Methylene Chloride Proposed Rulemaking under TSCA Section 6(a)

Public Webinar

RIN 2070-AK70

June 7, 2023

Office of Chemical Safety and Pollution Prevention

U.S. Environmental Protection Agency

For more information: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride

Agenda

- Purpose and Overview of Rulemaking
- Methylene Chloride Background
- TSCA Regulatory Toolbox
- Developing Effective Regulations
- Proposed Regulation
- Alternative Regulatory Action
- Benefits
- Requests for Comment and Opportunities for Engagement
- Next Steps
- Additional Resources

EPA's Proposal and the Toxics Substances Control Act (TSCA)

- In June 2016, Congress amended the Toxic Substances Control Act (TSCA)
  - Amended TSCA requires EPA to assess and address risks from chemicals currently in commerce
  - Amended TSCA imposes statutory timeframes for regulation
  - Provides protection for the public and predictability for the regulated community
- Methylene Chloride was identified in 2016 as one of the first chemicals for risk evaluation
  - 2020 Risk Evaluation followed a public draft and peer review process
  - EPA determined that methylene chloride presents an unreasonable risk under its conditions of use

Purpose and Overview Of Rulemaking

- The proposal addresses the unreasonable risk identified in the TSCA section 6 risk evaluation of methylene chloride (June 2020) which assessed all uses subject to TSCA
- The proposed rule, when finalized, will prevent consumer and occupational deaths and illness while ensuring identified essential uses can continue safely where possible
  - EPA's proposal would allow select uses to continue with strict workplace protections, while prohibiting all remaining uses
- EPA's proposed rule is open for public comment until **July 3**, 2023
- EPA will then consider public comments and finalize new regulations of methylene chloride under TSCA

Methylene Chloride Background

- Methylene chloride is a volatile chemical used in a wide range of industrial, commercial, and consumer applications
- Acute methylene chloride exposure resulted in at least 85 occupational deaths in the U.S. between 1985-2018, with the most recent fatality in June 2020
  - Methylene chloride is an acutely lethal neurotoxicant, and chronic exposure can affect liver function and cause cancer
- EPA found that unreasonable risk from methylene chloride is driven by risks to workers, consumers, and bystanders for 52 of the 53 conditions of use

Methylene Chloride Risk Evaluation: Unreasonable Risks for Workers and Consumers

Chronic liver effects from inhalation and dermal exposures

Acute central nervous system effects from inhalation and dermal exposures

Chronic cancer effects from inhalation exposures

- **Chronic liver effects are the most sensitive endpoint driving unreasonable risk**
- Acute central nervous system effects were also considered because relatively small increases in exposure can range from blurred vision to more severe effects, including death
- No unreasonable risk to environment

TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
  - Distributors
  - Manufacturers (including importers) and processors (e.g., formulators)
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
  - Under TSCA, EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
  - These authorities allow EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers

TSCA Section 6(a) Regulatory Options (cont.)

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture (includes import), processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

The section 6(a) menu of regulatory options can be applied alone or in combination.

Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement during risk management helps EPA develop practical and protective regulations
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Consultation and coordination with other Federal agencies
  - OSHA, NIOSH, and CPSC to promote a consistent approach, facilitate compliance, and avoid duplicative requirements
  - DOD and NASA to determine uses that might affect U.S. critical infrastructure or national security and to facilitate compliance
- Extensive dialogue helps people understand risk evaluation findings, the TSCA risk management process, and available options for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers

Developing Effective Regulations

EPA's priority is to address identified unreasonable risks

- TSCA additionally requires EPA's proposal to consider:
  - Effects and magnitude of exposure to human health and the environment
    - For this, EPA included potential risks from the ambient air pathway to fenceline communities (EPA's analysis identified a small number of facilities) and potential risks from water pathway to fenceline communities
  - Benefits of a chemical substance
  - Economic consequences of the rule
  - Availability of alternatives
- EPA's proposal is based on best available science and reasonably available information

Developing Effective Regulations (cont.)

