

# A primer on the new Toxic Substances Control Act (TSCA) and what led to it

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## Summary

This paper briefly summarizes the body of scientific research that has drawn attention to the potential risks of exposures to chemicals that fall under the jurisdiction of the Toxic Substances Control Act (TSCA) and led to growing calls for reform that culminated in passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act in June 2016. As background and to provide context, the paper describes the scope and purposes of the original law and why it largely failed to achieve those purposes. Key drivers are then discussed that led to passage of reform legislation with strong bipartisan support despite the deep partisan divisions in the Congress. An overview of the reforms made to TSCA by the Lautenberg Act is presented, along with a description of the basic decision-making framework of the new law. Finally, the paper highlights those provisions of most relevance to the public health community.

## Introduction

Over the past several decades, evidence has mounted that chemicals in our environment and in the products and materials we use every day can affect human health and well-being, especially of children whether exposed pre- or post-natally (Landrigan and Goldman 2011; Makri et al. 2004; Woodruff et al. 2011). From this research several lines of evidence have emerged. First, certain chronic diseases and disorders are on the rise in the human population, in a manner that can only be explained by environmental factors. Second, studies in laboratory animals as well as human epidemiological studies link exposures to certain chemicals to those same chronic

diseases. Third, through biomonitoring and other exposure studies, we now know that many of those same chemicals are in our bodies and that they can reach us not only through the environment but from our use of products and exposure to materials in our everyday lives (Carpenter et al. 2002; Caserta et al. 2011; Herbstman et al. 2010; Meeker 2012; Mendell 2007; Rappaport 2010; Rudel et al. 2011; US Centers for Disease Control and Prevention 2016).

Yet the core provisions of our nation's primary chemical safety law, the Toxic Substances Control Act (TSCA), had not been updated since its initial adoption in 1976, rendering it (among other shortcomings) woefully out of step with the best and latest science relating chemical exposures to human health. A long-overdue overhaul of TSCA finally came in June 2016, when President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (hereafter the "Lautenberg Act").



Credit: Fred Watkins

Adoption of the new law, more than a decade in the making, is remarkable for a number of reasons (Denison 2016). It was the first major environmental legislation to be enacted in more than two decades, and passed both Houses of Congress with overwhelming bipartisan support despite a starkly divided Congress. The reforms were comprehensive in nature, amending virtually all major provisions of the original law. The legislation significantly strengthens the Environmental Protection Agency's (EPA) authority to regulate chemicals, and provides the Agency with authority to collect fees from the chemical industry to help fund enhanced chemical reviews. Such enhancement of Agency authority came at a time when most environmental issues and certainly any proposed expansions in government oversight were highly polarizing and contentious issues.

Among the many enhancements made by the new law is an explicit requirement that EPA identify, consider and regulate the potential and actual risks that chemicals pose to vulnerable subpopulations, including children. No such mandate existed in the original law. Remarkably, this feature of the new law was not controversial or ever subject to much debate. Indeed, the need for the law to ensure children's health protection was a core tenet of TSCA reform principles articulated as far back as 2009 not only by health and environmental groups (American Academy of Pediatrics 2011), but by the Obama Administration (US EPA undated (a)), state governments (Adams et al. 2009), and even the chemical industry (American Chemistry Council 2009).

This paper will start with a basic description of the scope and purposes of TSCA, why the original law failed to achieve those purposes, and the key drivers that led to its reform. It will then provide an overview of the reforms made to TSCA by the Lautenberg Act and describe the basic decision-making framework of the new law. Finally, it will highlight those provisions of most relevance to the public health community.

### **Scope and purposes of TSCA as originally enacted**

TSCA covers the great majority of chemicals in commerce, including those used in industry and in commercial and consumer products and materials. However, certain chemicals fall outside of TSCA's jurisdiction (TSCA Section 3(2)(B)). Among the exclusions are: 1) chemicals used in personal care products and cosmetics, food and food packaging, and drugs, all of which are regulated by the Food and Drug Administration (FDA) under different

laws; and 2) pesticides, which are regulated by EPA but under a different law.

As enacted in 1976, both the purposes and potential regulatory reach of TSCA were quite broad. TSCA was intended to drive the development and dissemination of information on the health and environmental impacts of chemicals, and the regulation of any chemical found to present an "unreasonable risk" to health or the environment. It provided EPA with broad authority to regulate chemicals found to present such risks, while cautioning that such authority "should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." These purposes remain intact under the Lautenberg Act (Section 2(b)).

TSCA's scope was and remains expansive, extending to the full lifecycles of chemicals, chemical mixtures and chemical-containing products and, in principle, providing EPA with authority to regulate virtually all activities involving chemicals and chemical information (see box).

#### **Scope of TSCA**

- Applies to the full lifecycle of chemicals:
  - Manufacturing
  - Processing
  - Distribution
  - Use
  - Waste management
- Provides potential authority over:
  - Chemicals/mixtures/products
  - Chemical testing and monitoring
  - Review and regulation of new and existing chemicals
  - Regulation of imports and exports
  - Information collection
  - Information sharing and trade secret protection

The original law mandated that EPA establish an "inventory" of chemicals in commerce at that time, which numbered some 62,000 distinct substances. These "existing chemicals" were distinguished from "new chemicals," of which companies were required to notify EPA at least 90 days prior to commencing manufacture; some 23,000 "new chemicals" have been added to the TSCA inventory since its first establishment in 1979, accounting for the present total of about 85,000 chemicals listed as having been in commerce in the U.S. at some point since that year (US EPA undated (b)).

## **Problems with the old law**

Many analyses of the failings of the original TSCA have been published (Denison 2009a, 2009b; Jones 2015; US Government Accountability Office 2005, 2015a, 2015b; Vogel and Roberts 2011; Wilson and Schwarzman 2009) and only a brief summary will be provided here.

Until TSCA reform passed in June 2016, TSCA's core provisions had never been amended, despite enormous changes over the past four decades both in chemical production and use and in our understanding of human and environmental exposures and biological effects of chemicals.

