – *General Duty Clause of the OSH Act*, 88 Fed. Reg. 28284, 28288 (May 3, 2023))

<sup>5</sup> OSHA *Occupational Exposure to Methylene Chloride, Final Rule*, 62 Fed. Reg. 1494, 1562 (Jan. 10, 1997).

EPA however does not provide analysis of susceptible subpopulations that handle methylene chloride that are not adequately protected. ACA recommends further data and analysis of susceptible subpopulations by chemical and use, for methylene chloride and for each risk evaluation chemical going forward. This data is needed to narrowly tailor risk mitigation strategies within the meaning of TSCA Section 6(a).

#### **V. Ban on distribution adversely impacts mixed distributors.**

EPA is implementing a prohibition on distribution of methylene chloride that is similar in scope to the prohibition in the consumer paint stripper rule from 2019 for methylene chloride. EPA's proposal would ban distribution to retailers, defined as distributors supplying any chemical to a consumer, including via e-commerce or internet sales. Although EPA has proposed a ban on distribution identical to the 2019 consumer paint stripper rule, that rule was limited in scope to consumer paint stripping products.

The current proposed ban affects a wider range of uses, including distribution for permissible uses, such as laboratory use. Some ACA members manufacture products, distribute products and then sell through company-operated retail locations. EPA's current proposal would operate as a ban on such companies even for EPA-authorized uses, due to mixed distribution channels. ACA suggests narrowing the scope of prohibition by modifying the definition of retailer as follows:

*Retailer* means a person who [would otherwise] distribute in commerce or makes available a chemical [ or chemical product containing methylene chloride] ~~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 [ or chemical product containing methylene chloride] ~~substance or mixture~~ solely to commercial or industrial end users or solely to commercial or industrial businesses is not considered a retailer.

#### **VI. Conclusion**

ACA appreciates the opportunity to comment. As described above, ACA provides the following suggestions:

- EPA not finalize proposed bans on use of methylene chloride, while issuing a final WCPP allowing companies to determine whether compliance is feasible.
- EPA revise the ECEL and STEL with review and analysis from professional societies for industrial hygienists, with closer coordination with NIOSH, OSHA, etc.
- EPA conduct a case-by-case analysis of PELs and other commonly used exposure limits to determine necessity for a variance for each proposed revision to an exposure limit, including for the current methylene chloride limit, with consultation of the community of industrial hygienists.
- EPA consider the risk mitigation strategies typically used in industry when conducting a risk evaluation and during risk mitigation.
- EPA incorporate review of OSHA medical monitoring records into TSCA risk mitigation procedures and the written risk mitigation proposal to further consider current exposure limits and safety practices. The methylene chloride risk mitigation proposal does not include a discussion of current medical monitoring information.

- EPA specify susceptible subpopulations by chemical and use, with data quantifying affected subpopulations and current safety practices for methylene chloride. Further, EPA should adopt this as standard procedure for each risk mitigation process going forward.
- Modify the definition of *retailer* and the ban on retail sales to allow mixed distribution.

As noted above, due to the short time period to gather information about these matters, ACA may supplement this comment with information at a later time. In the meantime, feel free to contact me if you have any comments or questions. Thank you for your consideration.

Sincerely,

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