TETRA TECH

Southern California Joint Technical Symposium (JTS)

TSCA "Existing Chemical" Program - What Safety Professionals Need to Know

October 22, 2026

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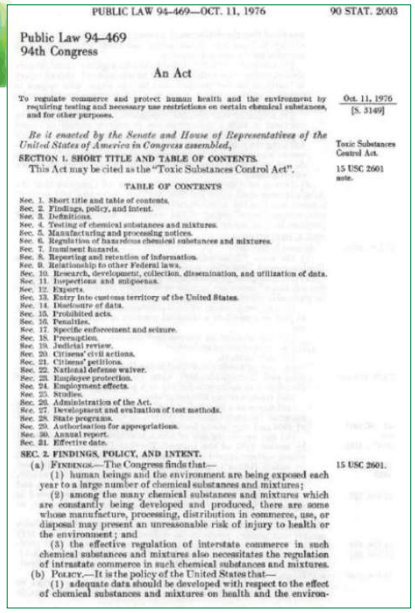


- Personal opinions of the presenter only – not the opinions of Tetra Tech , JTS organizers or anyone else
- Best efforts were made to ensure accuracy as of October 2026 however information change or be incorrect – make sure to conduct an independent confirmation before taking any compliance actions.
- This presentation includes a general discussion of legal issues however I am not an attorney, and this presentation is not intended to provide legal advice – please refer to a qualified attorney for relevant legal opinions

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PUBLIC LAW 94-469—OCT. 11, 1976 90 STAT. 2003

Public Law 94-469
94th Congress

An Act

To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes. Oct. 11, 1976 [S. 3149]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Toxic Substances Control Act.

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

This Act may be cited as the "Toxic Substances Control Act". 15 USC 2601 note.

TABLE OF CONTENTS

Sec. 1. Short title and table of contents.
Sec. 2. Findings, policy, and intent.
Sec. 3. Definitions.
Sec. 4. Testing of chemical substances and mixtures.
Sec. 5. Manufacturing and processing notices.
Sec. 6. Regulation of hazardous chemical substances and mixtures.
Sec. 7. Imminent hazards.
Sec. 8. Reporting and retention of information.
Sec. 9. Relationship to other Federal laws.
Sec. 10. Research, development, collection, dissemination, and utilization of data.
Sec. 11. Inspections and subpenas.
Sec. 12. Exports.
Sec. 13. Entry into customs territory of the United States.
Sec. 14. Disclosure of data.
Sec. 15. Prohibited acts.
Sec. 16. Penalties.
Sec. 17. Specific enforcement and seizure.
Sec. 18. Preemption.
Sec. 19. Judicial review.
Sec. 20. Citizens' civil actions.
Sec. 21. Citizens' petitions.
Sec. 22. National defense waiver.
Sec. 23. Employee protection.
Sec. 24. Employment effects.
Sec. 25. Studies.
Sec. 26. Administration of the Act.
Sec. 27. Development and evaluation of test methods.
Sec. 28. State programs.
Sec. 29. Authorization for appropriations.
Sec. 30. Annual report.
Sec. 31. Effective date.

SEC. 2. FINDINGS, POLICY, AND INTENT. 15 USC 2601.

(a) FINDINGS.—The Congress finds that—

(1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures;

(2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment; and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

(b) POLICY.—It is the policy of the United States that—

(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environ-

TSCA - 1976

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- Toxic Substances Control Act of 1976
  - Intended as comprehensive legislation that would identify and control potentially dangerous chemicals.
  - Passed with strong, bi-partisan support.
- Authorized US EPA to:
  - "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances".
- Regulated asbestos, also PCBS, new chemicals and "significant new uses" of existing chemicals .

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TSCA Origins

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- 1971 President's Council on Environmental Quality report recommended comprehensive legislation to identify and control dangerous chemicals.
- In 1973, the Michigan Chemical Company accidentally shipped bags of Polybrominated Biphenyl (PBB) fire retardant to a livestock feed plant
  - Mixed into animal feed, distributed to farmers across Michigan
  - Millions ate contaminated food before issue was discovered in 1974
- TSCA signed into law by President Gerald Ford on October 11, 1976
  - PBB production banned in 1976 under TSCA



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What Does TSCA Do?

