



AMERICAN PUBLIC HEALTH ASSOCIATION
For science. For action. For health.

December 27, 2019

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Re: TSCA Draft Risk Evaluation for Methylene Chloride (Docket No. EPA-HQ-OPPT-2019-0437)

Dear Administrator Wheeler:

On behalf of the American Public Health Association, a diverse community of public health professionals that champions the health of all people and communities, I appreciate the opportunity to comment on the U.S. Environmental Protection Agency's draft risk evaluation for methylene chloride, issued under the Toxic Substances Control Act, as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.¹ These comments were developed in collaboration with APHA's Environment and Occupational Health and Safety Sections. Produced at more than 260 million pounds annually, methylene chloride is a solvent with a variety of consumer, commercial and industrial uses.² Human exposures to methylene chloride are associated with well-documented 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 Methylene chloride has been effectively banned in the European Union since 2012.⁴

As a result of these health risks, EPA concluded in 2017 that methylene chloride consumer and commercial stripping uses posed an unreasonable risk. EPA proposed a rule prohibiting all consumer and almost all commercial uses.⁵ In a 2018 statement, EPA announced that it intended to finalize the 2017 proposed rule;⁶ however, in March 2019, EPA finalized a rule that only

¹ US EPA (2019) Methylene Chloride (MC); Draft Toxic Substances Control Act (TSCA) Risk Evaluation. Available at: <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 ECHA. (2012) "Annex XVII to REACH - Conditions of restriction. Entry 59 Dichloromethane containing Paint Strippers." Available at: <https://echa.europa.eu/documents/10162/0ea58491-bb76-4a47-b1d2-36faa1e0f290>.

⁵ 82 FR 7464.

⁶ EPA (2018) "EPA announces action on Methylene Chloride." Available at: <https://www.epa.gov/newsreleases/epa-announces-action-methylene-chloride>.

prohibited a narrow group of consumer uses which took effect in November 2019,⁷ leaving the commercial uses unaddressed.⁸

EPA’s risk evaluation must address commercial use and occupational conditions of use and exposures.

APHA is concerned that well-documented occupational risks from commercial uses are not adequately being addressed by EPA as required by TSCA. In March 2019, the agency also 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 were already analyzed and rejected by the agency due to inability of these techniques to mitigate unreasonable risks.⁹ Recently, EPA has released a draft risk evaluation for methylene chloride that is incomplete and inconsistent with EPA’s previous findings without adequate explanation or scientific basis. EPA had previously concluded findings of significant risks from occupational exposure from methylene chloride in EPA’s peer-reviewed 2014 final risk assessment.^{10,11,12} Between EPA’s 2017 proposed rule to eliminate methylene chloride and now, the chemical has been responsible for multiple fatalities.¹³ As presented at APHA’s 2019 Annual Meeting, a study conducted by researchers at the University of California at San Francisco found a persistent pattern among 85 methylene chloride-related fatalities in the U.S., mostly among younger, healthy men.¹⁴ Additional data has been presented by medical doctor researchers at past APHA Annual Meetings, supporting the need for the full ban.¹⁵

By delaying action on a commercial ban, EPA is leaving workers exposed to unreasonable health risks.¹⁶ This is contrary to plain statutory language, 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.”¹⁷ EPA is required to consider workers as a susceptible or highly exposed population in its risk evaluations. Because of the deficiencies noted above and on-going exposures, EPA’s draft

⁷ US EPA. (2019). EPA Bans All Retail Distribution of Methylene Chloride to Consumers for Paint and Coating Removal. Available at: <https://www.epa.gov/newsreleases/epa-bans-all-retail-distribution-methylene-chloride-consumers-paint-and-coating-removal>.

⁸ 84 FR 11466.

⁹ 82 FR 7464 pg. 7424.

¹⁰ 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.

¹¹ 78 FR 1856.

¹² US EPA. Risk Evaluation for Methylene Chloride. Available at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-methylene-chloride-0>.

¹³ The Center for Public Integrity (2018) Some paint strippers are killing people. The EPA promised to act – but hasn’t. Available at: <https://publicintegrity.org/workers-rights/worker-health-and-safety/unequal-risk/these-paint-strippers-are-killing-people-the-epa-promised-to-act-but-hasnt/>.

