

December 30, 2019

Comments from Academics, Scientists and Clinicians on the Draft Risk Evaluation for Methylene Chloride

Submitted online via *Regulations.gov* to docket EPA-HQ-OPPT-2019-0437

These comments are submitted on behalf of the undersigned academics, scientists, and clinicians. We declare collectively that we have no direct or indirect financial or fiduciary interest in any chemical or product that is the subject of these comments. The co-signers' institutional affiliations are included for identification purposes only and do not imply institutional endorsement or support, unless indicated otherwise.

We appreciate the opportunity to provide written comments on the draft risk evaluation for methylene chloride, issued under EPA's Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("amended TSCA").¹ Methylene chloride is a solvent produced at more than 260 million pounds every year with a variety of consumer, commercial and industrial uses.² Exposures to methylene chloride are associated with serious health impacts including death, liver toxicity, kidney toxicity, reproductive toxicity, cognitive impairments, brain cancer, liver cancer, non-Hodgkin's lymphoma and multiple myeloma.³

EPA has released a draft risk evaluation for methylene chloride that re-evaluates uses already assessed. The 2014 final risk assessment⁴ went through the public comment and peer-review process before being finalized and found significant risks of concern for paint stripping uses.^{5,6} Between EPA's 2017 proposed rule to eliminate consumer and commercial methylene chloride paint stripping uses and now, the chemical has been responsible for multiple fatalities.⁷

By delaying action on a commercial ban, the Agency is leaving workers exposed to unreasonable health risks.⁸ This is contrary to the mandate under the law, which states that if the Administrator determines a chemical presents an unreasonable risk, the Administrator *shall* promulgate a rule "to the extent necessary so that the chemical substance or mixture no longer presents such risk."⁹ EPA should immediately move forward to finalize a ban on commercial paint stripping uses as proposed in 2017.

¹ US EPA (2019) Methylene Chloride (MC); Draft Toxic Substances Control Act (TSCA) Risk Evaluation. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437>

² EPA (2017) Scope of the Risk Evaluation for Methylene Chloride (Dichloromethane, DCM). Office of Chemical Safety and Pollution Prevention.

³ EPA (2014) TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. Office of Chemical Safety and Pollution Prevention.

⁴ US EPA (2014). TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. Office of Chemical Safety and Pollution Prevention.

⁵ 78 FR 1856

⁶ US EPA. Risk Evaluation for Methylene Chloride. Available: <https://www.epa.gov/assessing-and-managing-chemicals-under-tasca/risk-evaluation-methylene-chloride-0>

⁷ The Center for Public Integrity (2018) Some paint strippers are killing people. The EPA promised to act – but hasn't. Available: <https://publicintegrity.org/workers-rights/worker-health-and-safety/unequal-risk/these-paint-strippers-are-killing-people-the-epa-promised-to-act-but-hasnt/>

⁸ 82 FR 7464 pg. 8

⁹ 15 USC §2605(a)

In its draft risk evaluation, EPA continues to utilize its TSCA systematic review methodology, which has come under critique by multiple experts for its problematic scoring of studies, which may downgrade epidemiological studies and has resulted in exclusion of relevant studies. Additionally, EPA continues to employ its “hierarchy of preferences” which for this evaluation excludes almost 100 studies without adequate justification. Although EPA finds methylene chloride presents unreasonable risks for some conditions of use, the Agency fails to calculate those risks in a way that adequately and realistically protects vulnerable populations including workers, understating the risks of this acutely toxic chemical contrary to the framework rules.¹⁰ This is concerning as our research shows that workers face a particularly high risk of fatality due to inadequate protections under existing policies.

Our comments address the following main points:

- 1. EPA should immediately move forward with finalizing a ban on commercial methylene chloride paint stripping uses.**
- 2. EPA’s TSCA systematic review methodology for identifying and evaluating the evidence continues to have serious scientific flaws; persistent use of a method which is not evidence-based, lacks transparency, and is not peer reviewed is likely to have resulted in a biased evidence base for the methylene chloride draft risk evaluation.**
 - a. EPA continues to use methods that lack transparency to identify “key/ supporting/ influential information,” and does not provide the details of the methods for the approach for using the “hierarchy of preferences” to exclude relevant studies.**
 - b. EPA’s revised criteria for evaluating the quality of epidemiological studies are inconsistently and incorrectly applied, making it more likely that relevant epidemiological studies will be downgraded or excluded.**
- 3. In a recent report, the National Academies of Sciences, Engineering, and Medicine (NASEM) provided critical recommendations needed to improve the U.S. Department of Defense (DOD) systematic review method used to derive an occupational exposure level for the solvent trichloroethylene (TCE). We highlight key recommendations directly relevant to the TSCA systematic review method which EPA should implement.**
 - a. A validated systematic review method should be used.**
 - b. A protocol is needed prior to commencing the systematic review (also required in EPA’s framework rules).**
 - c. A validated evidence evaluation method should be used.**
 - d. Best practice methods should be used to synthesize and integrate each evidence stream.**
- 4. EPA’s draft risk determinations are not protective of potentially exposed or susceptible subpopulations such as workers and persons with existing cardiovascular disease.**
 - a. Persons with existing cardiovascular disease (CVD)**
 - b. Workers**
 - i. EPA relies on the OSHA methylene chloride standard, however OSHA found that standard compliance did not improve over time.**
 - ii. EPA has already found that commercial uses of methylene chloride pose an unreasonable risk to workers.**

¹⁰ 40 FR 702 pg. 33732

- iii. **The draft risk evaluation contains scientifically unsupported assumptions about use of personal protective equipment (PPE).**
5. **Our research on methylene chloride fatalities finds current policies inadequate to protect workers and recommends elimination of methylene chloride use in commercial settings.**

We appreciate the opportunity to provide public input. Please do not hesitate to contact us with any questions regarding these or any of our previous comments on methylene chloride.

Sincerely,

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DETAILED COMMENTS

1. EPA should immediately move forward with finalizing a ban on commercial methylene chloride paint stripping uses.

In 2017, EPA found that methylene chloride consumer and commercial stripping uses posed an unreasonable risk and proposed a rule prohibiting all consumer and almost all commercial uses.¹¹ In a 2018 statement, EPA announced that it intended to finalize the 2017 proposed rule.¹² Instead, in March 2019, EPA finalized a rule that only prohibited consumer uses which took effect in November 2019,¹³ but this left the commercial uses unaddressed.¹⁴ Also in March 2019, the Agency proposed to reassess the feasibility of a training, certification, and limited access program for commercial uses of methylene chloride paint and coating removal, options which the Agency already analyzed and rejected previously due to their inability to mitigate unreasonable risks; we also submitted comments to that effect.^{15, 16}

In 2017, we highlighted the science supporting that a ban of methylene chloride in consumer and commercial settings would address the unreasonable risks found by EPA, and also noted the science

¹¹ 82 FR 7464

¹² EPA (2018) "EPA announces action on Methylene Chloride." Available: <https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride>

¹³ US EPA. (2019). EPA Bans All Retail Distribution of Methylene Chloride to Consumers for Paint and Coating Removal. Available: <https://www.epa.gov/newsreleases/epa-bans-all-retail-distribution-methylene-chloride-consumers-paint-and-coating-removal>

¹⁴ 84 FR 11466

¹⁵ 82 FR 7464 pg. 7424

¹⁶ US EPA (2019). Commercial Paint and Coating Removal Training, Certification and Limited Access Program: Methylene Chloride, Comment submitted by Swati Rayasam, Science Associate, Program on Reproductive Health and the Environment, University of California, San Francisco Program on Reproductive Health and the Environment (UCSF PRHE). Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0844-0037>

“EPA made the decision to leverage the literature published in previous assessments to identify key and supporting data and information for developing the methylene chloride risk evaluation. This is discussed in *Strategy for Conducting Literature Searches for Methylene Chloride (DCM): Supplemental File to the TSCA Scope Document* (U.S. EPA, 2017d).”²⁰