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TSCA provide federal authority for:

- Testing of Chemical Substances (Section 4)
- New and Significant New Use Rules (Section 5)
  - Pre-Manufacture Notification (PMN)
- Regulation of Existing Chemicals (Section 6)
- Reporting and Recordkeeping (Section 8)

Intended to assess chemical risks, require testing, regulate hazardous substances, and ensure public and environmental safety.

- Implemented through EPA regulations (40 CFR)
  - And possibly additional state regulations

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TSCA Accomplishments

- Polychlorinated Biphenyls – PCBs (1979)
  - Manufacture, processing and distribution
  - Storage, clean-up and disposal
- Asbestos (1986)
  - AHERA – starting point for many IH careers!
  - Inspection/management in in schools
- Lead-based Paint (1996)
  - Inspections, abatement in "target housing" and child-occupied facilities.
  - Training, certification, and lead-safe work practices for contractors







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Problem - TSCA (1976) exempted the majority of "existing" chemicals with no mandate or mechanism for review

- Structure ("cost/benefit") made it difficult to restrict harmful chemicals.
- Lack of transparency ("confidential business information")
- No enforceable deadlines

Solution - Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016)

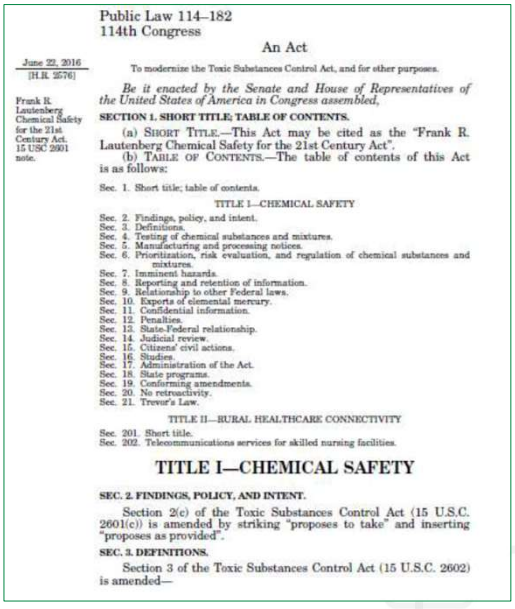




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TSCA - 2016

- Frank Lautenberg Chemical Safety for the 21st Century Act
  - Response to criticism, intended to modernize TSCA
- Mandated the EPA to:
  1. Conduct risk-based chemical evaluations.
  2. With clear and enforceable deadlines
     - 10 ongoing risk evaluations in the first 180 days, 20 ongoing risk evaluations in 3.5 years
  3. And increased chemical information transparency
  4. Including a consistent source of funding



Public Law 114–182
114th Congress

An Act

June 22, 2016
[H.R. 2576]

To modernize the Toxic Substances Control Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Frank R. Lautenberg Chemical Safety for the 21st Century Act.
15 USC 2601 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—CHEMICAL SAFETY

Sec. 2. Findings, policy, and intent.
Sec. 3. Definitions.
Sec. 4. Testing of chemical substances and mixtures.
Sec. 5. Manufacturing and processing notices.
Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.
Sec. 7. Imminent hazards.
Sec. 8. Reporting and retention of information.
Sec. 9. Relationship to other Federal laws.
Sec. 10. Exports of elemental mercury.
Sec. 11. Confidential information.
Sec. 12. Penalties.
Sec. 13. State-Federal relationship.
Sec. 14. Judicial review.
Sec. 15. Citizens' civil actions.
Sec. 16. Studies.
Sec. 17. Administration of the Act.
Sec. 18. State programs.
Sec. 19. Conforming amendments.
Sec. 20. No retroactivity.
Sec. 21. Trevor's Law.

TITLE II—RURAL HEALTHCARE CONNECTIVITY

Sec. 201. Short title.
Sec. 202. Telecommunications services for skilled nursing facilities.

