American Chemistry Council

NAVIGATING REGULATORY CHANGES:

UNDERSTANDING THE NEW TSCA REGULATIONS FOR METHYLENE CHLORIDE

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- Individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- Individual company data on costs, production, capacity, inventories, sales, etc.; and
- Industry pricing policies, price levels, price changes, differentials, etc.

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- Rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

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- Matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

Housekeeping

Questions? Ask them in the Chat

Webinar slides and recording will be shared and made available online

Technical Support during Webinar

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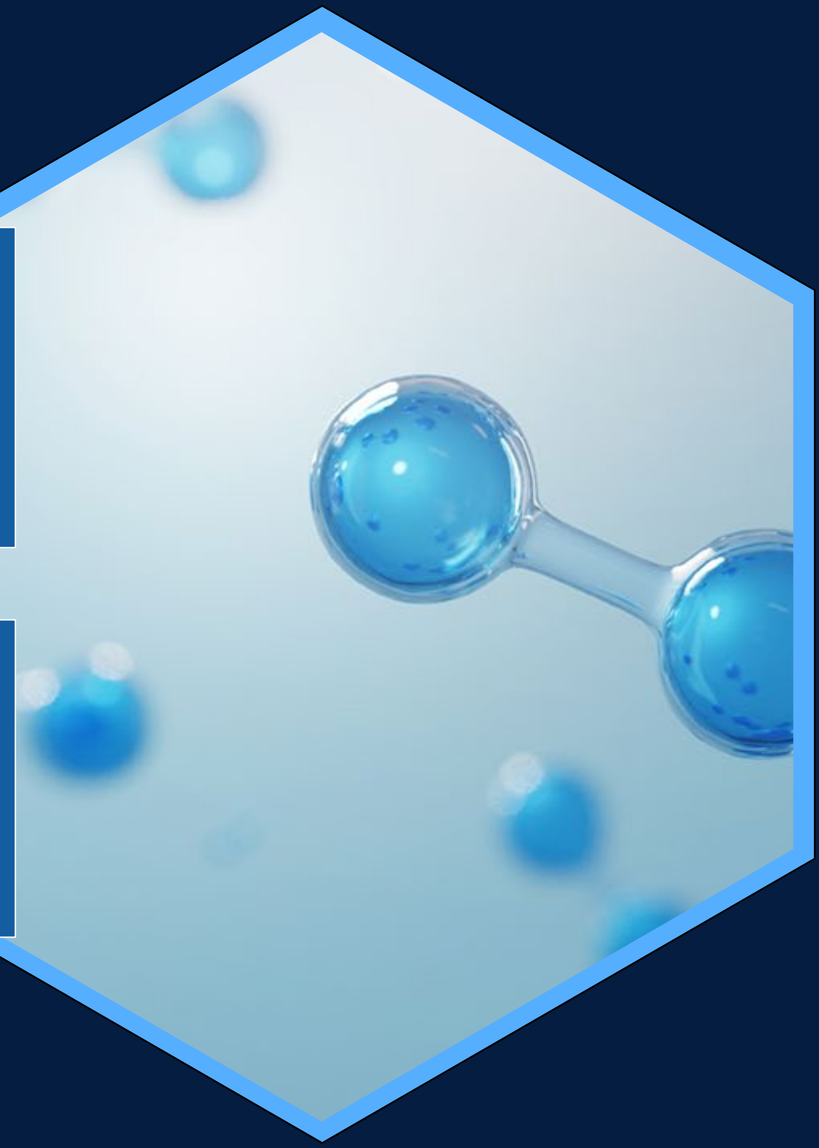

WEBINAR OBJECTIVES

- Understand the new TSCA regulations for MC
- Explore the impact on the chlorine value chain
- Discuss resources for compliance

ABOUT US

American Chemistry Council

The American Chemistry Council (ACC) represents more than 190 companies engaged in the business of chemistry—an innovative, economic growth engine that is helping to solve the biggest challenges facing our country and the world.

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The Chlorine Panel, operating under the umbrella of ACC, represents major producers and users of chlorine in North America. The Panel works to promote and protect the sustainability of chlorine chemistry processes, products and applications in accordance with the principles of Responsible Care®.

METHYLENE CHLORIDE

Brief Description

Methylene Chloride, also known as dichloromethane (DCM). A solvent used in a variety of consumer and commercial applications, including adhesives and sealants, automotive products, and paint and coating removers.

METHYLENE CHLORIDE USED IN CLOSED LOOP PROCESSES

Particularly used in heat transfer processes to minimize environmental exposure and enhance worker safety.

