Know Your Chemical's Potential without TSCA Oversight: The Test Marketing Exemption Explained

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Manufacturers, importers and processors of chemical substances in the United States, know full well the regulatory burdens placed on their industry by the Toxic Substances Control Act (TSCA). TSCA requirements can be cumbersome and difficult to understand. Luckily, TSCA contains several exemptions offering relief for companies in certain circumstances. One exemption available for companies considering bringing products to market that contain new chemical substances (not already registered in the U.S), is the Test Marketing Exemption (TME). TSCA exempts from Premanufacture Notification (PMN) requirements new chemical substances manufactured solely for test marketing. Chemical substances manufactured pursuant to the TME are also excluded from the Active Chemical List notification rule promulgated under the recent TSCA amendments.

The manufacture and import of chemical substances in the United States is governed by TSCA. TSCA mandates that all chemical substances manufactured in the United States be included on the "TSCA Inventory." Manufacturers of a chemical substance not currently on the TSCA Inventory must submit a PMN to EPA at least 90 days prior to manufacturing the substance. Pursuant to the 2016 amendments to TSCA, EPA promulgated regulations in 2017 requiring companies manufacturing chemical substances from June 21, 2006 to June 21, 2016 to upload information concerning the substances into a database being developed by EPA ("Notification Rule"); those TSCA Inventory chemicals not registered on the Active Chemical List (ACL) revert to the Inactive Chemical List (ICL) and are barred from distribution in commerce in the U.S. after the ICL/ACL lists become effective.

The TME enables manufacturers to focus on the market's interest in and demand for a product where it will be competing with other goods. "Test Marketing" is defined as:

[T]he distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

EPA may exempt a manufacturer from PMN requirements and permit them to manufacture new chemical substances for test marketing, but only if the agency finds the import, use, and disposal of the substances for test marketing purposes will not present an unreasonable risk of injury to health or the environment.

The TME is not automatic. A company must first request it from EPA. A TME application must include information regarding health and environmental effects of the chemical substance to be manufactured, including physical and chemical properties. Importantly, this information should be generated using "all existing data," although the manufacturer need not conduct new studies of the substances' effects. The TME application must designate the maximum quantity of the substance to be manufactured, the maximum number of people who will be provided the substance during test marketing, and the maximum number of people to be exposed (including duration and route of exposure) to the substance during test marketing. The manufacturer must describe the test marketing activity, state its duration, and state how the test marketing activity will be different from full-scale production.

Immediately following receipt of a TME application, EPA is required to publish a notice in the Federal Register summarizing information in the application. The notice will give the public an opportunity to submit comments on the application. EPA must either approve or deny the TME application within 45 days of receipt. Upon approval or denial, EPA must publish a second notice in the Federal Register explaining the reasons for its decision. EPA may approve the TME with conditions if the agency determines the conditions are necessary to ensure that no unreasonable risk of injury to health and the environment is presented.

If the TME application is granted, the manufacturer may manufacture the approved volume of the chemical substance and conduct the test marketing activities in the approved manner for the approved time. Following the expiration of the approved TME period, EPA guidance suggests that residual exempt material may continue to be used for approved marketing activities until the expiration of a 90-day PMN review period, if (1) the only test marketing activities are distribution or use (i.e., no additional exempt material may be manufactured after the TME period); and (2) the volume and recipients of the exempt material were accounted for in the original TME application.

A substance that is granted TME (which is not added to the TSCA Inventory) is not a "chemical substance subject to commercial activity designation" or a "reportable chemical substance." Thus, the TME substance cannot become an "active substance" or an "inactive substance." The ACL notification rule specifically exempts the manufacture of substances "solely for test marketing purposes," stating that this is an activity "for which notification is not required."

If a company is considering manufacturing a product with chemical substances not currently on the

TSCA Inventory solely for test marketing, it should take the following steps to comply with the TME:

Step No. 1: Apply to EPA for a TME at least 45 days prior to manufacture; the application must contain information regarding any health or environmental effects of the substance, a description of the test marketing activities and intended duration, a statement of the maximum volume of the substance to be manufactured, and the maximum number of people who will be provided with or exposed to the substance.

Step No. 2: If the TME application is approved, the company may only manufacture, distribute and use the exempt materials in compliance with the approved Test Marketing purposes and for the approved time.

Step No. 3: Substances that are manufactured pursuant to an approved TME are not subject to the Active Chemical List Notification Rule and need not be on the Active Chemical List to be test-marketed in the U.S.

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