May 28, 2019

Comments from Academics, Scientists and Clinicians on a Commercial Paint and Coating Removal Training, Certification and Limited Access Program for Methylene Chloride

Submitted online via Regulations.gov to docket EPA-HQ-OPPT-2018-0844

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 EPA's Advance Notice of Proposed Rulemaking (ANPRM) on a potential training, certification, and limited access program for methylene chloride use for paint and coating removal in commercial settings.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 Methylene chloride has caused multiple fatalities in the last 2 years alone.⁴

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.⁵ In a 2018 statement, EPA announced that it intended to finalize the 2017 proposed rule.⁶ Instead, in March 2019, EPA finalized a rule that only prohibited consumer uses, leaving the commercial uses unaddressed.⁷ Now in this ANPRM, EPA is re-assessing the feasibility of a training, certification, and limited access program for commercial uses of methylene chloride paint and coating removal, options which were already explored and rejected in the Agency's previous analysis because they failed to mitigate unreasonable risks.⁸ By delaying action on a commercial ban, the agency is leaving workers exposed to unreasonable health risks.⁹ This is contrary to the mandate under the law, which states that

¹ 84 FR 11466

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

⁵ 82 FR 7464

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

^{7 84} FR 11466

⁸² FR 7464 pg. 7424

⁹ 82 FR 7464 pg. 8

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."¹⁰

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 indicates that EPA should include commercial furniture refinishing in the ban.¹¹ The science was clear in 2017 and it is clear now; the only way to properly address unreasonable risks is to prohibit methylene chloride paint and coating removers in commercial and consumer settings. A limited access, training and certification program for commercial uses of methylene chloride is insufficient to mitigate unreasonable risk. Methylene chloride is dangerous and restriction of use for *both* consumer and commercial uses is the most effective way to remove unreasonable risks and prevent further unnecessary tragedies.

Our comments address the following main points:

- 1. EPA found that commercial uses of methylene chloride pose an unreasonable risk to workers in 2017.
- 2. Training, certification and limited access are inadequate to remove unreasonable risks of methylene chloride.
- 3. EPA should finalize a rule to prohibit methylene chloride in commercial uses, including furniture refinishing.

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,

Swati Rayasam, MSc Science Associate Program on Reproductive Health and the Environment University of California, San Francisco

Veena Singla, PhD Associate Director, Science and Policy Program on Reproductive Health and the Environment University of California, San Francisco

Tracey Woodruff, PhD, MPH Director Program on Reproductive Health and the Environment University of California, San Francisco

¹⁰ 15 USC §2605(a)

¹¹ UCSF PRHE, et al. (2017) Comments from Academics, Scientists and Clinicians on the Methylene Chloride in Commercial Furniture Refinishing. Available: https://prhe.ucsf.edu/sites/g/files/tkssra341/f/wysiwyg/2017%2011%2012%20UCSF%20comments%20methylen e%20chloride%20FINAL.pdf

Mary Gant, MSc Policy Analyst (retired) National Institute of Environmental Health Sciences

Annie Hoang Medical student University of California, San Francisco

Elizabeth Hom, PhD, MPH Postdoctoral Scholar Program on Reproductive Health and the Environment University of California, San Francisco

Jyotsna S. Jagai, MS, MPH, PhD Research Assistant Professor University of Illinois at Chicago

Ulrike Luderer, MD, PhD, MPH Professor and Director, Center for Occupational and Environmental Health University of California, Irvine

Rachel Morello-Frosch, PhD, MPH Professor, School of Public Health University of California, Berkeley

Ted Schettler MD, MPH Science Director Science and Environmental Health Network

Patrice Sutton, MPH Research Scientist Program on Reproductive Health and the Environment University of California, San Francisco

DETAILED COMMENTS:

1. EPA found that commercial uses of methylene chloride pose an unreasonable risk to workers in **2017**.

EPA did not prohibit commercial uses of methylene chloride in the March 2019 rule,¹² despite its clear findings of significant risks of concern for occupational exposure, estimated to affect about 32,600 workers total, in the 2014 final risk assessment.¹³ The 2014 risk assessment had gone through the public comment and peer-review process before being finalized.^{14, 15}

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."¹⁶ (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.¹⁷ It found that occupational cancer risks were consistently greater than the denoted allowable risk,¹⁸ and for contractors and furniture refinishers specifically, excess occupational cancer risks due to chronic exposure exceeded the threshold even with personal protective equipment (PPE).¹⁹ In fact, across many industries, Margins of Exposure (MOEs) indicating risk occurred with the highest achievable level of respiratory protection.²⁰ EPA therefore found that methylene chloride when used in paint and coating removal posed an unreasonable risk to workers.²¹

While the 2014 assessment also found unreasonable risks for consumers, the worker exposures consistently exceeded consumer exposures. Therefore, it both defies logic and the mandate of the law that EPA's 2019 final rule restricted only consumer uses of methylene chloride, when the greatest risks are to workers.

