



TESTIMONY OF

RICHARD A. DENISON, Ph.D.  
LEAD SENIOR SCIENTIST  
ENVIRONMENTAL DEFENSE FUND

BEFORE

THE U.S. SENATE  
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

AT A HEARING ON

S. 697  
THE FRANK R. LAUTENBERG  
CHEMICAL SAFETY FOR THE 21<sup>ST</sup> CENTURY ACT

18 MARCH 2015

Environmental Defense Fund (EDF) has been working to reform the Toxic Substances Control Act (TSCA) for 20 years, and I have for the past 15 years. That is why I am so pleased today to provide EDF's endorsement of the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The bill is a solid compromise that fixes the biggest problems with our current law, is health-protective – and has the strong bipartisan support necessary to become law.

This legislation did not suddenly arise in this Congress; it is the culmination of a decade of legislative effort, most of it led by the late Senator Frank Lautenberg, who grasped early on the pressing need to reform TSCA, and had the courage to recognize that such reform would never be realized without opening up a bipartisan path forward.

The legislation is built on the Chemical Safety Improvement Act, a bill introduced by Senator Lautenberg and Senator David Vitter in May 2013 that garnered 13 Democratic and 13 Republican cosponsors in the last Congress. Since then, the bill has only gotten better: Its health protections have steadily been strengthened as a result of negotiations led by Senator Tom Udall with Senator Vitter to address major concerns raised about the original bill. The Senators have worked tirelessly to listen to and incorporate input from other Members and hundreds of stakeholders, and to strike a balance between competing interests on dozens of contentious issues within the scope of the legislation.

The need for reform is indeed urgent: TSCA's core provisions, the main law that is supposed to protect us from toxic chemicals, haven't been updated for almost 40 years. In that time, the diversity and uses of industrial and consumer chemicals have greatly expanded. Americans are exposed to thousands of chemicals every day, and only a small fraction have ever been adequately reviewed for safety. The law is so badly broken that our government lacks the ability to regulate even known dangers such as lead, formaldehyde and asbestos. And the current patchwork of state regulations covers only a small number of chemicals and extends its protections to only a fraction of the American public.

The law hasn't kept pace with science, which increasingly links common chemicals to cancer, infertility, diabetes and Parkinson's and other illnesses. Pregnant woman, infants, and children are especially vulnerable: A growing body of research from fields such as cell biology and epigenetics is demonstrating how even low-level exposures to certain chemicals can interfere with early development in ways that have life-long consequences for health. Babies in the U.S. are born with hundreds of chemicals already in their bodies.

During my 28 years at EDF, I have experienced firsthand the failings of our current law. I've spent much of my professional career pressing the Environmental Protection Agency (EPA) to find ways to use or work around its highly constrained authority under the law to address chemical risks. Most of this time, right up to the present day, I've been on the opposite side of the table from the chemical industry on nearly every issue.

Rare political circumstances have opened a narrow window to pass meaningful reform. This has come about in part because much of the industry finally realizes that a stronger federal system is necessary to restore Americans' confidence in the safety of chemicals. EDF believes that Congress now has the best chance in a generation to better protect our health by bringing TSCA into the 21st century. But every day we wait means another day before we can start to protect millions from the threats posed by dangerous chemicals.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (FRL21) fixes the key flaws in our current law. With respect to each core element of TSCA, the bill gives the EPA the tools necessary to strengthen health protections for American families:

- It mandates safety reviews for all chemicals in active commerce.
- It requires a safety finding for new chemicals before they can enter the market.
- It replaces TSCA's burdensome cost-benefit safety standard—which prevented EPA from banning asbestos—with a pure, health-based safety standard.
- It explicitly requires protection of vulnerable populations like infants and pregnant women.
- It gives EPA enhanced authority to require testing of both new and existing chemicals.
- It sets aggressive, judicially enforceable deadlines for EPA decisions.
- It makes more information about chemicals available, by limiting companies' ability to claim information as confidential, and by giving states and health and environmental professionals access to confidential information they need to do their jobs.

I have attached a [factsheet](#) and a [detailed analysis](#) of these and other major improvements FRL21 makes over both TSCA and the original bill.

