

# TOXIC SUBSTANCE CONTROL ACT (TSCA)

## Toxicology & Regulatory Affairs Services—US

On June 22, 2016 the Toxic Substances Control Act (TSCA) was updated for the first time in 20 years. With this update will come many changes in how applications are handled from start to finish. 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 EPA to make affirmative determinations on new chemicals before they can come to market. The fee schedule will change in addition to the timeline on applications, but **toXcel** staff remain abreast of these changes as they happen and will keep you informed and on-schedule. EPA 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 new chemical's Premanufacture Notification (PMN).

**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, and assist you through this transitory period of change while EPA modifies its processes.

**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 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 using the eTSCA system required for electronic submission of notifications and supporting documentation.

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)

For further discussion on how **toXcel** can best serve your TSCA regulatory needs, please contact Alan Katz at 703-754-0248 extension 111 or by email at [Alan.Katz@toxcel.com](mailto:Alan.Katz@toxcel.com).

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