Schiff Hardin

Toxic Substances Control Act Reform Key Questions and Answers

By Jane Montgomery, Amy Antoniolli, and Patrick Veasy

On June 22, 2016, President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Act). The Act works significant changes to the 1976 Toxic Substances Control Act (TSCA), which governs how the Environmental Protection Agency (EPA) assesses risks for chemical substances before they are marketed and allowed to be used in consumer products. Although the law takes effect immediately, EPA is required to promulgate new rules in order to implement the new law. The rulemaking process may take several years and EPA will post an implementation plan on its website. Given these sweeping changes, we have put together the following Q&A to address questions that might arise within the regulated community.

Q: Does the Act affect me?

A: The Act affects almost every business sector in the United States that is engaged in some form of manufacturing, processing, distributing, using, or disposing chemical substances. Unlike the regulatory framework before the changes, the Act is expected to provide EPA with greater authority to regulate not only the producers of new chemical substances, but businesses that process and manufacture products containing chemical substances.

Q: What actions does the Act regulate?

A: The Act regulates chemical substances and mixtures that may present an unreasonable risk of injury to health or the environment. EPA achieves this goal through a process of reviewing and then regulating harmful chemical substances. A safety determination is made as to whether the chemical meets the safety standard under the use conditions proposed by the applicant. A cost-benefit analysis is required if EPA decides to regulate a chemical.

A significant new facet of the law also requires industry to pay for the chemical review process. The Act will provide EPA with expanded authority to collect more and higher fees from producers of chemical substances to offset the agency's costs of reviewing new and existing substances and determining whether to take regulatory actions.

Q: How are "imported" chemical substances treated differently under the Act?

A: Under the changes, EPA may require a premanufacture notification (PMN) for a chemical substance that is imported or processed as part of an "article" or category of articles if there is a reasonable potential for exposure to the substance through the article. TSCA defines "article" as "a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) depending in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition that have no commercial purpose separate from that of an article, and that results from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles." EPA is then permitted to apply prohibitions or restrictions on the article to address identified risks from exposure to the chemical substance.

Q: What if my substance is made using a confidential formula?

A: Manufacturers and processors may assert claims of confidentiality and trade secret but must substantiate the claim at the outset, that is, when the notification is submitted to EPA. Formerly, the substantiation was only submitted upon request.

Q: I heard that first responders can get CBI. Is that true?

A: The Act requires the release of CBI to states and medical professionals in situations involving a medical, environmental or public health emergency. Confidentiality agreements must be signed after the emergency abates and penalties can be assessed if the first responders improperly release the CBI.

Q: What are the changes in the CBI prove up procedure?

A: EPA will promulgate rules that specify how to substantiate a claim of confidentiality. As a threshold matter, the entity claiming confidentiality must submit a statement that it has taken reasonable measures to protect the information, the information is not required to be disclosed by law, there is a reasonable basis to conclude that disclosure will cause substantial harm to the competitive nature of the claimant, and there is a reasonable basis to believe that the information is not readily discoverable through reverse engineering. Finally, claims of confidentiality will expire after 10 years unless the claim is reasserted.

Q: How long will it take EPA to perform a risk evaluation? Can I speed the process up?

A: The Act requires EPA to establish new rules for a risk-based screening process within one year. The rules must include criteria for designating chemical substances as "high-priority" substances for a risk evaluation or "low-priority" substances for a risk evaluation. High-priority substances will be those substances that EPA concludes, without considering costs or other non-risk factors, might present an unreasonable risk because of a potential hazard and a potential route of exposure under the conditions for using the chemical. Moreover, high-priority substances include substances that pose an unreasonable risk to vulnerable subpopulations.

The Act also allows EPA to designate any of its current "work plan chemicals" as high-priority chemicals and EPA must give preference to those that rank high on persistence and bioaccumulation. Asbestos and asbestos-like fibers are item 7 on the work plan list and EPA has characterized them as "known human carcinogens."

Once the rulemaking is finalized, EPA will then make a high-risk or low-risk priority designation for a substance within nine months to one year. This time period is intended to allow interested parties to submit information and comment. EPA must publish the scope of the high-risk evaluation it conducts within six months of initiating the assessment. In the end, EPA must complete an overall risk evaluation no more than three years after it initiates a risk evaluation.

Parties hoping to escalate EPA's review of a chemical substance may request a risk evaluation, subject to the payment of relevant fees. EPA will choose whether to grant these requests based on EPA's determination that restrictions imposed by at least one State have the potential to significantly impact interstate commerce, health or the environment. Finally, industries should be aware that the Act also changes EPA's process for reviewing PMNs, but EPA will flesh these changes out in future rulemakings.

Q: I also heard that animal testing is banned. Is this true?

A: The Act requires alternatives to be used before testing a chemical with vertebrates. It does not ban animal testing. EPA must develop a strategic plan to explore and develop new testing methods such as computer simulations, grouping of similar chemicals, and many others.

Q: When will the changes be implemented?

A: EPA will begin to implement all of these changes almost immediately, including through a variety of rulemakings. However, these rulemakings will not be finalized for a number of years due to the length of the rulemaking process. In this regard, EPA is developing an Implementation Plan to guide the agency's efforts to meet the deadlines in the new law. Nonetheless, parties can be proactive about protecting their interests by participating in the rulemakings and the EPA's ongoing risk evaluations. For example, within 180 days, EPA must ensure that risk

evaluations are being conducted on 10 chemical substances from the 2014 TSCA Work Plan for Chemical Assessments, which identifies existing chemicals for EPA to review.

Although the Act significantly reforms TSCA, EPA's implementation of the changes will raise new questions as the agency promulgates new rules and issues agency guidance. Industries engaged in some form of the manufacture and processing of chemical substances, including products containing chemicals, should be aware of TSCA's evolving landscape.

Please contact any member of the Schiff Hardin Environmental Group with questions about the Lautenberg Act.