None of these provisions is perfect from our perspective – indeed, most of them clearly represent compromises. However, taken both individually and in aggregate, they are much more health-protective than current law. And they will deliver more and better information on the safety of chemicals to the public, consumers and the market so that they, too, can act to reduce harm from exposures to toxic chemicals.

Let me briefly address the most contentious aspect of the debate over TSCA reform: the extent to which the bill would preempt state authority to restrict chemicals. The bill is more preemptive than current TSCA, but far more narrow than the original 2013 bill. Striking the right balance has proven to be both exceedingly difficult and critical to garnering the bipartisan support needed to pass a law. Here's what the bill does:

- All state actions taken on all chemicals before 2015 are grandfathered in and never preempted regardless of subsequent EPA action.

- State actions taken after 2015 on a chemical remain in effect until and unless EPA lists that same chemical as a high priority, and takes final action to address the same uses and the same health and environmental concerns.
- State actions are not preempted by EPA's designation of a chemical as low-priority.
- Once EPA initiates and sets the scope of an assessment of a high-priority chemical, a state cannot take a *new* action to restrict that chemical.
  - However, existing state actions not grandfathered in remain in effect until EPA completes its safety assessment and determination and any required regulation.
- Even after EPA takes final action on a chemical, federal preemption is limited:
  - Only states' *restrictions* on chemicals are pre-empted; other types of requirements for reporting, assessment, monitoring, and the like are never preempted.
  - Only state restrictions on uses and health or environmental concerns that *fall within the scope* of EPA's review of a chemical are preempted; states can still regulate that chemical for other uses and to address other concerns.
  - States can apply for waivers to allow them to impose restrictions beyond EPA's, although the waiver requirements are more onerous than under current TSCA.

Let me conclude with this: The failures of TSCA represent a serious and growing public health calamity. Congress must act now; American families can't afford to have the best opportunity ever to reform this broken law squandered.

Environmental Defense Fund looks forward to working with this Committee and other stakeholders to move this bipartisan legislation forward and ensure the strongest possible bill becomes law. We urge the Committee to take up and advance the Frank R. Lautenberg Chemical Safety for the 21st Century Act as if our lives depended on it – because they do.



**Richard A. Denison**  
*Lead Senior Scientist*  
*Environmental Health Program*  
*Washington, DC Office*



Richard A. Denison, Ph.D., has 30 years of experience in the environmental arena, specializing in policy, hazard and risk assessment and management for industrial chemicals and nanomaterials.

Richard is a member of the National Academy of Sciences' Standing Committee on Emerging Science for Environmental Health Decisions. He recently served on the NAS Board on Environmental Studies and Toxicology and the Green Ribbon Science Panel for California's Green Chemistry Initiative.

Richard has testified before various Congressional committees on the need for fundamental reform of US policy toward industrial chemicals and on nanomaterial safety research needs. He served as a member of the National Academy of Sciences' Committee to Develop a Research Strategy for Environmental, Health and Safety Aspects of Engineered Nanomaterials. He was a member of EDF's team that worked jointly with the DuPont Corporation to develop a framework governing responsible development, production, use and disposal of nanoscale materials.

Richard is a frequent contributor to [EDFHealth's blog](#), where he posts both commentary and detailed analyses of the emerging science and policies affecting chemicals and nanomaterials in the U.S. and internationally.

## **Background**

Ph.D., Molecular Biophysics and Biochemistry, Yale University, 1982.

Denison joined EDF in 1987, after several years as an analyst and assistant project director in the Oceans and Environment Program, Office of Technology Assessment, US Congress.

## **Recent Publications**

- [Chemical Safety Reform: Will the Center Hold?](#) *The Environmental Forum* (2014).
- [TSCA Reform: Information Confidentiality, Availability, and Sharing](#), *Environmental Law Reporter* (2012).
- [TSCA Reform: The Current Safety Standard](#), *Environmental Law Reporter* (2011).
- [Ten Essential Elements in TSCA Reform](#), *Environmental Law Reporter* (2009).
- [Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals](#), Environmental Defense Fund (2007).

