

The US Environmental Protection Agency (EPA) has issued a "[First Year Implementation Plan](#)" outlining the steps it will take over the next year (and beyond) toward implementing the requirements of the new Frank R. Lautenberg Chemical Safety for the 21st Century Act, the legislation signed into law by President Obama on June 22 to modernize the Toxic Substances Control Act (TSCA). The Lautenberg Act imposes a number of new requirements and responsibilities on US EPA, with several major tasks that must be completed within the first 12 months after the law's enactment, including promulgating several significant rulemakings, initiating risk evaluations on 10 Work Plan chemicals and other efforts.

In announcing the Implementation Plan, US EPA underscored its commitment "to engage partners and stakeholders early in the process, and to be as transparent as possible." The agency emphasized that the Plan "is not intended to be a comprehensive listing of all requirements in the new law," but instead "is intended to be a roadmap of major activities EPA will focus on during the initial year of implementation." US EPA also stated that the Plan is a "living document" that will be "further developed over time."

The Implementation Plan is organized into four broad categories of tasks that US EPA must fulfill: (i) Immediate Actions, (ii) Framework Actions, (iii) Early Mandatory Actions and (iv) Later Mandatory Actions.

Immediate Actions

US EPA has identified three TSCA program areas for which it is taking "immediate action" under the Lautenberg Act: (i) new chemicals, (ii) confidential business information and (iii) ongoing TSCA Section 6 rulemakings.

New Chemicals

On the day that President Obama signed the Lautenberg Act, US EPA announced that the Act's requirement that US EPA make an affirmative determination on Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) before the manufacturing, importation or processing of a chemical can commence would be applied to all PMNs and SNUNs, including ones that had been submitted prior to June 22, 2016. US EPA also announced that the Lautenberg Act had "effectively reset" the 90-day review period for PMNs and SNUNs, meaning that the 90-day clock had restarted on June 22.

The Implementation Plan reiterates US EPA's prior statement that for PMNs and SNUNs submitted prior to enactment and currently undergoing review, US EPA "will make every effort to complete its review and make a determination within the remaining time under the original deadline."

Confidential Business Information (CBI)

The Implementation Plan notes that US EPA must review – and make a determination on – all new confidentiality claims for chemical identity of chemicals within the 90-day review period and "where claim is upheld, apply a unique identifier to the chemical and any associated information." The Implementation Plan states that it is US EPA's goal to meet the 90-day deadline. US EPA also will "create a plan to link associated information" within 30 days, with a target date of mid-July 2016.

The Implementation Plan also notes that US EPA must review and make a determination on "at least 25% of new confidentiality claims for other types of information" within 90 days. US EPA's goal is to develop an "approach for routine review" of such CBI claims within 30 days, with a target date of mid-July 2016.

Ongoing TSCA Section 6 Rulemakings

The Implementation Plan points out that for chemicals with risk assessments completed prior to June 22, 2016 (the date of enactment), the Lautenberg Act expressly allows US EPA to publish proposed and final rules consistent with the scope of the risk assessments, "even if they do not cover all conditions of use." The Implementation Plan states that US EPA will continue to move forward with rulemakings to address the risks it has identified with certain uses of trichloroethylene (TCE), methylene chloride (MC) and N-methylpyrrolidone (NMP), as follows:

- For TCE use in spot cleaning and aerosol degreasing, US EPA plans to issue a proposed TSCA Section 6 rule by early October 2016, with the final rule anticipated by early October 2017.
- For TCE use in vapor degreasing, US EPA plans to issue a proposed TSCA Section 6 rule by early December 2016, with the final rule anticipated by early December 2017.
- For MC and NMP use in paint removers, US EPA plans to issue a proposed TSCA Section 6 rule by early December 2016, with the final rule anticipated by early December 2017.

Framework Actions

The Implementation Plan notes that US EPA also must take several actions during the next several months that will establish "processes to guide longer term program" efforts. These are:

Initial Risk Evaluations

The Lautenberg Act requires that within 180 days of enactment, US EPA must publish list of 10 Work Plan chemicals and formally initiate risk evaluations on those chemicals. The Implementation Plan states that US EPA will publish the list by mid-December 2016 and then publish the scope of each risk evaluation within six months after that, i.e., by mid-June 2017. (The Lautenberg Act generally requires US EPA to publish the scope of a risk evaluation no later than six months after the risk evaluation is initiated.)

Prioritization Process Rule

The Lautenberg Act requires US EPA to publish a final rule establishing the process and criteria for designating chemicals as high-priority or low-priority for purposes of risk evaluations within one year after enactment, i.e., by June 22, 2017. The Implementation Plan states that as an “interim milestone” for meeting this requirement, US EPA will publish a proposed rule by mid-December 2016.

Risk Evaluation Process Rule

The Lautenberg Act also requires US EPA to publish a final rule establishing US EPA’s process for conducting risk evaluations of high-priority chemicals within one year after enactment, i.e., by June 22, 2017. The Implementation Plan states that as an “interim milestone” for meeting this requirement, US EPA will publish a proposed rule by mid-December 2016.