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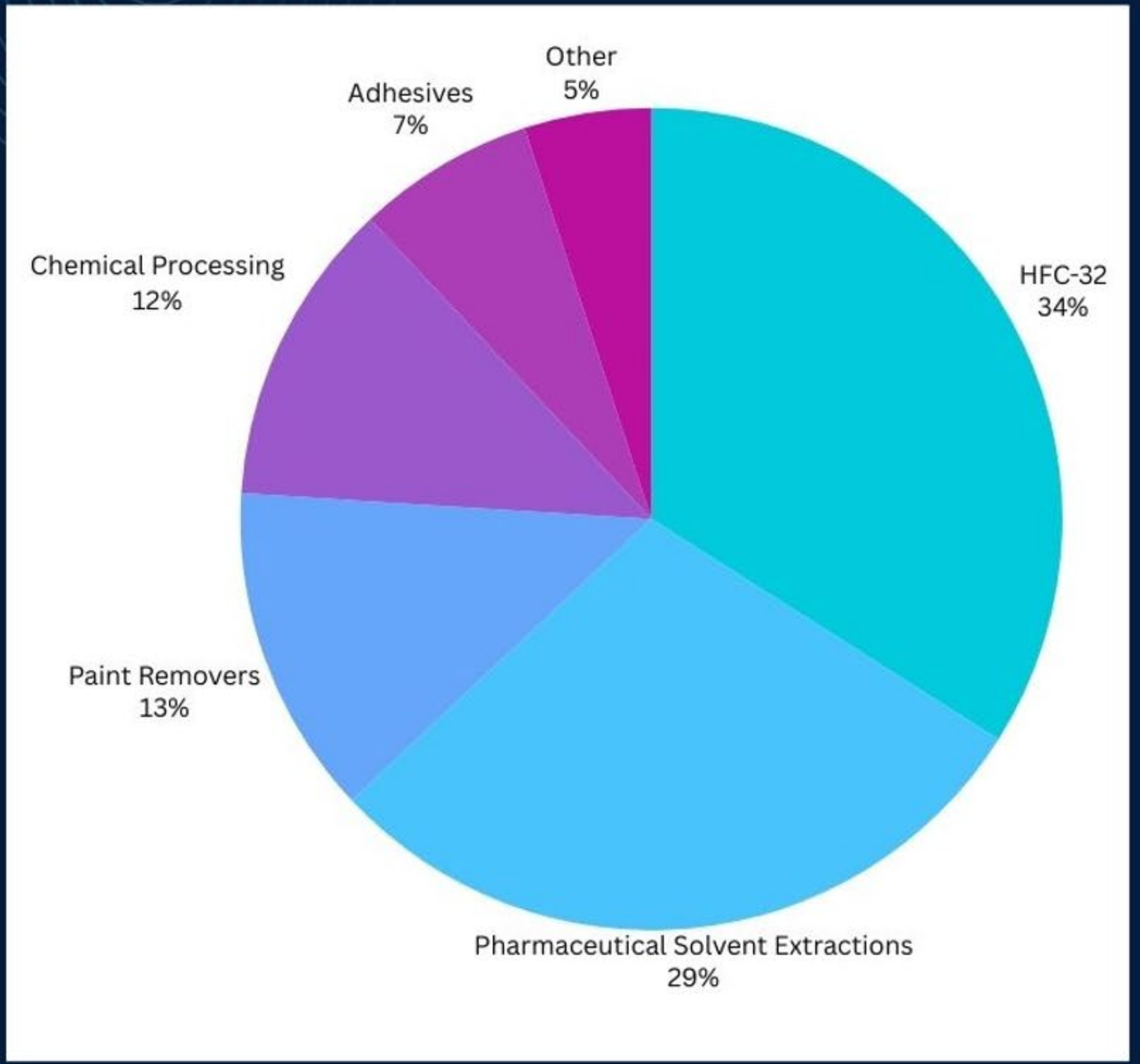
Methylene Chloride U.S. Consumption in 2020

- **75%** of specific industries rely on closed-loop processing system.
  - Pharmaceuticals
  - HFC-32 production
  - Chemical processing