Echoing our previous comments,²¹ the supplemental documents EPA references do not contain the phrasing “key and supporting information.” EPA states that it excluded 99 sources based on its hierarchy of preferences – which we have previously critiqued as a new methodology that the Agency introduced in its draft risk evaluations. This new methodology, to reiterate, is not part of the TSCA systematic review method document, nor in the scope or problem formulation documents, and has not been subject to peer-review or public comment and is not in the framework rules. EPA identified 22 key sources that were taken forward to data extraction and evaluation. There has been and continues to be a lack of clarity on how EPA chose and evaluated the key sources. We have previously given comments on the 1,4- dioxane, HBCD, and 1-BP risk evaluations about how EPA has failed to have a consistent protocol despite the risk evaluation rule laying out a clear guidance.^{22,23}

Although in this draft risk assessment, the Agency has outlined whether studies were initially included or excluded,²⁴ there still exists no transparent process nor rationale for how studies are scored or why they are included or excluded. These problematic methodologies form the likely biased evidence base for methylene chloride which EPA used to make decisions on hazard endpoints, with result that some endpoints (such as immunotoxicity and reproductive/developmental toxicity) could be underestimated or excluded; it is critical that these methods be subject to peer-review evaluation by experts. We acknowledge that the NAS is planning to review of EPA’s TSCA Systematic Review methodology and in the meantime would recommend EPA utilize one of two validated systematic review approaches used

²⁰ US EPA (2019) Methylene Chloride (MC); Draft Toxic Substances Control Act (TSCA) Risk Evaluation and TSCA Science Advisory Committee on Chemicals (SACC) Meeting; Notice of Availability, Public Meeting. Page 56. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0001>

²¹ US EPA (2019). Draft Toxic Substances Control Act (TSCA) Risk Evaluations and TSCA Science Advisory Committee on Chemicals (SACC) Meetings; Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4-Dioxane; Notice of Availability and Public Meetings. Comment submitted by Swati Rayasam, Science Associate, Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco et al. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0237-0059> and <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0056>

²² US EPA (2019). Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals Review of Risk Evaluation for 1-Bromopropane. Comment submitted by Swati Rayasam, Science Associate, Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco et al. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0053>

²³ US EPA (2019). Draft Toxic Substances Control Act (TSCA) Risk Evaluations and TSCA Science Advisory Committee on Chemicals (SACC) Meetings; Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4-Dioxane; Notice of Availability and Public Meetings. Comment submitted by Swati Rayasam, Science Associate, Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco et al. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0237-0059> and <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0056>

²⁴ US EPA (2019). Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals Review of Risk Evaluation for Methylene Chloride. Draft Systematic Review Supplemental File: Data Quality Evaluation of Human Health Hazard Studies - Epidemiological Studies. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0010>

currently on environmental health topics, such as the Navigation Guide²⁵ and the Office of Health Assessment and Translation (OHAT).²⁶

b. EPA’s revised criteria for evaluating the quality of epidemiological studies are inconsistently and incorrectly applied, making it more likely that relevant epidemiological studies will be downgraded or excluded.

We have previously commented on issues with regard to the EPA’s scoring methodology, particularly that it is inconsistently applied to studies and particularly to epidemiological studies.^{27, 28} With regard to data quality evaluation for epidemiological studies in the methylene chloride draft risk evaluation, we find that the methodology is both inconsistently and incorrectly, applied. For example, on page 3 of the *Data Quality Evaluation of Human Health Hazard Studies –Epidemiological Studies Supplement*, EPA scores Domain 1, Metric 2 (Attrition) as **Low**,²⁹ stating in its rationale that:

Of the 91 potential study participants who met all the medical and demographic criteria and were invited to participate in the field study, only 46 (25 solvent-exposed, 21 unexposed) participated. The low participation rate is not explicitly explained, although a logical assumption may be that these eligible subjects elected not to participate.

The definition of attrition is the reduction in the number of participants in a study as it progresses (i.e., during follow-up of a cohort study or a randomized controlled trial). Of particular concern is differential loss to follow up of exposed and unexposed populations in a study.³⁰ Additionally, EPA’s definition of a low score for cohort studies in its Attrition metric in the Updates to the Data Quality Criteria for Epidemiological Studies Supplemental File³¹ is:

“For cohort studies: The loss of subjects (e.g., loss to follow up, incomplete outcome or exposure data) was moderate and unacceptably handled (as described below in the unacceptable confidence category) (NTP, 2015).

²⁵ Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. *Environ Health Perspect.* 2014;122(10):1007-1014.

²⁶ National Toxicology Program (NTP). Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration. Research Triangle Park, NC: National Toxicology Program; 2019.

²⁷ US EPA (2018). Problem Formulations for Risk Evaluations To Be Conducted Under Toxic Substances Control Act, and General Guiding Principles To Apply Systematic Review in TSCA Risk Evaluations. Comment submitted by Veena Singla, Associate Director, Science and Policy, Program on Reproductive Health and the Environment, University of California, San Francisco et al. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0107>

²⁸ US EPA (2019). Draft Toxic Substances Control Act (TSCA) Risk Evaluations and TSCA Science Advisory Committee on Chemicals (SACC) Meetings; Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4-Dioxane; Notice of Availability and Public Meetings. Comment submitted by Swati Rayasam, Science Associate, Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco et al. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0237-0059> and <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0056>

²⁹ US EPA (2019). Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals Review of Risk Evaluation for Methylene Chloride. Draft Systematic Review Supplemental File: Data Quality Evaluation of Human Health Hazard Studies - Epidemiological Studies. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0010>

³⁰ Bankhead C, Aronson JK, Nunan D (2017). Catalogue of Bias Collaboration. Attrition Bias. Available: <https://catalogofbias.org/biases/attrition-bias/>

³¹ US EPA (2019). Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals Review of Risk Evaluation for Methylene Chloride. Draft Systematic Review Supplemental File: Updates to the Data Quality Criteria for Epidemiological Studies. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0012>

OR

Numbers of individuals were not reported at important stages of study (e.g., numbers of eligible participants included in the study or analysis sample, completing follow-up, and analyzed). Reasons were not provided for nonparticipation at each stage (Von Elm et al., 2008)."

Based on both definitions, the rationale that EPA provides to justify a low rating on attrition in Lash et al. is not correct as EPA's rationale is describing a concern with participant selection, and not with attrition. If for some reason there was a concern about participant selection, this should be categorized as a concern of participant recruitment and external generalizability of a study, and more aptly placed in Metric 1: Participant selection.

With regard to concerns of participant selection, Lash et al. conducted two bias substudies to understand the generalizability of their research and account for potential non-response bias/participation bias. The first substudy addressed potential non-response bias through the questionnaire survey and the second to compare those who were eligible who chose to participate or chose not to participate; neither of these bias substudies found significant differences.³² The incorrect scoring of the Lash et al study raises concerns about the accuracy and consistency of EPA's evaluation of other epidemiological studies; if other studies were also scored incorrectly they could be inappropriately downgraded or excluded.

One purpose of a systematic review is to evaluate the evidence base of all science relevant to the review question and determine conclusions from the body of evidence as a whole. EPA's method is not consistent with established methods for systematic review, is inconsistently and incorrectly applied, and is missing critical pieces- including pre-established protocols that are necessary to avoid bias (Point 3b).

3. In a recent report, the National Academies of Sciences, Engineering, and Medicine (NASEM) provided critical recommendations needed to improve the U.S. Department of Defense (DOD) systematic review method used to derive an occupational exposure level for the solvent trichloroethylene (TCE). We highlight key recommendations directly relevant to the TSCA systematic review method which EPA should implement.

