TSCA reform legislation in the 113th Congress

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TSCA reform legislation in 2013

- April 10: Safe Chemicals Act (S. 696)
  - Lead sponsor Lautenberg, 28 co-sponsors (all Ds)
- *ca. May 1: "The Vitter Bill"*
  - *Lead sponsor Vitter, ?? co-sponsors (likely 2-3 Ds)*
- May 22: Chemical Safety Improvement Act (S. 1009)
  - Lead sponsors Lautenberg and Vitter, 25 co-sponsors (12 Ds, 13 Rs)
- June 3: Lautenberg dies

Safety standard/determination (Sec. 6)

Key flaws in TSCA	Key fixes in CSIA	Trade-offs/remaining or new concerns
• Standard requires cost-benefit analysis • Imposes "least burdensome" requirement on any regulation • No definition or specific criteria to identify chemicals of concern	• Standard is applied based on health/env impacts only • Strikes "least burdensome" requirement • Requires EPA to consider exposures of vulnerable populations • Requires EPA to consider multiple exposures to a chemical • Requires EPA to use "best available science"	• Bans still must be based on cost-benefit • No explicit inclusion in standard of protection of vulnerable populations or to assess aggregate exposure • "Best available science" does not reference NAS recommendations

Existing chemicals (Sec. 6)

Key flaws in TSCA	Key fixes in CSIA	Trade-offs/remaining or new concerns
• No mandate to review existing chemicals for safety • Lack of data is presumed to indicate lack of risk • No criteria for triggering review of an existing chemical	• Requires a safety review of all chemicals in active commerce • Lack of data is basis for high-priority designation • High hazard or exposure sufficient for high-priority designation • Requires safety determinations for all high-priority chemicals • Requires risk mgmt for chemicals found not to meet safety standard	• Initial review (prioritization) is based only on existing data, and lack of data does not assure high-priority ranking • Pace of review is unspecified, left to EPA and subject to available resources • Prioritization decisions not subject to court challenge (cuts both ways) and can trigger pre-emption of state authority

New chemicals (Sec. 5)

Key flaws in TSCA	Key fixes in CSIA	Trade-offs/remaining or new concerns
• No affirmative safety decision is required before market entry • Burden is on EPA to find concern even when safety data are lacking • Decisions are largely a "black box" because consent orders need not be made public	• An affirmative decision of "likely safety" is required for market entry • Prohibitions or restrictions can be imposed by order • All new chemical notices and orders and submitted data must be made public (subject to CBI provisions)	• EPA cannot require testing of new chemicals (but can suspend review or impose conditions, as in status quo) • No means provided to ensure compliance for chemicals "likely" to meet safety standard (unless EPA issues a Significant New Use Rule, or SNUR)

Testing (Sec. 4)

Key flaws in TSCA	Key fixes in CSIA	Trade-offs/remaining or new concerns
• EPA must promulgate a regulation to require testing • EPA has to show potential risk or high exposure to require testing, a Catch-22 • Testing done by consent orders is non-transparent, not always made public	• EPA can use orders to require testing (must justify why an order rather than a rule or consent agreement) • Testing orders avoid lengthy rulemaking and court challenges • EPA does not need to make risk findings to require testing • Testing agreements and orders and all test data must be made public (subject to CBI provisions)	• Testing can only be required to do safety assessments or determinations, hence limited to chemicals in commerce deemed high-priority • No minimum information sets are required; all testing is on the basis of EPA demonstrating specific need • An overly prescriptive tiered testing framework must be followed

Confidential business info (Sec. 14), #1

Key flaws in TSCA	Key fixes in CSIA	Trade-offs/remaining or new concerns
• Companies can claim any information they submit to be CBI • Substantiation of CBI claims is typically not required • EPA reviews very few CBI claims and must challenge them case-by-case	• Information never eligible (as well as eligible) for CBI is delineated • All other CBI claims must be substantiated at the time asserted • Resubstantiation can be required for any CBI claim upon designation of a chemical as high-priority • EPA must review CBI claims (all or representative subset)	• Only health and safety data on existing – not new – chemicals is precluded from being claimed CBI • Except as noted for chemical identity and high-priority chemical CBI claims, EPA cannot require documentation or redocumentation of a CBI claim made prior to the date of enactment