Source: Chemical Economics Handbook, 2021

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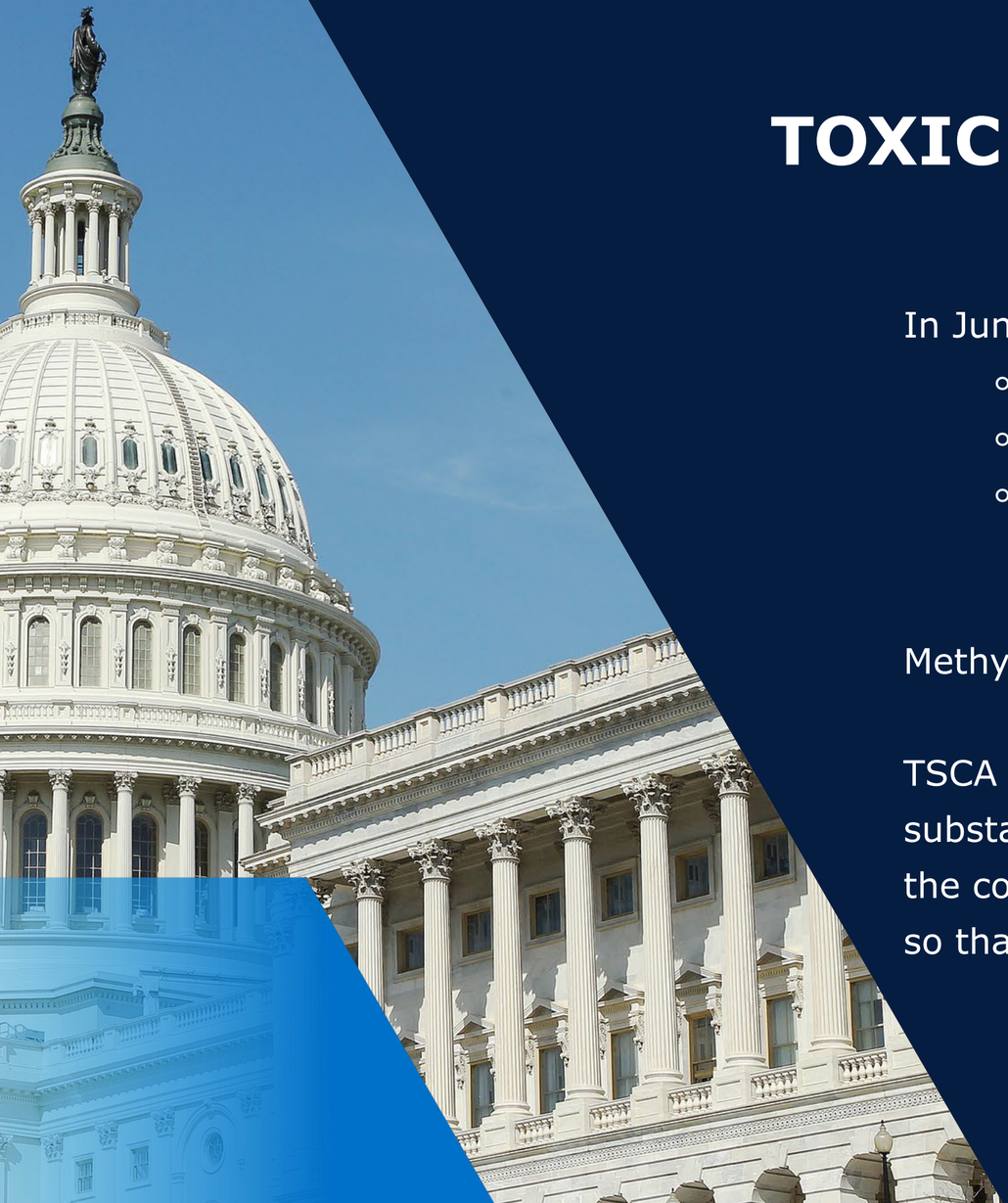
Overview of TSCA



TOXIC SUBSTANCES CONTROL ACT (TSCA)

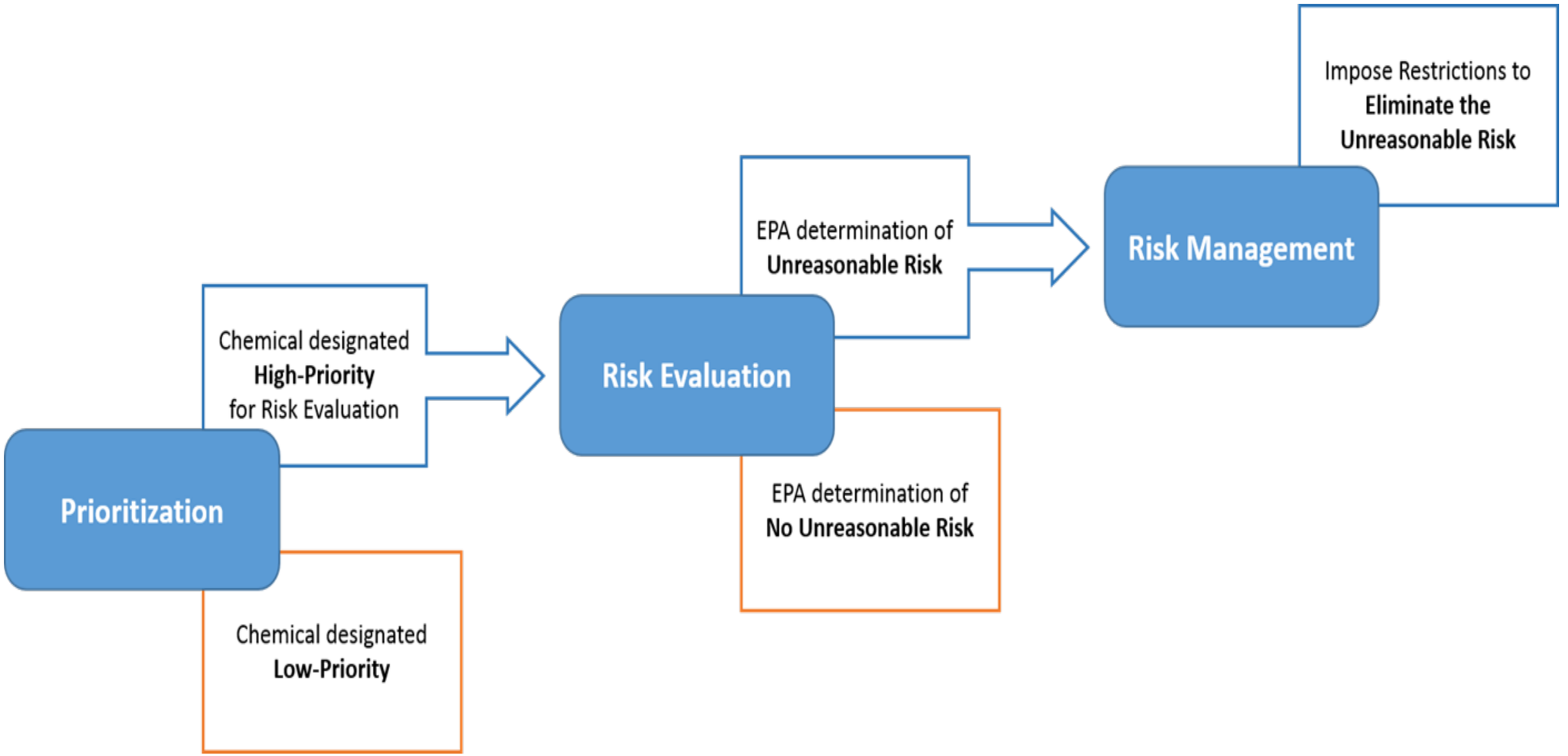
In June 2016, Congress amended TSCA

- Requires EPA to assess and address risks from chemicals currently in commerce
- Imposes statutory timeframes for regulation
- Provides protection for the public and predictable process for the regulated community