Foremost among its core structural flaws, the original TSCA:

- failed to provide EPA the authority to deliver the information needed to identify unsafe – as well as safer – chemicals;
- required EPA to demonstrate that the benefits of a regulating a chemical outweighed the costs even in determining whether or not a chemical presented an unreasonable risk;
- forbade EPA from sharing much of the limited information it did obtain; and
- imposed an essentially unachievable burden on EPA to prove actual harm in order to control or replace a dangerous chemical.

For drugs and pesticides (which are regulated under different laws) to enter or stay on the market, their producers have the burden of providing to the government information sufficient to demonstrate their safety. Yet for chemicals regulated under TSCA, the opposite was true: the burden was on the Agency—and the public—to prove harm. The tens of thousands of chemicals on the market at the time TSCA was passed – and which still today constitute the vast majority of chemicals in use – enjoyed a strong “presumption of innocence.” They were simply presumed safe, grandfathered in with no requirements for testing, review or demonstration of safety.

In what amounted to a classic Catch-22, EPA had to have information sufficient to document potential risk or extensive release of or exposure to a chemical in order to require a company to test it to determine whether there was an actual risk. EPA also had to utilize the time- and resource-intensive process of full notice-and-comment rulemaking—a process that can take years to complete—to require testing. These burdens were so high that EPA was

able to require testing for only a few hundred chemicals under TSCA (Jones 2015).

EPA faced onerous requirements under TSCA to protect any information claimed by chemical manufacturers and processors) to be confidential. The Agency lacked the resources necessary to challenge the large number of questionable claims, further exacerbating the lack of transparency and accountability of its actions.

Over time, a broad acknowledgment emerged that TSCA had failed both to generate and provide access to the information needed to identify unsafe chemicals, and to provide EPA with the authority it needed to mitigate harm from chemicals widely known to be dangerous. TSCA put into place a system where tens of thousands of chemicals were allowed to remain on the market without any review of their safety, and hundreds of new chemicals came on the market every year without any demonstration that they were safe.

As noted above, the government faced an evidentiary Catch-22 in seeking to require companies to test their chemicals. Finally, companies were given wide latitude to claim any chemical information they submitted to the government to be trade secrets, hiding critical information from the public and even from state and local governments, medical professionals and first responders.

## **Other drivers of TSCA reform**

In addition to mounting scientific evidence of health concerns and growing recognition of TSCA's failings, numerous other political, social and economic factors drove TSCA reform to the national agenda.

The growing urgency of the potential health threat posed by unregulated chemicals fueled public and consumer concerns. Spurred by concerned parents, public interest advocates turned to individual states to enact legislation and regulations to address specific uses of certain toxic chemicals and in a few cases to more systematically identify and act on chemicals of concern (Interstate Chemicals Clearinghouse 2014). They also demanded greater transparency from companies about chemical ingredients and evidence of their safety. Product manufacturers and retailers began to respond to these demands, going as far as restricting chemicals from products, actions the chemical industry labeled “retail regulation” (Berzon 2015; Bomgardner 2014).

Another critical driver was the reform of chemicals policies in other parts of the world. Canada was perhaps first to tackle the problem; reforms to the Canadian

Environmental Protection Act in 1999 sought to address the thousands of “legacy” chemicals that had never been reviewed for safety (CEPA 1999). The European Union soon followed with its sweeping Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH) (European Chemicals Agency, undated). These developments both lent credence to the view that the U.S. was falling behind in chemical safety and made it increasingly difficult for U.S. companies to operate and compete globally under such different regimens.

Collectively, these actions drove the chemical industry to seek a national solution. In 2009, the industry issued principles for what it called TSCA “modernization,” effectively abandoning its longstanding opposition to TSCA reform (American Chemistry Council 2009). Its decision to come to the negotiating table and seek a federal solution was an acknowledgment of a growing loss of confidence in the safety of chemicals both among the public and in the marketplace (Dooley 2009).

From the outset, the Obama Administration identified TSCA reform as a top priority. In a memo issued on her first day on the job, former EPA Administrator Lisa Jackson, made clear that TSCA failed to provide the Agency with the tools to do its job and argued that reform was urgently needed (Jackson 2009), a commitment renewed by her successor Gina McCarthy (Anderson 2013). In 2009, the Administration issued its principles for TSCA reform (US EPA, undated (a)), and EPA staff became deeply engaged in shaping the reform effort.

The legislative and political path to TSCA reform was a long and winding one. The late Democratic Senator from New Jersey, Frank Lautenberg, a longstanding champion on this and other public health issues, first introduced reform legislation in 2005, and continued to press this issue with his colleagues for his last eight years in office. The persistent efforts by him and ultimately dozens of other members of Congress from both parties and their staff, who played significant roles in both developing and passing the final legislation, have been covered elsewhere (Denison 2016; Eilperin and Fears 2016; Obama 2016).

## Discussion of Key Reforms

The Lautenberg Act made major changes to most of the key provisions of TSCA. These are outlined below, comparing and contrasting the old and new laws.

### Health-based safety standard and vulnerable subpopulations

*Changes to the “unreasonable risk” standard:* Arguably

the most sweeping change made to TSCA by the Lautenberg Act is to the meaning given to TSCA’s so-called “safety standard.” TSCA required that EPA determine whether or not a chemical presents (or in some cases may present) an *unreasonable risk*. While that term was not expressly defined in the law, other qualifying language as well as case law effectively defined it as a standard that required EPA to analyze and balance the costs and benefits of any proposed regulatory action in order to determine whether or not a chemical presented an unreasonable risk (Corrosion Proof Fittings 1991). The old law further required EPA to demonstrate that any regulatory requirements were the “least burdensome” (Breggin et al. 2011).

Over the course of debate on TSCA reform, a broad consensus emerged that the law should clearly separate the determination as to whether a chemical presented an unreasonable risk from the decision about *how* to manage such risk where it is identified. The risk determination should be based only on consideration of health and environmental risks, whereas the risk management decision should require the reasonable consideration of other factors, such as costs, benefits, and the availability of alternatives, in deciding among options sufficient to eliminate the identified risk (American Chemistry Council 2009; Denison 2009b; US EPA 2015).

