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ENVIRONMENTAL LAW

TSCA Amendments Promise New Chemical Regulation in 2017

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On June 22, President Barack Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which fundamentally changes certain aspects of the Toxic Substances Control Act (TSCA), a statute that gives the U.S. Environmental Protection Agency (EPA) broad authority to impose restrictions on the manufacture, processing, use, distribution, use or disposal of any chemical substance currently or proposed to be placed in commerce. These changes, which are designed to promote the more frequent, timely and systematic review and regulation of new and existing chemical substances, have the potential to result in a number of new regulatory requirements for a wide range of industries.

EXISTING CHEMICAL SUBSTANCES

TSCA has always given the EPA authority to promulgate regulations designed to address risks posed by chemical substances in commerce at the time TSCA was originally enacted in 1976. The EPA, however, has exercised this authority infrequently to date, in part because TSCA required that any TSCA regulation address these risks "using the least burdensome requirements."

The act addresses this logjam by removing the "least burdensome" requirement and substituting a two-step process whereby the EPA first identifies risks associated with a chemical substance through a risk evaluation and then manages these risks by promulgating risk management regulations. At the risk evaluation stage, the EPA is required to determine whether the chemical substance "presents an unreasonable risk of injury to health or the environment." In making this determination, the EPA is not allowed to consider cost or other nonrisk factors and must take into account susceptible subpopulations (e.g., children). If the EPA identifies an unreasonable risk, then the risk management rule promulgated by the EPA must address that risk through various measures, including prohibitions or restrictions on the manufacture, processing, use, distribution or disposal of the chemical substance, requirements for warning labels and instructions, enhanced record-keeping, or notifications to consumers with an offer of replacement.

In addition to providing a more workable framework to evaluate and manage risk, the act imposes rules that require the EPA to start the process for a minimum number of chemicals and push them through the evaluation and management process. At the outset, the act directs the EPA to identify and commence the risk evaluation process for ten chemical substances by mid-December 2016. Furthermore, the EPA is required to finalize a rule by June 2017 that allows EPA to divide


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the universe of existing chemicals into "high priority" substances that must undergo a risk evaluation to determine whether the substance may pose unreasonable risks, and "low priority" substances for which a risk evaluation is currently unwarranted. By December 2019, the EPA must be conducting at least 20 risk evaluations and must have designated at least 20 substances as low priority. Furthermore, the EPA must develop any necessary risk management rule within two years after a risk evaluation is completed, although that timeline can be extended up to four years under certain circumstances.

In addition to the EPA driven process outlined above, the act contemplates that manufacturers will supplement the process by providing an avenue for manufacturers to request that the EPA complete a risk assessment for a particular chemical, so long as the manufacturer commits to pay for 50 to 100 percent of the costs of the evaluation. In fact, the act requires that 25 to 50 percent of the EPA's ongoing risk assessments must be at a manufacturer's request. Moreover, the act directs the EPA to publish guidance for any interested person who wants to develop and submit their own risk evaluations, which the EPA must consider, regardless as to whether the risk evaluation was requested or not.

NEW CHEMICALS

The act also provides notable changes in how the EPA will regulate new chemicals. In particular, the act now requires the EPA to make an affirmative finding on the safety of new chemicals before the chemical can enter the marketplace. The act gives the EPA financial incentive to make this determination within, in most instances, 90 days, as the EPA is required to refund applicable fees for an applicant's premarket notice if the EPA fails to make a determination.

The EPA's review of new chemicals must result in one of three findings: that the chemical presents an unreasonable risk of injury; that information is insufficient to permit a reasoned evaluation of the chemical; or that the chemical is not likely to present an unreasonable risk. If the EPA finds that the chemical presents an unreasonable risk of injury, the EPA must either promulgate regulations pertaining to the chemical or publish a statement explaining why no regulations will be promulgated. Notably, prong represents a significant change, as it now allows the EPA to regulate a new chemical based solely on the finding that there is insufficient information to permit an evaluation of the chemical.

CBI, STATE PRE-EMPTION AND DATA REPORTING

In addition to providing a new framework for the more timely and systematic regulation of new and existing chemical substances, the act clarifies a number of related issues including the handling of confidential business information (CBI), the pre-emption of state chemical safety laws, and supplementing chemical inventory reporting programs.

To address CBI, the act now includes Section 14, which generally affirms that regulated entities can continue to assert that information submitted to the EPA under TSCA should be protected from public disclosure as CBI. The results of health and safety studies, however, do not qualify as CBI. Additionally, health professionals can obtain access to information that otherwise qualifies as CBI so long as it is needed for treatment purposes and the health professional agrees to maintain the information as confidential. Section 14 also provides that entities must be prepared to substantiate certain CBI claims going forward, or even re-substantiate CBI claims made before the act went into effect.

The act also includes provisions preempting certain state laws and actions while exempting others. Generally, the act pre-empts state laws and actions which regulate the manufacture, processing, distribution in commerce or use of a chemical for which EPA has already made a determination that the chemical does not present an unreasonable risk of injury or for which the EPA has already taken a final action relating to the chemical's risk. The act exempts state laws and actions on any chemical on which the EPA has not acted. Further, the TSCA amendments exempt any state action taken before April 22, that regulates a chemical, and any state action pursuant to a state law passed on or before Aug. 31, 2003. Additionally, states can still promulgate laws and regulations relating to air, water and waste.

Regarding TSCA data reporting, before passage of the act, the EPA had established a chemical data reporting rule that requires manufacturers every four years to provide the EPA with information on the production and use chemicals in commerce if production volumes exceed 25,000 pounds in a reporting year. The most recent reporting deadline was Oct. 31 of this year. While nothing in the act directly affects the current data reporting rule, the act directs the EPA to promulgate a final "inventory reset rule" that will require affected entities to confirm by Dec. 17, 2017, which chemicals currently on the TSCA chemical inventory remain active in commerce, even if they fulfilled their data reporting obligations this past October.

DECEMBER RULES

The EPA has announced an aggressive implementation timeline to meet the deadlines imposed by the act. In particular, the EPA is scheduled to issue four proposed rules in mid-December, including rules related to the prioritization process, the risk evaluation process, the inventory reset and the imposition of new TSCA fees, in addition to announcing the first ten chemicals for risk evaluation. As of this writing, however, the EPA has not submitted these rules to the Office of Management and Budget, so this holiday present may be a little late. Regardless, 2017 promises to be an eventful year with respect to chemical regulation. •

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