Visualizing the US EPA Sustainable Futures Program

Katherine Sullivan; Kelly E. Mayo; Jeffrey Hafer; Elizabeth Dederick, PhD

Disadvantages of Not Conducting a Pre-Screening Assessment

A Tier 1 approach is when companies do not take full advantage of the tools available on the EPA's Sustainable Futures website and provide only minimal information to the EPA. This will result in the EPA using conservative values and worst-case scenarios in the risk assessment, which may (1) jeopardize the potential success of the pre-manufacture notice (PMN), (2) increase the EPA's review time, and (3) result in additional unexpected testing requirements.



No effort to collect data/ information on notified chemical or related analogs

Significant regulatory delays and unanticipated costs to company

The Benefits of Conducting Pre-Screening Analysis Prior to Submission of a US New Chemical Notification under the Toxic Substances Control Act (TSCA) Section 5

Under the US New Chemicals Program, the Environmental Protection Agency (EPA) must determine the potential risk of a new substance before it enters commerce. The program functions as a "gatekeeper" to identify conditions, up to and including a ban on production, to be placed on the use of a new chemical before it enters commerce. Without base set testing requirements, the EPA uses screening-level tools and conservative assumptions to conduct an initial risk assessment and identify additional testing needs or risk mitigation options. Using the tools and educational materials available on the EPA's Sustainable Futures website, submitters can access these predictive models, default assumptions, and risk assessment approaches before submission to help anticipate risk concerns and potential regulatory decisions.

Available Predictive Approaches Include:

Literature Screening and Analog Identification

- EPA New Chemical Categories Document
- Analog Identification Methodology (AIM) Tool
- Chemical Assessment Clustering Engine (ChemACE)

Predictive Models for Hazard Identification

- **EPISuite:** Physical/Chemical Data and Environmental Fate
- Ecological Structure Activity Relationships (ECOSAR)
- OncoLogic Cancer Expert System
- The Model Averaging for Dichotomous Response Benchmark Dose (MADr-BMD) Tool

Predictive Models for Exposure Analysis

- ChemSTEER: Screening Level Tool to Identify Worker Exposure and Environmental Releases
- E-FAST: Screening Level Tool to Identify General Population Exposure and Environmental Impacts
- CEM/E-FAST: Screening Level Tool to Identify Consumer Exposures and Subsequent Environmental Releases

Advantages of Conducting a Pre-Screening Assessment

A Tier 2 approach uses the tools available on the EPA's Sustainable Futures website and available data to create a risk characterization by the company. The benefit of this analysis in advance of submission is that it (1) allows companies to identify concerns prior to PMN submittal, (2) prepares the submitter for questions from the EPA, (3) helps companies identify potential risks, (4) allows for the modification of modeling variables based on input data, and (5) provides in-depth understanding of the PMN process.

Tier 2