Fees Rule

The Lautenberg Act gives US EPA the authority to collect fees to help defray the cost of implementing certain provisions in the Act, as well as to fully defray the cost of industry-requested risk evaluations. The Act requires US EPA to issue a rule to put the fees in place. While the Lautenberg Act does not specify a deadline for this rule, the Implementation Plan states that the “authority to require fees will be needed ASAP.” As such, the Plan states that as an “interim milestone,” US EPA will “consult and meet with parties potentially subject to the fees” and publish a proposed rule by mid-December 2016. The Plan also states that US EPA’s goal is to publish the final rule within one year after enactment by mid-June 2017.

Inventory Rule

The Lautenberg Act requires US EPA to publish a final rule within one year after enactment (i.e., by June 22, 2017) requiring companies to report the chemicals they manufactured (or processed) in the previous 10 years in order to designate chemicals as “active” or “inactive” on the TSCA Inventory. The Implementation Plan states that as an “interim milestone” for meeting this requirement, US EPA will publish a proposed rule by mid-December 2016.

Science Advisory Committee on Chemicals

The Lautenberg Act also requires that, within one year after enactment (i.e., by June 22, 2017), US EPA must establish a committee “to provide independent advice and expert consultation with respect to the scientific and technical aspects of issues related to implementation of the statute.” The Implementation Plan states that it is US EPA’s goal to establish this committee within six months – by mid-December 2016 – instead of taking the full year to do so. Further, the Plan states that as an “interim milestone,” US EPA will publish a Federal Register Notice about formation of the committee in early September 2016, with the comment period ending in early November 2016.

Early Mandatory Actions

The Implementation Plan outlines several additional tasks that US EPA must perform during the first year after enactment.

Scope of Initial Risk Evaluations

As noted, the Lautenberg Act requires US EPA to publish the scope of a risk evaluation within six months after the evaluation is initiated. The Implementation Plan notes that US EPA must publish the scope of the risk evaluations for the first 10 chemicals (the Work Plan chemicals) by mid-June 2017.

Annual Plan for Risk Evaluations

The Lautenberg Act requires US EPA to publish a plan at the beginning of each year identifying the chemicals for which risk evaluations are expected to be initiated or completed that year, as well as the resources needed to conduct the evaluations, the status of other chemicals under evaluation, and updated schedules as appropriate. The Implementation Plan notes that US EPA’s first such plan is due in early January 2017.

Additions to Mercury Export Ban

In addition to the changes it makes to the core TSCA program, the Lautenberg Act also bans the export of mercury compounds (in addition to the pre-existing ban on exports of elemental mercury). The Implementation Plan notes that the Act requires US EPA to publish an initial list of mercury compounds prohibited from export within 90 days of enactment (by mid-September 2016).

Mercury Inventory

The Implementation Plan notes that the Lautenberg Act also requires US EPA to publish, by April 1, 2017, an inventory of mercury “supply, use, and trade” in the US and update it every three years.

Small Business Definitions

The Lautenberg Act requires US EPA to review the adequacy of standards for identifying small manufacturers and processors, and to revise those standards as warranted. The Implementation Plan notes that US EPA must determine within 180 days of enactment whether any such revisions are warranted. The Plan also states that US EPA’s goal is to publish a plan and schedule for any such revisions at the time it issues its determination.

Report to Congress

The Lautenberg Act requires US EPA to periodically report to Congress on the agency’s capacity to conduct risk evaluations and to issue rules to address unreasonable risks, along with the resources needed to perform those endeavors. US EPA also must report on its capacity to conduct industry-requested risk evaluations, the likely demand for such requests and the anticipated schedule for accommodating the demand. The Implementation Plan notes that US EPA’s first such report must be submitted to Congress within 180 days after enactment (by mid-December 2016) and every five years thereafter.

Later Mandatory Actions

Finally, the Implementation Plan identifies several longer-term efforts that US EPA is required to perform by certain deadlines:

- A rule for reporting by manufacturers and users of mercury and mercury-added products, within two years after enactment (by mid-June 2018)
- A rule establishing a plan for reviewing CBI claims for active chemicals, within one year after enactment (by mid-June 2017)
- Guidance document on the development of generic names for CBI chemicals, within two years after enactment (by mid-June 2018)
- A negotiated rulemaking on byproducts reporting for the Chemical Data Reporting (CDR) rule, with a proposed rule (if produced by negotiations) within three years from enactment (by mid-June 2019)
- A strategy for alternative testing methods, within two years after enactment (by mid-June 2018)

We will monitor closely the actions that US EPA takes pursuant to its Implementation Plan, as well as the steps the agency takes toward implementing the numerous other requirements of the Lautenberg Act. The impacts of US EPA's actions under the Act on the manufacture, importation, processing, distribution and use of chemicals – and products containing chemicals – in the US will be significant and far-reaching. US EPA's actions over the next months will be critically important and will set the tone for EPA's long-term approach to the new law.

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