**Figure 1: Health-based safety standard and vulnerable subpopulations**

Problem in Old TSCA	Lautenberg Act
<b>Paralyzing regulatory hurdle</b> <ul style="list-style-type: none"> <li>Required an onerous cost-benefit analysis that paralyzed EPA.</li> </ul>	<b>Health-only safety standard</b> <ul style="list-style-type: none"> <li>Prohibits EPA from considering costs in safety decisions.</li> </ul>
<b>No requirement to protect most vulnerable</b> <ul style="list-style-type: none"> <li>No mandate to consider elevated risks to children, pregnant women, and the elderly.</li> </ul>	<b>Explicit protections for vulnerable populations</b> <ul style="list-style-type: none"> <li>Expressly requires the protection of those most susceptible to harm from chemicals.</li> </ul>

The Lautenberg Act embodies this consensus. It strikes the “least burdensome” requirement altogether, and clarifies throughout the law that unreasonable risk is to be determined “without consideration of costs or other nonrisk factors” (TSCA sections 4(f)(2), 5(a)(3), 5(b)(4), 5(e)(1), 5(f)(1), 6(b)(1), 6(b)(4), 6(d)(3), 7(b)(1), 7(f), 9(a)(1), 14(d)(3), and 21(b)(4)) When determining which risk management measures to impose on chemicals found to present an unreasonable risk, EPA is required, “to the extent practicable” and “based on reasonably available

information,” to consider costs and other nonrisk factors, as long as its regulation is that necessary to eliminate the unreasonable risk (Section 6(c)(2)).

**Vulnerable subpopulations:** Another major change made by the Lautenberg Act is the addition of an explicit requirement that EPA consider, identify, assess and eliminate any unreasonable risk a chemical presents or may present to “potentially exposed or susceptible subpopulations.” No such factor was present in the original law.

The law defines “potentially exposed or susceptible subpopulations” as follows:

The term ‘potentially exposed or susceptible subpopulation’ means a group of individuals within the general population identified by the [EPA] Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly. (Section 3(12))

Importantly, while the definition specifies several examples, it provides EPA with clear authority to identify additional such subpopulations.

**Conditions of use:** Under the new law, the safety standard is to be applied to chemicals under their “conditions of use.” The law defines this term as follows:

The term ‘conditions of use’ means the circumstances, as determined by the [EPA] Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. (Section 3(4))

What is notable about this definition is its inclusion of “reasonably foreseen” circumstances. The term allows for recognition of the fact that exposures to chemicals may arise not only through known or intended activities, but also through activities that can be reasonably expected even if not intended. While the scope of such activities is not further defined under the law, it potentially could encompass, for example, accidental releases of a chemical or the use by a child of a product not intended for his or her use. Such a scope is an acknowledgment that people and the environment may be exposed to chemicals indirectly or inadvertently, and that understanding their potential risks requires consideration of such unintended circumstances.

## Mandated chemical safety reviews

**Existing chemicals:** The original TSCA “grandfathered in” some 62,000 chemicals in production and use at the time it passed in 1976, providing no requirement that EPA review their safety. As a result, fewer than two percent of those chemicals – which still constitute the great majority of chemicals in use today (Wilson and Kirschner 2012) – have ever been reviewed for safety (US Government Accountability Office 2005).

The Lautenberg Act provides EPA with a clear mandate to review the safety of chemicals in commerce, first through the prioritization process and then, for chemicals deemed high-priority, through full risk evaluations used to determine whether or not the substance presents an unreasonable risk. See “Basic Framework of the Lautenberg Act” below. While the pace of reviews is modest to reflect current resources and capacity, the expectation established by the legislation is ultimately for EPA to examine all chemicals in production and use (US Congress 2016).

**Figure 2: Mandated chemical safety reviews**

Problem in Old TSCA	Lautenberg Act
<p><b>Existing chemicals were presumed safe</b></p> <ul style="list-style-type: none"> <li>62,000 chemicals grandfathered in under TSCA with no requirement to review their safety.</li> </ul>	<p><b>Mandate to review chemicals</b></p> <ul style="list-style-type: none"> <li>Requires prioritization of all existing chemicals.</li> <li>Risk determinations on all deemed high-priority.</li> </ul>
<p><b>New chemicals lacked adequate safety check</b></p> <ul style="list-style-type: none"> <li>Even chemicals with little or no safety data were allowed onto market.</li> </ul>	<p><b>Safety finding for all new chemicals</b></p> <ul style="list-style-type: none"> <li>Affirmative safety finding required for a new chemical to enter the market.</li> </ul>

**New chemicals:** EPA estimates that 500-1,000 new chemicals enter commerce each year (US EPA 2015; US Government Accountability Office 2005). While companies are required to notify EPA at least 90 days prior to commencing manufacture, the original law did not provide any mandate for EPA to review new chemicals prior to market entry. As a result, although EPA had established a program to review such chemicals, those reviews had no statutory basis. In addition, as was the case for existing chemicals, EPA shouldered the burden of showing evidence of harm in order to limit or condition market entry.

This task was made more difficult by the fact that the vast majority of new chemical notices (pre-manufacture notices, or PMNs) received by EPA included no health or

environmental safety data (Denison 2009b; US EPA 2004). EPA generally had to complete its review within 90 days of receipt of a PMN, although such period could be extended unilaterally “for good cause” for up to 90 additional days (Section 5(c)), or for longer if the company consented to a suspension.

Unless EPA could demonstrate within that timeframe that a new chemical “may present an unreasonable risk” or that it would be produced in large amounts and result in substantial release or exposure, EPA could not act to preclude or condition manufacture, which could commence upon expiration of the notice period (Section 5(e)(1) as passed in 1976 and prior to amendment by the Lautenberg Act). The absence of sufficient information to conduct a meaningful review was not a sufficient basis for extending the review or for placing conditions on market entry.

The new law makes several significant changes to the new chemicals process, while retaining aspects of the old law deemed important for innovation and competitiveness: maintaining the ability of companies to bring new chemicals to the market relatively quickly. It retains a baseline 90-day review period for new chemicals and does not impose any upfront requirements to generate new safety data (as under the old law, any already existing data must be submitted with the new chemical notice). However, EPA is now mandated to review all new chemicals, and it must make an affirmative finding for each chemical as to whether the chemical presents or may present an unreasonable risk or is not likely to do so (Section 5(a)(3)). See “Basic Framework of the Lautenberg Act” below.