Confidential business info (Sec. 14), #2

Key flaws in TSCA	Key fixes in CSIA	Trade-offs/remaining or new concerns
• State governments cannot be given access to CBI • Health and medical professionals cannot be given access to CBI • CBI claims do not expire	• States/localities and health professionals have access to CBI, subject to confidentiality agreements • For chemical identity CBI claims: ▪ Redocumentation can be required at any time ▪ Ready capability for reverse engineering disallows such claim ▪ A time period must be specified for each such CBI claim and found by EPA to be reasonable	• Notifications to submitters prior to release of CBI are generally required • A new appeals process is provided under which claimants can challenge EPA's intention to release CBI

Chemical information reporting (Sec. 8)

Key flaws in TSCA	Key fixes in CSIA	Trade-offs/remaining or new concerns
• The full range and identity of chemicals in active commerce, and their producers and processors, are not known • Information on use of chemicals is collected only from chemical manufacturers with limited knowledge of downstream use	• Companies must notify EPA of all chemicals on the TSCA Inventory they are producing or processing (used to "reset" the Inventory) • Chemicals not notified as active are placed on an inactive list; a company must notify EPA before making them • Processor reporting is required for the first time for all chemicals in active commerce	• Chemicals on the confidential portion of the TSCA Inventory can remain so if reasserted (though EPA can require (re)substantiation – see above) • The scope of manufacturer and processor reporting programs is left to EPA to develop through rulemaking

Pre-emption (Sec. 18), #1

TSCA	CSIA	Issues/Concerns
• States can't require testing of a chemical "for purposes similar to those" for which EPA requires testing • If EPA regulates a chemical by rule, States can only: (a) have the identical requirement or (b) regulate it under a different Federal law or (c) entirely prohibit the chemical in the State	• States can't require testing "reasonably likely to produce the same data" as EPA requires, or require notification of uses of a chemical for which EPA requires the same notification • States can't establish or continue to enforce a requirement that restricts a chemical once EPA has completed a safety determination on the chemical	• States need to be able to enact requirements identical to EPA's to allow for co-enforcement • "Restriction" can be read broadly to apply to warning labels, etc. (e.g., CA Prop 65) • The safety determination doesn't regulate a chemical found not to meet the safety standard; the trigger for any preemption should be the final risk management rule required for such chemicals

Pre-emption (Sec. 18), #2

TSCA	CSIA	Issues/Concerns
• Only final rules or orders have a pre-emptive effect	• States can't impose a <u>new</u> restriction on a chemical once EPA has: (a) designated it low-priority, or (b) for high-priority chemicals, upon publication of EPA's schedule for conducting a safety assessment and determination	• Low-priority designations can't be challenged in court as final EPA actions • The trigger for any preemption should only be (a) a determination that a chemical meets the safety standard or (b) the risk management rule required for chemicals found not to meet the standard
• Waivers available for State requirements that are more protective and don't unduly burden interstate commerce	• Waivers available if State cannot wait for EPA to act or EPA finds its actions are being unreasonably delayed	• States must also show "compelling local" conditions or interests and sufficient scientific basis to obtain waivers

An overarching concern: Time to action

Lack of deadlines *<u>and</u>* major new procedural requirements = long delay before decisions

Conservative timeline for implementation:

- *Date of enactment to:*
  - first prioritized chemicals = 39 months or 3.25 years
  - first final safety determination = 86 months or 7.17 years
  - first final rule imposing restrictions = 104 months or 8.67 years

Key improvements needed

- more deadlines, fewer procedural requirements
- defining and explicitly protecting vulnerable populations
- narrowing the bill's preemption of state authority to ensure that states can act when EPA does not
- ensuring low-priority designations of chemicals are based on sufficient hazard and exposure information and do not preempt state authority
- providing EPA with adequate resources, with a fair share coming from industry

For more information

EDF's Chemicals Policy Webpage
www.edf.org/health/policy/chemicals-policy-reform

EDFHealth Blog
http://blogs.edf.org/health/