

Pollution Prevention (P2) Framework Chemical Assessments



The Pollution Prevention or P2 Framework methodology is a collection of screening assessment tools, models, and processes designed to evaluate chemical hazard, exposure, and risk potential in the absence of measured data.

The methodology was developed by the US EPA over the past 35 years to assess potential hazards and risk for new chemicals submissions, designed to mimic the review process used by the EPA for New Chemical submissions under TSCA, and is a vital part of the US EPA Sustainable Futures program. With the recent Frank R. Lautenberg Chemical Safety for the 21st Century Act (TSCA 21) update to the Toxic Substance Control Act prescreening of New Chemicals submissions has become more important than ever.

CERM is a recognized expert in the application of the P2 Framework methodology and the Sustainable Futures program. CERM has worked with US EPA and chemical industry partners and clients for over 15 years completing hundreds of P2 chemical assessments and participating in Sustainable Futures/P2 Framework training workshops. We have utilized the tools on hundreds of substances and have experience integrating these tools with many types of regulatory submissions, such as PMNs or LVEs. We can provide a snapshot of how EPA may review a submission to help maximize success!

The assessment consists of three steps: Fate and Hazard Assessment, Release and Exposure Assessment; and Risk Screening Assessment, designed to duplicate the EPA PMN/New Chemical Review process. Below is a brief description of the three assessment steps. Our costs are competitive, usually a complete assessment can be done for less than a single acute fish toxicity test.

In-Depth Fate and Toxicity Hazard Assessment – The initial phase of the assessment is to evaluate the environmental fate and potential toxicity of the chemical substance. Fate assessment includes characterizing bioaccumulation, environmental partitioning, and environmental degradation (both biodegradation and other potential removal routes). The toxicity hazard assessment evaluates both human health and aquatic toxicity effects, with quantitative effect level endpoints provided where applicable. These may be based on nearest analog analysis or predictive modeling.

Exposure and Release Assessment – When manufacturing or using a chemical substance, there is the potential for environmental release or worker exposure. The P2 Framework tools provide a screening level methodology for predicting release and exposure. Release modeling includes multiple potential routes for aquatic, air-borne, or land-based release, as applicable. Exposure predictions can be modeled for human populations, both in occupational settings and for the general population, as well as environmental exposure. The exposure and release assessment can be of particular value when evaluating a new chemical substance for TSCA PMN or LVE submission.

Risk Screening Assessment – Risk is a function of hazard and exposure, therefore to adequately establish risk, this phase of the assessment builds on the previous steps. The P2 risk assessment is completed by evaluating the predicted exposure levels in light of the relevant human and aquatic toxicity effect levels determined previously. Separate screening methodologies are used for human and aquatic risk. The risk assessment can provide information about potential risks to human health or the environment and may hold clues to steps to address any concerns. This overall assessment paradigm mirrors that used by the US EPA in TSCA PMN review and can support new chemical submissions.

Please feel free to contact us for more information:

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