***Pass the Frank R. Lautenberg Chemical Safety for the 21st Century Act  
to Protect the Health of American Families***

***March 10, 2015***

**THE PROBLEM: UNTESTED AND UNSAFE CHEMICALS THAT THREATEN OUR HEALTH**

**Americans are exposed to thousands of chemicals every day, and only a small fraction have ever been adequately tested for safety. Our primary chemical safety law, the 1976 Toxic Substances Control Act (TSCA), hasn't been updated for almost 40 years. The law is so badly broken that EPA is powerless to restrict even known deadly carcinogens such as asbestos, which kills 10,000 Americans every year.**

- *Our health is at risk.* Science has linked common chemicals to cancer, infertility, diabetes and Parkinson's and other illnesses. Pregnant women, infants, and children remain especially vulnerable: many babies are born with hundreds of chemicals already in their bodies.
- *The current law is broken.* Only a small fraction of the chemicals in cleaning products, clothing, furniture, and most other products have ever been reviewed for safety. Our government lacks the ability to regulate even known dangers such as lead and formaldehyde. And the current patchwork of state regulations covers only a small number of chemicals.
- *The current law is outdated.* It hasn't kept pace with science and the greatly expanded use of chemicals. Most other developed countries have modernized their chemical safety laws, but the U.S. has fallen behind.
- *For more than a decade, Congress—under both Democratic and Republican control—has failed to pass chemical safety reform.* American families can't afford to wait any longer.

**THE SOLUTION: THE FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21<sup>ST</sup> CENTURY ACT**

**Congress has the best chance in a generation to protect our health by bringing our nation's main chemical safety law into the 21<sup>st</sup> century. After years of debate and inaction, a bipartisan group of Senators has introduced legislation – the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697) – that fixes the biggest problems with our current law. Rare political circumstances have opened a narrow window to pass meaningful reform that protects the health of American families.**

- *All parties agree we need a new law.* Our broken law doesn't work for anyone: not for the public, for consumers or for business. After years of denial, many companies are now willing to accept more regulation to secure a predictable system that restores consumer confidence in the safety of their products.

- *The problem requires a federal solution.* With tens of thousands of chemicals in use today, the problem is much too big for individual consumers, product companies, retailers or states to handle on their own. We need a robust national program, rather than the current piecemeal approach that leaves many without any protections whatsoever.
- *Congress can get this done.* This legislation is built on a bill introduced by the late Sen. Frank Lautenberg and Sen. David Vitter in 2013. Since its introduction, negotiations led by Sen. Tom Udall and Sen. Vitter have yielded a much-improved bill that represents a major advance over current law and enjoys the strong bipartisan support needed to actually become law.

### THE FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21<sup>ST</sup> CENTURY ACT (S. 697)

*The bill would update the current law and give EPA the tools necessary to ensure the safety of chemicals and significantly strengthen health protections for American families. Notably, the bill:*

- **Mandates safety reviews for all chemicals** in active commerce.
- **Requires a safety finding for new chemicals** before they can enter the market.
- Replaces TSCA's burdensome safety standard—which prevented EPA from banning asbestos—with **a pure, health-based safety standard.**
- **Explicitly requires protection of vulnerable** populations like children and pregnant women.
- Gives EPA **enhanced authority to require testing** of both new and existing chemicals.
- **Sets aggressive, judicially enforceable deadlines for EPA decisions.**
- **Makes more information about chemicals available**, by limiting companies' ability to claim information as confidential, and by giving states and health and environmental professionals access to confidential information they need to do their jobs.

Nearly two years of negotiations have yielded other key recent improvements over earlier drafts, in addition to those listed above, including:

- Narrows the extent of preemption of state authority:
  - All state actions taken before 2015 remain intact, regardless of subsequent EPA actions.
  - After enactment, states can act to restrict a chemical until and unless EPA takes up that same chemical and addresses the same uses.
  - State actions that do not restrict a chemical's production, distribution or use, or are taken to address a different problem, e.g., climate change, are not affected.
  - Pre-emption triggered by EPA's designation of a chemical as "low-priority" has been eliminated.
- Allows states that recommend against EPA designating a chemical as low-priority to judicially challenge an EPA decision to do so.
- Requires companies to pay fees to ensure that EPA has adequate resources to carry out its responsibilities.
- Increases the number of high-priority chemicals undergoing reviews from the initial designation of at least 10 chemicals to a minimum of 20 within 3 years, and 25 within 5 years, after enactment.
- Establishes an interagency Sustainable Chemistry Program.