In effect, the Lautenberg Act shifts the new chemical review process from a passive one to an active one, and provides the Agency with the mandate and authority to make affirmative findings and, when necessary, restrict market access.

**Expanded testing authority**

The original TSCA placed significant evidentiary and administrative burdens on EPA in order for it to require companies to test the chemicals they manufacture or process.

As noted earlier, EPA had to have information sufficient to document potential risk or extensive release of or exposure to a chemical in order to require a company to test it to determine whether there is actual risk. In addition, to require testing, EPA had to promulgate a rule

subject to procedures that typically took years to complete (US Government Accountability Office 2005).

The Lautenberg Act addressed both of these constraints. First, the new law provides an additional authority for EPA to require testing without first having to demonstrate either potential risk or high production volume coupled with high release or high exposure potential (Section 4(a)(2)). That authority can be used to generate information needed to inform or conduct any of the major activities called for under the law, including prioritization, review or risk evaluation of new or existing chemicals, and implementation of risk management, as well as to meet the regulatory testing needs of any other Federal agency. Second, EPA can now issue orders to require testing (Sections 4(a)(1) and (2)), instead of always having to use more onerous and time-consuming test rules or negotiated consent agreements with companies, as previously authorized.

**Figure 3: Expanded testing authority**

Problem in Old TSCA	Lautenberg Act
<p><b>Weak testing powers</b></p> <ul style="list-style-type: none"> <li>EPA could only require chemical testing through a multi-year rulemaking process.</li> <li>EPA had to first show potential risk/high exposure before it could require testing – a Catch-22.</li> </ul>	<p><b>New testing authority</b></p> <ul style="list-style-type: none"> <li>EPA can simply order testing.</li> <li>Catch-22 is eliminated.</li> </ul> <p>But EPA must:</p> <ul style="list-style-type: none"> <li>use a tiered approach to testing</li> <li>explain any decision to require testing on vertebrate animals</li> <li>explain why an order is warranted instead of a rule or consent agreement</li> </ul>

Several conditions apply: EPA must provide a statement of need for the information requested, and must generally utilize a “tiered” approach to testing, under which the screening-level tests or assessments of available information are required prior to requiring more advanced testing of potential health or environmental effects or potential exposure (Sections 4(a)(3) and (4)). EPA must explain the basis for any decision to require testing using vertebrate animals. Finally, it must also provide a justification for its use of an order rather than a test rule or consent agreement.

## Information sharing and confidential business information

EPA receives substantial amounts of information on chemicals from companies under TSCA. The old law provided broad allowances for companies to claim virtually any of this information to be confidential business information (CBI), which EPA is then required to protect from disclosure. Unless a specific claim was challenged and rejected by EPA, any such CBI could not be shared, not only with the public, but with anyone outside the federal government, thereby denying access by state or local governments, health or environmental officials or professionals, or even first responders. And such protection from disclosure was of unlimited duration, never expiring even if the original circumstances warranting protection changed.

**Figure 4: Information sharing and confidential business information**

Problem in Old TSCA	Lautenberg Act
<p><b>Excessive CBI claims</b></p> <ul style="list-style-type: none"> <li>Companies could claim virtually any information as CBI</li> <li>EPA couldn't share CBI with public, states, or health providers.</li> </ul> <p><b>CBI kept indefinitely</b></p> <ul style="list-style-type: none"> <li>Claims had no time limits, unless challenged by EPA.</li> </ul>	<p><b>Greater transparency</b></p> <ul style="list-style-type: none"> <li>Upfront justification and EPA review required for most claims.</li> <li>States and health providers are given access.</li> </ul> <p><b>Time limits on CBI claims</b></p> <ul style="list-style-type: none"> <li>Claims expire after 10 years unless renewed.</li> </ul>

The new law establishes three categories of information to which different CBI requirements apply (Sections 14(b) and (c)). Certain specified types of information are presumed to be protected if claimed CBI, and substantiation of those claims is not required, nor are they subject to time limits. Examples include the identity of a chemical prior to commercialization, a company's customer or supplier lists, and the specific process used to make a chemical.

Other types of information are not eligible for CBI protection, including general information on chemicals' uses and functions. For all other types of information, including the identity of a chemical after commercial introduction, they can only be protected if substantiated at the time a CBI claim is asserted (US EPA 2017a), and such claims expire after 10 years unless reasserted and resubstantiated.

EPA is required to review all CBI claims to mask the identity of a chemical after it is in commercial distribution,

and a representative subset of at least 25% of all other types of CBI claims (Section 14(g)(1)(C)). Where a CBI claim is found not to be warranted, is withdrawn, or expires, the information cannot be protected from public disclosure (Sections 14(b)(3)(C)(ii), 14(e)(1) and 14(g)(1).

One notable exception to the original TSCA's broad CBI allowance was with respect to health and safety information. Under a provision retained under the new law, the general requirement that EPA not disclose CBI "does not prohibit the disclosure of" health and safety studies or their underlying data, with two limited exceptions: where such disclosure would reveal the process used in manufacturing or processing a chemical or, in the case of a mixture, the portion of the mixture comprised by any of the chemicals in the mixture (Section 14(b)(2)).

The new law also expands access to CBI, providing that state and local governments, health and environmental officials, health professionals and first responders be given access to CBI, subject to confidentiality agreements and statements of need for the information (Section 14(d)(4)-(6)). Expedited access is provided in emergency situations (Section 14(g)(2)(C)(ii)).

CBI is a particularly complex aspect of the new law, and only a few of the major changes made to old TSCA have been discussed here. More information is available elsewhere (Environmental Defense Fund 2016a; US EPA 2016a, 2016b).

## Dedicated funding source

The original TSCA authorized EPA to collect fees from industry only for new chemical reviews or for chemicals for which EPA required testing. Such fees were capped at low levels, and any fees collected went to the general treasury, not to EPA to help defray its costs.

