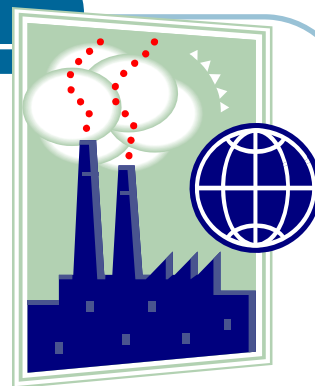


TSCA – PREMANUFACTURE NOTIFICATION AND OTHER TSCA § 5 SUPPORT



The Toxic Substances Control Act (TSCA) requires the notification of any “new” chemical substances being imported into or manufactured in the United States for the first time. Any company intending to manufacture or import a new chemical substance must give USEPA’s Office of Chemical Safety and Pollution Prevention 90-day notification under TSCA § 5. EPA will review the intended use of a new chemical substance and evaluate any hazards associated with its use and, if necessary, regulate a new chemical substance. **toXcel** can compile all information concerning chemical identity, use profile, manufacture/import volume, and exposure potential to human health and the environment into the required documentation to complete a new chemical’s Premanufacture Notification.

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 a chemical substance or its use. **toXcel** can be your source for the preparation of PMNs and other TSCA § 5 Notices and can coordinate submission of documents and materials to EPA and track their progress during Agency review. We are prepared and ready for upcoming technological advances with EPA’s submission process for PMNs and continue to stay abreast of any changes in the TSCA regulation.

toXcel is an experienced and reliable source of scientific and regulatory support for manufacturers and distributors. Examples of **toXcel’s** in-house technical support capability include cost-effective assessment of toxicology data and selection of appropriate data sets for regulatory utilization, conduct of risk assessments, development of bridging, justification for “cluster” grouping and waiver arguments, management of new data generation projects, document preparation, submission coordination, and collaboration/communication with EPA personnel.

Areas of Scientific Expertise include:

- Toxicology (including acute, subacute, mutagenicity, chronic and carcinogenicity, developmental and reproductive toxicity, and other special studies)
- Structure Activity Relationships (SAR), bridging, and waiver argument development
- Exposure Modeling (occupational, user, dietary) and Risk Assessment
- Environmental Fate
- Ecotoxicity

toXcel has decades of experience in regulatory affairs and has prepared full Premanufacture Notifications for an array of industrial chemicals. Let us help you!