Methylene Chloride was identified as one of the first chemicals for risk evaluation

TSCA Section 6 requires EPA to conduct a risk evaluation and determine if a chemical substance “presents an unreasonable risk of injury to health or the environment under the conditions of use.” If so, EPA must regulate the substance "to the extend necessary" so that it "no longer presents such risk.”

From Prioritization to Risk Management



What did EPA find?

EPA found that 52 of 53 conditions of use of MC contribute to the unreasonable risk of injury to health of workers, consumers, and bystanders

On May 3, 2023, EPA proposed to:

- Prohibit manufacture, processing, and distribution for all consumer uses
- Prohibit most industrial and commercial uses
- Allow 10 uses to continue under a Workplace Chemical Protection Program (WCPP)
- Grant time-limited exemptions under TSCA section 6(g) for emergency use of MC in furtherance of the National Aeronautics and Space Administration mission
- The alternative regulatory actions included several additional uses under WCPP and longer compliance timeframes

What is a Workplace Chemical Protection Program (WCPP)?

Includes comprehensive requirements for the protection of workers from exposures from certain conditions of use (COU).

- Applies to owners or operators and potentially exposed persons, which in some cases is broader definition than “employers” and “employees”
- Includes exposure limits and ancillary requirements in support of those limits

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What did ACC Comments Find?

Questionable Scientific Foundation

EPA's proposed exposure limits (ECEL and STEL) are misaligned with the bulk of scientific evidence, overlooking inputs from NAC-AEGL and EPA’s own SACC.

Data Interpretation Issues

Challenges with EPA's use of acute and chronic toxicity data, especially regarding central nervous system effects and liver vacuolation. EPA’s analysis ignores key epidemiological evidence and alternative, yet valid, scientific views.

Methodological Concerns

EPA's dismissal of PBPK modeling for exposure estimation, favoring less accurate methods contrary to scientifically robust approaches.

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Existing Chemical Exposure Limit (ECEL) Concerns

EPA should clarify when exceedance of the ECEL represents non-compliance. Compliance should be based on:

(1) At least six personal breathing zone monitoring samples, consistent with guidance from the American Industrial Hygiene Association, with

- A “rolling average” calculated with these recent measurements;

(2) Incorporation of task-based measurements that permit the inclusion of Assigned Protection Factors (APFs) when assessing exposure for short-terms tasks, as per current methods

- Use the APF for PPE to determine compliance against the EPA ECEL or STEL; and

(3) The 'control-banding-by-task' approach, allowing for a more targeted evaluation of task-specific scenarios within well-defined Similar Exposure Groups, rather than relying solely on full 8-hour data.

If the ECEL is implemented as an occupational exposure limit, instead of assuming exposure for total work hours, the final rule should allow the ECEL to be refined using the time spent completing tasks with potential exposure.

ESTABLISHMENT OF A *DE MINIMIS* LEVEL IS ESSENTIAL

Issue: The absence of a *de minimis* exemption for methylene chloride content in products.

Consequences:

- Potential widespread non-compliance.
- Unnecessary penalization of minor, non-risk-contributing uses of methylene chloride.

Proposal: EPA should set a *de minimis* level across the board to support regulatory harmonization and compliance certainty.

Benefits:

- Reduces the burden on businesses while maintaining health and safety standards.
- Encourages compliance by acknowledging practical usage contexts.

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ECONOMIC IMPACT AND ALTERNATIVES

- Economic impact on small businesses not fully considered, especially on commercial furniture refinishing.
- Questionable availability of safer, effective alternatives.

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COMPLIANCE TIMELINES

To allow an orderly transition and compliance with the proposed rule, extended timelines are essential. EPA should allow **3-5 years** after publication of the final rule for full implementation of the WCPP.

Areas Needing Extension:

- Initial monitoring phases.
- Development of WCPP.
- Adoption of engineering and administrative controls.

Rationale: Longer periods are essential for industry to:

- Adequately prepare and implement safety measures.
- Ensure thorough training and awareness for staff.
- Integrate new protocols without disrupting operations.

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The Final Regulation

On May 8th, 2024, EPA published the final TSCA risk management rule for MC.

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SCOPE OF APPLICATION

TSCA Conditions of Use: All TSCA conditions of use for MC are covered under this final rule.

Exclusions: Non-TSCA uses, such as pesticides, foods, cosmetics, and medical devices, are not subject to this rule.