¹² 84 FR 11466

¹³ EPA (2014) TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use. CASRN 75-09-2. Office of Chemical Safety and Pollution Prevention.

^{14 78} FR 1856

¹⁵ EPA. Risk Evaluation for Methylene Chloride. Available: <u>https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-methylene-chloride-0</u>

¹⁶ 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.

¹⁷ 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.

¹⁸ Ibid.

¹⁹ 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.

²⁰ 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.

²¹ 82 FR 7464 pg. 7478

2. Training, certification and limited access are inadequate to remove unreasonable risks of methylene chloride.

Workers face a number of obstacles with regard to workplace safety and are largely at the mercy of their employers. Therefore, they may not be in a position to influence their employer's decisions about the type of paint removal method, or ensure that their employer provides appropriate PPE and an adequate respiratory protection program.²² EPA previously evaluated the option of a training and certification program to mitigate unreasonable risks from methylene chloride paint removers in 2017 and stated:

"EPA viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach."²³

However, in the advanced notice of proposed rulemaking,²⁴ EPA states that:

"... workplaces that have robust environment, safety and health protection programs and are in compliance with OSHA's methylene chloride standard (which contains requirements for the use of engineering controls, personal protective equipment, training, and other requirements to protect employees from methylene chloride exposure) are likely to address any risks EPA could potentially find to be present from exposure to methylene chloride during commercial paint and coating removal so that they are no longer unreasonable." (emphasis added)

In the above quote, EPA indicates that OSHA's methylene chloride standard (1910.1052)²⁵ would be sufficient to address unreasonable risks posed by methylene chloride. This is incorrect for several reasons.

First, the assertion that workplaces are in compliance with OSHA's standard is incorrect. In the 2017 proposed ruling, EPA found that industries where paint and coating removal was conducted were regularly in violation of the OSHA limit of 25 ppm and sometimes in gross excess of it.²⁶ 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.²⁷ The most common violations are listed below:²⁸

• Each employer whose employees are exposed to methylene chloride shall perform initial exposure monitoring to determine each affected employee's exposure

²² 82 FR 7464

²³ 82 FR 7464 pg. 7424

²⁴ 84 FR 11466 pg. 15

²⁵ 29 CFR 1910.1052

²⁶ 82 FR 7464 pg. 7477

²⁷ 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

²⁸ 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

- 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.
- 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.

Importantly, OSHA did not find that compliance with the standard improved over time.²⁹ This indicates that employers are regularly out of complicance with the OSHA standard, and that they are not likely to change in the future—directly contradicting EPA's assertion of OSHA compliance.

Second, EPA's assertion that compliance with the OSHA standard would remove unreasonable risks is also incorrect. The standards established by EPA for 'acceptable' cancer risks are 1 in 10 million, or 1 in a million conservatively.^{30, 31, 32, 33, 34} 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," ^{35, 36} — 3,200 times greater than the 1 in a million standard.

The OSHA standard has an appreciable allowance of cancer risk that TSCA deems unreasonable, making OSHA's standard insufficient.³⁷ In the 2017 proposed ruling EPA concluded, based on the cancer risk alone for commercial users and bystanders, the "proposed determination is that chronic methylene chloride exposures during paint and coating removal present unreasonable risks."³⁸

Third, there are considerable gaps in the OSHA standard that leave some particularly vulnerable workers unprotected. Take for example Drew Wynne, a 31-year-old owner of a startup coffee company in Charleston, South Carolina. 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.³⁹ As a small

²⁹ 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-finalfor-publication-May-2010.pdf

³⁰ 82 FR 7464 pg. 7471

³¹ 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

 ³² Congressional Research Service. (1998) "Pesticide Legislation: Food Quality Protection Act of 1996 (P.L. 104-170)" pg. CRS-13 Available: <u>https://www.everycrsreport.com/files/19980911_96-</u>759_cae29ffc2edda2c1edd8ea3578133e1cf1d09374.pdf

³³ 82 FR 44254 pg.

³⁴ EPA (1999) "Residual Risk Report to Congress." Pg. 105 Available: <u>https://www.epa.gov/sites/production/files/2013-08/documents/risk_rep.pdf</u>

³⁵ 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-finalfor-publication-May-2010.pdf

³⁶ 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.