The U.S. Army Public Health Center has developed and applied novel methodology utilizing systematic review techniques to derive an occupational exposure level (OEL) for the solvent trichloroethylene (TCE).³³ The U.S. Department of Defense (DOD) asked the National Academies of Sciences, Engineering, and Medicine (NASEM) to review the scientific and technical basis of the new proposed DOD approach and provide analysis of the individual components of the report that that may "*lead to improvements in the accuracy of the proposed process.*"³⁴ The committee identified fundamental issues with DOD's approach, describing the systematic review DOD produced as a "*critically low-quality review, as it lacked*

³² Lash AA, Becker CE, So Y, Shore M. 1991. Neurotoxic effects of methylene chloride: Are they long lasting in humans? *British Journal of Industrial Medicine* 1991;48:418-426. Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1035389/pdf/brjindmed00030-0058.pdf>

³³ Sussan, T.E., G.J. Leach, T.R. Covington, J.M. Gearhart, and M.S. Johnson. 2019. Trichloroethylene: Occupational Exposure Level for the Department of Defense. January 2019. U.S. Army Public Health Center, Aberdeen Proving Ground, MD.

³⁴ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 1. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

a protocol, had inadequate methods to assess risk of bias, and had incomplete descriptions of individual studies."³⁵ Therefore, the committee could not endorse DOD's approach for deriving the OEL.

A number of the concerns raised by NASEM about the DOD method are also relevant to EPA's TSCA systematic review method. EPA's Science Advisory Committee on Chemicals (SACC) raised similar concerns in peer review of the TSCA Draft Risk Evaluations of C.I. Pigment Violet 29 (PV29), 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD).^{36,37}

Below, we highlight the concerns raised by the NASEM on the DOD systematic review method, along with the NASEM's recommendations to improve the process. As EPA works to improve the TSCA method, it should incorporate the NASEM's recommendations to DOD along with the recommendations it has received from the SACC.

a. A validated systematic review method should be used.

The NASEM found that the DOD produced a "*critically low-quality systematic review*" and questioned why the DOD deviated from "*Established systematic review methods [that] have set the bar for objectivity, rigor, and transparency.*"^{38,39} This deviation from using established methods means that DOD has to "*defend a different approach, which is particularly difficult when applied to a chemical with a large and controversial database, such as TCE.*"⁴⁰

The NASEM has highlighted that in the Institute of Medicine (IOM) report 'Finding What Works in Health Care: Standards for Systematic Review' it defines a systematic review as "*a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies.*"⁴¹ There are 21 IOM standards that cover the entire systematic review process that if adhered to, result in a "*scientifically valid, transparent, and reproducible systematic review.*"⁴² Several of these elements are included in the AMSTAR-2, the appraisal tool NASEM used to rate the DOD's systematic review process as a "*critically low-quality*

³⁵ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 3-4. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

³⁶ US EPA (2019) Peer Review of the Draft Risk Evaluation for Pigment Violet 29 (PV29). Available: <https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2018-0604> D=EPA-HQ-OPPT-2018-0604

³⁷ US EPA. (2019). Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals Review of Risk Evaluation for 1, 4 Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD); SACC July 2019 Meeting Minutes and Final Report Docket. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0063>

³⁸ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 52. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

³⁹ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 2. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁴⁰ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 2. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁴¹ IOM (Institute of Medicine). 2011. Finding What Works in Health Care: Standards for Systematic Reviews. Washington, DC: The National Academies Press

⁴² National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 28. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

*systematic review.*⁴³ This rating was driven by several factors including the lack of a systematic review protocol, inadequate methods to assess risk of bias, and incomplete description of individual studies.⁴⁴

Further, several of these IOM methodological standards are incorporated into validated systematic review approaches used currently on environmental health topics, such as the Navigation Guide⁴⁵ and the Office of Health Assessment and Translation (OHAT).⁴⁶ The World Health Organization (WHO) is currently utilizing the Navigation Guide methodology to assess the global burden of work-related injury and disease.⁴⁷ Further, these methods have been peer-reviewed, validated and have been recommended for use previously by the NASEM.

NASEM Recommendation: If DOD's intent is to perform a credible systematic review, the committee suggests following one of the established methods (e.g., Woodruff and Sutton 2014; NTP 2019).⁴⁸

Similar to DOD, EPA created a novel method under TSCA that deviates significantly from established methods. EPA should follow this recommendation for its TSCA systematic reviews.

b. A protocol is needed prior to commencing the systematic review (also required in EPA's framework rules).

The use of pre-established protocols minimizes bias in the evidence base by explicitly defining question formulation, the conduct of searches, and study evaluation, *a priori*.⁴⁹ Most importantly, decision-making transparency throughout the systematic review process is fundamental to the integrity of evidence-based evaluations.⁵⁰ EPA's 2017 framework rules mandate that the agency use "a pre-established protocol" to conduct risk assessments. Further, in its review of the EPA IRIS program's proposed systematic review methods, the NASEM stated that "Completing the literature search as part of protocol development is inconsistent with current best practices for systematic review, and the IRIS program is encouraged to complete the public-comment process and finalize the protocol before initiating the systematic review."

⁴³ Shea, B.J., B.C. Reeves, and G. Wells. 2017. AMSTAR 2: A critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. *BMJ* 358:j4008.

⁴⁴ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 52. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁴⁵ Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. *Environ Health Perspect.* 2014;122(10):1007-1014.

⁴⁶ National Toxicology Program (NTP). Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration. Research Triangle Park, NC: National Toxicology Program; 2019.

⁴⁷ Mandrioli, D., Schlünssen, V., Ádám, B., Cohen, R. A., Colosio, C., Chen, W., ... Scheepers, P. T. J. (2018, October 1). WHO/ILO work-related burden of disease and injury: Protocol for systematic reviews of occupational exposure to dusts and/or fibres and of the effect of occupational exposure to dusts and/or fibres on pneumoconiosis. *Environment International*, Vol. 119, pp. 174–185. <https://doi.org/10.1016/j.envint.2018.06.005>

⁴⁸ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 36. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁴⁹ National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: National Academies Press; 2014.

⁵⁰ Institute of Medicine Committee on Standards for Systematic Reviews of Comparative Effectiveness Research. Finding What Works in Health Care: Standards for Systematic Reviews J Eden, L Levit, A Berg, S Morton (Eds.), National Academies Press (US) Copyright 2011 by the National Academy of Sciences, Washington (DC) (2011)

The NASEM stated that:

*“ No mention of a protocol is made in DOD’s draft report (Sussan et al. 2019), and the methods described were insufficient for understanding all of the steps that were performed. This led to a lack of clarity as to whether a particular step was performed but not discussed in DOD’s draft report, whether the step was omitted, what decisions were made before performing the review, and what decisions were made or changed during the course of the review.”*⁵¹

The use of pre-established protocols minimizes bias in the systematic review process by pre-defining *“search terms, search strategy, inclusion/exclusion criteria, and procedures for study selection.”*^{52,53} The NASEM highlights that the *“The protocol is a critical component to a systematic review because it minimizes author bias, allows for feedback at the early stages of the review, facilitates reproducibility, replication, and future updates, and increases transparency and scientific rigor.”*⁵⁴

Throughout its report, the NASEM highlights how missing this vital step in the systematic review process has critically reduced the transparency of the DOD’s decision making. For example, the NASEM state, *“the eligibility criteria were not explicitly stated and were not pre-specified in a protocol... how DOD determined the subset of older studies and other expert reviews to include in its evaluation was unclear... DOD’s report does not provide a complete set of information to determine the studies that were included in the systematic review... Furthermore, how 56 animal studies were selected for critical evaluation was not described. In contrast, special attention is given to evaluating the evidence on congenital heart defects, with particular emphasis on reasons to exclude a study...The lack of transparency and inconsistency with standard reporting practices limits the ability to determine the appropriateness of the results from this review or to reproduce and/or update it.”*⁵⁵

To address these issues and to enhance transparency and reproducibility, the NASEM recommended that a protocol describing the methods for the systematic review be published and peer-reviewed **prior**

⁵¹ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 30. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁵² National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: National Academies Press; 2014.

