

TSCA REFORM, TAKE 2: RECONCILING TRUMP'S DEREGULATORY AGENDA AND A CONGRESSIONALLY-MANDATED PROGRAM

4C HEALTH / SAFETY / ENVIRONMENTAL
CONFERENCE

April 3, 2018

Matt Paulson
Bracewell LLP

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WHAT IS TSCA ANYWAY?

- Toxic Substances Control Act
 - Federal law, passed in 1976, governing introduction of new chemicals into the U.S. marketplace
- Who does it cover?
 - Chemical manufacturers, processors, and importers
- Who administers it?
 - OPPT of the OCSP of the U.S. EPA

HOW DOES TSCA WORK?

- Requires review of the toxicological properties of new or imported chemicals prior to listing on the “TSCA Inventory”
- Once a chemical is on the Inventory, no further approval is required to manufacture, process or import
- Unless use would be inconsistent with conditions imposed during the listing process

HOW DOES TSCA WORK (CONT.)?

- Pre-Manufacture Notices (PMNs)
 - Pre-market approval required before manufacturing or importing a chemical not already on the TSCA Inventory
 - PMN submitted to EPA at least 90 days before manufacture or import
 - 90-day (with extensions) review process to determine if unreasonable risk posed
 - Possible Outcomes
 - No action within 90 days, approval deemed granted
 - Approval, subject to restrictions on use (e.g., volume, protective equipment, waste handling)
 - Outright ban – very rare

HOW DOES TSCA WORK (CONT.)?

- Significant New Use Rules (SNURs)
 - If PMN approved with restrictions, consent order imposed pending issuance of SNUR, which extends restrictions to all entities
 - SNUR Modification Process
 - If company wants to use chemical in a way not covered by SNUR, risks associated with new use must be approved and SNUR modified
- Reporting
 - Quadrennial reporting to EPA
 - Covering chemicals imported or manufactured in prior reporting year
 - Chemical Data Reporting (“CDR”) system

HOW IS TSCA ENFORCED?

- Violations can be discovered by formal EPA inspections, but more often come to light through internal corporate audits
- Corrective actions depend on nature of violation
 - Recordkeeping and reporting violations – new submissions to EPA; updates to corporate files; may involve penalties
 - Importation/manufacture of unapproved chemicals – immediate cessation; often involve penalties for entire violations period; submission of required pre-market approval applications

HOW DO COMPANIES ENSURE COMPLIANCE WITH TSCA?

- Development of compliance programs that:
 - Educate relevant personnel about TSCA triggers
 - Compile information for compliance review
 - Integrate regulatory requirements into commercial planning
- Use of data management systems, pre-set to reflect information required to be reported

WHAT IS “TSCA REFORM”

- Efforts to amend TSCA that culminated with passage of major amendments in 2016
- Why did TSCA need to be reformed?
 - Industry
 - Patchwork of conflicting state requirements
 - Environmental NGOs
 - Too few attempts to regulate existing chemicals
 - Public disclosure of risks too limited

HOW WAS TSCA REFORMED?

- U.S. Approach (pre-TSCA Amendments)
 - Allow chemistry in commerce unless it is shown to be excessively risky
- European Model
 - Assume risk unless proven safe
- TSCA Amendments
 - Paradigm shift away from U.S. approach and toward European model

KEY ASPECTS OF TSCA AMENDMENTS

- More Safety-Focused Than Cost- or Burden-Focused
 - Pre-Amendment
 - Mandated “least burdensome” alternative
 - Required cost-benefit calculation
 - Post-Amendment
 - Prioritization of active chemicals for review
 - “Unreasonable risk to human health or environment” standard
 - For high priority chemicals, risk evaluation must be completed within 3 years

KEY ASPECTS OF TSCA AMENDMENTS (CONT.)

- Retroactive Evaluations of Grandfathered Chemicals
 - Pre-Amendment
 - Tens of thousands of chemicals already in existence in 1976
 - All were essentially grandfathered in – *i.e.*, assumed to be in compliance
 - Post-Amendment
 - EPA required to evaluate the safety of chemicals *already on* TSCA Inventory
 - Review will occur in five phases:
 - » Inventory reset
 - » Prioritization
 - » Risk Evaluation
 - » Risk Management
 - » Implementation

KEY ASPECTS OF TSCA AMENDMENTS (CONT.)

- **More Bans and Limitations on Chemicals Likely**
 - Pre-Amendment
 - EPA only attempted to ban 5 chemical substances out of tens of thousands that were grandfathered in upon initial passage
 - Post-Amendment
 - With new emphasis on safety over cost, EPA likely to propose more bans and restrictions
- **Particular Emphasis on Vulnerable Populations**
 - Chemicals expected to be deemed high priority include those that pose threat to vulnerable populations – e.g., children and the elderly

KEY ASPECTS OF TSCA AMENDMENTS (CONT.)

- More Federal and Less State/Local Chemical Regulation
 - State regulations already in place will remain in force
 - Going forward, once EPA begins chemical review, state cannot take action until EPA's risk evaluation is complete, subject to waivers
- More Openness of Information and Less Corporate Privacy
 - Generally harder to maintain business confidences regarding regulated chemistry
 - CBI claims must be substantiated at the outset and reasserted over time

WAIT, WHAT HAPPENED TO THE DEREGULATORY AGENDA?

- The Trump Administration is generally committed to reducing regulatory burdens
- But new TSCA requires:
 - More agency reviews
 - Higher regulatory burdens for applicants
 - More stringent standards for approving the sale and use of chemicals

WHEN WORLDS COLLIDE

- Over the last year and a half:
 - Career staff at OPPT have demonstrated a commitment to aggressive implementation of TSCA Amendments
 - Meanwhile, political leadership has struggled to define and implement more streamlined processes
- Its one thing to accomplish regulatory streamlining in areas where no legislation has been passed in decades (*i.e.*, every other area)
- It's entirely another thing to reduce regulatory burdens when Congress has mandated the implementation of new, intentionally more burdensome requirements

ONGOING CHALLENGES

- EPA's approach to PMN and SNUR reviews under TSCA Amendments has resulted in significant delays
- SNUR modification process in particular has seen significant delays
 - Reviews that are supposed to take 90 days are taking over a year
- Concerns raised by industry that EPA is planning to require extensive testing of chemicals by applicants
- Concerns raised by small business advocates that proposed application fees could limit innovation by dissuading smaller companies from seeking chemical reviews

ONGOING CHALLENGES (CONT.)

- Attempts to streamline new chemical review process are coming under fire from environmental NGOs, who see it as a move to unlawfully dial back burdens imposed by law
- Similar concerns are being raised regarding attempts to protect CBI under a law designed to limit such protections

BOTTOM LINE

- Tension between Trump Administration deregulatory focus and increased regulatory burdens imposed by new TSCA
- Attempts to streamline process running up against a law designed to create more, not fewer, procedural burdens
- Some progress has been made in reducing delays, but challenges remain



MATT PAULSON

111 Congress Avenue, Suite 2300
Austin, Texas 78701-4061
512.494.3659

711 Louisiana Street, Suite 2300
Houston, Texas 77002-2770
713.221.4959

matthew.paulson@bracewelllaw.com