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Toxic Substances Control Act:
Comparison of Current Law to the Chemical Safety Improvement Act

Topic	Toxic Substances Control Act of 1976 (TSCA), Title I, 15 U.S.C. §§ 2601-2629	Chemical Safety Improvement Act of 2013
1. Safety Standard	"Presents or will present" (or, in some provisions, "may present") an "**unreasonable risk to health or the environment**."	"**No unreasonable risk of harm to human health or the environment will result from exposure** to the chemical substance." All assessments, determinations, or other analyses are whether a chemical meets this safety standard "**under its intended conditions of use**."
2. Scope	EPA has authority to regulate mixtures and articles, but rarely does so and has adopted various administrative exemptions.	No significant changes from current TSCA treatment of mixtures and articles.
3. Minimum Information Set	None.	None.
4. Testing and Development of Data	Gives EPA rulemaking authority to require testing if it finds either that a substance or mixture may present an unreasonable risk, or that there will be substantial production or exposure. Manufacturers or processors may be required to submit information, but processors rarely are. Data compensation provisions are included. Limited provisions for public availability of data.	Gives EPA **rule, consent agreement, or order authority** to require testing. EPA must implement a tiered toxicity testing framework and consider costs and laboratory availability. Limited to manufacturers and processors. EPA must establish the need for the data in safety assessments or determinations. Some procedural changes from current TSCA data compensation provisions. Test data and other information to be publicly available, subject to § 14 CBI protections.
5. Information Sources and Data Quality	No general provisions or provisions regarding animal testing.	Broadly requires EPA to consider data that is reasonably available and encourages alternative testing methods before animal testing is required. Requires EPA to publish **scientifically sound criteria** for its data evaluation and to use a structured evaluation framework. With justification, EPA may still consider data which do not meet the criteria.
6. Confidentiality and Disclosure of Information	Prohibits disclosure of information that is exempt from disclosure under exemption (b)(4) of FOIA (trade secrets), subject to exceptions. Prohibits CBI protection for health and safety studies except to	Prohibits disclosure of information that is exempt from disclosure under exemption (b)(4) of FOIA. Various types of information are presumed confidential, subject to a somewhat wider range of exceptions. Provides that information on **specific chemical identity is presumed**

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	the extent they reveal process or portion of mixture information. **Chemical identity is generally eligible for CBI protection**, except when in health and safety studies. Allows data to be designated CBI; no up-front substantiation and no expiration provision.	**confidential**, but requires up-front justification of those claims. Provides procedures for EPA review of CBI claims and 30 day notice before release of information. Confidentiality lasts as long as requested by the submitter or as EPA deems reasonable; renewable.
7. New Chemicals	Requires manufacturers of new chemicals to submit PMNs, to include existing information known to or reasonably ascertainable by the submitter. EPA has 90 days to review (may be extended). EPA is not required to make an affirmative finding of low risk. However, EPA may issue § 5(e) orders to require testing or control measures if it finds that a PMN chemical "may pose an unreasonable risk" or that there will be substantial production or exposure. Requires summaries of PMNs to be published in the Federal Register.	Requires manufacturers to submit PMNs for new chemicals, to include the detailed information required under current regulations, but no minimum information set. As under current TSCA, EPA has 90 days to review (may be extended another 90 days without Federal Register notice) based on **reasonably available information** and evaluate whether the chemical (with any necessary restrictions) **is likely to meet the safety standard** under its intended conditions of use. • If not, EPA must impose restrictions or prohibitions by consent agreement or order. • If the chemical is likely to meet the safety standard under its intended conditions of use, it is added to the Inventory after the PMN submitter submits a NOC, and EPA may consider whether to conduct a prioritization screening. • If more information is needed, EPA must provide opportunity to submit it and may extend review. Maintains current TSCA requirement for summaries of PMNs to be published in the Federal Register.
8. New Uses	If EPA has designated by rule (SNUR) that a use of a substance is a significant new use, a manufacturer or processor of that substance must submit a SNUN, similar in form, timing, and procedures to a PMN.	**Similar to current TSCA**, if EPA has designated by rule (SNUR) that a use of a substance is a significant new use, a manufacturer or processor of that substance must submit a SNUN, similar in form, timing, and procedures to a PMN.
9. Notification Exemptions	Provides for exemptions for test marketing (notice and comment required), non-isolated intermediates (same), and R&D in § 5(h)(1), (3), (5). Under § 5(h)(4), other chemicals that will not present an	Current TSCA's statutory exemptions (e.g., R&D, non-isolated intermediates) are retained. EPA may adopt rule-based exemptions (e.g., for polymers,

