14 major improvements in the Frank R. Lautenberg Chemical Safety for the 21st Century Act

May 17, 2015

Comparing the Udall-Vitter chemical safety reform bill to the past bill and current law

This table compares the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697) as reported out by the Senate Environment and Public Works Committee on a bipartisan 15-5 vote on April 28, 2015, to the Toxic Substances Control Act (TSCA) of 1976 and the Chemical Safety Improvement Act (CSIA, S. 1009) introduced in May 2013. Our analysis identifies 13 major areas of overall improvement in the bill in comparison both to CSIA as introduced and to TSCA; both positive and negative changes are noted. It also identifies aspects of the bill that are more preemptive of state authority than current TSCA, but much less preemptive than CSIA as introduced (see item 14 below).

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
1. Safety standard	• "Unreasonable risk" requires cost-benefit analysis and balancing.	• Retained "unreasonable risk" language but to be based "solely on considerations of risks to human health and the environment."	• Explicitly precludes EPA from considering costs and other non-risk factors in making safety determinations. • Clarification is made throughout TSCA where "unreasonable risk" is used that it excludes consideration of costs, either by striking "unreasonable" or adding "without taking into account cost or other non-risk factors."
2. Protection of vulnerable populations	• No special consideration.	• Required EPA to consider "the vulnerability of exposed subpopulations."	• Defines "potentially exposed or susceptible population" to include vulnerability due both to elevated chemical exposures and to heightened susceptibility to their effects. • Specifies such populations include (but are not limited to) infants, children, pregnant women, workers, the elderly. • Expressly requires protection of such populations.

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
3. Adequacy of restrictions for chemicals found not to meet safety standard	• Authority but no mandate to restrict chemicals found to present an unreasonable risk. • No provision to ensure the sufficiency of restrictions.	• Mandated EPA restrict any chemical found not to meet the safety standard. • No requirement that restrictions be sufficient to meet standard.	• Explicitly requires that restrictions must either phase out or ban the chemical, or be sufficient to ensure the chemical meets the safety standard. • For PBTs that do not meet the safety standard, EPA is to reduce exposure to the maximum extent practicable. • EPA is to restrict articles "only to the extent necessary for the chemical substance to meet the safety standard". • Compliance deadlines for bans or phase-outs are to be "as short as practicable."
4. Cost-benefit requirements for regulation	• EPA must conduct a formal analysis and show benefits of any proposed restriction outweigh costs. • Restrictions must be "least burdensome" among those able to address identified risks.	• Struck "least burdensome" requirement and, for most restrictions, would not require formal cost-benefit analysis. • But all potential regulatory and chemical alternatives would have to be identified, and their technical and economic feasibility, costs and benefits, and risks analyzed. • Proposed ban or phase-out still required showing that its benefits outweigh costs.	• Makes clear that cost considerations cannot override requirement for restrictions to ensure chemical safety. • Balancing of costs and benefits is not required, to be considered only "to the extent practicable based on reasonably available information". • Strikes requirement that bans and phase-outs be based on full cost-benefit justification. • Only alternatives deemed relevant and technically and economically feasible by EPA need to be considered.
5. Pace of reviews and deadlines	• No mandate to review the safety of existing chemicals. • No deadline for completing initiated assessments or imposing restrictions.	• Required EPA to prioritize *all* chemicals in active commerce, and to set general schedules for conducting assessments of those designated high-priority. • Very few deadlines were set for establishment of rules and	• Specifies concrete deadlines for all major steps: prioritization, safety assessment and determination, and regulation. • Sets a 2-year deadline by which all rules to establish requirements and procedures must be issued. • EPA must also specify a deadline for

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
		procedures or for evaluations of chemicals.	companies to submit any information it requests. • EPA must include at least 10 chemicals on the initial high-priority list, as well as at least 10 on the low-priority list. o By 3 years after enactment, at least 20 high-priority and 20-low-priority chemicals must have been listed. o By 5 years after enactment, at least 25 high-priority and 25-low-priority chemicals must have been listed. • At least 50% of chemicals are to be work plan chemicals until all of them have been listed, with preference given to chemicals ranking high for persistence and bioaccumulation. • Companies can request EPA to assess a chemical; at EPA's discretion it can grant such requests (not to exceed 30% of all assessments), but cannot give them preference over high-priority chemicals, and initiation of such assessments does not trigger preemption. • Companies can request EPA to assess a work plan chemical it has not yet designated high-priority, and if EPA starts such an assessment, it triggers preemption of new state restrictions.
6. Procedural and scientific requirements	• Virtually no procedures or criteria specified to assess information quality, identify chemicals warranting further	• Prescribed highly-specific, and in some cases biased, scientific methodologies. • Required EPA to develop from scratch extensive procedures and	• Consolidates and streamlines procedural requirements and eliminates prescriptions to use controversial risk assessment methodologies. • Simplifies transition to new system by,