⁵³ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 29. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁵⁴ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 29. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁵⁵ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 32. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

to commencing the review . Multiple past reports by the NASEM have also recommended this critical step.^{56,57,58,59}

NASEM Recommendations: Preparation of a systematic review protocol that details the pre-defined methods and criteria, which is peer-reviewed and publicly posted before the review is undertaken. Pre-specifying the criteria that will be used to include or exclude studies. Documentation of how studies from each evidence stream (human, animal, and mechanistic) are identified, assessed, and synthesized.⁶⁰

Similar to DOD, EPA has not published any protocols for TSCA reviews. EPA should follow these recommendations for its TSCA systematic reviews.

c. A validated evidence evaluation method should be used.

“The NASEM found critical flaws in the design of DOD’s study applicability tool, because it combined criteria for evaluating individual study quality with criteria for evaluating a body of evidence (a collection of studies) and had some elements that are inappropriate for evaluating individual study quality. ⁶¹ Most significantly, the quantitative scores are contrary to standard systematic review practices, as numerical scores falsely imply a relationship between scores and effect or association, along with several other critical limitations.”⁶²

In its review of the EPA IRIS program’s method for systematic review, the NASEM strongly supported a methodology that did not incorporate quantitative scoring.⁶³ The use of weighted quality scores are not able to distinguish between studies with a high and low risk of bias in meta-analyses and lacks both

⁵⁶ NRC (National Research Council). 2011. Review of the Environmental Protection Agency’s Draft IRIS Assessment of Formaldehyde. Washington, DC: The National Academies Press.

⁵⁷ 2014. Review of EPA’s Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press

⁵⁸ NASEM (National Academies of Sciences, Engineering, and Medicine). 2017. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, DC: The National Academies Press

⁵⁹ NASEM. 2018. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press

⁶⁰ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD’s Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 36. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁶¹ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD’s Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 3-4. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁶² National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD’s Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 3-4. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁶³ National Research Council. Review of EPA’s Integrated Risk Information System (IRIS) Process. Washington, DC: National Academies Press; 2014

empirical and statistical justification.^{64,65,66} Therefore, it is vital that the primary studies that underpin evidence-based decision are assessed with transparent and accepted methods.⁶⁷

Additional issues that the NASEM identified with how the evidence was evaluated was that the “DOD was inconsistent in the degree to which it evaluated different types of evidence identified with the tool.”⁶⁸ The tool was only “designed to score *in vivo* controlled animals studies” and therefore **no evaluation of the epidemiological literature was performed**, even though “the epidemiological studies are used by DOD to determine potential cancer risks at the proposed occupational exposure level.”⁶⁹ The NASEM reported it was unclear why DOD did not evaluate this line of evidence. Further, “the tool was applied only to studies of noncancer outcomes in animals” with no explanation “provided for why it was not applied to cancer studies in animals.”⁷⁰ Therefore, NASEM recommended that the DOD “abandon the use of this study applicability tool in favor of established tools to assess risk of bias of animal and human studies” and use the “approach developed by the National Toxicology Program’s Office of Health Assessment and Translation.”⁷¹

NASEM Recommendations: Numeric scores are not used to evaluate studies. Assess risk of bias and quality of individual studies and then, separately, determine certainty in the body of evidence.⁷²

Similar to DOD, the TSCA method uses a quantitative scoring system for study evaluation. EPA should follow these recommendations for its TSCA systematic reviews.

d. Best practice methods should be used to synthesize and integrate each evidence stream.

“In the DOD assessment, no separate synthesis and determination of certainty of evidence was conducted for animal and human studies. It was not clear how mechanistic evidence was identified or assessed. Furthermore, Figure 2 in the DOD draft report illustrates that the three

⁶⁴ Juni P, Witschi A, Bloch R, Egger M. The hazards of scoring the quality of clinical trials for meta-analysis. *Jama*. 1999;282(11):1054-1060

⁶⁵ Higgins J, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions*. Chichester: The Cochrane Collaboration and Wiley-Blackwell; 2008.

⁶⁶ Herbison P, Hay-Smith J, Gillespie WJ. Adjustment of meta-analyses on the basis of quality scores should be abandoned. *J Clin Epidemiol*. 2006 Dec; 59(12):1249-56.

⁶⁷ A.A. Rooney, G.S. Cooper, G.D. Jahnke, et al. How credible are the study results? Evaluating and applying internal validity tools to literature-based assessments of environmental health hazards *Environ. Int.*, 92-93 (Supplement C) (2016), pp. 617-629

⁶⁸ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 34. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁶⁹ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 34. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁷⁰ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 34. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁷¹ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 3-4. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁷² National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 36. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

evidence streams were to be considered but it is not clear from this figure, or accompanying text, how or if evidence integration was conducted in making any conclusions about hazard.”⁷³

As previously demonstrated by the NASEM, when completing the hazard identification process, human evidence should be synthesized and a determination made on the certainty of evidence.⁷⁴ However, despite DOD developing a PECO statement that yielded 58 human epidemiologic studies, human epidemiologic studies were excluded from this synthesis because:

“Due to the generally limited quantitative information on exposure assessment from human epidemiologic studies as well as the known and unknown co-exposures typically inherent in human exposure studies, epidemiologic studies were considered, as mentioned below, as alternative lines of evidence in the selection of the PODs.”

The NASEM highlights that this is inconsistent with best practice and not appropriate.^{75 76}

The NASEM also highlighted that:

“DOD assessments could include separate synthesis and determination of certainty of evidence for animal, human, and, when appropriate, mechanistic evidence....then also include methods for integrating the evidence streams to reach a final causal determination of hazard. These measures will strengthen DOD’s assessment by allowing rigorous assessment and integration of the robust information on TCE.”⁷⁷

Such approaches have already been successfully used by the NASEM⁷⁸, International Agency for Research on Cancer (IARC),⁷⁹ OHAT⁸⁰ and the Navigation Guide.⁸¹ The process consists of an overall rating in the confidence of the body of evidence for each specified outcome, for each evidence stream. The overall rating should then be translated into a conclusion on the level of evidence for a health effect, and then finally into a hazard identification conclusion. Human epidemiological and animal

⁷³ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 35. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁷⁴ NASEM (National Academies of Sciences, Engineering, and Medicine). 2017. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, DC: The National Academies Press.

⁷⁵ NRC. 2014. Review of EPA’s Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press

⁷⁶ NASEM (National Academies of Sciences, Engineering, and Medicine). 2017. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, DC: The National Academies Press.

⁷⁷ National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 56. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁷⁸ NASEM. (2017). Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, D.C.: The National Academies Press; 2011

⁷⁹ IARC Monographs on the Evaluation of Carcinogenic Hazards to Humans. Lyon (FR): International Agency for Research on Cancer; 2019 Available from:<https://monographs.iarc.fr/wp-content/uploads/2019/07/Preamble-2019.pdf>

⁸⁰ National Toxicology Program Office of Health Assessment and Translation. Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration. National Institute of Environmental Health Sciences; 2019

⁸¹ Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. Environ Health Perspect. 2014;122(10):1007-1014

studies, when available, should then be integrated, while mechanistic data should be used to help support the final conclusions. The NASEM highlight that these approaches for evidence integration, including those of the Navigation Guide and OHAT should be considered by DOD to be incorporated in their systematic review process.

Recommendation: Conduct separate evidence synthesis and determinations about the certainty of the evidence for each stream of evidence and describe how different streams of evidence are integrated.⁸²

Similar to DOD, the TSCA method does not have steps for determining certainty of the evidence for each evidence stream or integrating evidence streams to draw conclusions. EPA should follow the recommendations of the NASEM recommendations for its TSCA systematic reviews.

