President Signs Historic Toxic Substances Control Act Amendments

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On June 22, 2016, President Obama signed a bill that extensively reforms the federal Toxic Substances Control Act (TSCA). TSCA, which had remained substantially intact since its passage in 1976, provides the authority for the U.S. Environmental Protection Agency's (EPA) most important program for controlling risks to human health and the environment from chemical substances introduced into commerce.

The new law takes effect immediately. Any business that imports, manufactures, processes or distributes products in the U.S. should understand the new provisions in order to avoid adverse business consequences or potential enforcement exposure.

The most immediate impacts are related to the new chemical review process. Now, for the first time, the EPA is required to make an affirmative determination concerning risks to human health or the environment on all notices for new chemicals (PMNs) and significant new uses of existing chemicals (SNUs) before they can enter commerce. The standards that EPA is to apply when reviewing a PMN are more protective of human health and the environment than that previously required. The new affirmative determination requirement for PMNs and SNUs effectively "resets" the 90-day review period for PMNs pending as of June 22, 2016, the date the amendment was signed into law.

In the long run, the most significant aspect of the amendment is the increased power and responsibility given to the EPA to systematically address chemical substances already on the TSCA Inventory to deal with risks considered to be unreasonable. This aspect of the TSCA program will be taking shape over the next several years under an aggressive schedule imposed by the amendment. It begins with a requirement that the EPA establish a notification and reporting process for manufacturers, importers or processors of chemical substances that will allow the agency to identify "active" chemicals (those manufactured or processed over the last 10 years) and "reset" the TSCA Inventory. Thereafter, anyone seeking

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to manufacture, import, or process an "inactive" chemical substance will need to notify the EPA before doing so.

At the same time that the EPA is setting up the process to reset the Inventory, the agency must select 10 chemical substances for risk evaluations from a list of 90 on its Work Plan. It must have risk evaluations underway for at least 20 chemical substances within the first 3 ½ years.

The EPA must also set up a process for categorizing chemical substances for risk evaluations as "high priority" or "low priority." These designations are to take between 9-12 months to complete. If the information available is insufficient to make the determination, the EPA receives an additional 90 days to complete its task and can require testing to fill the gap. If, at the end of the additional period of time, the agency still lacks sufficient information, the chemical substance is to be assigned a high priority.

If the EPA determines in a risk evaluation that a chemical poses an unreasonable risk, the agency must promulgate rules to regulate the manufacture, distribution, or use of that chemical to address the risk. If there is insufficient information to determine the risk for a particular chemical, the EPA can limit its manufacture, import, or use to the extent necessary to protect health and the environment while information is developed regarding its safety.

The new process for reviewing existing chemicals includes a 90-day period for industry to submit information regarding a chemical substance prior to the agency's proposal of a priority for it. The public will have 90 days to submit comments after the priority is proposed.

In anticipation of the EPA's upcoming rulemaking and actions on prioritization of chemical substances and risk management, companies should review their product lines and EPA's TSCA Work Plan list of chemicals to determine whether important products are likely candidates for EPA high priority risk evaluations. Recently, under REACH (the European Union's counterpart to TSCA), the EU conducted a massive evaluation of all chemical substances in commerce. As part of that review, companies that manufactured, imported, or used a given chemical substance being reviewed organized themselves into consortiums to share the burden of collecting the information and conducting the additional testing required. Companies who manufacture or import chemical substances here in the U.S. should plan for similar cooperative efforts to prepare for the chemical review process soon to be rolled out by the EPA.

The following are some additional key features of the new law:

- Requires the EPA to evaluate the safety of new and existing chemicals in commerce under a new risk-based safety standard to determine whether a chemical poses an "unreasonable risk" based on human health and environmental considerations, including risks to vulnerable population subgroups
- Expands the EPA's power to require companies to conduct health and safety testing via administrative orders and consent agreements, to supplement existing rulemaking authority
- Requires the EPA to develop a plan to reduce and replace vertebrate animal testing and promote alternative test methods

- Authorizes the EPA to take a range of actions to address potential health and environmental concerns including imposing bans or limitations, or requiring additional testing
- Bolsters transparency by establishing new confidentiality claims substantiation requirements, requiring the EPA to make a decision on all new claims and review continued viability of past claims and allowing the agency to share Confidential Business Information (CBI) with state/tribal governments, health/environmental professionals and first responders
- Partially pre-empts state action on a chemical when the EPA has found a chemical to be safe or is regulating a chemical to address identified risk, and "pauses" state action when the EPA is evaluating a chemical subject to state law preservation and grandfathering provisions
- Authorizes the EPA to increase fees to the agency costs of implementing various aspects of the TSCA program, including new chemical review

In addition, for both pending and new notices, companies should understand that the EPA is required to engage in a more rigorous review process. Companies are therefore advised to review their current procedures and be positioned to provide appropriate levels of information to facilitate a "no unreasonable risk" determination from the agency.

Finally, companies should review their CBI procedures in light of the "new" TSCA and make any necessary modifications to ensure that CBI claims can be adequately substantiated. Companies should also review prior confidentiality claims, as the EPA is now required to revisit them under the new law.

For additional information regarding the information discussed in this Alert, please contact the authors, **David A. Roth** or **Daniel Flynn**, members of the firm's **Environmental Department**.