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
	scrutiny, or determine risk.	criteria before starting to prioritize or assess chemicals. • Coupled with a lack of deadlines, getting the new system up and running would take many years.	for example, allowing EPA to continue ongoing work, adapt current procedures, and act on current chemical priorities as new procedures are put in place. • Sets a two-year deadline for EPA to establish all policies, procedures and guidance.
7. Testing	• EPA must go through notice-and-comment rulemaking (typically a multiyear process) to require testing. • It must also show evidence of potential risk or high exposure, a *Catch-22*.	• Eliminated EPA's ability to require testing of new chemicals, and expressly prohibits EPA from requiring testing to inform prioritization decisions. • But allowed EPA simply to issue orders to require testing instead of going through rulemaking. • Struck requirement that EPA find potential risk in order to require testing.	• Retains CSIA's authority for EPA to use orders to require testing (with justification) and elimination of TSCA's risk findings requirement. • Restores full testing authority for new chemicals and to inform prioritization decisions. • 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.
8. Low-priority designations	• 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.	• Mandated EPA prioritize all active chemicals as high- or low-priority. • Low-priority designations were 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. • Lack of data could 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.	• 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". • Lack of data can now be a sufficient basis in itself (not just a factor) for designating a chemical as high-priority. • Restores EPA authority to require testing to inform prioritization decisions where data are lacking. • Anyone can judicially challenge an EPA designation of a chemical as low-priority.

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
		• Governors or state agencies could recommend that EPA prioritize or reprioritize a chemical. • States would be barred from imposing a *new* restriction on a chemical once EPA designated it low-priority (see item 14 below).	• States are no longer barred from imposing a restriction on a low-priority chemical (see item 14 below).
9. New chemicals	• 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". • No affirmative safety decision is required, and the burden is on EPA to find a concern even when safety data are wholly lacking.	• Mandated that EPA make a safety determination for each new chemical and impose "appropriate" restrictions if it determined the chemical was not likely to meet the safety standard. • Did not require that such restrictions be sufficient for EPA then to find the chemical is likely to meet the safety standard. • Lack of clarity as to whether companies could start producing a new chemical if EPA had insufficient information to determine whether it was likely to meet safety standard. • Barred EPA from requiring testing of new chemicals.	• Clarifies that manufacture of a new chemical can only start if EPA affirmatively finds it is likely to meet the safety standard. • Where EPA determines the chemical is *not* 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. • If EPA has insufficient information to 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. • To require notification of articles as a significant new use, EPA needs to make an affirmative finding of "reasonable potential for exposure."
10. Confidential business information (CBI) claims for chemical identity	• The identities of about 17,000 chemicals (out of the 85,000) on the TSCA Inventory are hidden from public view, having been	• Authorized EPA to review CBI claims for chemical identity at any time, but did not mandate any review of such claims.	• 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

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
	claimed by their makers to be CBI. • 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.	• Chemical identities were generally to be presumed protected from disclosure, both before and after they entered the market. • Such protection was time-limited, however, for a period set by the claimant if found reasonable by EPA. • Such a claim was not allowed if the identity could be readily discovered through reverse engineering.	and reviewed by EPA. • 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. • Chemical identities not already on the confidential portion of the inventory or added to it per prescribed procedures cannot be claimed confidential.
11. CBI claims for health and safety information	• Companies are free to claim virtually any information they submit to EPA is CBI. • EPA cannot disclose information claimed CBI to the public, to state and local agencies or even to first responders. • Health and safety studies 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.	• Health and safety information remained ineligible for CBI secrecy, as under current TSCA. • However, chemical identities were presumed protected from disclosure even in the context of health and safety information. • Severely limited EPA's authority to question past CBI claims. • For the first time, however, state and local governments as well as health professionals would have access to CBI, per agreements that they kept the information confidential.	• Retains current TSCA's exclusion of health and safety studies and their underlying data from being claimed CBI. • Unlike CSIA as introduced, does *not* affect current EPA policy that disallows masking of the identities of chemicals in those health and safety studies. • Restores EPA's authority to review all types of CBI claims made in the past. • For claims made going forward, they generally must be substantiated at the time they are asserted and are time-limited (see item 12 below). • 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. • For chemicals found not to meet the safety standard, EPA must to review all CBI claims and require substantiation.