**Figure 5: Dedicated funding source**

Problem in Old TSCA	Lautenberg Act
<p><b>Insufficient funding</b></p> <ul style="list-style-type: none"> <li>Fees only for new chemicals, capped at \$2,500/chemical.</li> <li>Fees did not go directly to EPA.</li> </ul>	<p><b>Broad dedicated fees</b></p> <ul style="list-style-type: none"> <li>EPA can collect fees from industry, capped initially at \$25 million/year.</li> <li>Fees go directly to EPA.</li> </ul>

The new law provides EPA with authority to collect fees to help defray the costs of most activities it undertakes under the law, including reviews of existing as well as new chemicals. Those fees are to be set to defray

approximately 25% of EPA’s costs under the new program, or \$25 million annually, whichever is lower. Fees can be adjusted over time to ensure defrayal of 25% of costs. Most importantly, the fees go into a dedicated fund for EPA’s use in TSCA implementation (Section 26(b)).

**Preemption of state authority**

Among the most contentious aspects of the debate over the new law was the extent to which federal action on chemicals would preempt state authority.

The new law strikes a balance between two objectives: first, preserving a substantial role for states in chemicals management, given the historic role they have played in the absence of an effective federal chemical safety system and the legitimate interest of states in protecting their citizens; and second, strengthening the federal program and creating greater uniformity in requirements applicable to substances and products that are marketed nationally.

**Figure 6: Preemption of state authority**

Old TSCA	Lautenberg Act
<p><b>Limited preemption</b></p> <ul style="list-style-type: none"> <li>EPA requirements on new or existing chemicals generally preempted states.</li> <li>EPA could grant waivers, but no recourse if denied or disregarded.</li> </ul>	<p><b>More preemption, applies:</b></p> <ul style="list-style-type: none"> <li>To both “safe” and “not safe” decisions</li> <li>During EPA review of a chemical (new state actions only)</li> </ul> <p><b>Less preemption:</b></p> <ul style="list-style-type: none"> <li>Only state <u>restrictions</u></li> <li>Only existing (not new) chemicals</li> <li>Only uses and risks EPA addresses</li> </ul> <p><b>Waivers available</b></p> <ul style="list-style-type: none"> <li>Higher bar</li> <li>State can challenge denial/no decision.</li> </ul>

To seek to achieve this balance, the new law has aspects that are less preemptive, and other aspects that are more preemptive, than the old law (Section 18). On the less preemptive side:

- All prior actions and certain future actions by states were preserved regardless of subsequent action by EPA.
- Only direct state restrictions on chemical production or use are subject to preemption – and then only where EPA is acting or has acted on the same chemical to address the same uses and risks. States remain free to take other types of actions, such as imposing reporting, monitoring, assessment or disclosure requirements. In contrast, the old law preempted all types of state requirements “designed

to protect against a risk” for which EPA had imposed a requirement designed to address the same risk.

- States can act to restrict uses and address risks of a chemical EPA has not addressed, or to restrict a chemical to address a different concern, such as air or water quality.
- EPA actions on new chemicals are no longer preemptive, leaving states free to act on such chemicals until and unless EPA takes them up under its existing chemical authorities.

On the more preemptive side:

- An EPA determination that a chemical does not present an unreasonable risk has preemptive effect; under the old law, EPA did not make such determinations. (Under both the old and new laws, EPA actions taken to address a chemical it finds presents an unreasonable risk had/have a preemptive effect.)
- During EPA’s risk evaluation of a high-priority chemical, states generally cannot impose new restrictions to address uses and risks included in EPA’s review. That preemption lifts, however, if EPA misses its deadline to complete its review. If EPA finds a chemical presents an unreasonable risk, states can again act to restrict the chemical during the period when EPA is developing its regulation to address the identified risk, but once that regulation is final, state restrictions are again generally preempted.

Under the old law, EPA could grant a waiver to a state to restrict a chemical even after final EPA action if the request met certain basic requirements. However, if EPA denied the waiver request or failed to act on it, the state had no clear legal recourse. Under the new law, EPA must grant states waivers to act during its review of a chemical if the requests meet basic requirements. However, more onerous requirements than those under the old law apply to state waivers to act after final EPA action, although a state can now legally challenge EPA’s denial of or failure to act on its waiver request.

Preemption is a particularly complex aspect of the new law, and only some of the features of the new law have been discussed here. More information is available elsewhere (Environmental Council of the States 2016; Environmental Defense Fund 2016b; Massachusetts Toxics Use Reduction Institute 2016).



## Basic framework of the Lautenberg Act

The Lautenberg Act maintains the structure of the original law even as it makes substantial changes to most of its core provisions (see box). As noted earlier, two key new definitions are added: one for the “conditions of use” under which chemicals are to be reviewed for safety; and a second for “potentially exposed or susceptible subpopulations.”

### Major sections of TSCA

- Sec. 3. Definitions.
- Sec. 4. Testing of chemical substances and mixtures.
- Sec. 5. Manufacturing and processing notices.  
[*New chemicals*]
- Sec. 6. Prioritization, risk evaluation, and regulation of chemical substances and mixtures.  
[*Existing chemicals*]
- Sec. 8. Reporting and retention of information.
- Sec. 9. Relationship to other Federal laws.
- Sec. 14. Confidential information.
- Sec. 18. Preemption.
- Sec. 26. Administration of the Act.

### Existing chemicals

Among the most fundamental changes are those made to the provisions of TSCA governing the assessment and regulation of so-called “existing chemicals,” those active in commerce (Section 6). A wholly new framework is provided for the identification, prioritization, risk evaluation, and regulation of such chemicals. Following is a basic description of the new framework, which is depicted graphically in Figure 7. (The process described in Step 1 below is set forth in section 8 of TSCA as amended by the Lautenberg Act, while those described in the other steps of the new framework are established by changes made to section 6 of TSCA.)

*Step 1: Identify all chemicals in active commerce.* Within one year of enactment, EPA is to issue a rule requiring each chemical manufacturer, and allowing each chemical processor, to identify each chemical on the TSCA Inventory it produced, imported or processed in the preceding 10-year period. These chemicals are then designated as active, while chemicals for which no notice is received become inactive, and require a subsequent notification in order to be activated (Section 8(b)(4) and (5)). These requirements effectively “reset” the Inventory so that it more accurately reflects the number of and identifies chemicals currently active in commerce (Denison 2015).