¹⁴ Hoang, Annie; Veena Singla, Robert Harrison, Dennis Shusterman, Kathleen Fagan, [A comprehensive review of consumer and occupational methylene chloride fatalities in the US from 1980-2018 and policy implications](#), Session 4334.0 Chemicals and Public Health, American Public Health Association 2019 Annual Meeting, Philadelphia, PA, November 5, 2019

¹⁵ Harrison, Robert [Case study of Methylene Chloride](#), Session 4152.0, APHA 2018 Annual Meeting, San Diego, CA, November 13, 2018.

¹⁶ 82 FR 7464 pg. 8.

¹⁷ 15 USC §2605(a).

risk evaluation is not protective of potentially exposed or susceptible subpopulations such as workers.

EPA’s risk evaluation must follow its own peer review guidelines and conduct a *bona fide* systematic review that avoids bias and fully evaluates the exposure and health evidence.

We are concerned about some of the processes by which EPA is evaluating the scientific literature because the procedures the agency used are not in keeping with best practices for evidence-based techniques and unnecessarily exclude health data. As a consequence, EPA’s risk evaluation will not fully evaluate the available evidence of risks from methylene chloride.

It is noteworthy that EPA is using the term “systematic review” to describe an approach which does not comport with established procedures in the field, as described in an APHA peer-reviewed publication.¹⁸ The inappropriate use of the term implies a level of steps (e.g., publishing protocols) that EPA has not taken. As a result, EPA’s use of the term “systematic review” is likely to cause confusion for the public and for reviewers. In these comments we distinguish the “TSCA systematic review” from other systematic reviews. In its “TSCA systematic review,” EPA is not systematically reviewing the studies it relies on in the draft risk evaluation. EPA uses an inappropriate scoring scheme shown to have bias, and EPA is excluding a significant proportion of the body of evidence without adequate rationale.

Although in this draft risk evaluation, the agency has outlined whether studies were initially included or excluded,¹⁹ EPA does not present a rationale for how studies are scored or why a given study is included or excluded. This lack of transparent explanation obscures the evidence base for this draft risk evaluation, leading to likely biased results. In the context of the evidence base for methylene chloride, these problematic methodologies are the basis of EPA’s decisions on hazard endpoints and may cause some effects such as immunotoxicity and reproductive/developmental toxicity to be underestimated.

EPA’s use of the “TSCA Systematic review method” is not consistent with established methods for systematic review and is missing critical elements - including pre-established protocols that are necessary to avoid bias. EPA’s “TSCA Systematic review method” has not been peer reviewed. Previous peer review bodies have criticized EPA’s TSCA approaches as inadequate. Concerns have been also been raised by EPA’s Science Advisory Committee on Chemicals (SACC). In the SACC peer review of EPA’s “TSCA systematic review method” regarding EPA’s draft risk evaluation of C.I. Pigment Violet 29 (PV29) and draft risk evaluations for 1,4-dioxane and cyclic aliphatic bromide cluster, the SACC criticized EPA’s “TSCA systematic review method” and risk evaluations for the following:

- Failure to use a validated systematic review method;

¹⁸ Singla, V. I., Sutton, P. M. & Woodruff, T. J. The Environmental Protection Agency Toxic Substances Control Act Systematic Review Method May Curtail Science Used to Inform Policies, With Profound Implications for Public Health. *Am. J. Public Health* 109, 982–984 (2019).

¹⁹ 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 at: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0010>.

- Failure to implement a protocol before the commencement of the systematic review process;
- Failure to use a validated evidence evaluation method; and
- Failure to synthesize and integrate each evidence stream according to best practice methods.

In the draft risk evaluation for methylene chloride, EPA’s “TSCA systematic review method” for evaluating study quality uses a non-empirically based scoring system and ‘hierarchy of preferences’ to exclude relevant studies. The application of “TSCA systematic review method” in the draft risk evaluation for methylene chloride demonstrates fundamental problems with the method. Furthermore, the new ‘hierarchy of preferences’ methodology is not part of the “TSCA systematic review method” document, nor in the scope or problem formulation documents for methylene chloride. EPA’s “Strategy for Conducting Literature Searches for Methylene Chloride (DCM): Supplemental File to the TSCA Scope Document”²⁰ does not contain the phrasing “key and supporting information” so EPA is arbitrarily defining these concepts after the literature search, not as part of a pre-published protocol. EPA continues to rely on “key/ supporting/ influential information,” the qualifications of which are still not clearly articulated in EPA’s documents.

