

CHEMISTRY CREATES AMERICA COMPETES™



Fixing the TSCA New Chemicals Program: Promoting Predictable, Science-Based Reviews

The Problem: Delays and Overreach in EPA's New Chemicals Program

Section 5 of the Toxic Substances Control Act (TSCA) requires the Environmental Protection Agency (EPA) to make a risk determination on a new chemical within 90 days, supporting both safety and continued U.S. innovation. However, EPA's approach has resulted in:

- More than 90% of active reviews exceeding the 90-day deadline.
- Over 60% of cases pending more than 1 year.
- Overly restrictive regulation of new chemicals without clear risk-based justifications.

Four Critical Areas for Improvement

1 Improve Science and Risk-Based Screening-Level Reviews

TSCA provides EPA 90 days to complete a new chemical review before the chemical can be added to the U.S. market. To meet this deadline, EPA should:

- Prioritize reviewing submitted data and information over modeling and default assumptions.
- Focus on realistic exposure scenarios rather than imposing improbable assumptions that lead to overregulation and delays in innovation.
- Streamline processes to allow data and science to drive regulatory decision-making and allow new chemistries to reach the market in a timely and predictable manner.

Solution: Develop and release publicly available metrics that demonstrate the Agency's progress in meeting the 90-day statutory deadline and focus reviews on actual data to support risk assessment requirements.

2 Focus on Intended Conditions of Use

EPA has included conditions of use in its review beyond those in the new chemical submission and reasonably foreseen uses, including speculative uses that may never occur. Manufacturers face delays and additional regulatory burdens for uses they do not intend, and this overly broad approach discourages innovation and increases regulatory uncertainty. To comply with TSCA's requirements, EPA should:

- Focus the evaluation on the intended and reasonably foreseen uses of a chemical, not theoretical scenarios.
- Prioritize review of the conditions of use requested by the submitter.

Solution: Limit the scope of the review to intended and reasonably foreseen uses as required by TSCA in order to meet the 90-day statutory deadline, rather than assessing hypothetical, speculative scenarios during this time-period.



3 Streamline Regulations for New Chemicals

EPA has regulated nearly all new chemicals with restrictive Consent Orders (COs) and Significant New Use Rules (SNURs), even when it is not necessary based on the available science. Overuse of COs and SNURs discourages the adoption of innovative and more sustainable, safe chemistries. To promote innovation, EPA should:

- Allow science to drive selection of the appropriate risk management tools instead of haphazardly utilizing COs and SNURs as the default for every new chemical.
- Consider and account for real-world controls, such as personal protective equipment (PPE), already implemented to protect workers.

Solution: Use actual data and science to support the issuance of “not likely to present risk” determinations, reinstate the use of non-consent order SNURs for low-risk chemicals, and base decisions on real-world exposure data rather than the worst-case modeling.

4 Consider Other TSCA Authorities

TSCA allows EPA to regulate throughout the chemical lifecycle, yet EPA has acted as if Section 5 is its only chance to impose controls on a substance, applying excessive restrictions rather than using other TSCA authorities, if necessary. This approach stifles new product development and pushes companies toward older, less sustainable chemicals. To efficiently review new chemicals, EPA should:

- Utilize applicable controls on new chemicals based on the best available and most relevant science, not overly conservative assumptions that are not supported by the data.
- Explore the use of TSCA Sections 4, 6, and 8 to promulgate additional regulation when and if needed.

Solution: Implement balanced regulation across TSCA sections rather than front loading restrictions on new chemical substances, based on default assumptions or inaccurate application of exposure scenarios.

The Path Forward: Sensible, Science-Based Chemical Reviews

To fix the TSCA New Chemicals Program, keep science at the forefront of decision-making and restore America’s leadership in chemical innovation, EPA must:

- Apply quantifiable metrics to meet the 90-day statutory deadline with clear accountability.
- Focus on screening-level reviews based on data as intended by the statute.
- Prioritize assessment reviews on intended and reasonably foreseen uses.
- Reduce unnecessary COs and SNURs, not driven by science.
- Use all TSCA authorities effectively, rather than overregulating new chemicals based on default assumptions, unrealistic exposure scenarios, and improbable uses.

A modernized, efficient, and science-driven process will support U.S. innovation, economic growth and supply chain resilience, while maintaining strong environmental and health protections.