TITLE I—CHEMICAL SAFETY

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended by striking "proposes to take" and inserting "proposes as provided".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

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Risk Assessment 101
(Side Topic #1)

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HAZARD vs **RISK**

A HAZARD is something that has the potential to harm you



RISK is the likelihood of a hazard causing harm



Risk = frequency x severity

Risk Assessment:

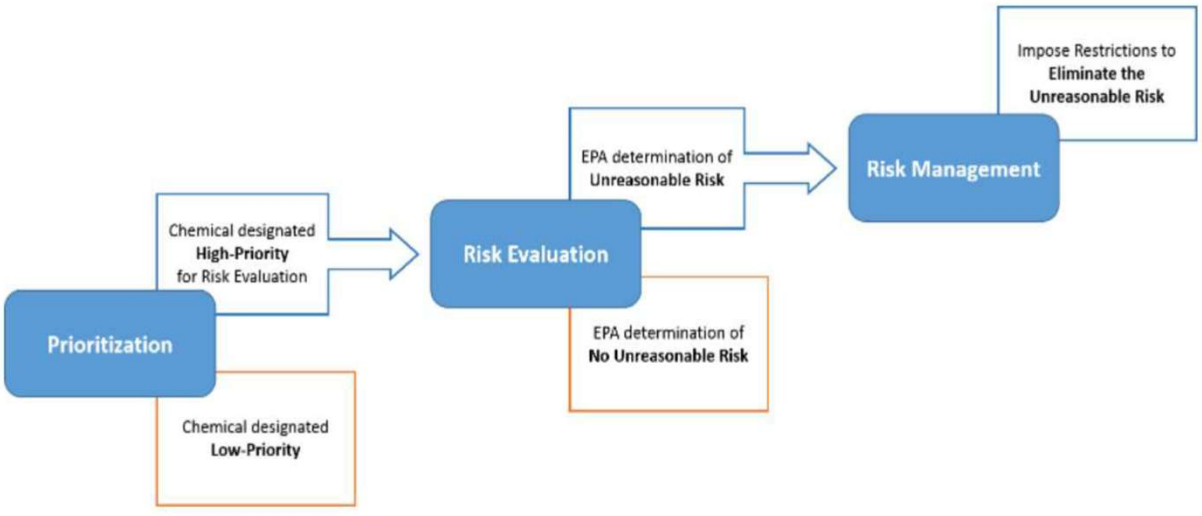
1. ID Hazards (Severity)
2. Assess likelihood (Frequency)
3. Assess risk

Add controls to reduce risk

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TSCA Existing Chemical Evaluation Process

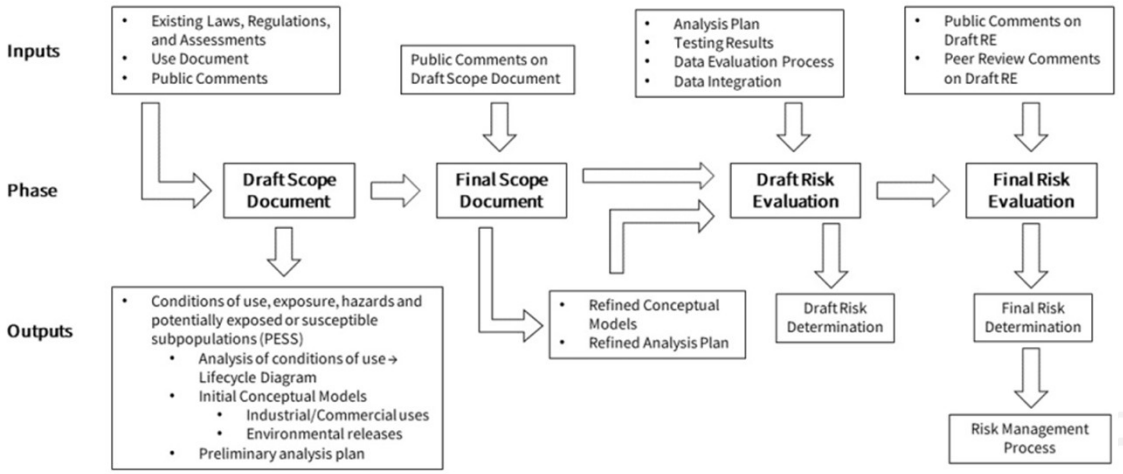
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Risk Evaluation



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Risk Management

- If the EPA conducts a risk evaluation and determines a chemical presents:
  - an unreasonable risk of injury to health or the environment (what is "unreasonable"?)
  - without consideration of costs or other non-risk factors, (No cost/benefit analysis?)
  - including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use
  - such as infants, children, pregnant women, workers, or the elderly"

Then:

- EPA must apply one or more requirements as needed so the chemical ("Must?") substance or mixture no longer presents such risk.
  - Prohibit or restrict manufacture, processing or distribution
  - Prohibit or restrict uses or above a specific concentration in products
  - Establish "Workplace Chemical Protection Program (WCPP), including "existing chemical exposure limits" (ECELs)

Wait… Workers are a "susceptible subpopulation"?

