

PRINCIPLES OF TOXIC SUBSTANCE CONTROL ACT (TSCA) RISK MANAGEMENT

1. Apply a Transparent, Consistent Framework

EPA should develop and apply a clear, consistent framework reflecting these principles, creating predictable outcomes, avoiding duplication or conflict with other federal programs, and ensuring meaningful stakeholder engagement.

- ✓ Establish and consistently apply a uniform framework with clear definitions, requirements, procedures, stakeholder engagement and documentation of key regulatory decisions.
- ✓ Coordinate with Federal agencies and document engagement.
- ✓ Design and implement an ongoing outreach strategy that includes stakeholder input on risk management activity that reaches all upstream and downstream supply chain stakeholders.
- ✓ Establish clear criteria and processes, including for evaluating and granting critical use exemptions when appropriate.
- ✓ Provide clear procedures for development of regulatory timeframes including extensions, effective dates, compliance dates, and sell-through provisions.
- ✓ Establish a standard process for gathering information to inform risk management decisions, including alternatives and economic analyses.
- ✓ Provide transparency by documenting in the regulatory record key assumptions, uncertainties, and decision criteria underlying risk management measures.

2. Regulate Only “To the Extent Necessary”

Restrictions can only be applied to the extent necessary so that the risk is no longer unreasonable.

- ✓ Apply requirements only to conditions of use (COU) that present unreasonable risk and activities and tasks within the COU that contribute to unreasonable risk.
- ✓ Ensure that the stringency of risk management requirements is proportionate to the nature, severity, and extent of the unreasonable risk identified.
- ✓ Evaluate the full range of risk management alternatives, including less burdensome alternatives; clearly document the rationale for including and excluding options.
- ✓ Apply a tiered approach, escalating incrementally and reserving broader restrictions only as a final measure.
- ✓ Document, consistent with TSCA Section 6(a) and Section 6(c) requirements, the effects and benefits of the chemical and economic consequences of the rule.

3. Drive Decisions with Weight of Evidence and Best Available Science

Risk management decisions and supporting analyses must use best available science and the weight of evidence.

- ✓ Use applicable Federal guidance and apply information, procedures, measures, methods, protocols, methodologies, and models consistent with the best available science when conducting economics and benefit analyses and making regulatory decisions.
- ✓ Account for confidence levels and limitations in underlying risk evaluation in establishing risk management requirements; uncertainty should not default to the most stringent restrictions.
- ✓ Apply a clear and robust approach to identify technically and economically feasible alternatives, when necessary, accounting for essential uses and supply chain impacts.

- ✓ Rely on reasonably available information and document assumptions, methods, variability, uncertainty, and any material limitations in the underlying evidence base.
- ✓ Apply these principles in accordance with TSCA Section 26(h) (best available science) and Section 26(i) (weight of the scientific evidence).
- ✓ Consider relevant new scientific information during risk management.

4. Develop Targeted, Flexible, and Tailored Measures

Risk management should be specific to the condition of use and underlying activities and tasks, including appropriate exemptions, critical-use allowances, phased implementation, and de minimis, byproduct and trace quantity thresholds.

- ✓ Target requirements to the populations and activities that contribute to unreasonable risk, including the use of geographically focused measures where appropriate.
- ✓ Provide flexibility to account for intermittent or limited uses.
- ✓ Establish approach for de minimis levels, trace quantities, by-products, and regulation of articles and replacement parts.
- ✓ Ensure that risk management actions do not result in risk-to-risk tradeoffs, including the transfer, substitution, or creation of new risks, and do not increase risk within the system(s) in which the chemical is used.

5. Avoid Regulatory Overlap and Achieve Balanced Outcomes

Risk management must be practical and balanced, fully considering economic consequences, including cost-effectiveness, cost-benefit, employment, technological innovation, feasibility, and supply chain continuity – including preservation of essential COUs - while avoiding overlapping or conflicting regulatory requirements.

- ✓ Avoid overlapping and conflicting regulatory requirements by deferring to the expertise and authorities of other Federal agencies pursuant to TSCA Section 9.
- ✓ Develop, document and consider full statement of effects on costs, benefits and effectiveness and meaningful regulatory alternatives.
- ✓ Evaluate on a continuing basis the potential effects of the rule's requirements on employment.
- ✓ When necessary, complete an analysis of reasonably available chemical substance alternatives.
- ✓ Fully implement the retrospective review requirements in TSCA Sections 24 and 26 and Section 610 of the Small Business Regulatory Enforcement Fairness Act.
- ✓ Consult and coordinate routinely with Federal agencies to develop management approaches that build on existing regulatory programs and avoid duplicative requirements.