

Toxic Substances Control Act (TSCA)

Wiley is a trusted legal advisor to companies that need to navigate the complexities of 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. Downstream company participation is essential to inform EPA's evaluation of the uses of new and existing chemicals.

The promise of TSCA includes robust, evidence-based TSCA risk evaluations to protect workers and consumers without stifling the economy. However, a critical task facing companies today is to convince EPA to recognize the use of engineering and administrative controls and personal protective equipment (PPE) in the workplace. We regularly are engaged to analyze, advise, and help prepare public comments during the TSCA risk evaluation and risk management process to build a strong administrative record 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 serve as defense counsel in TSCA enforcement proceedings on behalf of clients.

At Wiley, we are experienced in conducting TSCA due diligence and compliance audits so that they are protected by the attorney-client privilege, and we counsel companies in self-disclosure options.

We advise companies in connection with premanufacture notification (PMN) submissions and negotiate consent orders. It has never been more challenging to claim, support, and guard proprietary company information under TSCA than it is today. We work with companies to ensure robust substantiation of confidential business information (CBI) where this is required. We help companies respond to adverse determination outcomes from EPA reviews of CBI to prevent information disclosure. We negotiate, advise on compliance with, and help file modification requests for consent orders and significant new use rules (SNURs). Our firm is well-versed on TSCA chemical naming rules, in addition to toxicology and exposure data legal matters such as Section 8(e) reporting. Wiley has advised clients and prepared public comments on all of the major rules issued by EPA to implement the 2016 Lautenberg amendments.

Representative Experience

- Filed public comments on EPA's proposed Per- and Polyfluoroalkyl Substances (PFAS) reporting rule to explain how Section 8 of TSCA allows EPA the legal authority to establish exemptions from reporting.

- Representing lithium ion battery manufacturers in the n-Methylpyrrolidone (NMP) risk evaluation.
- Litigate on behalf of a coalition of trade associations to challenge EPA's regulation under TSCA that sought to prohibit Phenol, Isopropylated Phosphate (3:1) (PIP 3:1) within 60 days.
- 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.
- Represent companies who manufacture and process nanomaterials on TSCA premanufacture notices.
- Represent major bioplastics and other biotechnology companies to prepare Microbial Commercial Activity Notifications (MCANs) for genetically modified production organisms.
- Member of the U.S. Chamber of Commerce PFAS Working Group and representing PFAS interests before EPA's TSCA program.
- Advising a group of consumer product trade associations on EPA targeting of imported articles for regulation and fee payments under TSCA.
- Advising on the implementation of TSCA preemption as this pertains to state rules, regulation of flame retardants, PFAS, methylene chloride, and other chemicals.

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](#).

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