

On June 22, 2016 President Barack Obama signed into law the “Frank R. Lautenberg Chemical Safety for the 21st Century Act,” the landmark legislation modernizing the decades-old Toxic Substances Control Act (TSCA). The Lautenberg Act is the first substantive update of TSCA since it was passed 40 years ago and signed into law by President Gerald Ford. The Lautenberg Act was approved by large majorities in both houses of Congress: a 403-12 margin in the US House on May 24, 2016, and by a unanimous voice vote in the US Senate on June 7, 2016.

The Lautenberg Act makes a number of significant changes to TSCA, including:

- Requiring EPA to evaluate chemicals (both new and existing chemicals) to determine whether they present an “unreasonable risk of injury to health or the environment under the conditions of use.”
- Prohibiting consideration of costs or other non-risk factors in chemical evaluations.
- Requiring EPA to consider potentially exposed or susceptible subpopulations in evaluating chemicals.
- Requiring EPA to designate existing chemicals on the TSCA Inventory (the national list of chemicals in commerce) as either “active” or “inactive” (based on whether they have been manufactured, imported, or processed during the last 10 years).
- Requiring EPA to designate active chemicals as high-priority or low-priority and then conduct risk evaluations on the high-priority chemicals.
- Allowing chemical manufacturers to ask EPA to evaluate a chemical (instead of waiting for EPA to conduct a risk evaluation at the agency’s initiation).
- Giving EPA authority to issue administrative orders to require testing of chemicals, instead of having to go through a difficult and time-consuming formal rulemaking process to require testing, as was required previously.
- Requiring EPA to reduce the use of vertebrate animals in testing.
- Making it easier for EPA to restrict – or even ban – chemicals by eliminating the “least burdensome” requirement for chemical regulations.
- Preempting state chemical regulations under certain conditions.
- Putting limits on confidential business information (CBI) claims and allowing EPA to share CBI with states.
- Allowing EPA to charge higher fees for chemical reviews.

The Lautenberg Act became effective immediately upon the President’s signature, and EPA already is moving quickly to begin implementation of the Act’s provisions.

Shortly after President Obama signed the legislation, EPA stated that it is “developing an Implementation Plan to guide the agency’s effort on successfully meeting the deadlines in the new law”, including among other things:

- Identifying the initial ten Work Plan chemical risk assessments;
- Establishing a process and criteria for identifying high priority chemicals for risk evaluation; and
- Issuing a procedural rule that establishes EPA’s process for evaluating risks from high-priority chemicals.

Significantly, EPA emphasized that the “most immediate effects” from the new law “will be on the new chemicals review process.” In contrast to the prior procedure under TSCA whereby EPA could simply let the 90-day review period for a new chemical (or a significant new use of an existing chemical) expire without taking action, the Lautenberg Act requires EPA to make a formal affirmative determination that a new chemical (or a significant new use of an existing chemical) is “not likely to present an unreasonable risk of injury to health or the environment under the conditions of use” before the chemical can be manufactured, imported or processed in the US.

Because this new requirement is now in effect, EPA announced that the Lautenberg Act “effectively resets the 90-day review period” for companies that submitted Premanufacture Notices (PMNs) for new chemicals (or Significant New Use Notices (SNUNs) for a significant new use of an existing chemical) prior to the President’s signature on the Act. In other words, for PMNs and SNUNs submitted before June 22, the 90-day clock was restarted on that day. EPA also stated, however, that it “will make every effort to complete its review and make a determination within the remaining time under the original deadline.”

EPA also stated that, it “plans to begin making information available on opportunities to learn more about the changes in the new law and how and when specific stakeholder engagement will begin to take place.” Among other things, the “opportunities for input” may include briefings, webinars, public meetings and comment periods.

In addition, EPA announced that it plans to soon begin the process for consulting with stakeholders about developing the rule required under the Lautenberg Act to collect new fees to “help defray the costs of administering the provisions on collecting and managing information, implementing the new chemicals program, and evaluating and regulating existing chemicals.”

EPA's actions to interpret and implement the numerous new provisions and requirements in the Lautenberg Act in the weeks and months ahead will be critically important and will set the tone for EPA's long-term approach to the new law. EPA must soon begin work to develop and issue several significant rulemakings that must be completed within one year of the Law's enactment (i.e., by June 22, 2017), as well a number of policies, procedures, and guidance documents that must be completed within two years of enactment (i.e., by June 22, 2018). EPA also must begin its efforts to develop early lists of existing chemicals for prioritization and risk evaluation, collect data on chemicals and initiate risk evaluations on chemicals. Our lawyers will monitor EPA's actions closely.

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