

Development of a Risk Assessment Framework to Support New Chemical Notifications Under TSCA

Britt McAtee, Ph.D., DABT, PPG, Pittsburgh, PA

PPG has developed a risk assessment framework to evaluate substances prior to submission of new chemical notifications under US EPA TSCA. Under TSCA, new chemical notifications do not require any predetermined hazard or exposure data. After submission and review, EPA may require test data via test orders or publish restrictions around use of the substance to control risk based on data submitted or, in the absence of data, modeled values. This can result in significant delays in commercialization of products and hinder innovation. To facilitate EPA review, PPG has developed a risk assessment framework, to drive New Chemical Notifications that are scientifically robust. The framework utilizes a logical, tiered approach in which potential hazards and exposure pathways are evaluated, in a defined order, through reliable publicly available methodology that has been accepted by EPA and global regulatory authorities. At the conclusion of each tier, risk characterization is completed, incorporating transparency, clarity, consistency, and reasonableness (TCCR) principles. The data are assessed and if significant data gaps are found, the framework proceeds to the next tier. If it is determined at any step in the framework that the new chemical is not likely to present an unreasonable risk to human health or the environment at the sites where it is intended or reasonably foreseen to be produced, handled, or used, then the risk assessment is concluded without completing the subsequent steps. The new chemical notification is then submitted with the Framework assessment. The goal of the Framework is to provide EPA with a scientifically sound analysis to facilitate their review and decrease time to commercialization.