**14 major improvements in the Frank R. Lautenberg Chemical Safety for the 21st Century Act**  
*Comparing the new Udall-Vitter chemical safety reform bill to the past bill and current law*

**March 10, 2015**

This table compares the Toxic Substances Control Act (TSCA) of 1976, the Chemical Safety Improvement Act (CSIA, S. 1009) as introduced in May 2013, and the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697) introduced on March 10, 2015. Our analysis identifies 13 major areas of improvement in the new bill in comparison both to CSIA as introduced and to TSCA. It also identifies aspects of the new bill that are more preemptive of state authority than current TSCA, but much less preemptive than CSIA as introduced (see item 14 below).

	<b>Current TSCA</b>	<b>CSIA as introduced</b>	<b>Chemical Safety for the 21st Century Act</b>
<b>1. Safety standard</b>	<ul style="list-style-type: none"> <li>• “Unreasonable risk” requires cost-benefit analysis and balancing</li> </ul>	<ul style="list-style-type: none"> <li>• Retains “unreasonable risk” language but to be based “solely on considerations of risks to human health and the environment”</li> </ul>	<ul style="list-style-type: none"> <li>• Explicitly precludes EPA from considering costs and other non-risk factors in making safety determinations</li> </ul>
<b>2. Protection of vulnerable populations</b>	<ul style="list-style-type: none"> <li>• No special consideration</li> </ul>	<ul style="list-style-type: none"> <li>• Requires EPA to consider “the vulnerability of exposed subpopulations”</li> </ul>	<ul style="list-style-type: none"> <li>• Defines “potentially exposed or susceptible population” to include vulnerability due both to elevated chemical exposures and to heightened susceptibility to their effects</li> <li>• Specifies such populations include (but are not limited to) infants, children, pregnant women, workers, the elderly</li> <li>• Expressly requires protection of such populations</li> </ul>

	<b>Current TSCA</b>	<b>CSIA as introduced</b>	<b>Chemical Safety for the 21st Century Act</b>
<b>3. Adequacy of restrictions for chemicals not meeting standard</b>	<ul style="list-style-type: none"> <li>• Authority but no mandate to restrict chemicals found to present an unreasonable risk</li> <li>• No provision to ensure the sufficiency of restrictions</li> </ul>	<ul style="list-style-type: none"> <li>• Mandates EPA restrict any chemical found not to meet the safety standard</li> <li>• No requirement that restrictions be sufficient to meet standard</li> </ul>	<ul style="list-style-type: none"> <li>• Explicitly requires that restrictions must either phase out or ban the chemical, or be sufficient to ensure the chemical meets the safety standard</li> </ul>
<b>4. Cost-benefit requirements for regulation</b>	<ul style="list-style-type: none"> <li>• EPA must conduct a formal analysis and show benefits of any proposed restriction outweigh costs</li> <li>• Restrictions must be “least burdensome” among those able to address identified risks</li> </ul>	<ul style="list-style-type: none"> <li>• Strikes “least burdensome” requirement and, for most restrictions, would not require formal cost-benefit analysis</li> <li>• But all potential regulatory and chemical alternatives would have to be identified, and their technical and economic feasibility, costs and benefits, and risks analyzed</li> <li>• Proposed ban or phase-out still requires showing that its benefits outweigh costs</li> </ul>	<ul style="list-style-type: none"> <li>• Makes clear that cost considerations cannot override requirement that restrictions be sufficient to ensure chemical safety</li> <li>• Balancing of costs and benefits is not required, to be considered only “to the extent practicable based on reasonably available information”</li> <li>• Strikes requirement that bans and phase-outs be based on full cost-benefit justification</li> <li>• Only alternatives deemed relevant and technically and economically feasible by EPA need to be considered</li> </ul>
<b>5. Deadlines</b>	<ul style="list-style-type: none"> <li>• No mandate to review the safety of existing chemicals</li> <li>• No deadline for completing initiated assessments or imposing restrictions</li> </ul>	<ul style="list-style-type: none"> <li>• Requires EPA to prioritize <i>all</i> chemicals in active commerce, and to set general schedules for conducting assessments of those designated high-priority</li> <li>• Very few deadlines were set for establishment of rules and procedures or for evaluations of chemicals</li> </ul>	<ul style="list-style-type: none"> <li>• Specifies concrete deadlines for all major steps: prioritization, safety assessment and determination, and regulation</li> <li>• Sets a 2-year deadline by which all rules to establish requirements and procedures must be issued</li> <li>• EPA must also specify a deadline for companies to submit any information it requests</li> <li>• EPA must include at least 10 chemicals on the initial high-priority list, as well as at least 10 on the low-priority list <ul style="list-style-type: none"> <li>○ By 3 years after enactment, at least</li> </ul> </li> </ul>

