

TOXIC SUBSTANCE CONTROL Act (TSCA)

Toxicology & Regulatory Affairs Services—US

TSCA requires the notification of USEPA's Office of Chemical Safety and Pollution Prevention of any "new" chemical substances manufactured in the United States or imported for the first time. The new law requires the US EPA to make affirmative determinations on new chemicals before they can come to market. The Agency will review the intended use of a new chemical substance and evaluate the need for additional use information or data to address any concerns identified. **toXcel** offers experienced technical support to facilitate the compilation of the required documentation to complete a your chemical's Premanufacture Notification (PMN), Low Volume Exemption (LVE), or Significant New Use Notification (SNUN).

toXcel can help you determine whether the chemical you intend to manufacture or import is indeed a new chemical substance and what, if any, exclusions or exemptions may apply to that chemical substance or its use, and navigate you through your requirements under the US EPA/TSCA regulatory process.

toXcel's dedicated technical support capabilities include modeling exposure potential, conducting risk assessments; providing justification for "cluster" grouping, bridging, and waiver arguments; management of new data generation projects; PMN, LVE, and SNUN preparation; and working with both manufacturers and importers to shepherd submissions through the EPA review process. **toXcel** offers assistance in establishing CDX accounts and preparing documents for electronic submission of notifications and supporting documentation.

"Forever chemicals" are also a hot topic under TSCA. **toXcel** has staff with expertise in PFAS (per- and polyfluoroalkyl substances) chemicals and follows the numerous regulatory updates in this developing area. We review available information from companies to help determine their potential liabilities related to PFAS, develop strategies related to testing, determine reporting requirements, develop risk and exposure assessments, and help companies navigate forward in this evolving regulatory landscape. **toXcel** is also working with clients for support under the TSCA one-time reporting rule under TSCA Section 8(a)(7) for PFAS manufactured or imported into the US between 2011 and 2022. Contact us to determine your reporting requirements before the 2025-26 deadlines! EPA extended these deadlines by 8 months due to their budgetary constraints – **toXcel** continues to monitor events as PFAS regulations evolve.

Areas of Scientific Expertise include:

- Toxicology
- Chemistry
- Structure Activity Relationships (SAR), bridging, and waiver justification
- Exposure Potential Modeling and risk assessment
- Environmental fate projection
- Ecotoxicity assessment

toXcel can prepare your:

- Premanufacture Notifications (PMN)
- Low Volume Exemptions (LVE)
- Significant New Use Notifications (SNUN)
- Bona fide intent requests to search the TSCA Inventory
- PFAS reporting requirements under TSCA 8(a)(7)

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