The identities of more than 17,000 of the 85,000 chemicals on the TSCA Inventory are not public (US EPA

undated (c)), having been claimed at some point to be confidential business information (CBI). Under the new framework, companies making active chemicals with prior CBI claims must reassert those claims in order for them to be maintained. All such reasserted claims must then be reviewed by EPA over a five-year period; if found valid, the claim is extended but expires after 10 years unless renewed. The identities of chemicals with no valid claims are to be disclosed to the public (Section 8(b)(4)(B)-(E)).

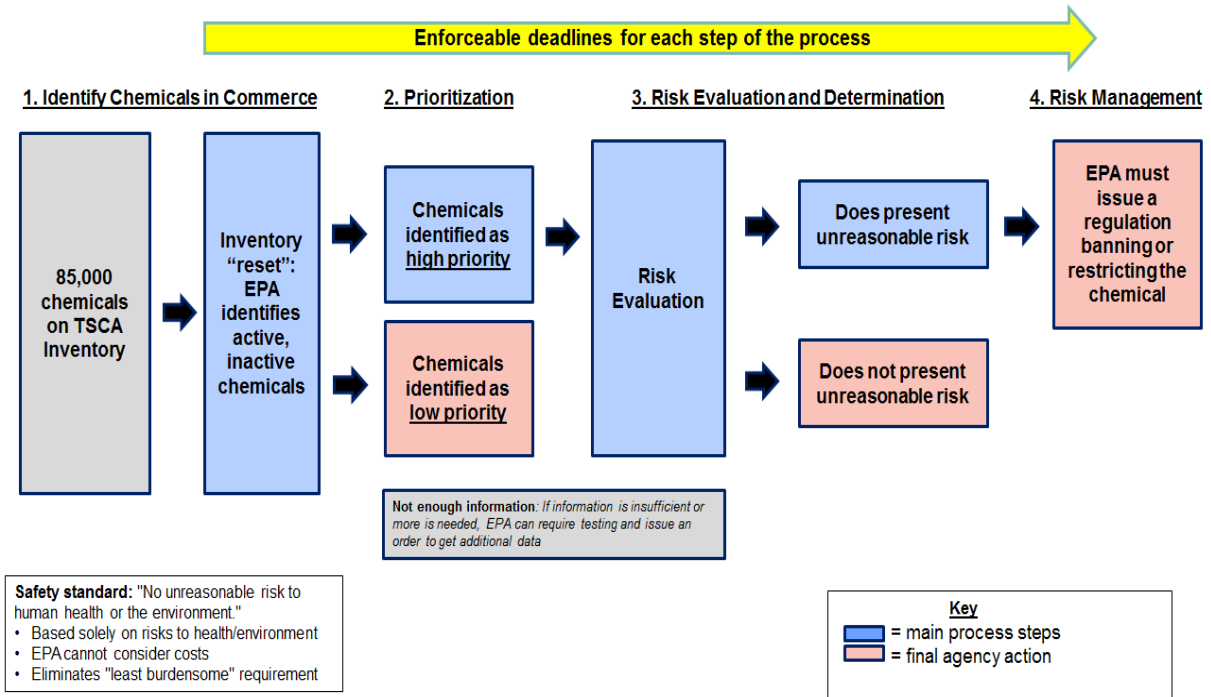
*Step 2: Prioritize chemicals as high- or low-priority.* Within one year of enactment, EPA is to issue a rule establishing a risk-based prioritization process and criteria to be used to determine whether each chemical in commerce is high-priority or low-priority. High priority chemicals are those that “may present an unreasonable risk” and warrant full risk evaluation. Conversely, low-priority chemicals are those that do not meet the criteria for being deemed a high-priority substance, based on sufficient information (Section 6(b)(1)). Low-priority chemicals are set aside until and unless new information emerges, although such a designation is considered a final Agency action and may be judicially challenged by any person (Section 19(a)(1)(C)).

The law specifies general criteria EPA is to use in prioritizing chemicals, which include consideration of risks to potentially exposed or susceptible subpopulations. Proposed priority designations are to be subject to public notice and comment before finalization. Chemicals are to be subject to prioritization at a pace commensurate with EPA capacity and resources (Section 6(b)(2)(C)), but the process ultimately extends to all chemicals in commerce (US Congress 2016).

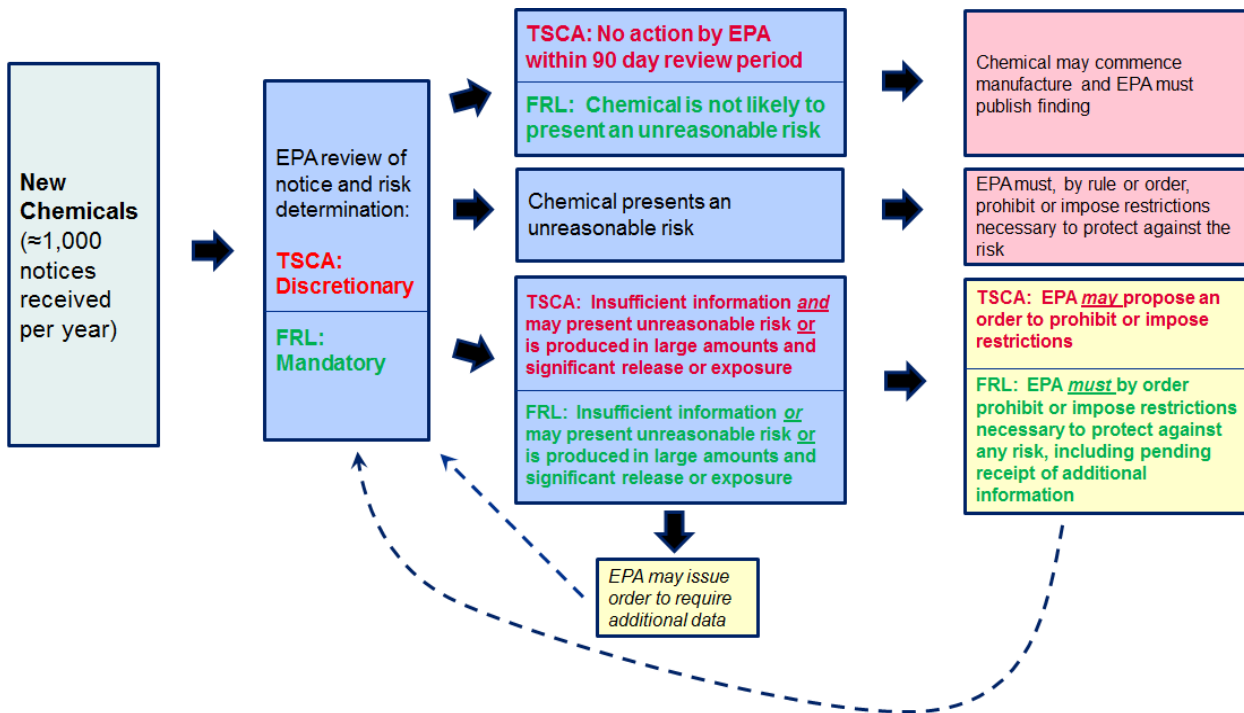
*Step 3: Risk evaluation and determination.* Each high-priority chemical must undergo a full risk evaluation, on the basis of which EPA is to determine whether or not it presents an “unreasonable risk.” Major changes have been made to alter the meaning of the term “unreasonable risk” relative to the original TSCA. Among these changes, which are discussed above under “Health-based safety standard and vulnerable subpopulations,” is a requirement that EPA consider only risks to human health and the environment, including risks to potentially exposed or susceptible subpopulations, in making the unreasonable risk determination.