³⁷ 82 FR 7464 pg. 7471

³⁸ 82 FR 7464 pg. 7478

³⁹ Friedman L (2019) "E.P.A., Scaling Back Proposed Ban, Plans Limits on Deadly Chemical in Paint Strippers." New York Times. Available: <u>https://www.nytimes.com/2019/03/15/climate/epa-paint-stripper-methylenechloride.html</u>

startup company, he was not covered by OSHA; however it is implausible to rule his death as a consumer fatality, because it was likely a position as a business owner that led him to purchase and use the paint remover that eventually killed him. This discrepancy leaves out some of the most vulnerable worker populations, small businesses. Additionally, restriction of use for consumers alone would not have likely protected him as even 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."⁴⁰

The OSHA standard should not be looked to for guidance 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.

In the ANPRM,⁴¹ EPA also proposes the UK certification exception to the European Union ban⁴² on methylene chloride as a possible option. However, the UK program operates under different regulatory requirements. EPA by law is required to follow the mandates of TSCA, which demands that EPA act to remove unreasonable risks. Therefore, even if such a certification program is allowed in the UK, it would not be allowed under TSCA in the US.

Others have also highlighted the drawbacks of a training/certification program and the inadequacy of PPE. (See comments from Drs. Dennis Shusterman, Robert Harrison et al., also submitted to the docket).

3. EPA should finalize a rule to prohibit methylene chloride in commercial uses, including furniture refinishing.

Widespread exposures to methylene chloride are avoidable as less toxic and equally effective alternatives to this risky chemical already exist.⁴³ Methylene chloride has been effectively banned in the European Union since 2012.⁴⁴ Unless EPA acts to finalize a ban in paint and coating removal uses and commercial settings, avoidable deaths and other debilitating, long-term health consequences that result from these exposures will continue.

Our comprehensive analysis found 83 documented methylene chloride fatalities since 1980 and the majority (87%) of them have occurred in occupational settings. (Appendix A) Specifically, paint removers have been responsible for the most fatalities (63%) of all methylene chloride product types. (Appendix A)

Prohibition of methylene chloride use in commercial settings is the most effective way to remove these risks of concern and protect workers, consumers, and bystanders. EPA has already found that methylene

⁴⁰ 82 FR 7464 pg. 7479

⁴¹ 84 FR 11466 pg. 12

⁴² UK Department for Environment, Food and Rural Affairs (2014). "The Reach Enforcement (Amendment) Regulations 2014 (SI 2014/2882)." Available: http://www.legislation.gov.uk/uksi/2014/2882/made.

⁴³ California Department of Public Health. "Occupational Health Hazard Alert: Methylene Chloride in Paint Strippers and Bathtub Refinishing." Available:

https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/OHB/HESIS/CDPH%20Document%20Library/MethyleneChl orideAlert.pdf

⁴⁴ ECHA. (2012) "Annex XVII to REACH - Conditions of restriction. Entry 59 Dichloromethane containing Paint Strippers." Available: https://echa.europa.eu/documents/10162/0ea58491-bb76-4a47-b1d2-36faa1e0f290

chloride poses an unreasonable risk based on its own definition, and it is therefore required by law to address it. Therefore, we strongly urge EPA to finalize as quickly as possible a rule to prohibit methylene chloride in commercial settings. Additionally, as recommended in our previous comments,⁴⁵ EPA should include commercial furniture refinishing in the prohibition.

 ⁴⁵ UCSF PRHE, et al. (2017) Comments from Academics, Scientists and Clinicians on the Methylene Chloride in Commercial Furniture Refinishing. Available: https://prhe.ucsf.edu/sites/g/files/tkssra341/f/wysiwyg/2017%2011%2012%20UCSF%20comments%20methylen e%20chloride%20FINAL.pdf

APPENDIX A: Methylene Chloride Fatalities in the US from 1980-2018 and Policy Implications, UCSF Program on Reproductive Health and the Environment (Poster)



Methylene Chloride Fatalities in the US from 1980-2018 and Policy Implications

Annie Hoang¹, Kathleen Fagan², Robert Harrison³, Dennis Shusterman³, Danielle Fries⁴, and Veena Singla⁴ ¹School of Medicine, University of California, San Francisco, California, USA ; ²OSHA, Office of Occupational Medicine and Nursing, Washington DC; ³Division of Occupational & Environmental Medicine, University of California, San Francisco, California, USA; ⁴Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California, San Francisco, California, USA

Background

- Methylene chloride or dichloromethane (CAS No. 75-09-2) is an organic solvent widely found in common consumer and industrial products including paint strippers, metal cleaners, degreasing agents, adhesives, and spray paints.
- Highly suggestive evidence from animal and human data has led the chemical to be classified as likely to be a human carcinogen.
- In 2012, the Centers for Disease Control and Prevention (CDC) reported that methylene chloride was responsible for 13 deaths from 2000-2011 among professional bathtub refinishers who used paint strippers.

