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

4C HEALTH / SAFETY / ENVIRONMENTAL CONFERENCE

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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 OCSPP 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
    o No action within 90 days, approval deemed granted
    o Approval, subject to restrictions on use (e.g., volume, protective equipment, waste handling)
    o 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
    o 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
    o Patchwork of conflicting state requirements
  – Environmental NGOs
    o Too few attempts to regulate existing chemicals
    o 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
    o Mandated “least burdensome” alternative
    o Required cost-benefit calculation
  – Post-Amendment
    o Prioritization of active chemicals for review
    o “Unreasonable risk to human health or environment” standard
    o 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
    o Tens of thousands of chemicals already in existence in 1976
    o All were essentially grandfathered in – *i.e.*, assumed to be in compliance
  – Post-Amendment
    o EPA required to evaluate the safety of chemicals *already on TSCA Inventory*
    o 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
    o EPA only attempted to ban 5 chemical substances out of tens of thousands that were grandfathered in upon initial passage
  – Post-Amendment
    o 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
• It's 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
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