Within one year of enactment, EPA is to issue a rule establishing the process to be used to conduct risk evaluations. EPA is required to be conducting risk evaluations on 10 chemicals within six months of enactment. Within 3.5 years after enactment, that

**Figure 7: How the Lautenberg Act Works; Existing Chemicals**



**Figure 8: How the Lautenberg Act Works; New Chemicals (FRL= Lautenberg Act)**



number must rise to at least 20 chemicals, and EPA is also to have designated at least 20 low-priority chemicals (Section 6(b)(2)).

EPA is to set the scope of each risk evaluation within six months of its initiation. The scope delineates the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations EPA will include in the risk evaluation (Section 6(b)(4)(D)). Drafts of the risk evaluations are to be published for public comment. Final risk evaluations leading to determinations that a chemical does not present an unreasonable risk are final Agency actions and subject to judicial challenge (Section 6(i)(1)).

Companies may request risk evaluations of their chemicals, subject to certain limitations. Such risk evaluations cannot be expedited or given preference over those risk evaluations EPA initiates using the prioritization process (Section 6(b)(4)(C) and (E)).

*Step 4: Risk management.* Where EPA's risk evaluation leads to a determination that a chemical presents an unreasonable risk, EPA must issue a regulation banning or restricting the chemical so as to eliminate that risk. Such regulations must be proposed within one year of the determination, and finalized within an additional year, subject to limited extensions where warranted. These regulations are final Agency actions subject to judicial challenge by any person (Section 6(i)(2)).

In selecting among prohibitions and other restrictions sufficient to eliminate the unreasonable risk, EPA must "consider" and "factor in, to the extent practicable": the nature and magnitude of the identified health and environmental effects; the benefits of the substance; the "reasonably ascertainable economic consequences" of EPA's regulation; and the costs and benefits and "cost-effectiveness" of the regulation and the primary regulatory alternatives EPA considered (Section 6(c)(2)).

The law requires EPA to identify certain chemicals that are persistent, bioaccumulative and toxic (PBT) for which risk evaluations and determinations are not required and risk management regulations must be issued to "reduce exposure to the extent practicable." These regulations must be proposed within three years of enactment and finalized within 18 months of proposal (Section 6(h)). In October 2016, EPA identified the five substances to be subject to this "expedited action" (US EPA 2016c).

### **New chemicals**

Figure 8 compares the new chemicals process and requirements under the original law and under the

Lautenberg Act. The new law mandates EPA to review all new chemicals, and to make an affirmative finding for each chemical as to whether the chemical presents or may present an unreasonable risk or is not likely to do so. Only if EPA finds a new chemical is not likely to present an unreasonable risk can its manufacture commence without condition. If EPA finds a new chemical presents an unreasonable risk, it must issue an order or propose a rule that prohibits or limits manufacture or use in a manner sufficient to protect against any unreasonable risk. EPA must also issue such an order if:

- it lacks sufficient information to "permit a reasoned evaluation of the health and environmental effects" of the chemical,
- it finds the chemical may present an unreasonable risk, or
- the chemical will be produced in substantial amounts and may result in substantial releases or exposures. (Sections 5(e) and (f))

### **Provisions of most relevance to the public health community**

Several provisions of the new law, discussed in this section, are directly relevant to issues and concerns of the public health community.

#### **Potentially exposed or susceptible subpopulations**

As noted earlier, the new law expressly requires EPA to consider risks to such subpopulations in virtually every activity it undertakes: when subjecting chemicals to the prioritization process; collecting chemical risk information; identifying the scope of and conducting chemical risk evaluations; deciding whether to apply available regulatory exemptions; determining whether disclosure of confidential business information (CBI) is necessary to protect health or the environment; deciding whether additional testing of a chemical is needed; and selecting members of the Science Advisory Committee on Chemicals required to be established under the new law (see below).

The law's definition of this term expressly encompasses greater potential vulnerability to chemicals due either to greater *exposure* to chemicals or to greater *susceptibility* to the effects of chemical exposures. It also expressly includes infants, children, and pregnant women among the examples of such subpopulations (Section 3(12)). There is ample reason for doing so: It is well-established that the developing fetus as well as infants and young children can be more vulnerable than adults due to either

or both factors (Agency for Toxic Substances and Disease Registry 2013; Landrigan and Goldman 2011; World Health Organization 2016).

The details of how EPA will consider risks to such subpopulations will be established through rulemakings and policies, procedures and guidance called for under the new law, as well as in chemical-specific prioritization decisions, risk evaluations and risk management actions. All of these documents and decisions are subject to public notice and comment under the new law. The public health community has an important role to play in providing input to ensure EPA possesses and is effectively incorporating into its decisions the best and latest scientific information regarding such risks.

