

The Frank R. Lautenberg Chemical Safety for the 21st Century Act First Year Implementation Plan

The new law imposes a number of new responsibilities on EPA, with comparatively short deadlines to carry out these actions. The Agency takes these responsibilities and deadlines seriously. For implementation to be successful, EPA believes it is important to engage partners and stakeholders early in the process, and to be as transparent as possible. This document is intended to be a roadmap of major activities EPA will focus on during the initial year of implementation. It is not organized by importance to the Agency, but rather by the statutory timeframes during which the activities must be completed. This is a living document, and will be further developed over time. It is NOT intended to be a comprehensive listing of all requirements in the new law.

Immediate Actions

*****Beginning on Day 1***

- **New Chemicals**

Requirement: Review and make an affirmative determination on all premanufacture notices (PMNs) and significant new use notices (SNUNs) before manufacturing can commence.

Goal: Meet the applicable deadlines. For companies that submitted PMNs prior to enactment and are currently undergoing review, EPA will make every effort to complete its review and make a determination within the remaining time under the original deadline. However, as a legal matter, the new law effectively resets the 90-day review period.

- **Confidential Business Information**

Requirement: Routine review of and determination on (within 90 days) all new confidentiality claims for chemical identity of chemicals that have been offered for commercial distribution and, where claim is upheld, apply a unique identifier to the chemical and any associated information.

Goal: Meet the 90 day deadline for incoming CBI claims and create a plan to link associated information in 30 days – mid-July 2016

Requirement: Routine review of and determination on (within 90 days) at least 25% of new confidentiality claims for other types of information

Goal: Develop approach for routine review in 30 days – mid-July 2016

Requirement: Claimants to submit required statement & certification for all asserted CBI claims

Goal: Provide stakeholders with additional information on statement and certification by mid-July.

- Ongoing Section 6 Rulemakings

Description: For chemicals with risk assessments completed prior to the date of enactment, section 26(l)(4) allows EPA to publish proposed and final rules consistent with the scope of those risk assessments, even if they do not cover all conditions of use

Goal: Continue work to address identified risks from trichloroethylene (TCE), methylene chloride (MC) and N-methylpyrrolidone (NMP):

- Proposed rule for TCE use in spot cleaning and aerosol degreasing by early October; final rule anticipated early October 2017.
- Proposed rule for TCE use in vapor degreasing by early December; final rule anticipated early December 2017.
- Proposed rule for MC and NMP use in paint removers by early December; final rule anticipated early December 2017.

Framework Actions

***Processes to guide longer term program*

- Initial Risk Evaluations

Description: Publish list of 10 Work Plan chemicals & formally initiate risk evaluation on those chemicals

Deadlines: Publish list of chemicals within 180 days after enactment – mid-December 2016; and
Publish scope of each assessment within 6 months – mid-June 2017

- Prioritization Process Rule

Description: Procedural rule to establish the EPA's process and criteria for identifying high priority chemicals for risk evaluation and low priority chemicals

Deadline: Final rule one year after enactment – mid June 2017

Interim Milestone:
Publish proposed rule – mid-December 2016

- Risk Evaluation Process Rule

Description: Procedural rule to establish the EPA's process for evaluating the risk of high priority chemicals

Deadline: Final rule one year after enactment – mid-June 2017

Interim Milestone:
Publish proposed rule mid-December 2016

- Fees Rule

Description: EPA is authorized to collect fees to help defray the cost of implementing certain provisions and to fully defray the cost of industry-requested risk evaluations, but must put a rule in place to require fees. There is no deadline in the bill, but authority to require fees will be needed ASAP

Goal: Final rule one year after enactment – mid-June 2017

Interim Milestones:

Consult and meet with parties potentially subject to the fees; and
Publish proposed rule – mid-December 2016

- Inventory Rule

Description: Rule to require industry reporting of chemicals manufactured/processed in the previous 10 years. Results will be used to designate active and inactive chemicals on the TSCA Inventory of existing chemicals.

Deadline: Final rule one year after enactment – mid-June 2017

Interim Milestones:

Publish proposed rule mid-December 2016

- Science Advisory Committee on Chemicals

Description: 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.

Deadline: Committee established one year after enactment

Goal: Committee established 6 months after enactment – mid-December 2016

Interim Milestones:

Federal Register Notice published early September 2016; and
Public comment period ending early November 2016

Early Mandatory Actions

***To be completed during the first year of implementation*

- Scope of Initial Risk Evaluations

Description: EPA must publish the scope of the evaluation of the first 10 chemicals

Deadline: Publish 6 months after initiation – mid-June 2017

- Annual Plan for Risk Evaluations

Description: Plan must identify chemicals for which evaluations are expected to be initiated or completed that year and the resources needed, status of other chemicals under evaluation, and updated schedules as appropriate

Deadline: The beginning of each calendar year after enactment – first plan due early January 2017

- Additions to Mercury Export Ban

Description: Mercury compounds are now banned from export, in addition to elemental mercury which was previously banned under MEBA.

Deadline: Publish initial list of mercury compounds prohibited from export within 90 days of enactment – mid-September 2016

- Mercury Inventory
Description: The EPA must publish an inventory of mercury supply, use, and trade in the U.S. and update it every three years
Deadline: First inventory published April 1, 2017
- Small Business Definitions
Description: EPA must review the adequacy of standards for identifying small manufacturers and processors, and revise as warranted.
Deadline: Determine whether revision is warranted within 180 days of enactment
Goal: Plan and schedule for revisions published with the determination
- Report to Congress
Description: The EPA must report to Congress on its capacity, and the resources needed, to conduct risk evaluations and to issue rules to address unreasonable risks. The Agency must also report on capacity to conduct industry-requested risk evaluations, the likely demand for such requests, and the anticipated schedule for accommodating the demand.
Deadline: First report must be submitted 180 days after enactment – mid-December 2016 – and every 5 years thereafter.

Later Mandatory Actions

***To be completed within the first few years of implementation*

- Mercury Use/Product Reporting Rule
Deadline: Final rule 2 years after enactment – mid-June 2018
- CBI Review/Substantiation Rule
Deadline: Final rule 1 year after publication of Inventory reset of active chemicals (not later than 1.5 years after enactment)
- Generic Names for CBI Chemicals
Deadline: Guidance 2 years after enactment – mid-June 2018
- Negotiated Rulemaking on Byproducts Reporting for CDR
Deadline: Proposed rule (if produced by negotiating process) 3 years from enactment – mid-June 2019
- Alternative Testing Methods Strategy
Deadline: Publish strategy 2 years after enactment – mid-June 2018