Gaps in Knowledge

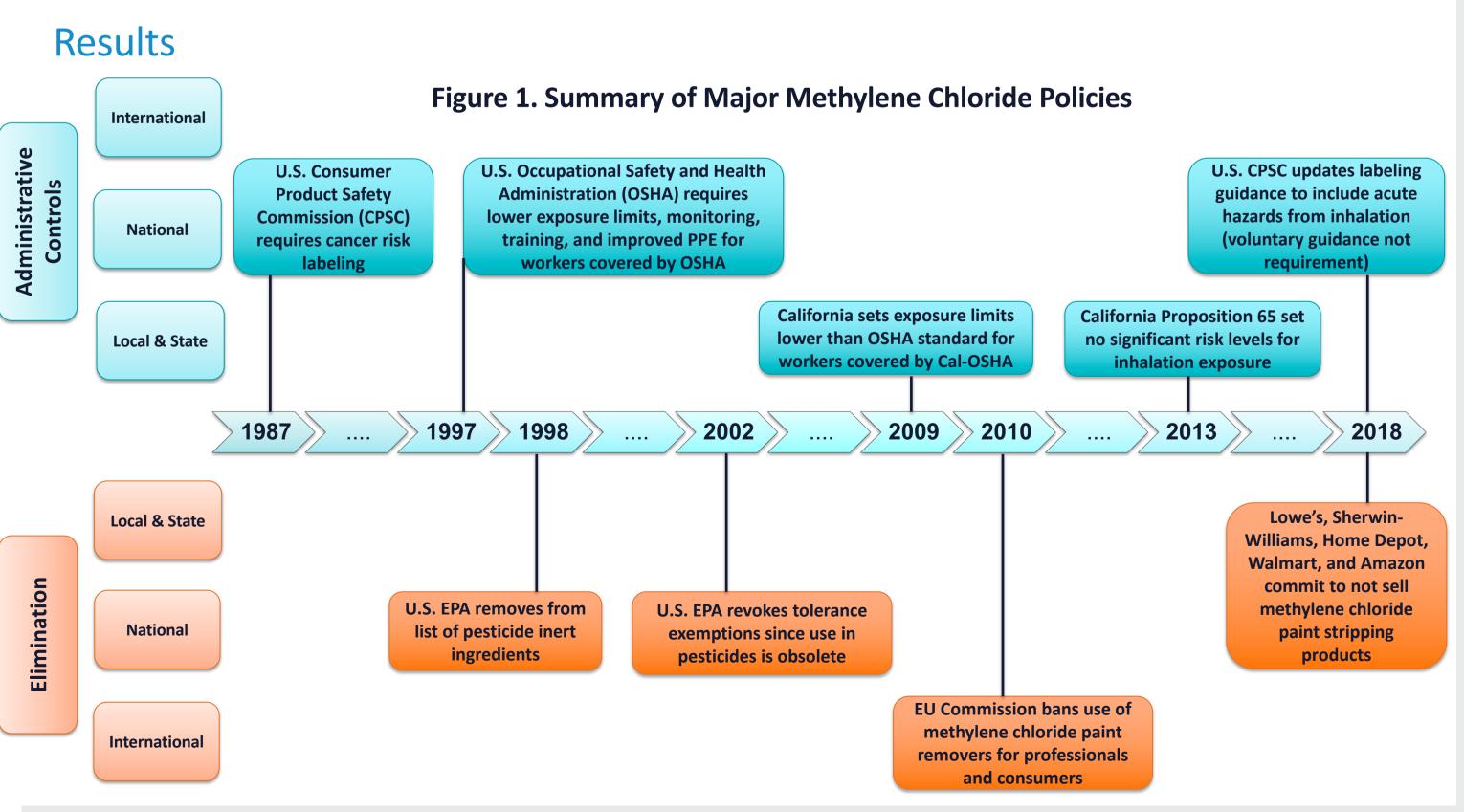
- Other than the CDC report on a small subset of workers, there has been no other systematic review on worker or consumer deaths related to the use of methylene chloride.
- Although there have been updates to methylene chloride safety and labeling standards for workers and consumers since 1987, there has been no analysis on whether these policy changes have been effective in preventing or reducing the number of fatalities.

