

Turning Regulatory Setbacks into Strategy: How Trinity Consultants Addressed a New Chemical Challenge under TSCA

CHALLENGE

A global specialty chemicals manufacturer faced LVE ineligibility under TSCA. Limited analog data and a complex new chemical structure made it difficult to differentiate the substance and address chemical-class hazard concerns without conducting new testing.

SOLUTION

Trinity redesigned the submission using a weight-of-evidence approach combining existing data, in vitro methods, analog comparisons, and mechanistic analysis to demonstrate reduced hazard potential and to develop a structured, mechanism-informed comparative hazard class.

RESULT

The revised submission differentiated the polymer from higher-risk substances and presented a strong scientific case for reduced hazard potential—without new animal testing—while improving submission quality and clarity.

A global chemicals manufacturer had been pursuing regulatory approval in the United States (U.S.) for their novel chemistry for more than a decade, and navigating the regulatory hurdles requires a dedicated and knowledgeable partner such as Trinity Consultants.

The Toxic Substances Control Act (TSCA), as administered by EPA, governs the manufacture, import, and use of chemical substances in the United States, requiring companies to demonstrate that new chemicals do not present unreasonable risk to human health or the environment. Under TSCA Section 5, manufacturers must submit to EPA premanufacture notices (PMNs) or qualify for exemptions such as Low Volume Exemptions (LVEs), which are subject to strict eligibility criteria and increasing regulatory scrutiny.

For specialty and industrial chemical manufacturers, navigating TSCA requirements can be particularly complex when dealing with substances that fall into higher-concern categories. Regulatory decisions are often driven not only by substance-specific data, but also by class-based hazard assumptions.

Trinity Consultants supports chemical manufacturers by translating complex regulatory expectations into actionable strategies, including TSCA submissions, comparative hazard assessments, and exposure modeling.

CHALLENGE

A global specialty chemicals company sought to import a new substance in the U.S. market under a Low Volume Exemption (LVE) but encountered a significant regulatory setback when its initial submission was deemed ineligible under TSCA Section 5. The determination was driven by class-based hazard concerns commonly associated with the chemical category (irritation and aquatic toxicity).

The company needed to address EPA's prior feedback while avoiding animal testing and protecting confidential business information. Conducting new studies would have not only increased costs but further extended the review process.

Bridging the gap between industry and regulation is a crucial piece of the chemical manufacturing approval puzzle. Each client's challenges may be unique to their situation and production, but having a strong base of communication from a partner helps narrow down the key pieces of the process needing greater insight.

SOLUTION

Trinity Consultants developed a structured, mechanism-informed comparative hazard case. A tiered weight-of-evidence approach incorporated substance-specific safety data, validated in vitro testing, and analogs. The substance demonstrated low toxicity, non-irritation, and minimal environmental risk.

Mechanistic analysis of charge density and structural features supported reduced biological interaction. Exposure scenarios reflected low-volume manufacturing and controlled conditions. The submission included a structured response to prior regulatory feedback.

RESULT

While the project started small in scope, by working closely with the support team, the client recognized the value of expanding their engagement. Attention to detail, supportive communication, and chemistry expertise from Trinity Consultants allowed the team to provide deeper insights to understand and solve foundational issues.

The updated submission was designed to address the basis for the prior ineligibility determination by distinguishing the substance from higher-risk analogs. The approach provided a framework to evaluate the substance based on its specific properties rather than class-level assumptions.

The manufacturer strengthened its regulatory position with improved submission clarity, without new animal testing, and established a stronger foundation for continued progress on its TSCA compliance pathway.

ABOUT TRINITY CONSULTANTS

Trinity Consultants, a leading global environmental consulting firm, provides services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Founded in 1974, Trinity has the technical expertise, industry depth, and capabilities to help clients achieve their goals across the natural and built environments.