EPA's goal is to promulgate regulations that are both practical and protective. EPA's proposal:

- Presents a familiar regulatory framework for occupational and consumer exposure
- Ensures that consumers do not have access to methylene chloride-containing products
- Prohibits certain occupational uses where EPA determined an inability to comply with the proposed WCPP requirements
- Meets TSCA requirement to address risk to the extent necessary so that it is no longer unreasonable, including risk to PESS
- Requires recordkeeping to ensure rule is enforceable

Developing Effective Regulations (cont.)

- EPA requests comment on all elements of the proposed and alternative regulatory action in the proposed rulemaking
- Based on consideration of new or additional information submitted to EPA on the proposed rule, EPA may in the final rule modify elements of the proposed regulatory action
- Public comments could result in changes to elements of the proposed regulatory actions when this rule is finalized
  - Timelines for phase out could be lengthened or shortened
  - WCPP could have conditions added, modified, or eliminated

The Proposed Regulation

EPA's proposed rule would:

- Prohibit manufacture, processing, and distribution of methylene chloride for all consumer uses
- Prohibit most industrial and commercial uses
- Require a Workplace Chemical Protection Program (WCPP) for certain uses
- Include two critical use exemptions under TSCA section 6(g)
- Establish recordkeeping and downstream notification requirements

Proposed Regulation: Consumer Uses

- EPA determined methylene chloride could not be used safely in consumer products
  - TSCA allows EPA to regulate upstream of consumers to address unreasonable risk
  - The proposed rule would prohibit manufacturing (including import), processing, and distribution for consumer use, and provides time for retailers to phase out their consumer product inventory
    - EPA concluded that some alternate approaches were not feasible. As an example, a protective weight fraction limit would be so low that it would essentially function as a prohibition
  - In almost all cases, alternatives are available

Proposed Regulation: Consumer Uses

EPA is prohibiting manufacture, processing, and distribution in commerce of methylene chloride for all consumer use, including:

- Solvent in aerosol degreasers/cleaners
- Adhesives and sealants
- Brush cleaners for paints and coatings
- Adhesive and caulk removers
- Metal degreasers
- Automotive care products (functional fluids for air conditioners)
- Automotive care products (degreasers)
- Lubricants and greases
- Cold pipe insulation
- Arts, crafts, and hobby materials glue
- Anti-spatter welding aerosol
- Carbon removers and other brush cleaners

Proposed Regulation: Industrial and Commercial Use

- EPA considers each use individually including factors such as:
  - Aspects of particular work activities that may create challenges for Workplace Chemical Protection Program (WCPP) implementation (e.g., challenges with meeting the ECEL, need to develop an industrial hygiene program)
  - Potential for regrettable substitution, among other factors.
- Uncertainty about WCPP implementation is a driving factor
- Staggered implementation within the supply chain to assure orderly phase out

Proposed Regulation: Industrial and Commercial Use

All industrial and commercial uses would be prohibited, except for uses covered by WCPP. Conditions of use that would be prohibited include industrial and commercial use of methylene chloride for:

- Solvent for batch vapor degreasing
- Solvent for in-line vapor degreasing
- Solvent for cold cleaning
- Solvent for aerosol spray degreaser/cleaner
- Adhesives, sealants and caulks
- Paints and coatings
- Paint and coating removers
- Adhesive and caulk removers
- Metal degreasers
- Finishing products for fabric, textiles and leather
- Automotive care products
- Apparel and footwear care products
- Spot removers for apparel and textiles
- lubricants and greases
- Aerosol degreasers and cleaners
- Non-aerosol degreasers and cleaners
- Cold pipe insulations
- Processing aid
- Propellant and blowing agent
- Electrical equipment, appliance, and component manufacturing
- Plastic and rubber products manufacturing
- Cellulose triacetate film production
- Anti-spatter welding aerosol
- Toys, playground and sporting equipment
- Lithographic printing plate cleaner