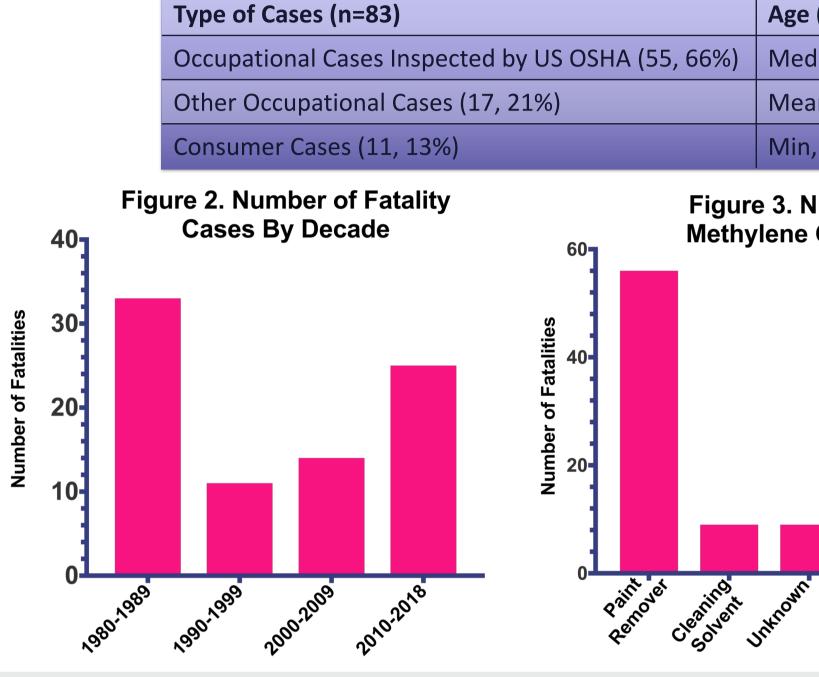
Research Question

- What are the incidents, circumstances, and demographic patterns of methylene chloride fatalities in the US? • How have federal hazard communication, worker protection, and other policies influenced fatality patterns?

Methods

- Mortality data were tabulated from surveillance systems, case reports in the peer-reviewed literature, legal databases, news reports, and government sources. Policy language regulating methylene chloride exposure in the US and the EU were compiled.
- We performed systematic searches in 10 databases including PubMed and Lexis Nexis. Additionally, we requested data from the American Association of Poison Control Centers and the US Consumer Product Safety Commission. Fatality incidents were recorded with case report details in REDCap, with data QA/QC performed by an independent reviewer.







Conclusion

Comprehensive case finding and review of data on 83 methylene chloride fatalities revealed a persistent pattern of mortality related to use in occupational and consumer settings. A policy approach focused on hazard elimination and safer substitutes would be more effective in addressing methylene chloride risks compared to the current reliance on hazard communication and administrative controls.

Table 1.

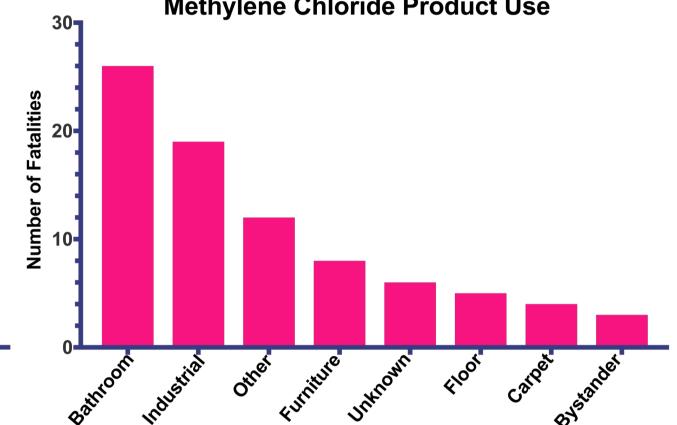


Program on Reproductive Health and the Environmer

Demographics of Fatalities			
(n=66)		Sex (n=74)	Race/Ethnicity (n=45)
lian, IQR	31 (24, 46)	Female (5, 7%)	White (29, 64%)
in, SD	36 (14)	Male (69, 93%)	Black (7, 16%)
, Max	14, 80		Hispanic (9, 20%)

Figure 3. Number of Fatalities By Methylene Chloride Product Type

Figure 4. Number of Fatalities By Setting of Methylene Chloride Product Use



Funding

This work was supported by grants from the UCSF School of Medicine and the JPB Foundation.