

## Toxic Substances Control Act (TSCA)

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Wiley is a trusted legal advisor to companies that need to navigate Toxic Substances Control Act (TSCA) compliance. TSCA is no longer the exclusive domain of chemical manufacturers: the U.S. Environmental Protection Agency's (EPA's) reach runs from factories to store shelves to households. Participation by downstream companies that use chemicals is essential to inform EPA's evaluation of the uses of new and existing chemicals.

Wiley's TSCA attorneys have deep experience in chemical regulation. We help clients comply with TSCA and other chemical control laws, while also advancing their business interests. Our team provides experienced counsel to clients on the current regulatory challenges facing companies at the federal and state level related to a number of chemistries including perfluoroalkyl and polyfluoroalkyl substances (PFAS). Wiley is convenor and counsel to the Complex Products Manufacturers Coalition (CPMC), an organization dedicated to science-based PFAS regulation for multi-component products that are essential to the health, safety, and the well-being of society.

The expanding universe of PFAS regulation is far from the only challenge facing products in commerce. We help companies and trade associations develop strategies to drive informed chemical risk evaluations for existing chemicals under TSCA Section 6. We provide clients with the foundation to proactively gather critical information, including developing tools to identify the presence of chemicals in supply chains, supporting the collection of confidential chemical use data, and reviewing the availability of chemical alternatives. We assist with public comments and help clients inform TSCA section 6 risk evaluations and negotiate and comply with a growing number of TSCA risk management rules.

Wiley attorneys understand the need to build a strong administrative record throughout these processes that guards the legal rights of clients to challenge adverse outcomes. We are among a small group of firms that represent industry in TSCA litigation challenges, and we advise on and prepare Section 21 citizens' petitions to advance industry initiatives through EPA rulemakings for existing chemicals and other areas of TSCA.

Wiley provides effective and comprehensive defense counseling in TSCA enforcement proceedings on behalf of clients, including representation in administrative hearings and judicial proceedings. We are experienced in conducting TSCA due diligence and compliance audits, and we counsel companies in self-disclosure options.

We advise companies in connection with reporting programs under TSCA, such as Chemical Data Reporting (CDR) and other chemical reports required by Section 8(a), Section 8(d) unpublished health and safety data reporting, and time-sensitive substantial risk information reporting under Section 8(e). Wiley also offers

strategic counseling on premanufacture notification (PMN) submissions and negotiated consent orders with EPA, and the applicability of PMN exemptions such as the R&D exemption. It has never been more challenging to receive EPA approval of a new chemical under TSCA than it is today. We help companies anticipate and respond to adverse determination outcomes and guard their confidential business information (CBI) to prevent information disclosure through robust substantiation of CBI claims under TSCA. We negotiate, advise on compliance with, and help file modification requests for consent orders and significant new use rules (SNURs). We have chemistry and toxicology expertise on staff to support our attorneys and clients on TSCA chemical naming rules, toxicity testing, and exposure assessment matters.

## Representative Experience

- Assisting companies in preparing for PFAS reporting rules at the federal level and in Minnesota.
- Representing clients in EPA risk evaluations of existing chemicals under TSCA and helping clients and industries to identify these chemicals in supply chains, conduct alternatives assessments, and develop strategies for their continued use where no alternatives exist.
- Advising on the implementation of TSCA preemption as it pertains to state rules, PFAS, methylene chloride, and other chemicals.
- Prepared *amicus* brief in support of EPA's TSCA Dust-Lead Hazard Standard to defend the interests of the construction, paint and coatings, and U.S. recycling industries. These standards apply to most pre-1978 housing and child-occupied facilities.
- Guiding companies on PMNs for new chemicals, negotiating improvements to consent order terms, and advising on options such as the research and development (R&D) exemption and low volume exemption (LVE).
- Extensive experience representing companies that manufacture and process new nanomaterials such as carbon nanotubes and graphene, as well as new battery ingredients such as cathode active materials and electrolyte components.
- Representing biotechnology companies before EPA on PMNs and Microbial Commercial Activity Notifications (MCANs) for genetically modified production strains.

Wiley's TSCA Resource Center is designed to be a convenient way for companies to locate key references associated with TSCA compliance. We keep clients apprised of new TSCA developments through timely client alerts accessible through social media and email. To subscribe to our complimentary alerts, please [click here](#).

## Contact Us

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