

**How the Frank R. Lautenberg Chemical Safety for the 21st Century Act, S. 697  
amends the Toxic Substances Control Act of 1976 (TSCA)  
and  
Changes made since the Committee Reported Substitute w/ Technical Corrections**

**Updated safety standard:** Ensures that only human and environmental health are considered in assessing the safety of chemicals, replacing TSCA's current standard which requires a cost-benefit balancing during safety review. Ensures that costs and other non-risk factors are to be considered only in deciding *how* to regulate a chemical found not to meet the health-based safety standard.

**Vulnerable populations:** Requires EPA to identify groups of individuals the Administrator identifies as relevant in assessing the safety of a chemical, to assess risks any relevant populations, and to ensure their protection.

**Safety reviews of existing chemicals:** Establishes for the first time a mandate for EPA to review the safety of all chemicals in active commerce, in contrast to TSCA's grandfathering-in of chemicals then in use without any safety review. The key steps in the review process are:

- Companies are to identify all chemicals they are currently manufacturing or processing.
- EPA is to establish the priority (high or low) of all active chemicals, at a pace commensurate with agency resources and capacity.
  - High-priority chemicals undergo full safety assessments and safety determinations against the updated safety standard.
  - For any chemical found not to meet the safety standard, EPA must impose restrictions sufficient for the chemical to meet the safety standard, and where restrictions cannot be imposed to ensure the chemical can meet the safety standard, EPA must either ban or phase it out.
  - Low-priority chemicals are those EPA concludes have sufficient information to establish that the chemical is likely to meet the safety standard.
- In identifying high-priority chemicals, EPA is to give preference to chemicals on its Work Plan that are persistent and bioaccumulative and those that are known human carcinogens and have high acute and chronic toxicity. EPA's criteria also must account for recommendations of the Governor of a State, hazard and exposure potential of a chemical substance, and storage near significant sources of drinking water.
- Companies may also request and provide funds for EPA to assess their chemicals; EPA must conduct a minimum number of such reviews and the maximum number is capped to ensure EPA-identified chemicals remain the primary focus.
- All steps in the review and regulatory process are subject to full notice and comment rulemaking, judicially enforceable deadlines, and minimum numbers of chemicals to be reviewed are specified, which rise over time as program implementation is completed and experience is gained.

**More effective authority to require testing of chemicals:** Eliminates TSCA's *Catch-22* requirement that EPA first have evidence of risk to require testing. Provides for EPA to issue an order requiring testing, rather than having to promulgate a rule, which can be a multiyear process. Testing authority applies to both new and existing chemicals and in limited instances for purposes of prioritization, specifying that EPA cannot require testing to establish minimum information sets for chemicals.

**Review of new chemicals:** Upgrades EPA's review of new chemicals while retaining a balance with the need not to unduly impede innovation and speed to market. Requires for the first time that EPA make an affirmative safety finding – that a new chemical is likely to meet the safety standard – as a condition for market entry. Maintains current TSCA's 90-day review period for new chemicals and shortens that period when EPA makes a positive safety determination.

**Regulation of chemicals presenting significant risks:** Strikes TSCA's unworkable mandate that EPA demonstrate that its regulations impose the "least burdensome" possible requirements. Requires EPA to consider, based on existing information, costs and the availability of alternatives in selecting among regulatory options while ensuring that EPA's regulations are sufficient to address identified risks.

**Confidential business information (CBI):** Requires EPA to review past CBI claims for active chemicals on the TSCA Inventory, the identities of which are not publicly available. Requires that certain CBI claims be substantiated when made, expire after 10 years unless re-substantiated, and are to be reviewed by EPA. Identifies specific types of proprietary information for which claims do not require substantiation or re-substantiation. Specifies types of information, including health and safety data, that are not eligible for CBI protection. Requires EPA to review all new CBI claims and require substantiation for chemicals found not to meet the safety standard, and creates a rebuttable presumption of disclosure for a chemical that EPA bans or phases out. For the first time, provides that CBI is to be shared with state governments, health and environmental professionals and first responders, subject to adequate protections and nondisclosure agreements.

**User fees:** Requires EPA to collect fees for the review of new and existing chemicals to defray a portion of the costs of implementing the program. Specifies that fees are capped at 25% of relevant EPA program costs, and that companies are to pay 100% of the costs of safety assessments they request (50% for those already on EPA's Work Plan).

**Federal-State authority:** Establishes preemption of state authority that is chemical-specific, applies only when EPA take up a chemical, and is confined to the hazards, exposures, risks, uses and conditions of use of a chemical that are included in EPA's safety assessment and safety determination (and, where required, risk management rule).

Preemption applies only to state statutes or administrative actions restricting a chemical, not to requirements for reporting, monitoring or disclosure. States can impose restrictions that are identical to a Federal requirement, adopted under the authority of a federal law, or adopted under a state air or water quality or waste treatment or disposal law, unless they conflict with federal requirements.

States can enforce existing restrictions until EPA takes final action on a chemical, but cannot impose new restrictions during EPA review of a chemical.

State actions taken on a chemical prior to August 1, 2015, or taken under a law in effect on August 31, 2003, remain in place regardless of EPA action. After enactment, states can: impose new restrictions on a chemical until and unless EPA begins to review that same chemical and addresses the same uses; continue to enforce existing restrictions on the chemical until EPA's review is completed; and, if EPA finds the chemical does not meet the safety standard, impose new or continue to enforce existing restrictions until EPA issues its regulation.