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What about OSHA?

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OSHA PELs, or Permissible Exposure Limits, are regulations that establish the acceptable amount or concentration of a substance in the air in the workplace. They are intended to protect workers from adverse health effects related to hazardous chemical exposure.

Of the thousands of chemicals used in workplaces, **OSHA has PELs for less than 500.**

Many of the PELs have not been updated since 1971, and current scientific data suggests that, in many instances, the outdated PELs are not sufficiently protective of worker health.

In 1989, OSHA attempted to update or set new PELS for more than 350 chemicals in a single rulemaking. Although OSHA presented analyses of the risks associated with these chemicals, as well as the feasibility and economic impacts, the analyses were not as detailed as those for individual rulemakings. The entire rulemaking was ultimately vacated by the Court.

Workers are essentially covered by the same PELs as they were 40 years ago and, while OSHA has been given no new tools to control workplace exposures, it has had to conduct increasingly resource-intensive analyses that have slowed the PEL rulemaking process to a crawl. Since 1971, OSHA has been successful in establishing or updating PELs for only about 30 chemicals

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OSHA vs. EPA

(Side Topic #2)



OSHA	EPA
Mission is "to assure safe and healthful working conditions for **working men** and **women**…."	Mission is to "protect **human health and the environment**". Includes susceptible and highly exposed populations.
Risk evaluation is based on "**the extent feasible**" (economic and technical)	"…determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, **without consideration of cost or other non-risk factors**"
"Significant risk" –1 in 1,000. **Defined** by the U.S Supreme Court	"Unreasonable risk" –**Not Defined** by TSCA
Some exposure limits have residual risk (may be significant)	Goal is for exposure limits to eliminate "unreasonable risk"
Primarily Civil Enforcement	Civil and Criminal Enforcement
Maximum $16,550 /violation (Serious)	$93,058/violation/day – no maximum

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Management of "Unreasonable Risk"

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- TSCA requires EPA to develop controls for "unreasonable risks" associated with specific "conditions of use" (COUs)
  - *Current* TSCA risk assessments are very (unrealistically?) conservative
  - (and what is "unreasonable" anyway?)
- Options:
  - Prohibit use /ban material (e.g., chrysotile asbestos) or specific uses
  - Allow limited "critical" COUs to continue when there are no alternatives
  - Establish "Risk Management" rules for COUs with manageable risks
    - Workplace Chemical Protection Program (WCPP), "existing chemical" exposure limits" (ECELs)



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Current/Proposed ECELs:

(Side Topic #3)

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Chemical	OSHA PEL	ACGIH TLV	ECEL	Sample Method?
Asbestos	0.1 fiber/cc		0.005 fiber/cc	High volume (1200 L) needed
Methylene Chloride	25 ppm	50 ppm	2 ppm	May exceed method air volumes
Perchloroethylene (Perc)	100 ppm		0.1 ppm	Whole Air (TO-15)
Carbon Tetrachloride (CTC)	10 ppm		0.03 ppm	Passive badge w/ low LOQ
Trichloroethylene (TCE)	100 ppm		0.0011 ppm	No
N-bromopropane	None	0.1 ppm	0.05 ppm	May exceed sample volumes

- "Toxicology" approach, not epidemiology
  - "Human Health Risk Assessment" model using highly conservative assumptions
- ECEL process does not address practicality or feasibility
  - "..without consideration of costs or other non-risk factors."
  - Dramatically lower than other OELs
- Current ECELs challenge existing analytical methods for air samples
- Other practical issues - asbestos ECEL (0.005 f/cc) - similar to background levels

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Example – Methylene Chloride Risk Management