	Current TSCA	CSIA as introduced	Chemical Safety for the 21st Century Act
			<ul style="list-style-type: none"> <li>20 high-priority and 20-low-priority chemicals must have been listed               <ul style="list-style-type: none"> <li>○ By 5 years after enactment, at least 25 high-priority and 25-low-priority chemicals must have been listed</li> </ul> </li> <li>● At least 50% of chemicals are to be work plan chemicals until all of them have been listed</li> </ul>
<b>6. Procedural and scientific requirements</b>	<ul style="list-style-type: none"> <li>● Virtually no procedures or criteria specified to assess information quality, identify chemicals warranting further scrutiny, or determine risk</li> </ul>	<ul style="list-style-type: none"> <li>● Prescribes highly-specific, and in some cases biased, scientific methodologies</li> <li>● Requires EPA to develop from scratch extensive procedures and criteria before starting to prioritize or assess chemicals</li> <li>● Coupled with a lack of deadlines, getting the new system up and running would take many years</li> </ul>	<ul style="list-style-type: none"> <li>● Consolidates and streamlines procedural requirements and eliminates prescriptions to use controversial risk assessment methodologies</li> <li>● Simplifies transition to new system by, for example, allowing EPA to continue ongoing work, adapt current procedures, and act on current chemical priorities as new procedures are put in place</li> <li>● Sets a two-year deadline for establishing all policies, procedures and guidance</li> </ul>
<b>7. Testing</b>	<ul style="list-style-type: none"> <li>● EPA must go through notice-and-comment rulemaking (typically a multiyear process) to require testing</li> <li>● It must also show evidence of potential risk or high exposure, a <i>Catch-22</i></li> </ul>	<ul style="list-style-type: none"> <li>● Eliminates EPA's ability to require testing of new chemicals, and expressly prohibits EPA from requiring testing to inform prioritization decisions</li> <li>● But allows EPA simply to issue orders to require testing instead of going through rulemaking</li> <li>● Strikes requirement that EPA find potential risk in order to require testing</li> </ul>	<ul style="list-style-type: none"> <li>● Retains CSIA's authority for EPA to use orders to require testing (with justification) and elimination of TSCA's risk findings requirement</li> <li>● Restores full testing authority for new chemicals and to inform prioritization decisions</li> <li>● EPA must first request submission of the needed information before requiring testing; and it cannot require testing as a means to establish minimum information sets for chemicals generally</li> </ul>