4. EPA's draft risk determinations are not protective of potentially exposed or susceptible subpopulations such as workers and persons with existing cardiovascular disease.

a. Persons with existing cardiovascular disease (CVD)

According to the CDC, heart disease is still the leading cause of death for men, women, and people of most racial and ethnic groups in the United States.⁸³ An estimated 92.1 million US adults have at least 1 type of CVD. By 2030, 43.9% of the US adult population is projected to have some form of CVD.⁸⁴ Methylene chloride's metabolite, carbon monoxide (CO), has well-documented ischemic and arrhythmogenic cardiac effects.

On page 32 of the draft risk evaluation, EPA states:

"Populations of particular concern are smokers who maintain significant constant levels of COHb, persons with existing cardiovascular disease (ATSDR, 2000), and fetuses and infants" (emphasis ours).

In addition, like other halogenated solvents, methylene chloride can directly sensitize the myocardium to arrhythmias, an effect that Stewart and Hake noted is dangerous for those with cardiovascular disease. We have commented before on EPA's pattern of not accounting for vulnerable populations and clinicians have previously submitted comments to EPA regarding the potential for methylene chloride to lead to "sudden death" for this population.

EPA's quantitative calculations of risk do not account for the increased susceptibility of those with CVD to methylene chloride acute toxicity, including higher risk of myocardial infarction and fatality. This risk group constitutes a large proportion of the population and EPA should add a data-derived or default adjustment factor to its risk calculations.

⁸² National Academies of Sciences, Engineering, and Medicine. 2019. Review of DOD's Approach to Deriving an Occupational Exposure Level for Trichloroethylene. Pp 36. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25610>.

⁸³ Heron, M. Deaths: Leading causes for 2017. *National Vital Statistics Reports*;68(6). Accessed November 19, 2019. Available: https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_06-508.pdf

⁸⁴ Benjamin, E. J., Blaha, M. J., Chiuve, S. E., Cushman, M., Das, S. R., Deo, R., ... American Heart Association Statistics Committee and Stroke Statistics Subcommittee (2017). Heart Disease and Stroke Statistics-2017 Update: A Report From the American Heart Association. *Circulation*, 135(10), e146–e603. doi:10.1161/CIR.0000000000000485

b. Workers

i. EPA relies on the OSHA methylene chloride standard, however OSHA found that standard compliance did not improve over time.

In its draft risk evaluation, EPA continuously references OSHA's methylene chloride standard (1910.1052)⁸⁵, employing its PEL throughout its risk determinations.⁸⁶ This is incorrect for several reasons, and this information has all been reasonably available to EPA during the drafting of this risk evaluation, including in comments we and other groups previously provided.

Workers face a number of obstacles with regard to workplace safety and are largely dependent on their employers. Therefore, they are often not in a position to influence their employer's decisions around workplace practices such as the type of paint removal method or ensure that their employer provides appropriate PPE and an adequate respiratory protection program.⁸⁷ OSHA's hazard communication rule expressly states "there is no requirement for employers to implement recommended controls."⁸⁸

In the 2017 proposed ruling, EPA found that "[m]any air concentrations reported and used in the risk assessment exceeded the current OSHA PEL of 25 ppm," and sometimes in gross excess of it reaching as high as 2,016 ppm.⁸⁹ This is confirmed by OSHA's methylene chloride lookback document, which outlines regular employer violations, with upholstery and furniture repair shops possessing the most violations.⁹⁰ The standard provisions top 3 most violated include requirements for exposure monitoring, training, and providing PPE as listed below:⁹¹

- Each employer whose employees are exposed to methylene chloride shall perform initial exposure monitoring to determine each affected employee's exposure. (486 violations)
- The employer shall provide information and training for each affected employee prior to or at the time of initial assignment to a job involving potential exposure to methylene chloride. (426 violations)
- Where needed to prevent methylene chloride-induced skin or eye irritation, the employer shall provide clean protective clothing and equipment which is resistant to methylene chloride, at no cost to the employee, and shall ensure that each affected employee uses it. (219 violations)

⁸⁵ 29 CFR 1910.1052

⁸⁶ US EPA (2019) Methylene Chloride (MC); Draft Toxic Substances Control Act (TSCA) Risk Evaluation. Pg. 109. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437>

⁸⁷ 82 FR 7464

⁸⁸ 77 FR pg. 17545 & 17693

⁸⁹ 82 FR 7464 pg. 7477

⁹⁰ U.S. Department of Labor, Occupational Safety and Health Administration. (2010) "Regulatory Review of 29 CFR 1910.1052: Methylene Chloride" pg. 29. Available: <https://www.osha.gov/dea/lookback/MC-lookback-Feb-2010-final-for-publication-May-2010.pdf>

⁹¹ U.S. Department of Labor, Occupational Safety and Health Administration. (2010) "Regulatory Review of 29 CFR 1910.1052: Methylene Chloride" Exhibit 3-10. Available: <https://www.osha.gov/dea/lookback/MC-lookback-Feb-2010-final-for-publication-May-2010.pdf>

Importantly, OSHA did **not** find that compliance with the standard improved over time.⁹² This indicates that employers are regularly out of compliance with the OSHA standard, and that they are not likely to change in the future—directly contradicting EPA’s assertion that workplaces are in compliance with OSHA.

The standards established by EPA for ‘acceptable’ cancer risks are 1 in 10 million, or 1 in a million conservatively.^{93, 94, 95, 96, 97} Yet OSHA estimates that full compliance with its methylene chloride standard would result in cancer risks of “3.62 deaths per 1000 workers who are occupationally exposed to 25 ppm of methylene chloride over a working lifetime,”^{98, 99} — 3,200 times greater than 1 in a million. Throughout the draft risk evaluation EPA continuously returns to OSHA PELs for reference, which is inappropriate considering the disparity between allowed exposure.

The OSHA standard has an appreciable allowance of cancer risk that EPA deems unreasonable as per its standard benchmarks, making OSHA’s standard insufficient.¹⁰⁰ In the 2017 proposed ruling EPA concluded, based on the cancer risk alone for commercial users and bystanders, that “workplaces are estimated to present exposure levels between 100 times to greater than 1,000 times more than those that are of concern. Not only workers, but also occupational bystanders, or workers engaged in tasks other than paint and coating removal, would be at acute risk for central nervous system effects.”¹⁰¹ Concluding that the Agency’s “proposed determination is that chronic methylene chloride exposures during paint and coating removal present unreasonable risks.”¹⁰²

Third, there are considerable gaps in the OSHA standard that leave some particularly vulnerable workers unprotected. For example, Drew Wynne, a 31-year-old owner of a startup coffee company in Charleston, South Carolina died while using methylene chloride in an occupational setting. Drew was removing paint from the floor of his small business with a common methylene chloride paint remover when he succumbed to the fumes and died.¹⁰³ As a small startup, he was not determined to be a worker by OSHA; however his death is not a consumer fatality because he was using the paint remover at work. Thus, relying on the OSHA standard would not address risks to certain vulnerable worker populations,

⁹² U.S. Department of Labor, Occupational Safety and Health Administration. (2010) “Regulatory Review of 29 CFR 1910.1052: Methylene Chloride” Available: <https://www.osha.gov/dea/lookback/MC-lookback-Feb-2010-final-for-publication-May-2010.pdf>

⁹³ 82 FR 7464 pg. 7471

⁹⁴ Rosenthal A, Gray GM, Graham JD. (1992) “Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals.” 19 Ecology L.Q. 269, pg. 300. Available: <https://pdfs.semanticscholar.org/1001/f111e05b9981986bcb364c721c3debc13530.pdf>

⁹⁵ Congressional Research Service. (1998) “Pesticide Legislation: Food Quality Protection Act of 1996 (P.L. 104-170)” pg. CRS-13 Available: https://www.everycrsreport.com/files/19980911_96-759_cae29ffc2edda2c1edd8ea3578133e1cf1d09374.pdf

⁹⁶ 82 FR 44254

⁹⁷ EPA (1999) “Residual Risk Report to Congress.” Pg. 105 Available: https://www.epa.gov/sites/production/files/2013-08/documents/risk_rep.pdf

⁹⁸ U.S. Department of Labor, Occupational Safety and Health Administration. (2010) “Regulatory Review of 29 CFR 1910.1052: Methylene Chloride” Available: <https://www.osha.gov/dea/lookback/MC-lookback-Feb-2010-final-for-publication-May-2010.pdf>

⁹⁹ Note: While these numbers are slightly outdated, there is no reason to doubt the overall trends; based on new data regarding cancer risks, these numbers are likely to increase.

