



EPA Issues TSCA PMN Guidance: Pointers for Submitters

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EPA recently published guidance for companies preparing to submit new chemical notifications pursuant to the Toxic Substance Control Act (TSCA). The guidance, entitled *Points to Consider When Preparing TSCA New Chemical Notifications* (the "Guidance"), is intended to assist submitters in preparing a Premanufacture Notice ("PMN") under TSCA Section 5. EPA states that it issued the Guidance to promote "early engagement and communication" and enhance industry's overall understanding of the TSCA submittal process.

TSCA requires companies planning to manufacture or import a chemical substance not listed on the TSCA Inventory to prepare and submit a PMN at least ninety (90) days prior to manufacture of the substance. The Guidance provides submitters an overview of what EPA considers "best practices" for submitting a proper PMN, including specific information regarding the chemical identity and physical-chemical properties of the substance, information regarding estimated production and use volumes, and proper submittal of health data.

Upon receipt of a completed PMN, EPA must evaluate whether the proposed chemical substance presents an unreasonable risk of injury to human health or the environment. EPA will make one of the following determinations: (1) the substance presents an unreasonable risk; (2) there is insufficient information to make a reasoned evaluation of the effects of the substance; or (3) the substance is not likely to present an unreasonable risk of injury to human health or the environment. The Guidance sets forth the review process that EPA uses to make this determination and provides additional information to submitters, which EPA claims may expedite the process.

In its announcement of the Guidance, EPA also encouraged "companies to contact EPA's new chemicals program to set up a pre-submission (or "pre-notice") meeting before submitting their PMN." According to EPA, a pre-submission meeting offers an "an opportunity to discuss the planned new chemical submission and to understand the Agency's approach to reviewing new chemicals for potential risks early in the process."

While the Guidance may seem helpful to companies manufacturing or importing chemicals, it is important to note one significant subject the Guidance fails to mention: exemptions to PMN requirements. TSCA provides several exemptions from some or all requirements for PMN submissions. Chemical substances manufactured for research and development purposes, polymers, byproducts, and articles are automatically exempt from PMN requirements if they meet regulatory requirements. Chemical substances manufactured in low volumes or for test marketing purposes, or those with low environmental releases and human exposures, may be exempted upon EPA approval. A thorough evaluation of whether a chemical substance may be eligible for an exemption from PMN requirements should be a company's primary consideration.

Points to Consider When Preparing TSCA New Chemical Notifications, EPA Office of Pollution Prevention and Toxics (June 2018).

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