States can seek waivers to act during or after EPA review. EPA decisions on waivers, or its failure to make a decision by a specified deadline, can be challenged by anyone in court.

**Other important provisions:**

- *Animal testing*: Requires EPA to minimize animal testing where scientifically reliable alternatives exist that would generate equivalent information.
- *Small Business*: Requires EPA to minimize the impacts of rules on small manufacturers and processors.
- *Sustainable chemistry*: Establishes a federal Sustainable Chemistry Program and National Sustainable Chemistry Initiative.
- *Articles*: Mandates EPA only apply prohibitions or other restrictions to articles to the extent necessary to address identified risks from exposure to the chemical substance from the article.
- *Persistent and bioaccumulative substances*: Such substances are given preference in prioritization process and, when found not likely to meet the safety standard, EPA is required to impose restrictions to reduce exposure to the maximum extent practicable.

**Changes made since the Committee Reported Substitute w/ Technical Corrections**

- **Prioritization**
  - Directs EPA to use its Framework for Metals Risk Assessment in prioritizing and assessing metals and metal compounds.
  - Requires EPA to identify the information and analysis on which its prioritization decisions, and any decision to postpone a prioritization decision, are based.
  - Adds two additional prioritization criteria: chemicals that are known human carcinogens and have high acute and chronic toxicity; and chemicals stored near significant sources of drinking water.
- **Safety Assessments and Safety Determinations**
  - Specifies that the annual plan for safety assessments and safety determinations identifies, for each assessment and determination, the resources needed for completion, its status and milestones met, and any updates to the schedule for completion.
  - Clarifies that determinations that a substance both meets and does not meet the safety standard are to be judicially reviewable under the same 'substantial evidence' standard of review.
  - Shortens the extension available to EPA for completion of safety determinations from 2 years to 1 year, and limits such extensions to cases where required information has not yet been

received or was submitted late in the time period allotted for the safety determination. For Work Plan chemicals, limits EPA from extending deadlines for completing a safety determination and for promulgating a rule, unless EPA publicly justifies the extension by demonstrating that the safety determination or rule cannot be adequately completed without additional information.

- Requires compliance with risk management regulations within 4 years for uses not exempted by the Administrator, extendable by up to 18 months if EPA determines that such compliance is technologically or economically infeasible.
  - Clarifies that when the Administrator identifies a relevant potentially exposed or susceptible population and finds a chemical substance does not meet the safety standard for that population, prohibitions or other restrictions must be applied to ensure the substance meets the safety standard for that population.
  - Conforms the definition of a high persistent, bioaccumulative and toxic chemical to EPA's current practice.
- **Information Collection and Reporting**
    - Requires EPA to periodically review, and revise as needed, its standards for identifying small manufacturers and processors (which are exempt from or subject to reduced reporting requirements).
- **Relationship to Other Federal Laws**
    - Mandates EPA to act if another federal agency to which it has referred a finding that a chemical does not meet the safety standard does not take required actions with the requisite time periods.
- **Confidential business Information**
    - Requires EPA to develop a request and notification system to facilitate access to confidential information allowed to be disclosed to health and environmental professionals.
- **State-Federal Relationship**
    - Clarifies preemption triggered by EPA safety assessments and safety determinations to state actions is applicable to the hazards, exposures and risks – as well as the uses or conditions of use – of a chemical that are identified by EPA and included in its safety determination and any requisite risk management rule.
    - Modifies the “science” showing a state must make to be granted a waiver to act after final EPA action to clarify that scientific evidence must support the identification of the risk being addressed, rather than the restriction being imposed.
    - Modifies that states applying for waivers must show compelling conditions warrant granting the waiver to protect health or the environment.
    - Simplified the process for a state to impose new restrictions while EPA is reviewing a chemical substance by lifting preemption following an EPA-missed deadline for publication of the safety determination instead of requiring EPA to automatically approve state waiver applications.
    - Eliminates the prior bill's on-again/off-again of the waivers during judicial review of EPA's waiver inaction.
    - Clarifies that a failure by EPA to decide on a waiver request is subject to a citizen's civil action because it is a failure of EPA to perform a mandatory duty.

- Specifies that a waiver granted by EPA stays in effect until EPA completes its safety determination for a chemical, EPA misses its deadline for publishing its safety determination, or a court directs EPA to deny the waiver in response to a judicial challenge.
  - Both EPA and States enforcing their own identical regulations can collect penalties for violations, although the combined total State and Federal penalty cannot exceed the federal statutory maximum.
- **User Fees**
    - Requires that fees be set at a level sufficient to annually defray:
      - the lower of 25 percent of the costs of the activities for which fees can be used, or \$25 million;
      - the full costs and the 50-percent portion of the costs of safety assessments and safety determinations requested by industry for chemicals not on, or on, EPA's Work Plan, respectively.
    - Clarifies that EPA can adjust the fees in the future both for inflation and to ensure the fees remain sufficient to defray 25 percent of relevant costs even if the fees would exceed the initial \$25 million cap.
- **Mercury**
    - Requires development of a long-term storage facility for elemental mercury, and provides for interim storage by generators; creates an inventory of supply, use, and trade of mercury; and prohibits export of certain mercury compounds.
- **Trevor's Law**
    - The bill provides improved direction for identification, designation, and investigation of potential cancer clusters.