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Methylene chloride	Formula: CH_2Cl_2	CAS#: 75-09-2	RTECS#: PA8050000	IDLH: Ca [2300 ppm]
Conversion: 1 ppm = 3.47 mg/m³	DOT: 1593 160			
Synonyms/Trade Names: Dichloromethane, Methylene dichloride				
Exposure Limits: NIOSH REL: Ca See Appendix A OSHA PEL: [1910.1052] TWA 25 ppm ST 125 ppm			Measurement Methods (see Table 1): NIOSH 1005, 3800 OSHA 59, 80	
Physical Description: Colorless liquid with a chloroform-like odor. [Note: A gas above 104°F.]				
Chemical & Physical Properties: MW: 84.9 BP: 104°F Sol: 2% FI.P: ? IP: 11.32 eV Sp.Gr: 1.33 VP: 350 mmHg FRZ: -139°F UEL: 23% LEL: 13% Combustible Liquid	Personal Protection/Sanitation (see Table 2): Skin: Prevent skin contact Eyes: Prevent eye contact Wash skin: When contam Remove: When wet or contam Change: N.R. Provide: Eyewash Quick drench		Respirator Recommendations (see Tables 3 and 4): NIOSH ¥: ScbaF:Pd,Pp/SaF:Pd,Pp:AScba Escape: GmFOv/ScbaE See Appendix E (page 351)	
Incompatibilities and Reactivities: Strong oxidizers; caustics; chemically-active metals such as aluminum, magnesium powders, potassium & sodium; concentrated nitric acid				
Exposure Routes, Symptoms, Target Organs (see Table 5): ER: Inh, Abs, Ing, Con SY: Irrit eyes, skin; lass, drow, dizz; numb, tingle limbs; nau; [carc] TO: Eyes, skin, CVS, CNS [in animals: lung, liver, salivary & mammary gland tumors]			First Aid (see Table 6): Eye: Irr immed Skin: Soap wash prompt Breath: Resp support Swallow: Medical attention immed	



GHS Classification
Skin Corrosion/Irritant - Cat. 2
Serious Eye Damage/Irritation - Cat. 2A
Carcinogenicity - Cat. 1B
STOT – Single Exposures (CNS) - Cat. 3
STOT – Repeat Exposures (Liver, Blood) - Cat. 2

Label Elements
Signal Word – DANGER
Causes skin irritation
Causes serious eye irritation
May cause drowsiness or dizziness
May cause cancer
May cause damage to organs through prolonged or repeated exposure

Carcinogenicity
Linked to lungs, liver, and pancreas cancer in animals
IARC 2B Possible Human Carcinogen
NTP Reasonably anticipated to cause cancer
EPA - reasonably anticipated to be a human carcinogen, Group B2
OSHA carcinogen
ACGIH A3 – confirmed animal carcinogen, unknown relevant to humans

Occupational Exposure Limits (OELs), as 8-hr time-weighted average (TWA) exposure:
OSHA PEL = 25 ppm
ACGIH TLV = 50 ppm
EU-OEL = 100 ppm
DFG MAK = 50 ppm
EU DNEL = 50.7

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Methylene Chloride Risk Management

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- Risk Evaluation Identified 53 Conditions of Use (COUs)
- 38 COUs prohibited under *current* RM rule:
  - Degreasing, coating/caulk removal and similar
- Limited prohibition for 2 COUs
  - Safety critical aerospace adhesives
- 13 other COUs allow usage subject to WCPP
  - Use as a solvent/reactant in a formulation/mixture
  - Processing Aid
  - Laboratory chemical

(not a complete list of all COUs)

Compliance Timelines* for the Workplace Chemical Protection Program

Initial Monitoring	Exposure Limits and Dermal Protections	Exposure Control Plan	Other Monitoring
Complete initial monitoring. Demarcate regulated area within 3 months of initial monitoring data. Provide respiratory protection within 3 months of initial monitoring data but no later than 15 months after final rule. Existing Facilities Before **May 5, 2025** (360 days after final rule publication). New Facilities Within 30 days of initiating use.	Ensure methylene chloride inhalation exposures do not exceed the ECEL (2 ppm as an 8-hr TWA) and EPA STEL (16 ppm as a 15-min TWA) for all potentially exposed persons. Provide respiratory and/or dermal protection if applicable. Existing Facilities Before **August 1, 2025** (450 days after final rule publication). New Facilities Within 90 days of initial exposure monitoring.	Develop and implement an exposure control plan. Notify potentially exposed persons of completion of exposure control plan within 30 days of its completion. Provide requested records by a potentially exposed person within 15 days of request. Existing Facilities Before **October 30, 2025** (540 days after final rule publication). New Facilities Update as necessary, but at least every five years.	Periodic Monitoring Conduct at a minimum **every 5 years, but could occur as frequently as every 3 months,** dependent upon initial monitoring results. As Needed Monitoring Conduct additional monitoring after any change that may introduce additional sources of methylene chloride exposure or result in a change in exposure levels.