	<b>Current TSCA</b>	<b>CSIA as introduced</b>	<b>Chemical Safety for the 21st Century Act</b>
<b>8. Low-priority designations</b>	<ul style="list-style-type: none"> <li>EPA has no mandate to prioritize chemicals, the result being that a chemical unexamined by EPA is effectively a low priority, with a lack of data presumed to indicate lack of risk</li> </ul>	<ul style="list-style-type: none"> <li>Mandates that EPA prioritize all active chemicals as either high- or low-priority</li> <li>Low-priority designations are to be based on available information, raising the specter of data-poor chemicals being designated low-priority and set aside indefinitely and with no authority to require they be tested</li> <li>Lack of data can be a factor in designating a chemical as high-priority, which would provide the only means by which EPA could require testing of such a chemical</li> <li>Governors or state agencies can recommend that EPA prioritize or reprioritize a chemical</li> <li>States would be barred from imposing a <i>new</i> restriction on a chemical once EPA designated it low-priority (see item 14 below)</li> </ul>	<ul style="list-style-type: none"> <li>States explicitly that a chemical cannot be designated as low-priority unless EPA concludes that there is “information sufficient to establish it is likely to meet the safety standard”</li> <li>Lack of data can now be a sufficient basis in itself (not just a factor) for designating a chemical as high-priority</li> <li>Restores EPA authority to require testing to inform prioritization decisions where data are lacking</li> <li>States that recommend against EPA designating a chemical as low-priority can judicially challenge an EPA decision to do so.</li> <li>The provision that indicated prioritization decisions were not final agency actions and not subject to judicial review has been struck</li> <li>States are no longer barred from imposing a restriction on a low-priority chemical (see item 14 below)</li> </ul>
<b>9. New chemicals</b>	<ul style="list-style-type: none"> <li>A company is generally free to start making and selling a new chemical at the end of a 90-day review period, unless EPA finds the chemical “may present an unreasonable risk”</li> <li>No affirmative safety decision is required, and the burden is on EPA to</li> </ul>	<ul style="list-style-type: none"> <li>Mandates that EPA make a safety determination for each new chemical and impose “appropriate” restrictions if it determines the chemical is not likely to meet the safety standard</li> <li>Does not require that such restrictions be sufficient for EPA then to find the chemical is likely to meet the safety standard</li> <li>Lack of clarity as to whether</li> </ul>	<ul style="list-style-type: none"> <li>Clarifies that manufacture of a new chemical can only start if EPA affirmatively finds it is likely to meet the safety standard</li> <li>Where EPA determines the chemical is <i>not</i> likely to meet the safety standard, it must preclude manufacture or impose restrictions sufficient for EPA then to find the chemical is likely to meet the safety standard</li> <li>If EPA has insufficient information to</li> </ul>

	<b>Current TSCA</b>	<b>CSIA as introduced</b>	<b>Chemical Safety for the 21st Century Act</b>
	find a concern even when safety data are wholly lacking	companies can start producing a new chemical if EPA has insufficient information to determine whether it is likely to meet safety standard <ul style="list-style-type: none"> <li>• Bars EPA from requiring testing of new chemicals</li> </ul>	make a determination, it can suspend the review pending receipt of the information, or impose restrictions sufficient for it to make the likely-safe determination even in the absence of the information
<b>10. Confidential business information (CBI) claims for chemical identity</b>	<ul style="list-style-type: none"> <li>• The identities of about 17,000 chemicals (out of the 85,000) on the TSCA Inventory are hidden from public view, having been claimed by their makers to be CBI</li> <li>• EPA can challenge such CBI claims on a case-by-case basis, but it has no mandate to review them and rarely mounts challenges because of the resources required</li> </ul>	<ul style="list-style-type: none"> <li>• Authorizes EPA to review CBI claims for chemical identity at any time, but does not mandate any review of such claims</li> <li>• Chemical identities are generally to be presumed protected from disclosure, both before and after they enter the market</li> <li>• Such protection is time-limited, however, for a period set by the claimant if found reasonable by EPA</li> <li>• Such a claim was not allowed if the identity could be readily discovered through reverse engineering</li> </ul>	<ul style="list-style-type: none"> <li>• Limits any presumption of protection from disclosure of chemical identities to the period before they enter the market; and any such claim for a chemical after market entry has to be substantiated and reviewed by EPA</li> <li>• EPA is also required to review and require substantiation of past chemical identity claims for all active chemicals now on the confidential portion of the TSCA Inventory within five years of enactment, and for any inactive chemical at the time it is moved to active status</li> <li>• Chemical identities not already on the confidential portion of the inventory or added to it per prescribed procedures cannot be claimed confidential</li> </ul>
<b>11. CBI claims for health and safety information</b>	<ul style="list-style-type: none"> <li>• Companies are free to claim virtually any information they submit to EPA is CBI</li> <li>• EPA cannot disclose information claimed CBI to the public, to state and local agencies or even to first responders</li> <li>• Health and safety studies</li> </ul>	<ul style="list-style-type: none"> <li>• Health and safety information remains ineligible for CBI secrecy, as under current TSCA</li> <li>• However, chemical identities are presumed protected from disclosure even in the context of health and safety information</li> <li>• Severely limits EPA's authority to question past CBI claims</li> <li>• For the first time, however, state</li> </ul>	<ul style="list-style-type: none"> <li>• Retains current TSCA's exclusion of health and safety studies and their underlying data from being claimed CBI</li> <li>• Unlike CSIA as introduced, does <i>not</i> affect current EPA policy that disallows masking of the identities of chemicals in those health and safety studies</li> <li>• Restores EPA's authority to review all types of CBI claims made in the past</li> <li>• For claims made going forward, they</li> </ul>