Based on these flawed approaches, EPA is inappropriately excluding a significant proportion of the body of evidence. EPA states that it excluded 99 sources based on its hierarchy of preferences –a new methodology that the agency introduced in its draft risk evaluations, and that has been criticized as inappropriate. EPA identified 22 key sources that were taken forward to data extraction and evaluation. There continues to be a lack of clarity on how EPA chose and evaluated the key sources.

We strongly recommend against utilizing a ”TSCA systematic review method” which does not meet the requirements of TSCA and raises serious concerns about bias in the evidence base of EPA’s risk evaluations. EPA’s methodological problems are significant and create bias in EPA’s risk conclusions. EPA is not systematically reviewing the studies it relies on in the draft risk evaluations, and it is inappropriately excluding a significant proportion of the body of evidence. Thus, EPA is not systematically reviewing the studies relied on in the draft risk evaluation, despite its misleading terminology.

In the Institute of Medicine report “*Finding What Works in Health Care: Standards for Systematic Review*,” a systematic review is defined 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.*”²¹ There are 21 IOM standards that cover the entire systematic review process that if adhered to, result in a “*scientifically valid,*

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 at: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0437-0001>.

²¹ IOM (Institute of Medicine). 2011. *Finding What Works in Health Care: Standards for Systematic Reviews*. Washington, DC: The National Academies Press.

transparent, and reproducible systematic review."²² These IOM methodological standards have been incorporated into validated systematic review approaches used currently on environmental health topics, such as the Navigation Guide²³ and the National Toxicology Program, Office of Health Assessment and Translation.²⁴ The World Health Organization is currently utilizing the Navigation Guide methodology to assess the global burden of work-related injury and disease.²⁵ Further, these methods have been peer-reviewed, validated and have been recommended for use previously by the National Academies of Science. EPA should use a credible systematic review method by following one of the established methods (e.g., Woodruff and Sutton 2014; NTP 2019).²⁶

EPA must revisit and fully evaluate risks, and EPA must act promptly to address unreasonable health risks from methylene chloride exposures from consumer and commercial uses.

In conclusion, methylene chloride is dangerous to consumers, bystanders, and workers, and primary prevention via restriction of use for *both* consumer and commercial uses is the most effective way to remove unreasonable risks and prevent further unnecessary tragedies.²⁷ EPA has not presented an adequate justification for excluding commercial uses from the ban. As required by TSCA, EPA must conduct a thorough risk evaluation that examines risk to all potentially susceptible and highly exposed populations, including workers occupationally exposed through commercial uses.²⁸ EPA has failed to conduct a *bona fide* systematic review and thus EPA has not fully evaluated the evidence for a risk determination as required by TSCA. EPA should improve its systematic review methods and EPA should rely on an established method developed by the Navigation Guide or the National Toxicology Program.

²² 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>.

²³ 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.

²⁴ 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.

²⁵ 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. Available at: <https://doi.org/10.1016/j.envint.2018.06.005>.

²⁶ 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. Available at: <https://doi.org/10.17226/25610>.

²⁷ US EPA (2017). Methylene Chloride in Commercial Furniture Refinishing. Comment submitted by Academics, Scientists and Clinicians on behalf of Veena Singla, PhD, Program on Reproductive Health and the Environment, University of California, San Francisco et al. Available at: <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0139-0012>.

²⁸ Koman, P. D., Singla, V., Lam, J. & Woodruff, T. J. Population susceptibility: A vital consideration in chemical risk evaluation under the Lautenberg Toxic Substances Control Act. *PLOS Biol*. 17, e3000372 (2019).

Widespread exposures to methylene chloride are avoidable as less toxic and equally effective alternatives to this risky chemical already exist.²⁹ Unless EPA acts to finalize a full ban for *both* consumer and commercial uses, avoidable deaths and other debilitating, long-term health consequences that result from these exposures will continue.

Therefore, I respectfully urge EPA to revisit the draft risk evaluation for methylene chloride in light of these comments, and the comments of other public health stakeholders, and revise its analyses and approaches accordingly, while simultaneously pressing forward as quickly as possible with the ban for *both* consumer and commercial uses.

Sincerely,

A handwritten signature in black ink, appearing to read "Georges C. Benjamin". The signature is fluid and cursive, with the first name being the most prominent.

Georges C. Benjamin, MD
Executive Director

²⁹ California Department of Public Health. "Occupational Health Hazard Alert: Methylene Chloride in Paint Strippers and Bathtub Refinishing." Available at: <https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/HESIS/CDPH%20Document%20Library/MethyleneChlorideAlert.pdf>.