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	unreasonable risk (e.g., polymers, low volume chemicals) may be exempted by rule.	low volume, articles) if exempt chemicals are expected to meet the safety standard under intended conditions of use.
10. Prioritization and Expedited Action	No provision.	**Prioritization screening**: EPA must identify chemicals as high or low priority within 6 months after a chemical is recommended by a State to be identified as high priority, and otherwise at a pace and in an order determined in EPA's discretion, using a risk-based prioritization screening process and guidelines provided in the statute, and with notice and opportunity for comment. If more information is needed for prioritization, EPA must provide opportunity to submit information. No judicial review of prioritization screening decisions.
11. Safety Determinations	Allows EPA to determine that there is a reasonable basis to conclude that a chemical substance presents or will present an unreasonable risk of injury to health or the environment, but EPA is not required to make such determinations. Unreasonable risk determinations provide basis for risk management actions as described below.	**Safety assessment**: EPA must perform and publish a risk-based safety assessment of each high priority substance using the current best available science and all reasonably available data and information, and must adopt procedural rules and methodologies for doing so. No judicial review of safety assessments. **Safety determination:** Within a reasonable period after a safety assessment, EPA must determine whether a chemical meets the safety standard under its intended conditions of use, based on health and environmental considerations. Safety determinations are subject to public notice and comment. The safety determination must consider the assessment and reasonably available data and information. If the substance does not meet the safety standard, the availability of feasible alternatives and the economic and social benefits and costs of the chemical and its alternatives must be considered. Provisions for data submission are provided. A final determination is subject

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		to judicial review.
12. Risk Management	Under § 6, requires EPA to propose by rule "the least burdensome requirements" necessary to protect adequately against unreasonable risk of injury to health or the environment. EPA must also consider the benefits of the substances, the availability of substitutes, and the reasonably ascertainable economic consequences of the rule. Rulemaking procedures provided are in addition to Administrative Procedure Act (APA). Under § 7, allows EPA to commence civil actions for injunctive relief, including seizure, to control imminently hazardous chemicals or mixtures or articles containing such chemicals.	**Positive** determinations without restrictions do not limit future uses of a chemical. If the safety determination is **positive with restrictions**, EPA must issue a rule, which can include a wide range of requirements and controls, in proportion to the strength of evidence and magnitude of risk. If the safety determination is **negative**, EPA must issue a rule adopting necessary additional restrictions to the extent feasible (considering, e.g., the economic and social benefits and costs of the chemical and its alternatives), or in appropriate cases a rule requiring a ban or phase-out. No substantive change to current TSCA § 7.
13. Inventory	Under § 8(b), chemicals in commerce at the time of enactment in 1976 and chemicals for which NOCs have subsequently been submitted are listed on the Inventory; there are no express provisions for removal (unless found to be ineligible originally) or updating. Chemicals not on the Inventory are considered to be new.	**Notifications**: EPA must issue a candidate list of substances that may be identified as being in active commerce. EPA must issue a rule allowing manufacturers and processors to notify which chemicals have been manufactured or processed for non-exempt commercial purposes within the 5 years prior to enactment of CSIA. Submitters must certify the information. **Active chemicals on Inventory**: • Chemicals so notified, or added after filing of an NOC, or inactive substances subsequently notified to EPA, are active. EPA may consider whether and when to conduct a prioritization screening. **Inactive chemicals on Inventory**: • Chemicals not so notified are inactive; they remain on the Inventory but are not subject to the chemical assessment framework. • A manufacturer or processor must submit a brief notice