* Longer timeframes for Federal agencies and contractors acting for or on behalf of those agencies. See final rule for details.

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Existing Chemical Status

Chemical Name	Category	CASRN	Risk Eval	Risk Mgmnt.
Chrysotile Asbestos	NA	1332-21-4	Final (12/2020)	Final (03/2024)
Carbon Tetrachloride	Solvent	56-23-5	Final (11/2012)	Final (12/2024)
Methylene Chloride	Solvent	75-09-2	Final (06/2020)	Final (04/2024)
Perchloroethylene	Solvent	127-18-4	Final (12/2020)	Final (12/2024)
Trichlorethylene	Solvent	79-01-6	Final (11/2020)	Final (12/2024)
1-Bromopropane	Solvent	106-94-5	Final (08/2020	Proposed (07/2024)
C.I. Pigment Violet 29	Pigment	81-33-4	Final (01/2021)	Proposed (12/2024)
N-Methylpyrrolidone	Solvent	872-50-4	Final (12/2020)	Proposed (06/2024)
1,3-Butadiene	NA	106-99-0	Final (12/2025)	
Phthalates	Phthalates	Various	Final (12/2025)	
Formaldehyde	NA	50-00-0	Final (12/2024)	
Tris(2-chloroethyl) phosphate	Retardant	115-96-8	Final (12/2024)	
1,4-dioxane	Solvent	123-91-1	Final (11/2024)	
Asbestos Pt. 2 (Legacy Uses)	NA	1332-21-4	Final (11/2024)	
Cyclic Aliph. Bromide Cluster	Retardant	Various	Final (09/2020)	
1,1-Dichloroethane	Solvent	75-34-3	Final (06/2025)	
1,2-Dichloroethane	Solvent	107-06-2	Final (05/2026)	
TBBPA	Retardant	79-94-7	Draft (06/2026)	

Revised October 2026 – subject to change – confirm current status for any compliance decisions

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Why the slow progress?

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First final rules summer 2024?

Why the slow progress?

- 2016……
- 2020……
- 2024……

10 years since Lautenburg was signed – no final RM rules in place!

- Unlikely to see any final RM rules in the near future.

Despite attempts at procedural safeguards, this is a complex, ambitious regulatory project.

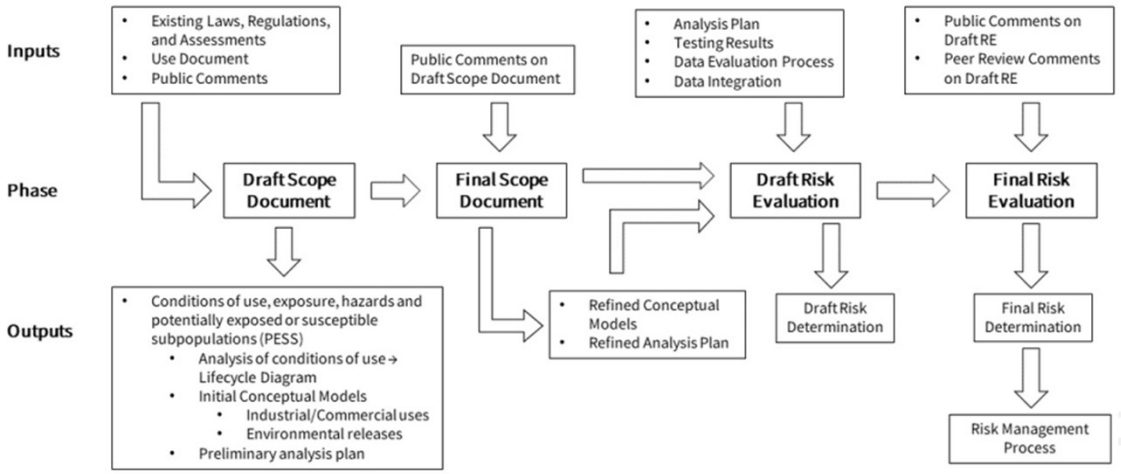
- Significant pushback from business groups (as would be expected)
- Most importantly - Major disagreements on technical approach between administrations responsible for implementation.

