

# Risk Management Updates Under the Toxic Substances Control Act (TSCA)

**Environmental Law Institute**

**TSCA at 8**

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# TSCA Section 6 Statutory Requirements

## Risk Evaluation

- Must evaluate the chemical to determine if the chemical presents an **unreasonable risk** of injury to health or the environment under the conditions of use
- Without consideration of cost or other non-risk factors
- Including unreasonable risk to potentially exposed or susceptible subpopulation(s) (**PESS**) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within **3 to 3.5 years**

## Risk Management

- EPA required to take action to address chemicals that pose **unreasonable risks** to human health or the environment
- Specific requirements for characterizing the effects of the regulation and alternatives
- Economics analysis
- Consider other EPA programs and other agency programs (e.g., OSHA)
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within **2 years**

# Unreasonable Risk

- TSCA requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a **potentially exposed or susceptible subpopulation (PESS)** identified as relevant to the Administrator, under the conditions of use (15 U.S.C. 2605(b)(4)(A))
- EPA considers relevant risk-related factors:
  - Effects of the chemical on health
  - Human and environmental exposure to such substance under the conditions of use
  - Population exposed (including any PESS)
  - Severity of hazard (including the nature and any irreversibility of the hazard);
  - Uncertainties (consideration of the Agency's confidence in the data used in the risk estimate, including strengths, limitations, and uncertainties associated with the information used to inform the risk estimate)
- EPA makes these decisions for the **whole chemical**, based on the conditions of use

# TSCA Section 6(c)

TSCA section 6(a) rules must consider:

- The effects and magnitude of exposure to **human health**
- The effects and magnitude of exposure to **environment**
- The **benefits** of the chemical for various uses
- The reasonably ascertainable **economic consequences** of the rule, including consideration of:
  - The likely effect on the national economy, small business, technological innovation, the environment, and public health
  - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives
  - The cost effectiveness of the proposed regulatory action and one or more primary regulatory alternatives



# Milestones: First 10 Chemicals

- 1,4-Dioxane
  - Pending supplemental risk evaluation
- 1-Bromopropane
  - Proposed rule publish Summer 2024
  - Final rule anticipated 2025
- Asbestos Part 1
  - Proposed rule published April 2023
  - Final March 2024
- Carbon Tetrachloride
  - Proposed rule published July 2023
  - Final Fall 2024
- C.I. Pigment Violet 29
  - Propose Late 2024
  - Final 2025/2026
- Methylene Chloride
  - Proposed rule published May 2023
  - May 2024
- n-Methylpyrrolidone (NMP)
  - Proposed June 2024
  - Final 2025
- Perchloroethylene
  - Proposed rule published June 2023
  - Final rule anticipated Fall 2024
- Cyclic Aliphatic Bromide Cluster (HBCD)
  - Propose 2025
  - Final 2026
- Trichloroethylene
  - Proposed rule published October 2023
  - Final rule anticipated Fall 2024

# Key Challenges Ahead

- ✦ Competing priorities
  - Court orders, Section 21, implementation, enforcement, other federal agencies
- ✦ Stakeholder requests will increase dramatically
  - Acquisition of needed data and information
  - More meeting requests
  - More data sharing with industry
  - More interest with NGO community
- ✦ Implementation, compliance and enforcement
- ✦ Chemicals with less information than first set
- ✦ Pipeline of rules
- ✦ Resource/budget

# Additional Information

- 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>
  - Includes links to dockets that have more information about each chemical