	<b>Current TSCA</b>	<b>CSIA as introduced</b>	<b>Chemical Safety for the 21st Century Act</b>
	and their underlying data are generally not eligible for CBI protection under TSCA, but, until recently EPA routinely allowed those studies, or the identities of the studied chemicals, to be hidden from public view	and local governments as well as health professionals would have access to CBI, per agreements that they keep the information confidential	generally must be substantiated at the time they are asserted and are time-limited (see item 12 below) <ul style="list-style-type: none"> <li>• EPA has authority to review the claims under a range of circumstances, including for chemicals designated high-priority or found not to have sufficient information for a safety determination</li> <li>• For chemicals found not to meet the safety standard, EPA is required to review all CBI claims and require their substantiation</li> <li>• Most CBI claims for a chemical that EPA bans or phases out automatically expire</li> </ul>
<b>12. Time limits on CBI claims</b>	<ul style="list-style-type: none"> <li>• CBI claims are not subject to time limits and remain in place until and unless challenged by EPA</li> </ul>	<ul style="list-style-type: none"> <li>• Requires that many CBI claims be substantiated, and that EPA review a representative subset</li> <li>• Claims for chemical identities would be time-limited for a period found reasonable by EPA, but other types of claims would not be time-limited and EPA could not subject them to routine periodic review or resubstantiation</li> <li>• Except for chemical identity claims, EPA could not require substantiation of past claims unless EPA designated a chemical as high-priority</li> </ul>	<ul style="list-style-type: none"> <li>• Most CBI claims are required to be substantiated at the time they are asserted, promptly reviewed by EPA, and either approved or denied</li> <li>• Approved claims expire after 10 years unless resubstantiated and reapproved</li> <li>• Even between 10-year intervals, EPA can review and require resubstantiation of CBI claims: <ul style="list-style-type: none"> <li>○ for high-priority chemicals;</li> <li>○ for chemicals lacking sufficient information for safety determination;</li> <li>○ for inactive chemicals; or</li> <li>○ where EPA finds that disclosure of information claimed CBI, if found not to warrant protection, would assist in conducting safety assessments/determinations or developing risk management rules</li> </ul> </li> </ul>

	Current TSCA	CSIA as introduced	Chemical Safety for the 21st Century Act
			<ul style="list-style-type: none"> <li>• EPA is mandated to review a CBI claim and require resubstantiation: <ul style="list-style-type: none"> <li>○ if necessary to comply with a FOIA request;</li> <li>○ if EPA has reason to believe the claim is not valid; or</li> <li>○ for chemicals found not to meet the safety standard</li> </ul> </li> <li>• Most CBI claims for a chemical that EPA bans or phases out automatically expire</li> </ul>
<b>13. User fees</b>	<ul style="list-style-type: none"> <li>• EPA can only charge fees to cover testing requirements or new chemicals</li> <li>• No fees can be charged to defray the typically much higher costs of EPA reviews of existing chemicals or the collection, management or evaluation of information on existing chemicals</li> <li>• Fees are capped at \$2,500 per company (\$100 per small company)</li> <li>• Any fees collected go to the general treasury and are not available to directly cover EPA's costs</li> </ul>	<ul style="list-style-type: none"> <li>• Maintains the current TSCA fee provisions</li> </ul>	<ul style="list-style-type: none"> <li>• EPA is to collect fees for both new and existing chemicals, as well as those designated as high-priority</li> <li>• Fees can be used to defray the costs of: prioritization screening; safety determinations and any needed regulation of new and existing chemicals; and the collection, review, and provision of public access to information, as well as protection of information found to warrant it</li> <li>• Fees go into a TSCA implementation fund and directly to EPA, not the general treasury</li> <li>• Fees are contingent on Congress providing sufficient funds through normal appropriations, to ensure collection of fees does not lead to a reduction in EPA's budget</li> <li>• The level of fees is to be set to cover approximately 25% of relevant EPA program costs up to \$18 million/year</li> </ul>