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Components of Risk Evaluation

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2024 Risk Evaluation Methodology

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- 2024 Risk Evaluation Framework Rule
  - Revised 2016 methodology
  - Formal rulemaking (40 C.F.R. Section 702.31)
  - Revised technical definitions
  - Requires evaluation to address all "conditions of use" and all exposure pathways
  - Single risk evaluation for all COUs
  - Prior risk evaluations reviewed
- Human health hazard model
  - e.g. excess cancers based on IUR
- Specific language regarding occupational exposures
  - Excludes use of PPE

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Proposed Revision to 2024 Risk Assessment Methodology

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EPA Notice of Proposed Rulemaking on Sept. 23, 2025, to amend the 2024 TSCA Risk Evaluation Framework Rule

- Rescinds requirement to evaluate all COUs, allows "discretion" to determine COUs to evaluate, focus on COUs with greatest exposure risk.
- Restores 2017 rule requirement for a determination of unreasonable risk for each COU , reversing the 2024 rule's requirement to make "a single risk determination on the chemical substance as a whole."
- Reverses the 2024 rule, allows EPA to account for "reasonably available information" on exposure controls when evaluating exposure risks.
  - Effectively, the agency currently assumes noncompliance, revision would consider whether existing workplace protections are sufficient to control risks.
- Generally reverts to 2017 rule.
  - Specific language about "risk-related factors" to be considered in risk evaluation
- Waiting for Final Rule (as of October 2026), litigation will follow.

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SEPTEMBER 17, 2026

Fifth Circuit Vacates EPA's Methylene Chloride Risk Management Rule Under TSCA

Court Finds EPA Committed Errors of Law and Lacked Substantial Evidence to Support Restrictions

In a Stinging Rebuke of the Biden EPA's Contorted Interpretation of TSCA, the Court of Appeals for the 5th Circuit Vacates EPA's Methylene Chloride Risk Management Rule

Fifth Circuit Vacates EPA's Methylene Chloride Rule: A Landmark Decision Reshaping TSCA Section 6

October 16, 2026

Fifth Circuit Vacates EPA's Methylene-Chloride Risk-Management Rule Under TSCA

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Methylene Chloride RM Rule Vacated

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- U.S. 5th Circuit Court of Appeals vacated the 2024 methylene chloride risk management rule and the underlying unreasonable-risk determination.
  - East Fork Enterprises, Inc. v. EPA, Nos. 24-60227 & 24-60256
  - Remanded the issue back to the EPA
- Findings:
  - Whole Chemical" approach rejected
  - "Unreasonable Risk" subject to limits
  - Risk Management must be limited to what is "Necessary"
  - PPE use must be accounted for where reasonable



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Court Findings (1)

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"Whole Chemical" Approach Rejected

- "TSCA required EPA to issue a separate risk determination for each condition of use that it considered"
- Different activities with different levels of risk must be evaluated accordingly

Limits placed on "Unreasonable Risk"

- EPA was "far more conservative than the statutory term connotes", TSCA is not a "zero-risk statute."
- " … at every juncture… EPA has gone with the most extreme position" – "unreasonable" necessarily allows for some risk
- "Unreasonable" is a legal (not technical) standard – subject to independent judicial interpretation following *Loper Bright Enterprises* decision.
- Determinations must be based on "best available science" and "weight of the scientific evidence."

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Loper Bright Enterprises v. Raimondo

(Side Topic #4)

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- Loper Bright Enterprises v. Raimondo (June 28, 2024) overturned the "Chevron doctrine" that deferred to agencies on regulatory interpretation
  - When there is not clear congressional guidance
- Requires courts to determine whether an agency interpretation is within statutory authority.
  - Courts may not defer to an agency's interpretation merely because a statute is ambiguous.
- Major shift in the balance of power between federal courts and administrative agencies



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Court Findings (2)

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Risk Management Must Be Limited to What Is "Necessary"

- Where "unreasonable risk" exists, EPA cannot automatically select the most protective regulatory option
- EPA must consider benefits, economic consequences and technically and economically feasible substitutes and justify the scope of the remedy "to the extent necessary"
- EPA "cannot simply ban a chemical substance whenever it is 'uncertain' whether a risk will remain reasonable";

- **EPA The EPA Must Account for PPE Where the Evidence Shows It Is Used**
  - EPA Must account for PPE as a "condition of use" where the evidence reflects that PPE is actually used
  - Risk evaluation must account for real-world circumstances, workplace protection and industry practices.
  - It is arbitrary and capricious to disregard demonstrated or foreseeable worker protections based on speculation that some employers or workers might fail to comply - unsupported by the TSCA's substantial-evidence standard

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Regulatory Implications

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Methylene chloride rule (and risk determination) are vacated.

