Unraveling the Toxic Substances Control Act Reform Bill

In June, the U.S. Senate and House of Representatives passed the long-pending Toxic Substances Control Act (TSCA) reform legislation, which will bolster the government’s power to regulate a wide variety of chemicals. The bill amends TSCA for the first time in forty years to ensure that only human and environmental health are considered in assessing the safety of chemicals. Under the new legislation, known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act, all chemicals in commerce will be reviewed by U.S. EPA to consider -- without regard to cost or benefits -- their health and safety impact. The legislation also shifts the burden and cost of evaluating and regulating chemicals to manufacturers, along with imposing new fees. EPA’s oversight of chemicals manufactured, sold or distributed in the U.S. will be greatly expanded, as will be the processes by which chemicals may be approved. The reform legislation was signed by President Obama on June 22, 2016.

The regulation of existing chemicals will be bifurcated into two steps: (1) risk evaluation of a chemical and (2) risk management of chemicals found to be problematic. The first step in deciding whether regulation is warranted is to conduct a scientific evaluation of the risks without regard to cost or benefits. If EPA concludes the chemical’s use presents an “unreasonable risk,” EPA is required to issue a risk management rule. The rule may range from requiring labeling or notice requirements to putting into effect an outright ban on the use of the chemical. To the extent practicable, the cost and benefits of the rule and the cost effectiveness of the regulation must be considered as a factor, but is not determinative.

For new chemicals, EPA will be required to review and make an affirmative finding about the level of risk posed without regard to cost. And indeed, the chemical may not be commercially produced until EPA rules on it, and it cannot be produced without being in compliance with EPA restrictions on that chemical. EPA must make a determination about, and choose the regulation for, a chemical within 90 days, but no later than 180 days if more time is needed.

Some additional key points of the legislation include:

- Requires EPA to identify individuals and groups relevant to assessing the safety of a chemical, including risks to relevant populations and ensuring their protection.
- A mandate for EPA to review the risks posed by chemicals in active commerce, thus eliminating the existing grandfathering-in of chemicals in use without any risk evaluation. This will require companies to identify all chemicals they are currently making or processing, with EPA to establish the priority of active chemicals.
- In establishing the priority of active chemicals, EPA must ensure high-priority chemicals undergo full safety assessment and safety determinations. For any chemical that does not meet the safety standard, EPA must impose
restrictions sufficient for the chemical to meet the safety standard; where restrictions cannot ensure the safety standard will be met, EPA must ban or phase out the chemical. To the extent sufficient information exists, EPA may conclude a chemical is likely to meet the safety standard, and is therefore a “low priority” chemical.

Notably, the bill will allow EPA to issue an order requiring testing, rather than having to promulgate a rule, avoiding the multi-year process typically associated with rulemaking. Testing authority applies to both new and existing chemicals, and in limited instances may also be applicable to the prioritization process. Historically, the rule making and consent agreement processes were lengthy and slow, so that EPA is likely, going forward, to simply order a test.

Several provisions of the bill also alter the process for the handling of Confidential Business Information (CBI) in ways that will impact manufacturers. Companies seeking to protect the specific chemical identity of a chemical substance will be required to submit a notice to EPA substantiating the confidentiality of the chemical compound, and substances for which no notification of CBI are received will be placed on the non-confidential portion of EPA’s §14 database list of regulated chemicals. The bill requires EPA to develop a retroactive review plan for evaluating whether chemicals on the existing list require CBI protection, or whether they can be placed on the non-confidential portion of the list.

The issue of preemption was one of the sticking points in the effort to reform TSCA. The result, and one way in which the new legislation differs from the prior version of TSCA, is that if EPA decides a chemical does not present an unreasonable risk and requires no regulatory action, that decision preempts state laws that may contradict that finding. Preemption of state and local law begins when EPA defines the scope of a risk evaluation, and ends either 30 months later or when the risk evaluation is completed, whichever is earlier. This does not restrict the state from enforcing a law enacted prior to risk evaluation, and federal preemption applies only to the scope of the risk evaluation and to the significant new uses under Section 5 of the Act. Specifically, TSCA will not preempt any state restriction or prohibition of a chemical enacted before April 22, 2016, or any other state law enacted before August 31, 2003.

The effect of the approach to preemption under the new law is that progress achieved by state regulatory processes up to the enactment of the reform Act will remain intact. So in California for example, the State’s “green chemistry” statute, which enables the State’s Department of Toxic Substances Control (DTSC) to initiate regulatory steps to identify and prioritize chemicals of concern in consumer products and to evaluate safer alternatives, will still govern the regulation and distribution of certain high-priority chemicals. During EPA review of a chemical, California and states with similar approaches may still enforce existing state regulations applying to those chemicals. And while states must wait to put in place any state-specific restrictions (while EPA looks at the safety of the chemical), states may apply for waivers to finalize new state requirements.

Significantly, TSCA reform does nothing to stand in the way of California’s longstanding warning and related discharge prohibition under the State’s Proposition 65, leaving intact California warning and
labeling requirements concerning cancer, birth defects or reproductive harm.

The coming months and longer term will reveal how quickly EPA acts to conduct new risk evaluations and how those might dovetail with action being taken and regulatory objectives already in place by states. In the meantime, the regulated community may continue to follow applicable state law, while of course watching EPA’s next steps closely.

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