

## The Chemical Safety Improvement Act of 2013 (S. 1009): How it seeks to address key flaws of TSCA, along with key tradeoffs and concerns

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The <u>Chemical Safety Improvement Act of 2013 (CSIA, S. 1009)</u> would amend the core provisions of the Toxic Substances Control Act (TSCA) for the first time since TSCA's passage in 1976. Over the years, <u>key flaws in these core provisions</u> have been identified by many observers. <u>Table 1</u> below shows how these key flaws in each core area of current TSCA would be addressed by the new legislation. It also identifies some of the main trade-offs and remaining concerns raised by these provisions of the legislation. **Boldfaced entries** are those I consider to be most central to addressing the question of how and to what extent the new legislation fixes the key flaws of TSCA.

The bill would significantly expand TSCA's currently limited pre-emption of state authority, which has largely been moot due to how few actions EPA has undertaken. <u>Table 2</u> below presents the key pre-emption provisions of current TSCA and CSIA are presented along with key issues and concerns raised by the bill's expanded provisions.

This analysis does <u>not</u> address other critically important aspects of the debate over TSCA reform, including the absence from the new legislation of provisions – <u>which I and many others support</u> – that would extend the scope of TSCA beyond its core provisions, including those relating to: (1) "hot spots" – areas with disproportionately high chemical exposures; (2) expedited exposure reduction for chemicals of very high concern, such as PBTs; and (3) green chemistry and alternatives assessment.

TABLE 1	Key flaws in TSCA	Key changes in CSIA	Trade-offs/remaining or new concerns
Safety standard/ determination (Section 6)	Standard requires cost-benefit analysis Imposes "least burdensome" requirement on any regulation No definition or specific criteria to identify chemicals of concern	<ul> <li>Standard is applied based on health/environment impacts only</li> <li>Strikes "least burdensome" requirement</li> <li>Requires EPA to consider exposures of vulnerable populations</li> <li>Requires EPA to consider multiple exposures to a chemical</li> <li>Requires EPA to use "best available</li> </ul>	<ul> <li>Bans still must be based on cost-benefit</li> <li>No explicit inclusion in standard of protection of vulnerable populations or need to assess aggregate exposure</li> <li>"Best available science" does not reference NAS recommendations</li> </ul>
Existing chemicals	No mandate to review existing chemicals for safety     Lack of data is presumed to indicate	science"  Requires a safety review of all chemicals in active commerce  Lack of data is basis for high-priority	<ul> <li>Initial review (prioritization) is based only on existing data, and lack of data does not assure high-priority ranking</li> </ul>
(Section 6)	<ul> <li>lack of risk</li> <li>No criteria for triggering review of an existing chemical</li> </ul>	<ul> <li>designation</li> <li>High hazard or exposure sufficient for high-priority designation</li> <li>Requires safety determinations for all high-priority chemicals</li> <li>Requires risk management to be imposed on chemicals found not to meet the safety standard</li> </ul>	<ul> <li>Pace of review is unspecified, with virtually no deadlines for EPA actions</li> <li>Prioritization decisions not subject to court challenge (cuts both ways) and can trigger pre-emption of state authority</li> <li>Overly prescriptive and redundant frameworks and criteria must be developed and followed</li> </ul>
New chemicals	No affirmative safety decision is required before market entry     Burden is on EPA to find concern	<ul> <li>An affirmative decision of "likely safety" is required for market entry</li> <li>Prohibitions or restrictions can be imposed</li> </ul>	EPA cannot require testing of new chemicals (but can suspend review or impose conditions, as in status quo)
(Section 5)	<ul> <li>even when safety data are lacking</li> <li>Decisions are largely a "black box" because consent orders need not be made public</li> </ul>	<ul> <li>by order</li> <li>All new chemical notices and orders and submitted data must be made public (subject to CBI provisions)</li> </ul>	<ul> <li>No means provided to ensure compliance for chemicals "likely" to meet safety standard (unless EPA issues a Significant New Use Rule, or SNUR)</li> </ul>
Testing	EPA must promulgate a regulation     to require testing	EPA can use orders to require testing	Testing can only be required for use in
(Section 4)	<ul> <li>to require testing</li> <li>EPA has to show potential risk or high exposure to require testing, a Catch-22</li> <li>Testing done by consent orders is non-transparent, not always made public</li> </ul>	<ul> <li>(must justify why it is using an order rather than a rule or consent agreement)</li> <li>Testing orders avoid lengthy rulemaking and court challenges</li> <li>EPA does not need to make risk findings to require testing</li> <li>Testing agreements and orders and all test data must be made public (subject to CBI provisions)</li> </ul>	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

TABLE 1	Key flaws in TSCA	Key changes in CSIA	Trade-offs/remaining or new concerns
Confidential business information (Section 14)	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-bycase  EPA cannot share CBI with state and local governments Health and medical professionals cannot be given access to CBI CBI claims do not expire	<ul> <li>Information never eligible (as well as eligible) for CBI is delineated</li> <li>All other CBI claims must be substantiated at the time asserted</li> <li>Resubstantiation can be required for any CBI claim upon designation of a chemical as high-priority</li> <li>EPA must review CBI claims (all or representative subset)</li> <li>States and localities have access to CBI, subject to confidentiality agreements</li> <li>Health professionals can access CBI under confidentiality agreements</li> <li>For chemical identity CBI claims:         <ul> <li>Redocumentation can be required at any time</li> <li>Ready capability for reverse engineering disallows such claim</li> <li>A time period must be specified for each such CBI claim and found by EPA</li> </ul> </li> </ul>	<ul> <li>Only health and safety data on existing – not new – chemicals is precluded from being claimed CBI</li> <li>Notifications to submitters prior to release of CBI are generally required</li> <li>A new appeals process is provided under which claimants can challenge EPA's intention to release CBI</li> <li>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</li> </ul>
Chemical information reporting (Section 8)	The full range and identity of chemicals in active commerce, and their producers and processors, is not known Information on use of chemicals is collected only from chemical manufacturers with limited knowledge of downstream use	<ul> <li>to be reasonable</li> <li>Companies must notify EPA of all chemicals on the TSCA Inventory they are producing or processing (used to "reset" the Inventory)</li> <li>Chemicals not notified as active are placed on an inactive list; a company must notify EPA before making them</li> <li>Processor reporting is required for the first time for all chemicals in active commerce</li> </ul>	<ul> <li>Chemicals on the confidential portion of the TSCA Inventory can remain so if reasserted (though EPA can require (re)substantiation – see above)</li> <li>The scope of manufacturer and processor reporting programs is left to EPA to develop through rulemaking</li> </ul>

TABLE 2	TSCA	CSIA	Issues/concerns
Pre-emption (Section 18)	States can't require testing of a chemical "for purposes similar to those" for which EPA requires	States can't require testing     "reasonably likely to produce the     same data" as EPA requires, or	States need to be able to enact requirements identical to EPA's to allow for co-enforcement
(Section 18)	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  Only final rules or orders have a pre-emptive effect  Waivers available for State requirements that are more protective and don't unduly burden interstate commerce	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 can't impose a new 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  Waivers available if State cannot wait for EPA to act or EPA finds its actions are being unreasonably delayed	<ul> <li>"Restriction" can be read broadly to apply to warning labels, etc. (e.g., CA Prop 65)</li> <li>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</li> <li>Low-priority designations can't be challenged in court as final EPA actions</li> <li>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</li> <li>States must also show "compelling local" conditions or interests and sufficient scientific basis to obtain waivers</li> </ul>