¹⁰⁰ 82 FR 7464 pg. 7471

¹⁰¹ EPA. 2015. TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. EPA Document # 740-R1-4003. Available” https://www.epa.gov/sites/production/files/2015-09/documents/dcm_opptworkplanra_final.pdf

¹⁰² 82 FR 7464 pg. 7478

¹⁰³ Friedman L (2019) “E.P.A., Scaling Back Proposed Ban, Plans Limits on Deadly Chemical in Paint Strippers.” *New York Times*. Available: <https://www.nytimes.com/2019/03/15/climate/epa-paint-stripper-methylene-chloride.html>

such as in small businesses or individual contractors. Additionally, if EPA relies on the prohibition of consumer use alone, workers like Drew would not have had protection, as EPA recognized in their 2017 proposed rule that “paint and coating removal products containing methylene chloride frequently are available in the same distribution channels to consumers and professional users.”¹⁰⁴

EPA cannot claim the OSHA standard is sufficient to remove unreasonable risks to workers as it does not improve workplace compliance over time, allows an appreciable cancer risk that is unreasonable as per EPA standards, and does not protect all worker populations. EPA is obligated under TSCA to take action to mitigate unreasonable risks.

ii. EPA has already found that commercial uses of methylene chloride pose an unreasonable risk to workers.

We have previously commented on EPA’s earlier finding that methylene chloride posed an unreasonable risk to workers.¹⁰⁵ EPA did not prohibit commercial uses of methylene chloride in the March 2019 rule,¹⁰⁶ despite its clear findings of significant risks of concern for occupational exposure in 2014,¹⁰⁷ which had gone through the public comment and peer-review process before being finalized.^{108, 109}

For example, EPA found:

*“Acute inhalation risks for CNS effects were reported for most of the relevant industries when occupational risks were evaluated with the California acute REL POD and respective benchmark MOE. These risks were **irrespective of the absence or presence of respirators** and were observed with central tendency or high-end DCM air concentrations.”¹¹⁰ (emphasis added)*

Additionally, EPA highlighted that workers employed at most industries showed non-cancer risks for liver effects when using methylene chloride strippers on a repeated basis.¹¹¹ Even within this draft risk evaluation, EPA found liver effects from chronic exposure to methylene chloride at levels as low as 5ppm (well below the OSHA PEL of 25ppm).¹¹² It found that occupational cancer risks were consistently greater than the denoted allowable risk,¹¹³ and for contractors and furniture refinishers specifically, excess occupational cancer risks due to chronic exposure exceeded the threshold even with personal

¹⁰⁴ 82 FR 7464 pg. 7479

¹⁰⁵ US EPA (2019). Methylene Chloride; Commercial Paint and Coating Removal Training, Certification and Limited Access Program. Comment submitted by Swati Rayasam, Science Associate, Program on Reproductive Health and the Environment, University of California, San Francisco Program on Reproductive Health and the Environment (UCSF PRHE). Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0844-0037>

¹⁰⁶ 84 FR 11466

¹⁰⁷ US EPA (2014). TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. Office of Chemical Safety and Pollution Prevention.

¹⁰⁸ 78 FR 1856

¹⁰⁹ US EPA. Risk Evaluation for Methylene Chloride. Available: <https://www.epa.gov/assessing-and-managing-chemicals-under-tasca/risk-evaluation-methylene-chloride-0>

¹¹⁰ US EPA (2014). TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. Pg. 92. Office of Chemical Safety and Pollution Prevention.

¹¹¹ US EPA (2014). TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. Pg. 108. Office of Chemical Safety and Pollution Prevention.

¹¹² US EPA (2019) Methylene Chloride (MC); Draft Toxic Substances Control Act (TSCA) Risk Evaluation. Pg. 283. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437>

¹¹³ US EPA (2014). TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. Pg. 108. Office of Chemical Safety and Pollution Prevention.

protective equipment (PPE).¹¹⁴ In fact, across many industries, Margins of Exposure (MOEs) indicating risk occurred with the highest achievable level of respiratory protection.¹¹⁵

iii. The draft risk evaluation contains scientifically unsupported assumptions about use of personal protective equipment (PPE).

We have addressed EPA's unscientifically supported PPE assumptions in our comments on prior TSCA risk evaluations.^{116, 117} However EPA continues to inappropriately assume that workers wear both respirators and protective gloves in its risk calculations.

*"Based on the protection standards, inhalation exposures may be reduced by a factor of 25, 50, 1862 1,000, or 10,000, if respirators are required and properly worn and fitted."*¹¹⁸

As demonstrated throughout the draft risk evaluation, EPA's risk determinations for methylene chloride make the assumption of respirators for many commercial uses of methylene chloride without any support. However, as demonstrated in point 2(a) above, the most common employer violation was not providing appropriate PPE for workers. Therefore, EPA should use evidence-based assumptions in its risk calculations- that workers do not wear PPE. The methylene chloride SACC also made this recommendation. Employing this scenario as requested by the experts on the SACC, EPA would at minimum determine that *"[f]or workers, acute and chronic non-cancer risks (i.e., central nervous system effects and non-cancer 165 liver effects) were indicated for all conditions of use under high-end inhalation or dermal exposure scenarios..."*¹¹⁹

Overall, this would result in greater findings of risk for many uses and finding that more uses present unreasonable risks.

5. Our research on methylene chloride fatalities finds current policies inadequate to protect workers and recommends elimination of methylene chloride use in commercial settings.

¹¹⁴ US EPA (2014). TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. Table 3-18 and 3-20. Office of Chemical Safety and Pollution Prevention.

¹¹⁵ US EPA (2014). TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. Table 3-17. Office of Chemical Safety and Pollution Prevention.

¹¹⁶ US EPA (2019). Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals Review of Risk Evaluation for 1-Bromopropane. Comment submitted by Swati Rayasam, Science Associate, Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco et al. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0235-0053>

¹¹⁷ US EPA (2019). Draft Toxic Substances Control Act (TSCA) Risk Evaluations and TSCA Science Advisory Committee on Chemicals (SACC) Meetings; Cyclic Aliphatic Bromide Cluster (HBCD) and 1,4-Dioxane; Notice of Availability and Public Meetings. Comment submitted by Swati Rayasam, Science Associate, Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco et al. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0237-0059> and <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0238-0056>

¹¹⁸ US EPA (2019) Methylene Chloride (MC); Draft Toxic Substances Control Act (TSCA) Risk Evaluation. Pg. 109. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437>

¹¹⁹ US EPA (2019) Methylene Chloride (MC); Draft Toxic Substances Control Act (TSCA) Risk Evaluation. Pg. 30. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437>

Data from a comprehensive review of 10 sources, all of which are reasonably available to EPA, identified 85 unique deaths related to acute methylene chloride exposure from 1980-2018 and was presented to the SACC (see Appendix).¹²⁰

The majority of our cases (87%) occurred in occupational settings, which we broadly defined as related to the workplace in order to accommodate gaps in OSHA's definition of worker (point 2(a)). Younger men with a median age 31 represented the majority of our fatalities. The most common product implicated was the paint strippers or paint removers (70%). Nearly 33% of the fatalities took place in bathrooms with industry settings second at 21%. Additionally, we included bystander cases, defined as ONUs who unknowingly entered environments where methylene chloride was being used and subsequently succumbed to fumes. Regarding ONU's, in the draft risk evaluation, EPA states:

*"Since ONUs do not directly handle formulations containing methylene chloride, EPA expects ONU inhalation exposures to be lower than worker inhalation exposures...relative exposure of ONUs to workers cannot be quantified."*¹²¹

The occurrence of these fatalities for ONUs means that EPA's rule should be expanded to protect ONUs as currently they represent a critical gap in the Agency's data.

