On June 22, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amends the Toxic Substance Control Act (TSCA), the nation’s primary chemical management legislation. The TSCA was originally enacted in 1976 and is administered by the United States Environmental Protection Agency (EPA). One of the main objectives of the TSCA was to assess and regulate new commercial chemicals before they enter the market. When the TSCA was originally enacted, all then-existing chemicals were considered safe for use and were “grandfathered” in. Under the 1976 law, tens of thousands of chemicals already in existence in 1976 were considered in compliance without any requirement for the EPA to review them for safety.

The 2016 amendment makes several significant changes to the existing law, including risk assessment and management of all chemicals in commerce (not just new ones), additional tools to prevent new chemicals from entering the market, changes to claims of proprietary information, and guaranteed funding of the new program. These amendments require the EPA to assess numerous chemicals previously deemed “safe” and signal a shift toward heavier regulation of the chemical industry.

**RISK ASSESSMENT**

The EPA is required to evaluate the safety of existing chemicals in interstate commerce and to start with those most likely to cause health risks. So-called “high-priority” chemicals must be assessed by the EPA starting with 10 assessments to be under way within 180 days, and 20 at any given time to be under way within a few years. Low-priority chemicals need not be tested but can be moved into high-priority with the development of additional hazard information. The initial assessment is a new risk-based safety standard that considers if the chemical poses an “unreasonable risk,” especially to susceptible or highly exposed populations (like children, the elderly, and industry workers), irrespective of cost. If there is an “unreasonable risk” identified, cost may be then considered in the mitigation of the health risks, along with bans, phase outs, or other actions.

**INCREASED SCRUTINY OF NEW CHEMICALS**

New chemicals may also have a tougher time getting to market. Under the 1976 law, companies would notify the EPA of their intention to manufacture a new chemical or a significant new use for the chemical by using a Pre-Manufacturing Notice (PMN). The 1976 act did not require any toxicity testing before submitting a PMN and did not require safety information to be included with the documentation. Under the 1976 law, in order to regulate new chemicals, the EPA needed to make a determination that the chemical might present “an unreasonable risk to human health or the environment...” If it could not satisfy this requirement within a narrow window of 90 days, the chemical was allowed to be legally marketed and sold. Now, the EPA must make an affirmative finding on the safety of a new chemical or significant new use of an existing chemical before it is allowed into the marketplace. While this may be a win for health and safety advocates, it may cause a significant backlog and therefore impede business and innovative progress.

**PROPRIETARY INFORMATION AND FUNDING**

The amendment also limits claims of confidentiality by chemical manufacturers with a rebuttable presumption that “the public interest in the disclosure of the information outweighs the public or proprietary interest” of the manufacturer. And finally, the EPA will be able to collect up to $25 million per year in user fees from chemical manufacturers and processors, supplemented by congressional budgeting to pay for these expanded regulatory activities.
EFFECT
The EPA may renew its previously unsuccessful effort to completely ban the use of asbestos. EPA Administrator Gina McCarthy states in her blog, “The dangers of inaction were never more stark than in the case of asbestos, a chemical known to cause cancer through decades of research.” McCarthy goes on to write that “[d]uring the first Bush Administration, EPA tried to ban asbestos under TSCA, but the rule was overturned in court. In the law’s 40-year history, only a handful of the tens of thousands of chemicals on the market when the law passed have ever been reviewed for health impacts, and only 5 have ever been banned.”

This amendment may cause turmoil in the chemical industry with the assessment, for the first time, of decades-old chemicals that previously were deemed “safe.” In the next six months, we will know which high priority chemicals are selected for the initial risk assessment. The bill can be found here.

ADDITIONAL INFORMATION
For more information, please contact:

- **Arun Kottha** | 216.696.2537 | arun.kottha@tuckerellis.com
- **Christopher Caryl** | 216.696.3959 | christopher.caryl@tuckerellis.com

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