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		to EPA prior to manufacture or processing of an inactive chemical; EPA must promptly designate the chemical as active, at which time the chemical is subject to prioritization.
14. Recordkeeping, Reporting, and Health and Safety Information	Under § 8(a), EPA may by rule require manufacturers and processors to maintain records and submit information and reports when "necessary for the effective enforcement" of TSCA. The Chemical Data Reporting (CDR) (formerly Inventory Update Reporting, IUR) rule under § 8(a) requires **manufacturers** of chemical substances meeting certain thresholds to submit periodic reports on chemical manufacturing, processing, and use. Allegations of significant adverse reactions caused by a substance or mixture (§ 8(c)) must be retained and provided on EPA request, and certain health and safety studies (§ 8(d)) must be reported; TSCA allows these requirements to be applied to manufacturers, processors, and distributors, but EPA has limited application by rule to **manufacturers and certain processors**. Substantial risk information (§ 8(e)) must be reported by **manufacturers, processors, or distributors**.	Current TSCA reporting and recordkeeping provisions are generally retained without significant change. Expands current TSCA § 8(a) to enhance EPA's ability to require **processor reporting** and to require guidance addressing different requirements for manufacturers and processors and ensuring that EPA's reporting requirements are driven by data needs. Makes no changes to sections 8(c)-(e).
15. Imports	US Customs must refuse entry to chemical substances, mixtures, or articles in violation of TSCA or its rules. Importers must certify that shipments of chemicals are compliant, or for certain imports (e.g. pesticides) that they are not subject to TSCA.	Minor changes to align to new framework. Following a safety determination, imports of the substance, mixture or article containing the substance may require notice, if appropriate following a safety determination.
16. Exports	Under § 12(a), chemicals manufactured and processed only for export are generally exempt from TSCA. Under § 12(b), any person exporting a substance subject to a test rule, consent order, risk management rule, or significant new use rule must provide an export notification to EPA.	Current § 12(a) exemption is retained and aligned with the safety standard; EPA may also determine that the exemption does not apply to a mixture or article above a threshold concentration. EPA may also add appropriate exemptions.
17. Relationship to Other Federal Laws	If EPA determines that another agency may act to reduce a chemical's unreasonable risk to a sufficient extent, EPA must request it to take action; if the other agency either takes action	No major substantive change from current TSCA.

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	or declares that the chemical does not present the described risk, EPA may not take action except to address imminent hazards.	
18. Preemption	Preempts state or local regulations that conflict with § 5 or § 6 rules or orders, except for bans. States or localities may apply to EPA for exemptions but this process has rarely been used.	EPA regulatory actions preempt state and local chemical regulatory requirements to the extent of the EPA decisions. Decisions by EPA to designate a substance as high or low priority only preempt future state/local regulation, and existing requirements continue in force until a safety determination is made. States may seek a waiver from the preemptive effect of an EPA decision, such as for compelling State or local conditions. Safety determinations may be admissible as determinative evidence in courts.
19. Enforcement and Citizens' Actions and Petitions	Authorizes citizens' suits for prospective enforcement of rules under §§ 4, 5, or 6. Citizens' petitions authorized only for certain rules and orders. Provides for prohibited acts, penalties (capped), and specific enforcement.	No major substantive change from current TSCA.
20. Judicial Review	The APA "arbitrary or capricious" standard of review is replaced for certain rules with the standard "not supported by substantial evidence in the rulemaking record."	No major substantive change from current TSCA.
21. Administration	Authorizes EPA, by rule, to require fees from any person required to submit data under TSCA §§ 4 or 5, up to a cap. No provision for fee payments to go to EPA's budget.	No major substantive change from current TSCA.
22. EPA Research and Green Chemistry Programs	Various research programs are ongoing under current law; none specifically created by statute.	No major substantive change from current TSCA.
23. International Cooperation	No provision.	No provision.

Abbreviations

APA.....Administrative Procedure Act, 5 U.S.C. §§ 551-59, 701-06

CBI .....Confidential Business Information
CBP .....U.S. Customs and Border Protection
CDR.....Chemical Data Reporting
EPA.....U.S. Environmental Protection Agency
FOIA.....Freedom of Information Act, 5 U.S.C. § 552
LRTAP POPs Protocol.....Persistent Organic Pollutants Protocol of the U.N. Convention on Long-Range Transboundary Air Pollution
NOC.....Notice of Commencement
PIC Convention .....Rotterdam Convention on Prior Informed Consent
PMN .....Premanufacture Notice
R&D.....Research and Development
SCA.....Safe Chemicals Act
SNUN .....Significant New Use Notice
SNUR.....Significant New Use Rule
Stockholm Convention .....Stockholm Convention on Persistent Organic Pollutants
SVHCs.....Substances of Very High Concern (i.e., either toxic, persistent in the environment, and bioaccumulative (PBT), or highly hazardous)
SVLCs.....Substances of Very Low Concern
TMA.....TSCA Modernization Act
TSCA.....Toxic Substances Control Act