Significant Changes to TSCA Will Affect a Broad Range of Companies That Manufacture and Use Chemicals

On June 7, Congress passed the landmark Frank R. Lautenberg Chemical Safety for the 21st Century Act, the first time the Toxic Substances Control Act (TSCA) has been substantively amended since its enactment in 1976. The bi-partisan legislation was a product of negotiations between the House and Senate, each of which had passed its own version of TSCA reform. A redline showing changes to the pre-existing TSCA is available here.

The legislation contains a host of new authorities and mandates for the Environmental Protection Agency (EPA). Because of the vastly changed TSCA landscape, it is important that all companies that manufacture, use, process, import, export or sell products containing chemicals become familiar with the new regulatory regime.

At the outset, five key changes include:

1. **Real-time inventory:** The EPA, based on industry-supplied data, will maintain an up-to-date inventory of all chemicals in active commerce in the U.S.

2. **Screening assessments:** All chemicals on the active inventory will undergo a risk screening based on health, hazard, use and exposure information supplied by the industry, by any interested party and in EPA’s possession. A chemical will be classified either as low priority and not subject to regulation or as high priority and subject to risk evaluation.

3. **Risk evaluations:** High-priority chemicals will undergo a risk evaluation for uses specified by EPA. If the evaluation finds the chemical “unsafe,” it will be subject to use restrictions or banned.

4. **Confidential business information:** Many claims that information provided to EPA should be protected as classified business information will need to be substantiated up front, and protection will need to be reasserted and resubstantiated after a period of time.

5. **Order authority:** EPA will now be able to compel the testing or submission of information through an order rather than a rule. Also, the legal standard to be met before ordering testing has been significantly lowered.

Sidley Offers CLE Webinar on the New TSCA as Well as Background Resources

Please join us for a 1.5 hour CLE webinar on Thursday, June 16, during which Sidley and other experts will discuss these developments and the most significant changes to TSCA that the regulated community needs to know.

For more information and to register, please click here.

To see a timeline of the implementation schedule, please click here.

To see a redline showing how the legislation amends TSCA, please click here.
Background
Congress enacted TSCA to create protections against the introduction into commerce of new chemical products that could create a serious risk of harm to human health or the environment. TSCA provided EPA with limited authority to gather information about existing chemicals, to require manufacturer testing of chemicals, and to regulate chemicals already in commerce when warranted. No chemicals that existed when TSCA was enacted were subject to any review at that time. Most have never been subsequently reviewed.

The new legislation will significantly change the way EPA approaches chemical management under TSCA. While the changes create challenges, a new centralized assessment program should remove incentives for states to enact inconsistent rules and allow the industry to rebut allegations that affect retailer and consumer decisions.

New Compliance Mandates
The legislation presents many new compliance mandates and the potential for increased enforcement and litigation. EPA will now be required to review the safety of every chemical in commerce. Furthermore, the new provisions have a more distinct focus on use of and exposure to chemicals. Because of these factors, the size of the population affected by TSCA will expand from the traditional chemical manufacturers and processors to potentially any manufacturer that incorporates chemicals into its products. This would include, for example, manufacturers of personal care products, automobile components, computer and electronics components, toys and even athletic wear. As the reach of the regulation is more vast than before, the impact it will have on foreign entities that utilize U.S. imports or which export to the U.S. will increase as well.

Under the legislation, the industry will have to identify chemicals in commerce — and EPA will then screen those to determine which are “high priority” and require risk evaluation. EPA must then establish a scope of uses and exposures to consider, and may order the testing or generation of new information. Based on the risk evaluation, EPA may require risk management measures such as use restrictions, labeling or bans. EPA will also perform risk evaluations on chemicals that manufacturers may nominate and that are funded by the industry.

Implementation Schedule
The implementation schedule, which is further summarized here, is aggressive: Within the first year, EPA must develop rules for the inventory reset, prioritization process and risk evaluation process, and develop guidance for industry-conducted risk evaluations. Within two years, EPA must develop needed policies, procedures and guidance. Within three years, it must have risk management rules for certain classes of chemicals, to be followed six months later by a mandate to have at least 20 risk evaluations underway and 20 low-priority designations completed. At each step, there will be an opportunity for the regulated community to engage with EPA and share its views.

Other Highlights
While these are some of the most significant requirements arising out of the new TSCA amendments, there are other provisions that are worth noting as well:

- **Development of new policies for how scientific information will be assessed and weighed:**
  The regulated community should carefully monitor the development of these regulatory materials to ensure that scientifically valid industry-funded studies are accorded proper weight and that there is transparency and predictability in the new regulatory processes.
• **Judicial review of EPA’s actions:** The industry may play a constructive role, by providing timely information to help EPA meet deadlines without being subject to lawsuits from outside entities. At the same time, the industry should carefully monitor new EPA regulations and decisions that may warrant judicial review.

• **Preemption of new state and local regulation:** State and local laws in effect as of April 22 will not be preempted by subsequent EPA action, but many others will be preempted.

Sidley will keep you updated through each step in the process and as new components are introduced and implemented.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

Roger R. Martella Jr.  
Partner  
+1 202 736 8097  
rmartella@sidley.com

Judah Prero  
Counsel  
+1 202 736 8451  
jprero@sidley.com

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