TSCA Existing Chemicals Qualifications

ToxStrategies is a multidisciplinary scientific consulting firm that strives to develop innovative solutions to address the scientific, technical, and regulatory challenges confronting our clients. We have a reputation for applying sound science in all that we do, for leading-edge thinking, and for tailoring our approach to meet the specific needs of our clients, whether a rapid response or a comprehensive analysis is needed.

Under Section 6(b) of the Toxic Substances Control Act (TSCA), EPA is required to make a carefully documented, affirmative determination that a substance is "not likely to present an unreasonable risk" for both new and existing chemical substances. For existing substances, EPA will prioritize chemicals on the TSCA inventory and conduct detailed risk evaluations of each high priority substance to assess its safety and determine whether any restrictions are needed during reasonably foreseeable uses over its life cycle.

Although chemical manufacturers and importers are directly involved in the TSCA risk evaluations of existing chemicals, downstream users of the substances may also be impacted by EPA's risk determinations and possible restrictions. Therefore, it is critical to understand the potential risks of a chemical substance throughout its life cycle and the potential impact on the use of the chemical and articles and products containing the chemical. ToxStrategies has extensive experience in compiling state-of-knowledge reviews to help inform all stakeholders so that they can proactively engage in chemical risk evaluations and ensure that the best science is available to EPA. Selected key services to support TSCA existing chemical risk evaluations include the following:

Toxicity Assessment

- Systematic Review (SR) of published literature to assess quality of toxicity data
- Quantitative structure activity relationship (QSAR) analysis and read-across assessment of test data on analogous substances
- Comprehensive epidemiological study review and meta analyses
- Physiologically based pharmacokinetic (PBPK) modeling
- Evaluation of in-vitro high-throughput screening assay data
- Toxicity study design, placement and monitoring, and data management and interpretation

Exposure Assessment

- Conceptual exposure model development
- Predictive exposure modeling for conditions of use
- Compilation and analysis of occupational and environmental exposure measurements
- Identification of susceptible populations
- Exposure simulation studies
- Biomonitoring data assessment
- Integrated exposure modeling across various sources