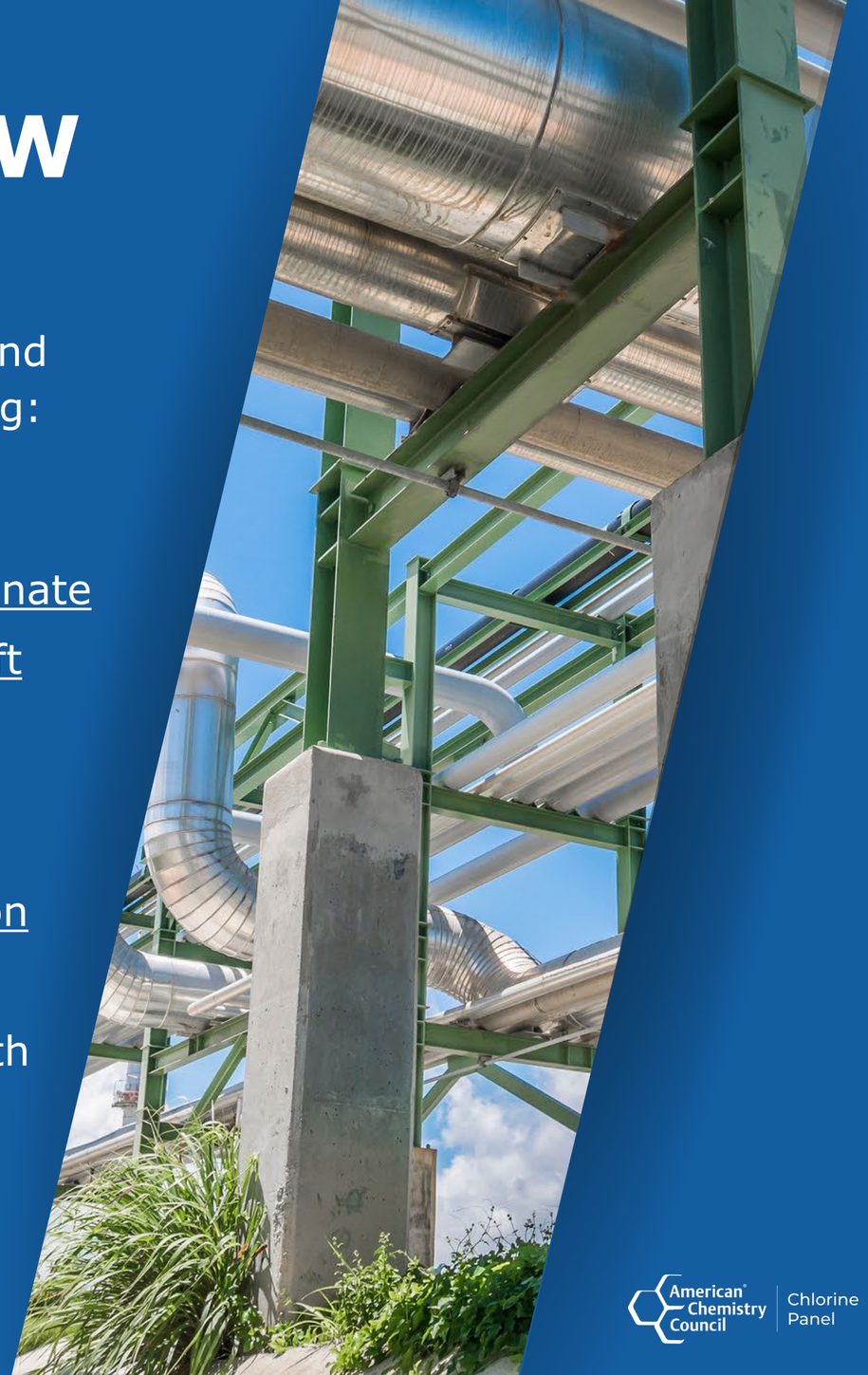
Preemption: The rule will preempt state restrictions on the covered TSCA uses of MC, promoting uniform federal standards.

ALLOWED USES UNDER NEW RESTRICTIONS

Industrial and Commercial Uses: Continued use in certain industrial and commercial applications is permitted under an ECEL and a WCPP, including:

- Use as a processing aid
- Use for plastic and rubber products manufacturing, including polycarbonate
- Use for paint/coating removal from safety critical spacecraft and aircraft components
- Use a bonding agent for solvent welding in military/space and general industry applications
- Use in a formulation/mixture in manufacturing, with solvent reclamation

- Manufacturing, processing and distribution for export in compliance with WCPP without regard for intended use in destination country



Full List of Allowable Uses of MC, subject to the WCPP Requirement

(1) Manufacturing (domestic manufacture);
(2) Manufacturing (import);
(3) Processing: as a reactant;
(4) Processing: incorporation into a formulation, mixture, or reaction product;
(5) Processing: repackaging;
(6) Processing: recycling;
(7) Industrial and commercial use as a laboratory chemical;
(8) Industrial or commercial use for paint and coating removal from safety critical, corrosion-sensitive components of aircraft and spacecraft;
(9) Industrial or commercial use as a bonding agent for solvent welding;
(10) Industrial and commercial use as a processing aid;
(11) Industrial and commercial use for plastic and rubber products manufacturing;
(12) Industrial and commercial use as a solvent that becomes part of a formulation or mixture, where that formulation or mixture will be used inside a manufacturing process, and the solvent (methylene chloride) will be reclaimed; and
(13) Disposal.