Proposed Regulation: Workplace Chemical Protection Program

- A Workplace Chemical Protection Program (WCPP) protects people from unreasonable risk posed by occupational exposures from certain conditions of use
  - Workers are one of the potentially exposed or susceptible subpopulations (PESS) under TSCA
  - EPA consulted with OSHA and NIOSH coordinated on WCPP development, and aligned requirements where possible
- EPA considers multiple factors in deciding risk management for industrial and commercial conditions of use
- Uncertainty regarding ability to comply with an ECEL or preventing direct dermal contact can influence whether a condition of use is considered to be a candidate for WCPP or whether prohibition is more appropriate

Proposed Regulation: Workplace Chemical Protection Program (cont.)

- Workplace Chemical Protection Program (WCPP)
  - Proposed inhalation exposure limits (Existing Chemical Exposure Limit, or ECEL):
    - 8-hour time-weighted average (TWA): 2 ppm (OSHA is 25 ppm)
    - 15-minute TWA: 16 ppm (OSHA is 125 ppm)
  - Additionally includes monitoring, recordkeeping requirements, dermal requirements
  - Provides flexibility for preventing exceedances of the identified EPA exposure limit and preventing direct dermal contact
  - Aligns with existing OSHA requirements wherever possible

Proposed Regulation: Industrial and Commercial Uses Continuing with Worker Protections

- Uses that are not prohibited would continue with strong, achievable, worker protections:
  - Manufacturing (Domestic)
  - Manufacturing (Import)
  - Processing: processing as a reactant (AIM Act refrigerants)
  - Processing: incorporation into a formulation, mixture, or reaction products
  - Processing: recycling
  - Processing: repackaging
  - Industrial and commercial use as a laboratory chemical
  - Industrial and commercial use as a paint and coating remover from safety critical, corrosion-sensitive components of aircraft and spacecraft owned or operated by DOD, NASA, DHS, FAA
  - Industrial or commercial use as a bonding agent in the production of specialty batteries for military or space applications
  - Disposal

Proposed Regulation: Workplace Chemical Protection Program (cont.)

- The methylene chloride WCPP reduces compliance burdens by following a familiar framework:
  - Initial monitoring to determine frequency of periodic monitoring
  - Periodic monitoring every 3 months, 6 months, or 5 years, based on ECEL, ECEL action level, and EPA STEL
  - Requirements to reduce exposures based on the NIOSH hierarchy of controls
  - Respirator selection criteria to protect workers from any remaining risks
- EPA's WCPP applies to Owners or Operators and Potentially Exposed Persons
  - Broader definition than "employers" and "employees"

Proposed Regulation: Exemptions Under TSCA Section 6(g)

- Section 6(g)(1)(B) permits an exemption if EPA finds that compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt:
  - national economy
  - national security
  - critical infrastructure
- EPA is proposing:
  - 10-year exemption for commercial aviation and commercial aerospace applications from the proposed prohibition on the use of methylene chloride in commercial paint and coating removal
  - 10-year exemption for emergency uses of methylene chloride in furtherance of NASA's mission
  - Exempt uses must document efforts to comply with provisions of the WCPP

Proposed Requirements for Recordkeeping and Downstream Notification

- Downstream notification of the prohibitions would be carried out through SDS updates
  - For conditions of use that would not be prohibited under the proposed regulation, the Safety Data Sheets (SDSs) must be updated by adding information on prohibitions and relevant dates
  - Downstream notification is to spread awareness throughout the supply chain of the restrictions on methylene chloride under TSCA as well as provide information to commercial end users about allowable uses of methylene chloride
- Recordkeeping requirements include maintenance of normal business records and records related to WCPP monitoring and compliance

Proposed Effective Dates

- Prohibitions related to consumer and commercial uses would become effective:
  - 3 months for manufacture, 6 months for processors, 9 months for distribution to retailers, and 12 months for retailers after publication date of final rule
- Compliance with a WCPP for the uses specified in slide 20 would be required:
  - 6 months for monitoring, 9 months for designating a regulated area, 12 months for implementation of an exposure control plan after publication date of final rule

