

Key Provision	TSCA 1976	Frank R. Lautenberg Chemical Safety for the 21st Century Act
<u>General Applicability:</u> Changes cost-benefit balancing standard and testing procedures for new and existing chemicals		
Safety Standard	"Unreasonable risk" requires cost benefit analysis and balancing.	Explicitly precludes EPA from considering costs in determining if a chemical presents an "unreasonable risk" and in deciding <i>whether</i> to regulate a chemical.
Least Burdensome	EPA must conduct formal analysis showing that benefits of any proposed restriction must outweigh cost and any restrictions must be the "least burdensome".	Requires cost to be considered in <i>how</i> to regulate a chemical but eliminates the requirement that regulations must be the least burdensome; instead requires consideration of costs and benefits, cost-effectiveness based on reasonably available information.
Vulnerable Populations	Not specifically considered.	Requires explicit consideration and protection of susceptible populations, such as infants, children, pregnant women, workers or the elderly in assessing and regulating chemicals.
Testing	EPA must have evidence of risk and issue a rule before requiring testing.	Provides greater flexibility to EPA to issue an order rather than a rule, to require testing of new and existing chemicals or testing to establish chemical prioritization. Requires reduction in animal testing "to the extent practicable".

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<p><u>New Chemicals and Significant New Uses:</u> <i>Requires affirmative EPA finding before new chemical or significant new use of an existing chemical can enter the market place</i></p>		
<p>Affirmative Finding</p>	<p>No affirmative safety decision is required. Instead, a company can make and sell new chemical at end of 90 day review period unless EPA finds that the chemical presents an unreasonable risk.</p>	<ul style="list-style-type: none"> • Requires affirmative finding by EPA that a new chemical or significant new use will meet safety standard before the chemical or new use can enter the marketplace. • Upon receiving a pre-manufacturing notice, EPA has 90 days to determine if the chemical would cause an “unreasonable risk” or if additional information is needed. • If EPA lacks sufficient information to make a safety determination it must issue an order or rule imposing conditions to prevent an unreasonable risk or precluding market entry.
<p>Articles</p>	<p>EPA retains authority to regulate articles of commerce containing chemicals; EPA has rarely regulated articles but recently proposed Significant New Use Rules for flame retardants and other chemicals that would regulate the products that use these chemicals in products.</p>	<ul style="list-style-type: none"> • EPA can restrict articles only to extent necessary to address identified risks from exposure to chemicals from the article; EPA must make an affirmative regulatory finding of reasonable potential for exposure before requiring notification of articles as a significant new use. • Transition period for chemicals in the pipeline is ambiguous. The language is unclear if the new “affirmative finding” provisions and process in “Lautenberg” would apply to pre-manufacturing notices already in the pipeline or if EPA would have to reissue its proposed SNURs for flame retardants and other chemicals which would regulate articles using these chemicals.

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<u>Existing Chemicals:</u> <i>Mandates review of existing chemicals and regulation of “high priority” chemicals</i>		
Review Process	No deadlines for completing chemical assessments or imposing restrictions.	Establishes process and criteria by EPA rulemaking within 1 year and a statutory timeline mandating EPA risk evaluations and subsequent prioritization of existing chemicals as either high or low priority. Companies must identify all existing chemicals and may request and pay EPA to assess their chemicals provided all such requests account for 25%-50% of all assessments.
Pace of Reviews	No deadlines for completing chemical assessments or imposing restrictions.	Requires 10 risk assessments in 6 months for chemicals drawn from EPA’s 2014 TSCA Work Plan and assessments for another 20 high and 20 low priority chemicals in 3½ years. Sets 3 year deadline for completion of assessments and a 2 year deadline (+ 2 year extension) for any rule.
Review Decisions	No deadlines for completing chemical assessments or imposing restrictions.	EPA must either ban, phase out or impose restrictions for any high priority chemical presenting an unreasonable risk. All steps in review and regulatory process are judicially enforceable deadlines.

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<u>State Preemption:</u> Provides process for preempting and grandfathering state actions		
General Rule	EPA actions generally preempt state law but preemption is rarely triggered because EPA has imposed so few restrictions.	<ul style="list-style-type: none"> • States may not take actions on an existing chemical that EPA is acting on. • States are preempted from taking actions on a final EPA action on a chemical that does not present an unreasonable and on a chemical presenting an unreasonable risk and subject to a regulation imposing restrictions <u>unless</u> the state action is identical to the Federal requirement, is adopted under authority of federal law, or adopted under a state air, water quality, waste treatment or disposal law. • States are not preempted from requiring reporting, monitoring or disclosure.
Timing	States are not bared from imposing requirement until EPA takes final action.	<ul style="list-style-type: none"> • States are generally preempted from imposing restrictions, except by waiver, once EPA defines the scope of a risk evaluation for a chemical and ending when the risk assessment is complete (i.e. review period). States may continue to enforce a law enacted prior to the risk evaluation. • EPA may issue a waiver to allow state action during the review period. Following the review period, preemption would reapply to chemicals that do not present an unreasonable risk and once EPA takes a final action on chemicals presenting an unreasonable risk. EPA has 180 days to grant or deny a waiver or it is automatically approved and subject to judicial challenge.
Grandfathering	More than 30 states have adopted measures restricting the use of individual chemical substances in place of action from the Federal government. These chemicals include: BPA, formaldehyde, lead, mercury and flame retardants.	All state actions taken before April 22, 2016 and past and future actions taken pursuant to a law in effect on August 31, 2003 are not preempted (preserving California Prop 65 and Massachusetts Toxics Use Reduction Act). States can enforce existing restrictions until EPA initiates a review of the same chemicals and takes final action on the same uses of that chemical.

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<p><u>Confidentiality:</u> Requires substantiation, assertion and re-assertion of claims</p>		
<p>CBI Claims</p>	<p>Provides stringent provisions for protecting trade secrets that must be shared with EPA during the regulatory process. Once claimed CBI remains protected until EPA finds it does not meet legal requirements for protection. Although EPA has authority to challenge CBI claims it rarely does because it often lacks resources necessary.</p>	<p>Prevents disclosure of information for which CBI claims have been asserted and substantiated.</p> <ul style="list-style-type: none"> • Provides authority to EPA to require anyone claiming CBI protection (before or after enactment) to reassert and substantiate or re-substantiate claims and make a determination if the information should continue to be protected from disclosure. Protects substantiated information for 10 years with a 10 year extension. • If CBI protection is denied, EPA shall provide a written statement of the reasons. <p>CBI protection shall no longer apply to information on chemicals that are banned or phased-out, health and safety studies offered for commercial distribution, and information EPA determines is necessary to protect health or the environment.</p>

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<p><u>TSCA Administration:</u> <i>Increases TSCA fees and fines and penalties</i></p>		
<p>Fees</p>	<p>Allows the EPA to collect a “reasonable fee” from companies seeking a review of their chemical. That fee may not exceed \$2,500 (or \$100 for a small business).</p>	<p>Establishes a TSCA Service Fee fund within Treasury and allows the Administrator to set forth a fee schedule. Fees are capped at 25% of costs or \$25 million, whichever is less, for regulating new and existing chemicals testing, evaluation and information protection.</p>
<p>Fines & Penalties</p>	<p>Fine for civil penalties: \$25,000. Penalty for violating “imminent danger” restrictions: \$25,000/day.</p>	<p>Increases civil fines for violations to \$37,500. Increases penalty for violating “imminent danger” restrictions to \$50,000/day, plus potential of one-year prison sentence.</p>