Prohibited Uses of MC

- 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
- 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
- Propellant and blowing agent
- Electrical equipment, appliance, and component manufacturing
- Anti-spatter welding aerosol
- Toys, playground and sporting equipment
- Lithographic printing plate cleaner

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5-YEAR DELAY IN COMPLIANCE DATE FOR PHASEOUT

- Use for refinishing of wooden furniture
  - Pieces of artistic, cultural or historic value
  - Interim exposure controls to be in place by July 7, 2024, including:
    - Establishing a regulated area
    - Implementation of local exhaust ventilation
    - Use of minimum respiratory protection
    - Recordkeeping
- Use in adhesives and sealants
  - Critical applications in aircraft, space vehicle, or turbines
  - Interim exposure controls not required

SAFETY MEASURES AND COMPLIANCE

Worker Protection Program

The rule mandates strict exposure limits, comprehensive monitoring, and worker training to minimize occupational exposure to MC.

Exposure Limits:
Existing Chemical Exposure Limit (ECEL)
Short-Term Exposure Limit (STEL)

EPA has set an ECEL of 2 ppm as an 8-hour time-weighted average (TWA) for MC. (Action level – 1 ppm)

A STEL of 16 ppm over a 15-minute sampling period has been established to address acute exposure scenarios.

De Minimis Level

A de minimis threshold of 0.1 percent by weight is set, with MC content below this level not subject to the rule.

Recordkeeping and Downstream Notification

- SDS updates are required for downstream notification of the prohibitions
  - For conditions of use that would not be prohibited under the final regulation, the Safety Data Sheets (SDSs) must be updated by adding information on prohibitions and relevant dates

- Recordkeeping requirements include maintenance of normal business records and records related to WCPP monitoring and compliance

COMPLIANCE & EXTENSION MEASURES

- Deadline for initial exposure monitoring extended to 360 days
  - Representative sampling of potentially exposed individuals permitted
- Regulated areas/PPE within 450 days (15 months)
- Full compliance with WCPP within 540 days (18 months)
- Guidance on responsibility for implementation of WCPP requirements

Timeframe of Prohibition of Industrial and Commercial Use

Lifecycle Designation	Final Prohibition Date	Working Timeframe from Publication of Final Rule
All persons – Distribution in commerce to retailers	February 3, 2025	9 months
All retailers – Distribution in commerce	May 5, 2025	12 months
Manufacturers	May 5, 2025	12 months
Processers	August 1, 2025	15 months
Distributors other than retailers	January 28, 2026	21 months
Most industrial and commercial use	April 28, 2026	24 months
M/P/D/Use of commercial paint and coating remover in furniture refinishing	May 8, 2029	5 years
M/P/D/Use of commercial adhesives/sealants in aircraft	May 8, 2029	5 years

Overview of Effective Dates

Prohibition	
Lifecycle Designation	**Final Prohibition Date**
All persons - Distribution in commerce to retailers	February 3, 2025
All retailers – Distribution in commerce	May 5, 2025
Manufacturers	May 5, 2025
Processers	August 1, 2025
Distributers other than retailers	January 28, 2026
Most industrial and commercial use	April 28, 2026
M/P/D/Use of commercial paint and coating remover furniture refinishing	May 8, 2029
M/P/D/Use of commercial adhesives/sealants in aircraft	May 8, 2029

WCPP		
Compliance Phase	**General Industry**	**Federal Agencies (and Federal contractors)**
Initial Monitoring	May 5, 2025	November 9, 2026
ECEL/EPA STEL	August 1, 2025	February 8, 2027
PPE/Respirators	August 1, 2025	February 8, 2027
Establish Regulated Area	August 1, 2025	February 8, 2027
Exposure Control Plan	October 30, 2025	May 10, 2027

JUDICIAL REVIEW

Legally Challenged:

- The final risk management rule issued by EPA for MC has been legally challenged
- These include both industry groups and non-governmental organizations (NGOs)

Current Status:

- The case is currently pending in the U.S. Court Appeals for the Fifth Circuit
- The outcome of this legal challenge could have legal implementation of the rule

Compliance Deadlines:

- Despite the legal challenges, the compliance deadlines for the rule remain unchanged
- Entities must continue to work towards meeting the established deadlines

Resources

FACT SHEET
2024 Final Risk Management Rule for Methylene Chloride under TSCA

EPA

What is methylene chloride?

Methylene chloride – also called dichloromethane or DCM – is a colorless liquid and a volatile chemical with a sweet odor. The solvent is used in a variety of consumer and commercial applications, including adhesives and sealants, automotive products, and paint and coating removers.

In April 2024, EPA issued a final rule regulating methylene chloride under the Toxic Substances Control Act (TSCA) to protect human health from health risks such as neurotoxicity effects and cancer from inhalation or dermal exposures.

Who is subject to the methylene chloride regulation?

Anyone who manufactures (including imports), processes, distributes in commerce, uses, or disposes of methylene chloride or products containing methylene chloride may be impacted by EPA's regulation of the chemical. The table below is a summary of key points; full details are in the final rule.

What is the methylene chloride regulation[1] under TSCA?