Primary Alternative Regulatory Action

- TSCA requires an alternative regulatory action to be considered in addition to the proposal
- The primary alternative regulatory action considered is a combination of prohibition and WCPP
- Though it is similar in some ways to the proposed action:
  - There are more conditions of use considered for the WCPP
  - There are longer compliance timeframes for prohibition (beginning at 12 months) and the WCPP (beginning at 12 months)
- EPA has less certainty that these uses could implement the WCPP successfully such that unreasonable risk is addressed; requests comment

Primary Alternative Regulatory Action Applicability

- Would include 8 additional uses under WCPP rather than prohibition:
  - Industrial and commercial use in finishing products for fabric, textiles, and leather
  - Industrial and commercial use as solvent that becomes part of a formulation or mixture
  - Industrial and commercial use as a processing aid
  - Industrial and commercial use for electrical equipment, appliance, and component manufacturing
  - Industrial and commercial use for plastic and rubber products manufacturing
  - Industrial and commercial use in cellulose triacetate film production
  - Industrial and commercial use for oil and gas drilling, extraction, and support activities
  - Industrial and commercial use of paint and coating remover from safety-critical, corrosion-sensitive components of aircraft owned or operated by air carriers or commercial operators
- EPA requests comment on the degree to which these conditions of use may be able to comply with the WCPP

Benefits of Proposed Rule

- ✓ Would address unreasonable risks for consumers and bystanders
- ✓ Would address unreasonable risks for workers and occupational non-users
- ✓ Would blanket the majority of facilities, addressing the potential exposures to the neighboring communities
- ✓ Would directly address conditions of use that have previously resulted in fatalities
- ✓ Would provide regulated community with confidence in a protected and healthier workforce

Request for Comments

EPA is requesting comments and substantiative information regarding several topics, including:

- The Workplace Chemical Protection Program (WCPP) and its various components (e.g., monitoring frequency, engineering controls, process changes)
- Feasibility of complying with and monitoring for an Existing Chemical Exposure Limit (ECEL) of 2 ppm
- Timeframes for implementation of the requirements
- Alternatives to methylene chloride as a processing aid
- What regulatory flexibilities may be afforded to certain uses under the WCPP to reduce burden with compliance
- Data on whether additional flexibilities for a compliance timeframe for furniture refinishing is needed as well as the availability of alternatives for the industry
- The need for a *de minimis* level for formulations containing methylene chloride be afforded to certain uses under the WCPP
- Any uses that are currently proposed to be prohibited that may need a longer timeframe or could meet the requirements of the WCPP

Types of Information that Best Informs Comments

Examples of potentially useful information for key areas of uncertainty should include information within the last 20 years containing:

- Personal breathing zone and/or area monitoring data
- Process emission factors
- Descriptions of commercial worker activities and associated sources of exposure
- Product formulation information
- Relevant unpublished data

Next Steps

Process Step	Date
Publication of proposed rule on methylene chloride in docket (EPA-HQ-OPPT-2020-0465) and open comment period	May 3, 2023
Closure of comment period: EPA will review and consider new information submitted	July 3, 2023
Publication of Final Rule for methylene chloride (estimated)	2024
Prohibitions would begin 90 days after date of publication of final rule (estimated)	2024

Additional Resources

- Risk management for methylene chloride: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride
- Methylene Chloride risk evaluation, supplemental risk evaluation materials, and proposed rulemaking are in dockets EPA-HQ-OPPT-2019-0437, EPA-HQ-OPPT-2016-0742, and EPA-HQ-OPPT-2020-0465 respectively, and may be accessed through www.regulations.gov
- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Chemicals Undergoing Risk Evaluation under TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities

Contact Us

- All comments in order to be considered should be submitted to the docket at EPA-HQ-OPPT-2020-0465
- For general questions, email EPA at MethyleneChlorideTSCA@epa.gov