

## The essentials of TSCA practice

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The Toxic Substances Control Act (TSCA) is not the arcane federal law it once was. Amended in 2016 in response to a demand so loud and persistent from nongovernmental organizations, consumers, and, eventually, the industrial chemical community that Congress could no longer ignore it, TSCA is now a force with which to be reckoned. While the U.S. Environmental Protection Agency's (EPA's) implementation of the [2016 Lautenberg Act](#) that amended TSCA invites criticism among stakeholders, there is no disagreement that today TSCA is a more consequential law, deserving of legal practitioners' attention.

### Old TSCA's failures

Old TSCA was more an expression of national aspiration than an effective law. The statute authorized EPA to address unreasonable risks posed by industrial chemicals in commerce, but it offered no blueprint for whether, how, or when EPA could or should deploy this authority. Under old TSCA, EPA lacked any mandate to prioritize, evaluate, or regulate the 62,000-plus "grandfathered" chemicals already in commerce in 1976 when TSCA was adopted, which remained in commerce without safety review, although few had undergone evaluation. While new chemicals could not be commercialized without notifying EPA, that notice triggered no risk findings. EPA's authority to require manufacturer testing of chemicals proved difficult to implement. As a result, complicated supply chains evolved, largely unfettered by EPA inquiry into the human-health and environmental effects of chemicals used in manufacturing or included in finished goods.

These failures resulted from structural deficits in the law itself. EPA effectively bore the burden of demonstrating that a chemical was unsafe instead of requiring the chemical producer to prove that it was. EPA was required to conduct cost-benefit analyses of alternatives and select the "least burdensome" option for regulating a chemical, a nearly impossible legal hurdle to overcome. Many argued that too much health and safety information was claimed as confidential business information (CBI), interfering with the public's right to know and undermining consumer confidence in the federal government's ability to ensure chemical safety.

## New TSCA and implications for practitioners

To address the deficits in the old law, new TSCA gives EPA extensive new authority and duties; the resulting implications for commerce and public health are likely to be consequential. Below we summarize the changes of which legal practitioners should be aware.

**New Chemicals.** Under TSCA section 5 (new chemicals), before a new chemical can be commercialized, EPA is required to make and publish a finding that the substance is not likely to present unreasonable risk, effectively placing the legal burden of proof on the chemical producer. Chemical safety is considered based on known, intended, and reasonably foreseen “conditions of use,” a phrase new to TSCA. If EPA cannot make this finding, or lacks information on which to make it, commercialization can go forward only with regulatory limitations on the chemical’s production and use, typically expressed as a Consent Order and/or Significant New Use Rule (SNUR). To most chemical stakeholders, SNURs are unwelcome regulatory red flags that tend to make a chemical commercially less desirable.

The practical impact is that a producer of a new chemical must be more mindful of the health and safety implications of manufacturing the new chemical, and the consequences for downstream transporters, processors, and users of the new chemical, as well as populations potentially impacted by disposal or recycling. Unlike old TSCA, new TSCA does not reward ignorance about new chemicals.

**Existing Chemicals.** EPA’s expanded authority under TSCA section 6 (existing chemicals) requires methodical review of all active existing chemicals to identify “high priority” chemicals that will undergo risk evaluation against a health-based standard that requires protecting vulnerable populations, including children, pregnant women, and workers. EPA must do so within strict deadlines and must regulate and abate any unreasonable risk it identifies.

EPA’s soon-to-be-completed risk evaluations of the first 10 chemicals selected for review illustrate TSCA’s power. The intensity of the chemical selection and risk evaluation processes has driven public attention to the potential risks posed by chemicals in particular applications, with consumer uses and workplace exposures garnering the most scrutiny. Even in the absence of final EPA action, selecting a chemical as “high priority” and identifying potential risks associated with its use set into motion a series of events that can be far-reaching.

Methylene chloride, a carcinogenic solvent that is one of the first 10 chemicals undergoing risk evaluation, provides a useful example. Several large U.S. retailers disallowed the stocking of paint and coating removal products containing methylene chloride before EPA mandated this result, which appeared inevitable based on EPA’s proposed risk findings. These “soft law” standards set by retailers have the power to recalibrate consumer, stockholder, and retailer expectations. Ongoing risk evaluations under new TSCA will likely flag additional unreasonably risky chemical uses that will spur phase-outs and innovation of safer replacements. While the

phaseout of the retail sale of methylene chloride paint strippers reflects TSCA's power, EPA's decision not to regulate commercial use of methylene chloride has proven controversial and is now in litigation. Other key implementation questions—such as whether EPA must consider risks from exposure pathways that could be regulated under laws—are also likely to be decided by the courts.

**CBI.** New TSCA increases the effort needed to claim information as CBI. This higher bar has caused chemical innovators, manufacturers, and others to rethink product formulations, restructure compliance programs, and reconsider communications with downstream customers and others. The availability of more product information has also reconfigured the business relationship among chemical stakeholders and prompted product redesigns and reformulations. Yet, environmental organizations have voiced concerns that EPA is not enforcing disclosure requirements, leading to still-pending litigation.

Legal practitioners should be aware of TSCA's new provisions and anticipate their commercial, legal, and reputational implications. Counseling clients on the many implications of TSCA's expanded commercial reach is an important, consequential, and growing practice area. Community organizations representing populations at greater risk of harm from chemicals should also be aware that TSCA may offer much-needed protections.