

10 key enhancements in the new draft compared to CSIA as introduced

1. Further clarifies the definition of the safety standard to ensure that all chemical safety decisions are made solely based on consideration of risks to human health and the environment, and do not consider cost or other non-risk factors.
2. Ensures protection of vulnerable populations, such as children, pregnant women, the elderly, and workers, requiring that risks to them are analyzed when assessing chemicals and risk management decisions ensure their protection.
3. Eliminates red tape that could potentially undermine risk management decisions by EPA.
4. Ensures that aggressive but achievable deadlines for all major processes under the law are statutorily mandated.
5. Ensures EPA has adequate data and tools to prioritize chemicals.
6. Ensures that there is an enforceable schedule for issuing the initial priority list of chemicals that EPA will assess and that a mechanism is in place to ensure that a sufficient number of substances will be prioritized and assessed, starting from the date of enactment into the future.
7. Ensures that only final agency actions are subject to judicial review, with explicit designation of what is considered final agency action.
8. Ensures that procedural and scientific requirements for the prioritization, assessment, and management of chemical risks can be efficiently implemented and are balanced, attainable, and not overly prescriptive.
9. Ensures that new chemicals can enter the market only where EPA affirms that they are likely to meet the safety standard.
10. Maximizes public access to health and environmental information on chemicals, while protecting legitimate confidential business information (CBI).

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1. **Further clarifies the definition of the safety standard to ensure that all chemical safety decisions are made based solely on considerations of risk to human health and the environment, and do not consider cost or other non-risk factors.**
 - a. Under the new draft, the safety standard definition explicitly prohibits EPA from considering costs and other non-risk factors and requires protection of “potentially exposed or susceptible populations” as well as the general population. (pp. 5-6 of Senate Legislative Counsel Draft)
2. **Ensures protection of vulnerable populations, such as children, pregnant women, the elderly, and workers, requiring that risks to them are analyzed when assessing chemicals and risk management decisions ensure their protection.**
 - a. Under the new draft, a new definition of “potentially exposed or susceptible population” includes vulnerability due to elevated exposure and to heightened susceptibility to the effects of chemical exposures. In addition, the new definition states that a “potentially exposed or susceptible population” includes, but is not limited to, infants, children, pregnant women, workers, and the elderly. (p. 4 of SLC Draft)
 - b. Under the new draft, the safety standard definition now explicitly prohibits EPA from considering costs and other non-risk factors and requires protection of “potentially exposed or susceptible populations” as well as the general population. (pp. 5-6 of SLC Draft)
 - c. Under the new draft, new findings have been included that specifically require protecting the health of “children, pregnant women, the elderly, workers, consumers, the general public, and the environment from the risks of harmful exposures to chemicals substances and mixtures.” (p. 2 of SLC Draft)
3. **Eliminates red tape that could potentially undermine risk management decisions by EPA.**
 - a. Under the new draft, requirements for cost-benefit analysis have been clarified to ensure that the primary regulatory action is analyzed in comparison only to a limited list of relevant alternatives and can be based on already available information. (pp. 64-65 of SLC Draft)

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4. Ensures that aggressive but achievable deadlines for all major processes under the law are statutorily mandated.

a. Under the new draft:

- i. a new 2-year deadline is added for establishing all policies, procedures and guidance. (p. 6 of SLC Draft)
- ii. a 1-year deadline is added for the rule establishing prioritization screening. (p. 31 of SLC Draft)
- iii. a deadline of 6 months after enactment is added for EPA to initiate prioritization. (p. 32 of SLC Draft)
- iv. aggressive deadlines are added for completion of safety assessments and safety determinations (not longer than 3 years) and risk management rules (not longer than 2 years), with a limited ability to extend for due cause (not to exceed 2 years total). (p. 57 of SLC Draft)
- v. a 1-year deadline is added for the inventory reset rule and a 6-month deadline is added for companies to identify active chemicals. (pp. 77-78 of SLC Draft)