Workplace Chemical Protection Program

A workplace chemical protection program (WCPP) is required in order to continue 13 conditions of use of methylene chloride. These uses include:

1. Domestic manufacturing
2. Import
3. Processing as a reactant
4. Processing in incorporation into formulation, mixture, or reaction product
5. Processing in repackaging
6. Processing in recycling
7. Use as a laboratory chemical.
8. Use in paint and coating removers for safety critical, corrosion-sensitive components of aircraft and spacecraft
9. Use as a bonding agent for solvent welding
10. Industrial and commercial use as a processing aid
11. Use for plastic and rubber products manufacturing
12. Use as a solvent that becomes part of a formulation or mixture where the formulation or mixture will be used inside a manufacturing process and the solvent (methylene chloride) will be reclaimed
13. Disposal

The WCPP requires that owners and operators of facilities

Prohibitions for Consumer Uses

Distributing methylene chloride for consumer use is prohibited after **May 5, 2025**.

Prohibitions for Commercial Uses[2]

Most commercial uses are prohibited after **April 28, 2026.**

Commercial Furniture Refinishing

Methylene chloride may be used for only very specific furniture refinishing until **May 8, 2029**, with workplace protections. After this date, this use is prohibited.

Recordkeeping and Downstream Notification

Manufacturers, processors, and distributors are required to update Safety Data Sheets to spread awareness throughout the supply chain. Relevant SDS must be updated by **October 7, 2024** for manufacturers and

Compliance Guide

EPA

A GUIDE TO COMPLYING WITH THE 2024 METHYLENE CHLORIDE REGULATION UNDER THE TOXIC SUBSTANCES CONTROL ACT (TSCA) (RIN 2070-AK70)

Includes:

Includes Compliance Guidance on Prohibitions, Workplace Chemical Protection Program (WCPP), and Other Requirements

Question: Customer with Prohibited COU (both consumer and industrial sales)

"What are the nuances of the implementation timelines? Do they start from publication in Federal Register or from July 8, 2024?"
"When would Company X (who is an upstream manufacturer) no longer be prohibited from supplying the product?

Answer: The implementation timelines for the final rule start from the publication date in the FR. The final prohibition dates vary for different lifecycle stages:

- Distribution in commerce to retailers: February 3, 2025
- Distribution in commerce by retailers: May 5, 2025
- Manufacturing: May 5, 2025
- Processing: August 1, 2025
- Distribution other than by retailers: January 28, 2026
- Most industrial and commercial uses: April 28, 2026, For specific uses such as commercial paint and coating remover in furniture refinishing and adhesives/sealants in aircraft, the prohibition date is May 8, 2029.

Question: Customers with WCPP COU

What information is available on safe handling practices, and is there an opportunity for mutual knowledge sharing on ECELs/IH best practices?

Answer:

Safe Handling Practices:

- **Exposure Limits:** The WCPP finalizes inhalation exposure limits with an 8-hour TWA of 2 ppm and a 15-minute TWA of 16 ppm.
- **Monitoring and Recordkeeping:** Initial and periodic monitoring requirements based on ECEL and EPA STEL levels, along with comprehensive recordkeeping.
- **Protective Equipment:** Requirements for respiratory and dermal protection to prevent exposure exceedances.
- **Engineering Controls:** Implementing local exhaust ventilation and other controls to minimize exposure.

Mutual Knowledge Sharing: Larger companies with robust industrial hygiene teams can benefit from mutual knowledge sharing on best practices for compliance. This includes:

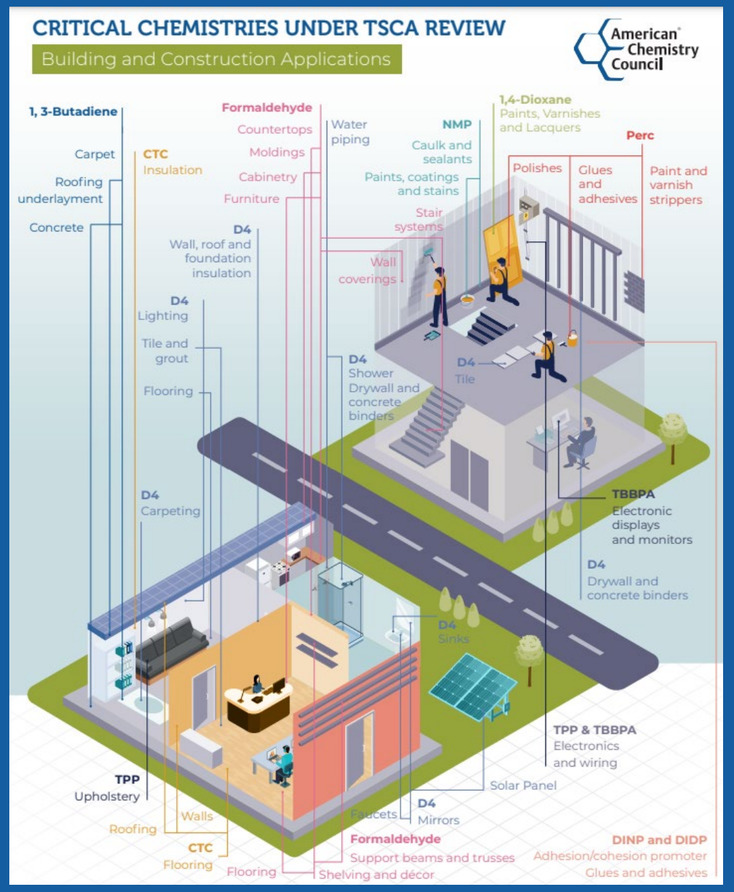
- Sharing case studies and success stories on implementing the WCPP.
- Collaborative training sessions and workshops on exposure monitoring and control strategies.
- Engaging with industry groups like the ACC to stay updated on regulatory changes and innovations in safety practices.