Regarding the impact of the type of policy on fatalities, we found that fatalities per year showed no significant trends in comparison to CPSC's 1987 mandatory labelling requirement and OSHA's updated standard in 1997 (though not fully updated until 2000). With regard to the labelling requirement, EPA has already identified that there was little scientific evidence to support the efficacy of labelling as a safety measure.⁴⁴ While we did not observe a trend in rate of fatalities over time, we found a significant increase in the number of paint stripper and bathroom cases after 2000 in comparison to other products and places. Of decedents with available autopsies, our study finds that they had greater prevalence of coronary artery disease than expected, consistent with previous data finding higher susceptibility to methylene chloride toxicity with cardiovascular disease (Point 3a).

Overall, there was a persistent pattern of fatalities, primarily affecting vulnerable populations such as workers that are not prevented by labeling policies. The number of fatalities we found is likely an undercount because fatalities may not be recognized as caused by methylene chloride considering those at risk for CVD are a potentially susceptible subpopulation;¹²² this may cause methylene chloride fatalities to be reported as CVD fatalities. Additionally, there is no overarching reporting requirement for anyone not covered by OSHA. Based on our findings, the most effective next step is to institute an elimination of methylene chloride in occupational scenarios to prevent further fatalities.

¹²⁰ Hoang, A., Fagan, K., Cannon, D., Rayasam, S.D.G., Harrison, R., Shusterman, D., and Singla, V. Fatalities from methylene chloride exposure in the United States, 1980-2018: A comprehensive clinical review and policy implications. (in preparation)

¹²¹ US EPA (2019) Methylene Chloride (MC); Draft Toxic Substances Control Act (TSCA) Risk Evaluation. Pg. 129. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437>

¹²² US EPA (2019) Methylene Chloride (MC); Draft Toxic Substances Control Act (TSCA) Risk Evaluation. Pg. 32. Available: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437>

Appendix:

Presentation: Fatalities from methylene chloride exposure in the United States, 1980-2018: A comprehensive clinical review and policy implications



Fatalities from methylene chloride exposure in the United States, 1980-2018: A comprehensive clinical review and policy implications

Anh Hoang, Kathleen Fagan, Dawn Cannon,
Swati Rayasam, Robert Harrison, Dennis
Shusterman, Veena Singla

Research questions

What are the patterns of methylene chloride fatalities in the U.S.?

How have policies influenced fatality patterns?

How might fatalities be reduced?

Comprehensive searches & integration of data from 10 sources

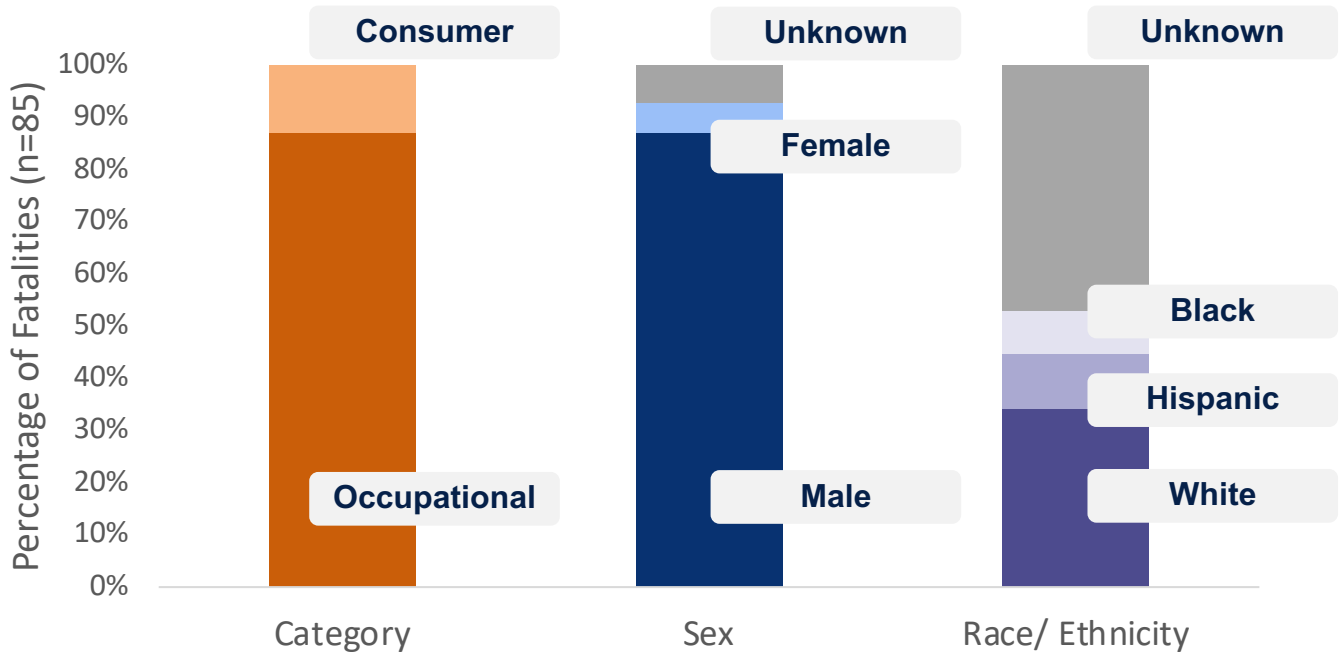
Population Humans in U.S.	Exposure Acute to methylene chloride product, 1980-2018	Comparator None	Outcome Unintentional death
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Pub Med	AAPCC	OSHA	CPSC	Lexis Nexis	News Bank	NIOSH	CPI	EASCR
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Add info from Social Security death index;
reconcile cases

85 unique fatalities

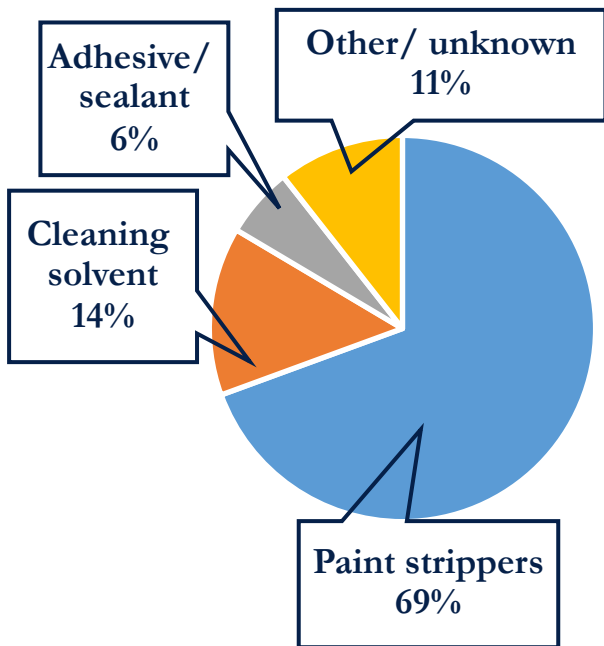
Majority of cases occupational



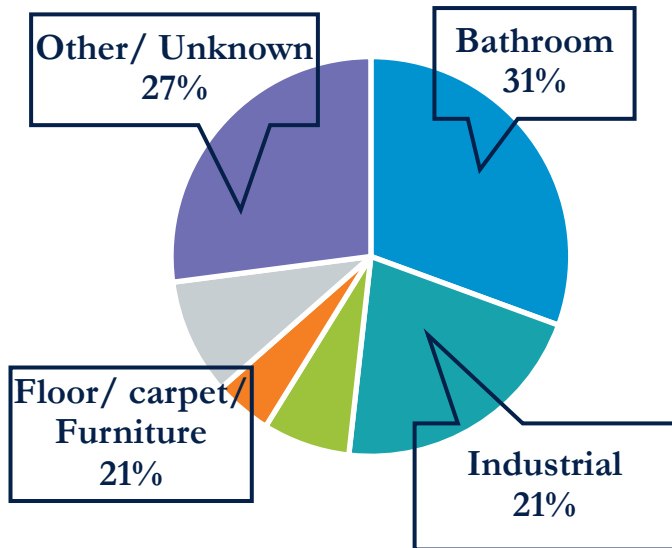
Age (n=69) | Median. 31 | Min. 14 | Max. 80