5. Ensures EPA has adequate data and tools to prioritize chemicals.

a. Under the new draft:

- i. any chemical whose prioritization is deferred due to lack of information must be identified along with the basis for that deferral. (pp. 40-41 of SLC Draft)
- ii. testing authority has been provided for informing prioritization, as long as no minimum information requirements are imposed on all chemicals. (p. 21 of SLC Draft)
- iii. low-priority designations must be based on sufficient information. (p. 40 of SLC Draft)
- iv. a chemical can be designated high priority on the basis of insufficient information. (pp. 37-38 of SLC Draft)

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6. Ensures that there is an enforceable schedule for issuing the initial priority list of chemicals that EPA will assess and that a mechanism is in place to ensure that a sufficient number of substances will be prioritized and assessed, starting from the date of enactment into the future.

- a. Under the new draft:

- i. a 1-year deadline for establishing the prioritization screening process has been added. (p. 31 of SLC Draft)
- ii. within 6 months of enactment, EPA is to establish an initial list of at least 10 high-priority chemicals, on which it may initiate or continue assessments and determinations. (p. 32 of SLC Draft)
- iii. EPA can draw from an interim list of active chemicals for prioritization without having to wait for the inventory reset. (p. 32 of SLC Draft)
- iv. the high-priority list must be repopulated as safety assessments/determinations are completed. (pp. 33-34 of SLC Draft)
- v. EPA must initiate prioritization within 6 months of enactment. (p. 32 of SLC Draft)

7. Ensures that only final agency actions are subject to judicial review, with explicit designation of what is considered final agency action.

- a. Under the new draft, judicial review is triggered only when EPA takes final action, either a final determination that a chemical meets the safety standard or a final rule for a chemical EPA finds does not meet the safety standard. (p. 70 of SLC)

8. Ensures that procedural and scientific requirements for the prioritization, assessment, and management of chemical risks can be efficiently implemented and are balanced, attainable, and not overly prescriptive.

- a. Under the new draft:

- i. a new 2-year deadline is set for establishing all policies, procedures and guidance. (p. 6 of SLC Draft)
- ii. policies and requirements have been substantially consolidated and streamlined. (Sec. 4 of SLC Draft – new Sec. 3A. Policies, Procedures, and Guidance)

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- iii. controversial definition of “best available science” has been struck.
 - iv. Provisions prescribing highly specific risk assessment methodologies have been struck or made less prescriptive. (p. 5 of SLC Draft; Sec. 4 of SLC Draft – new Sec. 3A. Policies, Procedures, and Guidance)
9. Ensures that new chemicals can enter the market only where EPA affirms that they are likely to meet the safety standard.
- a. Under the new draft:
 - i. New chemicals can only be made and used if EPA determines they are likely to meet the safety standard. (pp. 48-49 of SLC Draft)
 - ii. If EPA finds there is insufficient information for making that determination on a new chemical, it can require testing, and the chemical can enter the market only under restrictions that are sufficient for EPA to determine it is likely to meet the safety standard even in the absence of that information. (pp. 52-53 of SLC Draft)
10. Maximizes public access to health and environmental information on chemicals, while protecting legitimate confidential business information (CBI).
- a. Under the new draft:
 - i. Health and safety information is generally not eligible for CBI protection (restores current TSCA language). (pp. 105-106 of SLC Draft)
 - ii. CBI protection for chemical identities is presumed only before they are commercialized. (p. 104 of SLC Draft)
 - iii. Past CBI claims to protect the identity of chemicals in commerce are required to be substantiated and reviewed by EPA within 5 years (can be extended by 2 years for due cause). (pp. 79-83 of SLC Draft)
 - iv. CBI claims must generally be substantiated, reviewed and approved to stand, and expire after 10 years unless found to warrant renewal of protection. (pp. 109-111; 117-119 of SLC Draft)
 - v. EPA retains authority or a mandate to review CBI claims under a range of circumstances. (pp. 120-122 of SLC Draft)