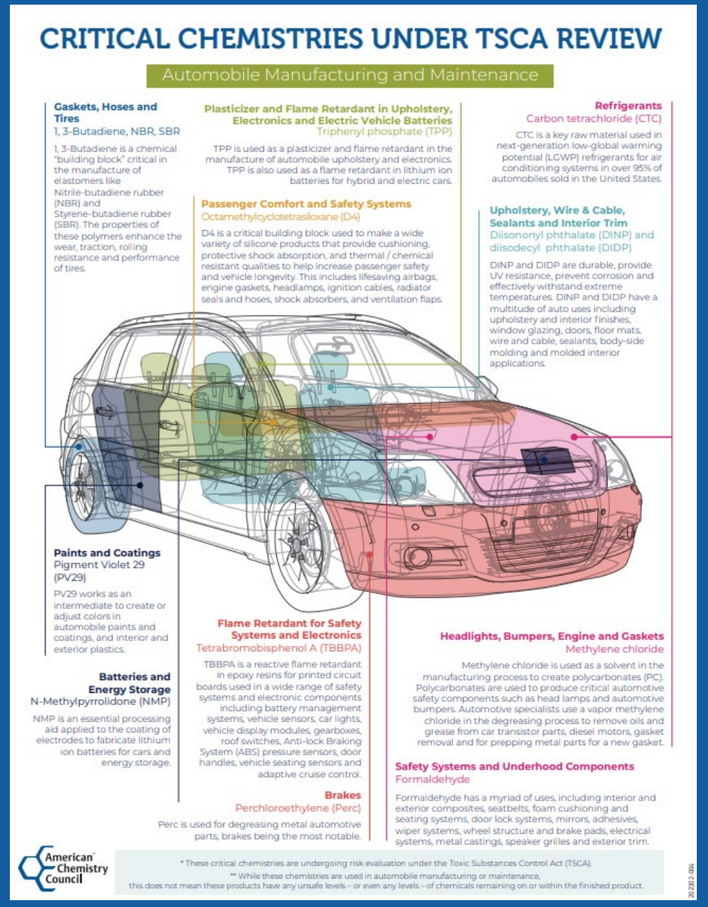
Resources

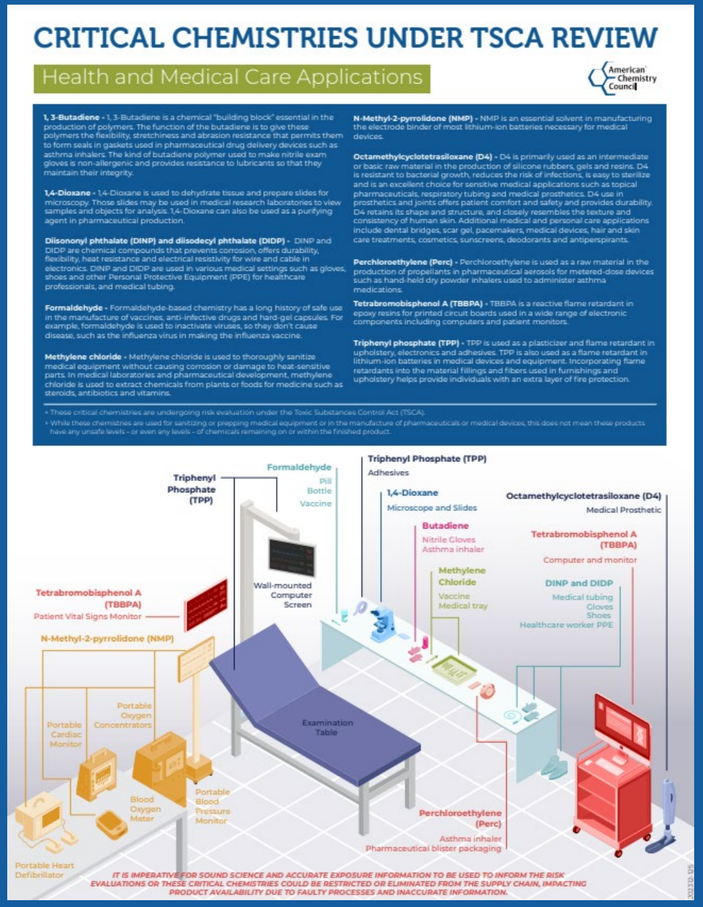
- Risk management for methylene chloride: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-methylene-chloride
- Methylene Chloride risk evaluation, supplemental risk evaluation materials, and proposed rulemaking are in dockets EPA-HQ-OPPT-2019-0437, EPA-HQ-OPPT-2016-0742, 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 and TSCA 101 URL
- 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
- Methylene Chloride Fact Sheet: https://www.epa.gov/system/files/documents/2024-06/mecl-fact-sheet_final_6-03-24.pdf
- OSHA Methylene Chloride Standard 29 CFR 1910.1052: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1052

ACC One-Pagers

- https://www.americanchemistry.com/better-policy-regulation/chemical-management/toxic-substances-control-act-tsca







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Thank you

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