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
			• CBI disclosure for banned or phased-out chemical presumed in the public interest.
12. Time limits on CBI claims	• CBI claims are not subject to time limits and remain in place until and unless challenged by EPA.	• Required that many CBI claims be substantiated, and that EPA review a representative subset. • 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. • Except for chemical identity claims, EPA could not require substantiation of past claims unless EPA designated a chemical as high-priority.	• Most CBI claims are required to be substantiated at the time they are asserted, promptly reviewed by EPA, and either approved or denied. • Approved claims expire after 10 years unless resubstantiated and reapproved. • Even between 10-year intervals, EPA can review and require resubstantiation of CBI claims: o for high-priority chemicals; o for chemicals lacking sufficient information for safety determination; o for inactive chemicals; or o 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. • EPA is mandated to review a CBI claim and require resubstantiation: o if necessary to comply with a FOIA request; o if EPA has reason to believe the claim is not valid; or o for chemicals found not to meet the safety standard. • Most CBI claims for a chemical that EPA bans or phases out automatically expire.

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
13. User fees	• EPA can only charge fees to cover testing requirements or new chemicals. • 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. • Fees are capped at $2,500 per company ($100 per small company). • Any fees collected go to the general treasury and are not available to directly cover EPA's costs.	• Maintained the current TSCA fee provisions.	• EPA is to collect fees for both new and existing chemicals, as well as those designated as high-priority. • 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. • Fees go into a TSCA implementation fund and directly to EPA, not the general treasury. • 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. • The level of fees is to be set to cover approximately 25% of relevant EPA program costs up to $18 million/year. • Companies must pay 100% of the costs of assessments they request (50% for those already on EPA's work plan).
14. State preemption	• Preemption has rarely if ever been applied because, in practice, EPA has imposed so few restrictions on chemicals under the current law. • EPA actions to protect against risks of new or	• States would be barred from imposing a new restriction on a chemical once EPA designated it low-priority or high-priority. • Prioritization decisions would not be judicially reviewable. • States would also be barred from	• Any state action taken on a chemical prior to August 1, 2015 remains in place regardless of EPA action. • States are generally barred from imposing a new restriction on a chemical EPA designates as high-priority during EPA's review of the chemical until EPA issues a final safety determination.

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
	existing chemicals generally preempt states' existing or new actions. • 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. • States can obtain waivers from Federal preemption for a requirement that is significantly more protective and does not unduly burden interstate commerce.	establishing a new requirement or continuing to enforce an existing requirement that restricts a chemical once EPA completed a safety determination on the chemical. • 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. • 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. • Unlike TSCA, EPA reviews of new chemicals would not have preemptive effect.	• Preemption is no longer triggered by a low-priority designation, so states can continue to act on such a chemical; in exchange: o 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. o Companies can request EPA to assess such a chemical; at EPA's discretion it can grant such requests (not to exceed 30% of all assessments), but cannot give them preference over high-priority chemicals, and initiation of such assessments does not trigger preemption. o Companies can request EPA to assess a work plan chemical it has not yet designated high-priority, and if EPA starts such an assessment, it triggers preemption of new state restrictions. • State restrictions on a chemical taken after August1, 2015 (but prior to EPA designating it as a high-priority) 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. • Preemption is now clearly limited only to the uses and conditions of use that are

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
			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. • Waivers can be obtained both before and after a final safety determination and risk management rule. • The conditions for granting a waiver before EPA final action are similar to those under current TSCA, while those after final EPA action are more onerous. o If EPA fails to meet its deadline for issuing a safety determination, or for deciding on a state waiver application, the state waiver is automatically approved. • Even after EPA determines a chemical meets the safety standard or imposes restrictions: o A state can adopt a requirement identical to the federal requirement for co-enforcement. o States can require reporting, monitoring, disclosure unless already required under TSCA or another Federal law. o States can still act on a chemical to address a different concern than EPA under TSCA (e.g., VOC restrictions to address ozone formation). • California's Proposition 65 is excluded from the scope of preemption. • A state cannot prohibit all use of the

.

	Current TSCA	CSIA (May 2013)	Chemical Safety for the 21st Century Act
			chemical in the state, except via co-enforcement or getting a waiver. • Finally, like CSIA as introduced and unlike TSCA, EPA reviews of new chemicals would not have preemptive effect.

.

.