Challenges the technical basis of all other risk evaluations (and associated RM measures) under the 2024 framework.

Comments generally align with proposed (2025) framework

Not binding on other circuit courts - other courts reviewing rules for other chemicals may adopt, distinguish, or disagree with the Fifth Circuit reasoning.

Likely to be relevant to on-going legal challenges t the 2024 RM rule itself (still legally in effect) as well as specific RM rules

5th Circuit Court decision subject to appeal.

EPA must rely on the "best available science" and the "weight of the scientific evidence for risk evaluation and risk management.

Relevant to other discussions internal to EPA and industry regarding hazard data and IRIS system

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"Best Available Science"

(Side Topic #5)



EPA is "re-evaluating" (or dismantling) IRIS
- Hazard data, used in risk assessments in multiple EPA programs

Concerns (mainly from industry groups) that IRIS data is not "best available science":

- Not Fit-for-Purpose
  - IRIS assessments have general applicability, not tailored to specific programs.
  - Hazard judgement (e.g., uncertainty factors, dose-response modeling choices, population selection) should be made by the programs using the information.
- Overly Conservative Assumptions.
  - Assessments stack conservative assumptions (e.g., uncertainty factors) leading "safe" levels that are unrealistically low - less than naturally occurring levels in environment or human body.
  - (Makes finding of unreasonable risk almost inevitable for at least one COU per chemical for TSCA Risk Evaluation and contributes to ECELs that are dramatically lower than current OELs)
- Failure to Consider All Available Science.
  - Some assessments are old, new information has not been applied, or information has been excluded (e.g., mode of action data, mechanistic data).
  - GAO, EPA Inspector General, advocacy groups express concerns about limited peer review, slow publication timelines, and insufficient public engagement before assessments are finalized
- De facto regulation
  - IRIS is effectively the basis for regulations or policy despite not being a regulatory or policy document

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Future of IRIS

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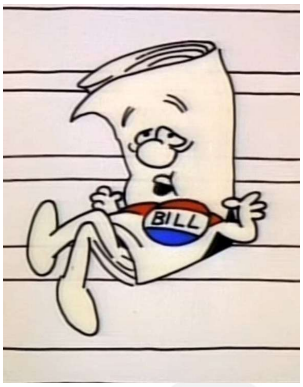
- EPA directives recommend decentralized, office-level chemical risk assessments
  - "Devolving" risk assessment to program offices intended to address stakeholder criticism
- Regulatory programs using IRIS values must decide whether to use existing data or develop independent toxicity criteria
  - Assess whether IRIS information is fit-for-purpose and reflects the best available science.
  - Ensure assessments meet regulatory, transparency, impartiality and reliability standards
- EPA views the changes as improving transparency, consistency, and fitness-for-purpose
- IRIS proponents are concerned the loss of a centralized repository may lead to inconsistent chemical risk assessments and gaps in data availability
  - Many toxicologists and environmental advocacy groups defend IRIS as an evidence-based repository that provides access to hazard data and ensures consistency across EPA offices.
  - IRIS scientists have no financial stake in their findings

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So where are we now?

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- Statutory requirement for risk evaluation and management.
  - Lautenberg requirements can only be changed by Congress
  - EPA regulations can only be changed through the rulemaking
- The 5th Circuit decision (and agency philosophy) require new rulemaking
  - Other legal issues and/or challenges may also apply
- Deadlines have been missed (under all administrations)
  - TSCA "Existing Chemical" obligations remain in effect
- 23 Risk Evaluations under 2017 rule must be re-visited
  - New risk assessment rule is critical path (then legal challenges)
- Methodological Issues:
  - "Best available science" (fit for purpose or paralysis by analysis)
  - Increased judicial participation (Neutral 3rd party or non-scientists reviewing of scientific issues



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But where are we going…

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- Aspects of chemical safety programs may still fall under OSHA but EPA is regulating workplace chemical exposures now
  - (personal opinion) This is unlikely to change
- This is a change in the way safety professionals have thought about chemical safety.
  - Safety pros with chemical safety responsibilities need to understand this program
  - Professional groups, businesses and other stakeholder need to engage with the process

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Any questions?

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