### **Setting the scope of chemical risk evaluations**

While EPA is to take into account risks to vulnerable subpopulations in all of its actions, a particularly critical stage is when EPA sets the scope of its risk evaluation for a chemical, which is to be completed within six months of the designation of a chemical as a high priority. The scope is to identify “the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider” in the risk evaluation (Section 6(b)(4)(D)).

While the law does not specify a formal opportunity for public comment on such scopes, EPA’s proposed rule governing the risk evaluation process proposes to do so (US EPA 2016d), and in any event, interested persons may provide EPA with input on which vulnerable subpopulations should be included in the scope based on the nature of the chemical, its uses and exposure potentials.

### **Access by health professionals to confidential business information**

For the first time under the new law, certain health professionals can gain access to chemical information EPA collects from companies that is otherwise protected from disclosure as confidential business information (CBI), subject to certain conditions prescribed in some detail in the law (Section 14(d)(4)-(6)). The old law blocked any such access.

Such information might, for example, include the identities of chemicals individually or in mixtures or products containing chemicals; the names of companies that produce, import or process specific chemicals; the specific concentrations or portions of a mixture or product a particular chemical comprises; or information on the

number of workers potentially exposed to a chemical at a given manufacturing or processing site.

Access is provided under both non-emergency and emergency situations. In the former case, the law provides that CBI “shall be disclosed to a ... treating physician or nurse in a non-emergency situation if such person provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator” (Section 14(d)(5)).

In the latter case, the law provides that CBI “shall be disclosed in the event of an emergency to a treating or responding physician, nurse, agent of a poison control center ... or first responder (including any individual duly authorized by a Federal agency, State, political subdivision of a State, or tribal government who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) if such person requests the information,” subject to certain conditions (Section 14(d)(6)).

Specifically, the law states:

Such person shall—

(A) have a reasonable basis to suspect that—

(i) a medical, public health, or environmental emergency exists;

(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

(iii) 1 or more individuals being diagnosed or treated have likely been exposed to, or a serious environmental release of or exposure has occurred to, the chemical or mixture; and

(B) if requested by a person who has the CBI claim—

(i) provide a written statement of need ... and agree to sign a confidentiality agreement ... ; and

(ii) submit to the Administrator such statement of need and confidentiality agreement as soon as practicable, but not necessarily before the information is disclosed ... .

Under both emergency and non-emergency situations, the law describes the referenced statement of need as “a statement that the person has a reasonable basis to suspect that—

(i) the information is necessary for, or will assist in—

(I) the diagnosis or treatment of 1 or more individuals; or

(II) responding to an environmental release or exposure; and

(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance or mixture concerned, or an environmental release of or exposure to the chemical substance or mixture concerned has occurred.” (Section 14(d)(5)(B))

Finally, CBI disclosure is subject to the condition that “[t]he person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person who has a claim under this section with respect to the information” (Section 14(d)(5)(C)).

EPA is to develop guidance that specifies the content and form of the required statements of need and confidentiality agreements (Section 14(c)(4)(B)). Health professionals who believe that the ability to access CBI would assist them in performing their jobs should provide input to EPA as it develops this guidance to ensure such requirements can be met in a manner that is reasonable and workable.

It should be noted that penalties apply to persons who knowingly and willfully disclose CBI they receive (Section 14(h)(1)). However, the law provides one notable exception: Such penalties do not apply “to any medical professional (including an emergency medical technician or other first responder) who discloses any [CBI] ... to a patient treated by the medical professional, or to a person authorized to make medical or health care decisions on behalf of such a patient, as needed for the diagnosis or treatment of the patient” (Section 14(h)(1)(C)).

#### **Providing health professionals ready access to CBI**

The new law anticipates that health professionals will need an efficient system for requesting CBI and that the form in which such information is provided needs to reflect the needs of the recipient. To that end, the law includes this provision (emphasis added):

**REQUEST AND NOTIFICATION SYSTEM.**—The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that, *in a format and language that is readily accessible and understandable, allows for expedient and swift*

*access to information* disclosed pursuant to” [these provisions]. (Section 14(g)(3))

Health professionals who expect to seek access to CBI should provide input to EPA as it develops this request and notification system to ensure both timely development and that it meets their needs.

#### **Science Advisory Committee on Chemicals**

Under the Lautenberg Act, within one year of enactment, EPA is directed to create a new advisory panel, known as the Science Advisory Committee on Chemicals (SACC) to provide EPA with expert input on the scientific and technical aspects of implementation of the law (Section 26(o)). According to the Act, the committee is to include stakeholder representatives, “including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations” (Section 26(o)(3)).

In August 2016, EPA published a notice calling for nominations for committee members to “provide advice and recommendations on the scientific basis for risk assessments, methodologies, and pollution prevention measures or approaches” (US EPA 2016e). Based on comments received, EPA published a second notice in December 2016 requesting comments on a list of 29 candidates for committee membership (US EPA 2016f). That committee has now been formed (US EPA 2017b). The committee is required to meet at least once every two years. Because the committee is subject to the Federal Advisory Committee Act (FACA) (US EPA undated (d)), its meetings and other proceedings are public, and interested parties may attend and provide input. This committee’s deliberations and advice to EPA are an opportunity for the public health community to ensure that EPA acts in a robust manner to address the risks chemical exposures may pose to women, children, and other potentially exposed or susceptible subpopulations.

## Conclusion

As originally passed in 1976, despite its lofty goals, the Toxic Substances Control Act gave EPA scant capacity to carry out its mission of ensuring protection of human and environmental health from toxic chemical exposures. Since then, rapid expansion in production and use of chemicals has occurred, and a large and growing body of scientific research has emerged that points to the substantial health and environmental impacts such chemical exposures can have, especially on those most likely to be exposed or most susceptible to chemicals' effects.

Passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act in the 114th Congress has at last provided EPA with new authority and tools it sorely needs to better ensure the safety of chemicals in use and entering the market. These authorities and tools include a health-based safety standard, a mandate to address risks to vulnerable subpopulations, required safety reviews of both new and existing chemicals, stronger testing authority, and expanded access to chemical information.

With strong and effective implementation of the new law's authorities, the new TSCA may at last bring our nation's chemical safety system into the 21st century.

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