	<b>Current TSCA</b>	<b>CSIA as introduced</b>	<b>Chemical Safety for the 21st Century Act</b>
<b>14. State preemption</b>	<ul style="list-style-type: none"> <li>• Preemption has rarely if ever been applied because, in practice, EPA has imposed so few restrictions on chemicals under the current law</li> <li>• EPA actions to protect against risks of new or existing chemicals generally preempt states' existing or new actions</li> <li>• Exceptions are provided for a state requirement that is identical to the federal requirement (providing for co-enforcement), is adopted under authority of a Federal law, or prohibits all use of the chemical in the state</li> <li>• States can obtain waivers from Federal preemption for a requirement that is significantly more protective and does not unduly burden interstate commerce</li> </ul>	<ul style="list-style-type: none"> <li>• States would be barred from imposing a new restriction on a chemical once EPA designates it low-priority or high-priority</li> <li>• Prioritization decisions would not be judicially reviewable</li> <li>• States would also be barred from establishing a new requirement or continuing to enforce an existing requirement that restricts a chemical once EPA has completed a safety determination on the chemical</li> <li>• Waivers could be granted for a state to act during EPA review of a high-priority chemical if the State made the case for why it could not wait for EPA to act or if EPA found that its own review was unreasonably delayed. No waiver would be available after final EPA action on a chemical</li> <li>• Unlike current TSCA, a state could not adopt a requirement identical to the federal requirement or prohibit all use of the chemical in the state</li> <li>• Unlike TSCA, EPA reviews of new chemicals would not have preemptive effect</li> </ul>	<ul style="list-style-type: none"> <li>• Any state action taken on a chemical prior to January 1, 2015 remains in place regardless of EPA action</li> <li>• States are generally barred from imposing a new restriction on a chemical EPA designates as high-priority during EPA's review of the chemical</li> <li>• Preemption is no longer triggered by a low-priority designation, so states can continue to act on such a chemical; in exchange: <ul style="list-style-type: none"> <li>○ States are to notify EPA of actions they take on such a chemical and if requested by EPA provide the basis for the action; and EPA is to prioritize the chemical if it has national impact</li> <li>○ Companies can request EPA to assess such a chemical; at EPA's discretion it can grant a limited number of such requests, but cannot give them preference over high-priority chemicals, and initiation of such assessments does not trigger preemption</li> </ul> </li> <li>• State actions taken after January 1, 2015 that restrict a chemical are preempted if EPA determines the chemical meets the safety standard; if EPA determines a chemical does not meet the standard, preemption is moved to the end of the process: when EPA issues a rule restricting the chemical</li> </ul>

	Current TSCA	CSIA as introduced	Chemical Safety for the 21st Century Act
			<ul style="list-style-type: none"> <li>• Preemption is now clearly limited only to the uses and conditions of use that are included in the scope of EPA's safety assessment and determination, which EPA must set within 6 months of designating a chemical as high-priority</li> <li>• Waivers can be obtained both before and after a final safety determination and risk management rule, although the conditions for granting a waiver are more onerous than under current TSCA</li> <li>• A state still cannot adopt a requirement identical to the federal requirement or prohibit all use of the chemical in the state, except via the granting of a waiver</li> <li>• States can still act on a chemical to address a different concern than EPA under TSCA (e.g., VOC restrictions to address ozone formation)</li> <li>• California's Proposition 65 is excluded from the scope of preemption</li> <li>• Finally, like CSIA as introduced and unlike TSCA, EPA reviews of new chemicals would not have preemptive effect</li> </ul>