Paint strippers and bathrooms: most common product and setting for fatalities

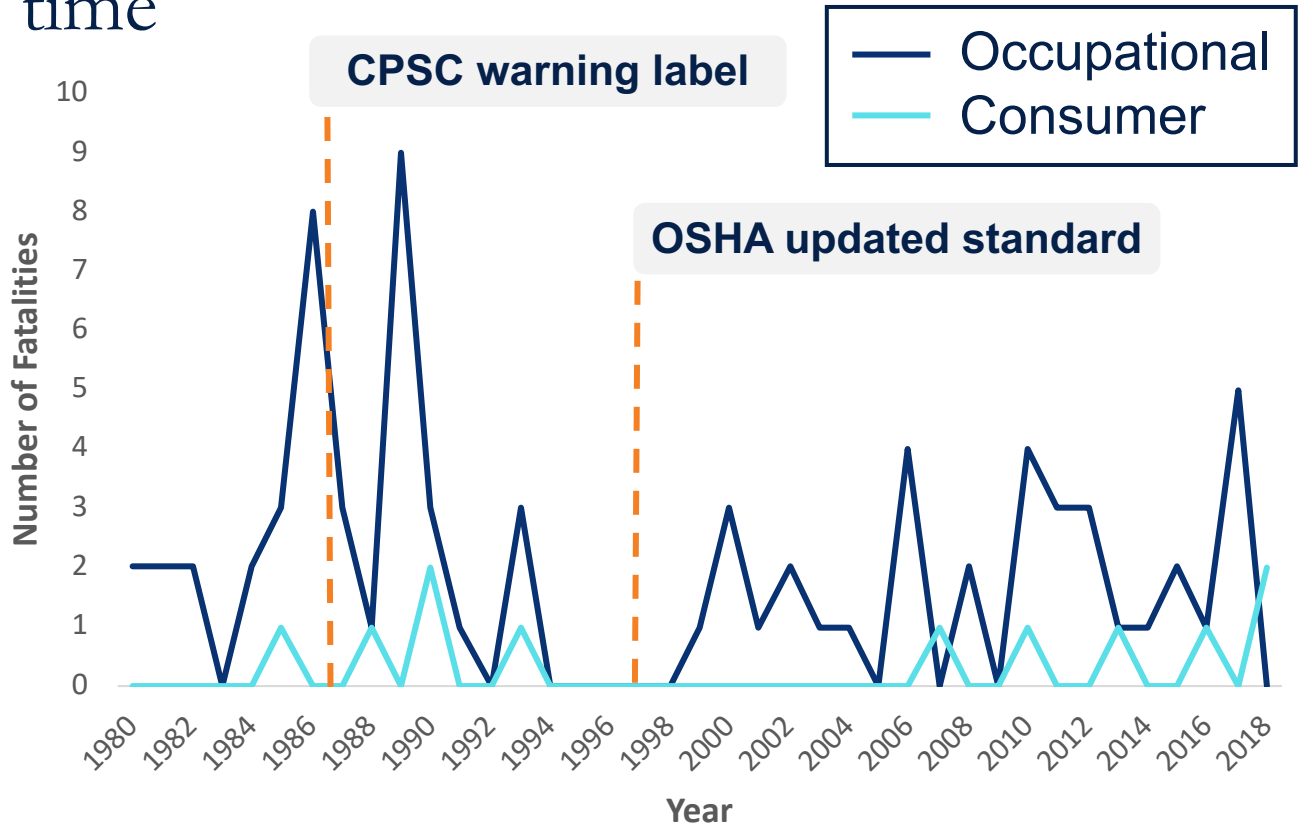
Product Type



Setting

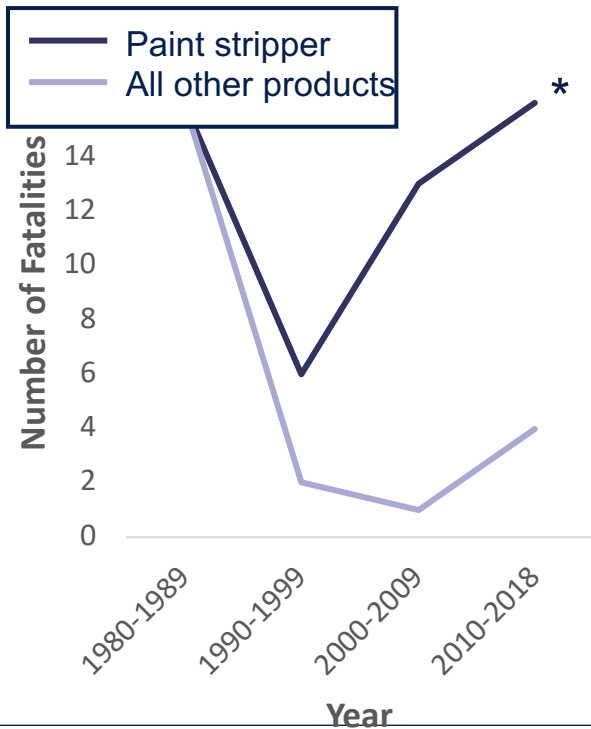


No significant trend in fatalities over time

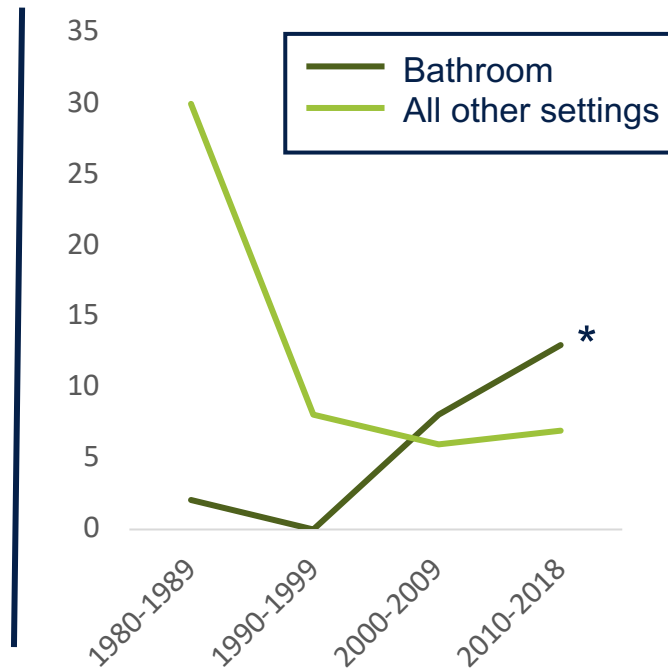


Occupational fatalities rose after 2000 with paint strippers; in bathrooms

Product Type



Setting



Summary and Recommendations

- Persistent pattern of fatalities- younger men
- Majority occupational
- Paint strippers, bathrooms commonly involved
- After 2000, occupational fatalities with paint strippers rose
- Elimination most effective strategy to prevent fatalities

