Following the hard-fought negotiations that led to the reauthorization of the Toxic Substances Control Act late last month, companies up and down the supply chain are becoming pragmatic: How do we adjust to this new era? Sidley Austin’s Judah Prero walks readers through the implementation process and how to position your organization for TSCA’s new requirements.

The Best Defense Is a Good Offense: Complying With the New Toxic Substances Control Act

BY JUDAH PRERO

Companies can face daunting compliance challenges when existing regulations are changed, especially when the entire regulatory structure gets a major overhaul. A good example are the major changes that will be coming with the chemical reform bill that President Obama just signed into law, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act). With the enactment of these sweeping changes to the Toxic Substances Control Act, any company that manufactures, processes or uses chemicals needs to become aware of potential obligations under the “new” TSCA which ultimately are also new enforcement opportunities for EPA.

As the saying goes, the best defense is a good offense. The best way for companies to protect themselves from a potential enforcement action is to take measures to ensure that one never arises. Therefore, the new requirements need to be understood and compliance strategies developed and implemented.

Basic Requirements

Under the Lautenberg Act, EPA will need to implement a new structure to: (a) identify the chemicals that are in active commerce, (b) screen those chemicals to determine which need a full risk evaluation, (c) perform risk evaluations of those selected chemicals, and (d) develop risk management measures or use restrictions for chemicals when needed. This new structure does not replace or affect the obligations a manufacturer has when seeking approval for a new chemical or complying with a new use notification requirement. Under both regimes, “manufacturer” means importer as well, so importers of chemicals, and the overseas manufacturers of those imported chemicals, also need to be cognizant of the changes.

Below are suggestions for making sure you stay in compliance with the new requirements:

1) Know your products
2) Know what you know—and what you want to know—about your products
3) Don't wait for EPA safety evaluations—be proactive
4) Identify potential partners for cost-sharing

Judah Prero is Counsel in Sidley Austin LLP’s Environmental group where he focuses on chemical management laws and regulations, including the Toxic Substances Control Act, Chemical Facility Antiterrorism Standards, the Occupational Health and Safety Act and the Clean Air Act’s Risk Management Plan program. This article does not represent the opinions of Bloomberg BNA, which welcomes other points of view.
5) Ensure your confidential business information is protected

6) Stay attuned to EPA enforcement trends

1) Know your products

EPA's identification of the chemicals in active commerce will require chemical makers to identify the chemicals they have manufactured during the 10-year period. In order to comply with this requirement, companies will need to know exactly what it has manufactured in the past 10 years, and be able to identify those products in a timely fashion.

Why is this important? If a chemical is not “active,” it cannot be manufactured or processed until EPA receives a notice as to the change in status. If that notice is not received by EPA and manufacturing commences, a violation of TSCA has occurred. Also, if you are not aware of what chemicals are in the products you manufacture, you have no way of tracking when EPA takes an action that will affect the use of that chemical, and potentially impact your product.

2) Know what you know—and what you want to know—about your products

Once active chemicals have been identified, EPA will start the prioritization process. EPA will ask for all available relevant information about the chemicals it has selected for prioritization. A company might ask “Should I be forthcoming?” The answer is yes.

Why? As EPA does have authority to order limited generation of information, forcing EPA to request information related to issuance of an order creates an unnecessary compliance requirement. Second, EPA needs sufficient information to conclude that a chemical does not meet the criteria for a high priority designation. That designation will create new compliance obligations and could cast a cloud of suspicion over the safety of that chemical. Therefore, a company should not only be forthcoming with information in the first instance, it should strongly consider whether it may be more beneficial to voluntarily generate more information so that regulation down the road could potentially be avoided.

3) Don’t wait for EPA safety evaluations—grab the bull by the horns

As mentioned, the next step in the process is EPA’s selection of chemicals deemed “high priority” to undergo the risk evaluation process. EPA has greater authority to order the generation and submission of new information needed for this process, which creates a compliance obligation to develop the information EPA has specified. Using the information it has combined with the information that is generated under orders issued, EPA will conduct the risk evaluation to determine if the chemical is safe, and whether any use restrictions or risk management is required.

There are two mechanisms that industry should consider for this process: Company funded EPA evaluations and company conducted evaluations.

A completed risk evaluation could determine that a chemical is indeed safe, and could clear the way for greater marketability of the chemical and eliminate any doubts that customers, consumers or regulators may have had regarding safety. On the other hand, the findings could result in restrictions and new compliance obligations that a company would prefer to see settled and addressed sooner rather than later. Therefore, there could be a benefit in utilizing the procedures authorized under the Lautenberg Act for “nominating” a chemical for risk evaluation which requires the company making that request to fund the evaluation.

The Lautenberg Act also allows interested persons to develop their own risk evaluations for EPA’s consideration. These evaluations are an opportunity for industry to generate sound evidence that would support a finding of safety for a chemical, and to discover any potential safety issues before EPA does, and then address those issues. In both cases, being proactive can reduce the possibility of additional compliance requirements and enforcement challenges.

4) Identify potential partners for cost-sharing: consortia and fees

The authority that EPA is granted under the Lautenberg Act to order the generation of new information is not limited to TSCA purposes: EPA can order the generation of information to meet regulatory testing needs under another federal law. Chemical testing is a costly proposition, and compliance with an order presents its own cost considerations and enforcement dangers.

New costs are also imposed under the Lautenberg Act’s new fee structure, whereby industry will pay EPA for certain activities it undertakes under TSCA.

Costs can be shared or reduced through formation of consortia, or entering into cost sharing or data compensation agreements with other manufacturers. Although any of these options will require the negotiation and execution of legal agreements, there is most definitely potential for reducing the costs required to comply with EPA requirements.

5) Ensure your confidential business information is protected

TSCA and the Lautenberg Act recognize that there is confidential business information in the EPA’s possession and that information should be protected from disclosure by EPA. However, claims for protection of certain information must be asserted and substantiated, and the protection period expires unless subsequently renewed and restated. Manufacturers who secure confidential business information protection must take great care to track those claims to ensure that renewal, if needed, is done in a timely fashion. Otherwise, valuable intellectual property could be lost.

6) Stay attuned to EPA enforcement trends: Next Gen

Recently, EPA has been focusing on a new model for its compliance programs: Next Generation Compliance (Next Gen). Next Gen is the EPA’s integrated strategy to modernize its approach to compliance that relies on information gathering, streamlined reporting and modern data analysis methods for targeting. As, under the new TSCA, EPA will have much more information about chemicals, and in particular chemical uses and exposures, industry should expect EPA to utilize this information in the context of the Next Gen compliance strategy. The increase in available information combined with an increase in compliance requirements un-
der TSCA will mean increased enforcement activity. Be prepared.

Be prepared!

Over the next year or so, EPA will be spending significant time laying the foundation for the new TSCA program. That time should be utilized by industry to prepare for what is yet to come. Industry has the opportunity to take stock of the new requirements, determine the resources needed to meet those requirements, and strategize how to make best use of the new regulatory structure and tools at the disposal of both EPA and industry. With good industry planning, the new TSCA program can be incorporated in a fashion that will allow both EPA and industry to benefit.