

Toxic Substances Control Act (TSCA)

At Wiley, we provide effective regulatory strategies and advocacy on behalf of our clients before the U.S. Environmental Protection Agency (EPA) on matters under the Toxic Substances Control Act (TSCA). Our clients attribute their success to Wiley's unparalleled substantive depth on TSCA and high-level leadership experience at EPA. Because our attorneys worked on the legislative drafting of the Frank R. Lautenberg Chemical Safety for the 21st Century Act and the implementation of those sweeping reforms, we are uniquely positioned to help companies and trade associations strategically navigate the 2016 changes in the law.

As a result of those changes, TSCA is no longer the exclusive domain of the chemical manufacturer. EPA's reach runs from factories to store shelves to households. The agency is able to access highly sensitive product details, and it has never been more challenging to claim, support, and guard proprietary company information. EPA has the authority to control how both new and existing chemicals on the TSCA Inventory are manufactured, processed, distributed, and used. The initial proposals for regulating existing chemicals are making extensive use of EPA's ability to ban chemicals to control exposure and manage risk.

We understand first-hand the importance of robust, evidence-based TSCA risk evaluations that protect worker and consumer health without overregulating. We routinely provide statutory analysis on all aspects of TSCA implementation to trade associations, industrial manufacturers, and brand owners. We are engaged in TSCA rulemakings and litigation, and work with companies to protect confidential business information (CBI) from disclosure. We represent companies in TSCA enforcement proceedings, conduct audits so that they are protected by the attorney-client privilege, and counsel companies in self-disclosure actions. We advise companies in connection with premanufacture notification (PMN) submissions, negotiate consent orders, and provide counsel in connection with 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. Our attorneys also provide counsel on the interface between TSCA and other statutes, including FIFRA, CSPIA, and the FFDCA.

Representative Experience

- Represent and advocate on behalf of manufacturers and trade associations in response to EPA's TSCA risk evaluation of a critical chemical.
- Litigate on behalf of numerous trade associations to challenge EPA's regulation under TSCA that sought to prohibit a widely used chemical within 60 days.

- Represent and advise client on widespread chemical substance for which EPA is conducting a TSCA risk evaluation.
- Draft comments, letters, and other documents in response to EPA's proposed rules and regulations under TSCA and the CAA.
- Represent clients from the scientific assessment phase through the final rulemaking process on matters relating to TSCA and the CAA.
- Drafted and submitted amicus brief on behalf of numerous trade associations in support of EPA's TSCA Dust-Lead Hazard Standards.
- Advise clients on TSCA enforcement and compliance questions.
- Advise clients on EPA's TSCA risk evaluations, rulemakings, and new chemical review process.
- Assist clients on compliance matters under FIFRA and the ESA in accordance with legal requirements and court orders.
- Represent multiple clients on TSCA premanufacture notices to successfully achieve timely approvals.
- Providing legal support on all aspects of TSCA to industrial manufacturers, importers, and consumer product companies.
- Advocacy and litigation on behalf of trade associations on EPA rulemakings to implement new TSCA requirements, including exposure and use considerations for existing chemicals during prioritization and risk evaluation under section 6 of TSCA.
- Member of the U.S. Chamber of Commerce Per- and Polyfluoroalkyl Substances (PFAS) Working Group and representing PFAS interests before EPA's TSCA program.
- Advising on TSCA CBI claims, substantiation requirements, and Freedom of Information Act (FOIA) requests.
- Advising a major automobile manufacturer on regulatory issues involving new chemicals including PMN development, conditions of use, and the applicability of the article exemption.
- Representing manufacturers and importers against proposed Significant New Use Rule (SNUR) regulations by EPA's new chemical program.
- Advising on accurate chemical nomenclature representations for global regulatory compliance.
- Conduct TSCA compliance audits for multinational companies that include a review of numerous toxicological test results for reporting as Section 8(e) substantial risk information.
- The leading firm for effective assistance with approvals of biotechnology microbial commercial activity notifications (MCANs) for yeast and other innovative fermentation platforms.
- Successful defense of the right to immediately commercialize nanomaterials under section 8(a). Advocacy efforts included favorable non-reporting ruling by EPA for emulsion polymers.
- Helped craft statutory language on preemption, section 8 equivalency, and sustainable chemistry for consideration during the legislative process that led to enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

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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