



Proposed Reform of the Toxic Substances Control Act (TSCA) in the 112th Congress: S. 847 Compared with Current Law

(name redacted)

Specialist in Environmental Policy

July 25, 2011

Congressional Research Service

7-....

www.crs.gov

R41937

Summary

Thirty-five years of experience implementing and enforcing the Toxic Substances Control Act (TSCA) have demonstrated the strengths and weaknesses of the law and led many to propose legislative changes to TSCA's core provisions. Stakeholders appear to agree that TSCA needs to be updated, although there is disagreement about the extent and nature of any proposed revisions. S. 847 in the 112th Congress legislation would amend core provisions of TSCA Title I. This report compares key provisions of S. 847, as introduced, with current law (15 U.S.C. 2601 *et seq.*).

Generally, S. 847 would increase the amount of information about chemical toxicity and usage that chemical manufacturers and processors would be required to submit to the U.S. Environmental Protection Agency (EPA), and would facilitate EPA regulation of toxic chemicals. The bill directs EPA to establish, by rule, varied or tiered minimum data set requirements for different chemical substances or categories of substances. Data would be required from chemical manufacturers and processors for all chemicals within five years of the date of enactment of S. 847, earlier for high-priority chemicals. All chemicals already in commerce are to be placed on a list and prioritized by EPA into three groups based on the need for risk management. A chemical must be included in the highest priority class if it “is, or is degraded and metabolized into, a persistent, bioaccumulative, and toxic substance with the potential for widespread exposure to humans or other organisms.” EPA is required to determine whether chemicals in the top two priority classes, as well as all new chemicals, meet a stringent new safety standard, given the imposition of any needed restrictions on manufacture, processing, distribution, use, or disposal. The bill would prohibit any activities with respect to an evaluated chemical substance that the EPA had not specifically allowed in the safety standard determination.

In contrast, current law authorizes data collection from manufacturers only if exposure is expected to be substantial or if EPA determines that a chemical may pose an unreasonable risk. TSCA as currently written allows all chemicals to enter and remain in commerce unless EPA can show that a chemical poses “an unreasonable risk of injury to health or the environment.” EPA then must regulate to control unreasonable risk, but only to the extent necessary using the “least burdensome” means of available control. This TSCA standard has been interpreted to require cost-benefit balancing.

S. 847 also would add new sections to TSCA. Of particular significance is a section authorizing actions that would allow U.S. implementation of three international agreements, which the United States has signed but not yet ratified. Other new sections would provide authority for EPA to support research in so-called “green” engineering and chemistry, promote alternatives to toxicity testing on animals, encourage research on children’s environmental health, and require biomonitoring of pregnant women and infants. A “hot spots” provision would require EPA to identify locations where residents are disproportionately exposed to pollution and to develop strategies for reducing their risks.

Key provisions of S. 847 are compared with current law in Tables 1 through 6.

Contents

Introduction	1
Effects of the Proposed Legislation on Current Law	1
Minimum Data Set Requirements.....	1
Prioritization of Chemicals.....	2
Safety Standard and Burden of Proof.....	2
EPA Authority to Manage Risks	3
State Preemption.....	3
Miscellaneous Provisions	4

Tables

Table 1. Titles and Definitions in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced	5
Table 2. Testing in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced.....	9
Table 3. Notices in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced.....	14
Table 4. Restrictions in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced	24
Table 5. Reporting Requirements in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced.....	32
Table 6. Other Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced.....	36

Contacts

Author Contact Information	48
----------------------------------	----

Introduction

In 1976, President Gerald R. Ford signed the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*; TSCA), giving the U.S. Environmental Protection Agency (EPA) authority to regulate production and use of industrial chemicals not otherwise regulated in U.S. commerce.¹ Thirty-five years of experience with TSCA implementation and enforcement have demonstrated the strengths and weaknesses of the law and led many to propose legislative changes to TSCA's core provisions in Title I.² Based on hearing testimony, stakeholders generally agree that TSCA needs to be updated, although there is disagreement about the extent and nature of any proposed revisions.³ Democrats introduced legislation to amend TSCA Title I in the 111th Congress (S. 3209 and H.R. 5820), but Congress did not vote on either bill. Those previous bills proposed generally similar changes to TSCA that were summarized in CRS Report R41335, *Proposed Amendments to the Toxic Substances Control Act (TSCA): Senate and House Bills Compared with Current Law*. On April 14, 2011, Senator Frank Lautenberg introduced similar, but not identical, legislation (S. 847) in the 112th Congress. To date, no other legislation has been introduced that would amend core provisions of TSCA Title I. Therefore, this report compares key provisions of S. 847, as introduced, with provisions of TSCA Title I (15 U.S.C. 2601 *et seq.*) that would be affected if S. 847 becomes law. These provisions are summarized in Tables 1 through 5. New provisions that would be added to the end of TSCA Title I by S. 847—for example, those related to reduced use of animals for toxicity testing—are summarized in **Table 6**.

Effects of the Proposed Legislation on Current Law

S. 847 would not affect Titles II through VI of TSCA, nor would it change the basic organization of TSCA Title I. For example, provisions related to testing would still be in Section 4, requirements for notifying EPA when a new chemical or new use is proposed would still be in Section 5, and regulatory authorities would remain in Section 6. Also unaffected would be changes to TSCA Title I that were enacted during the 110th Congress, such as a provision that bans exports of elemental mercury.⁴ However, S. 847 would amend or delete most of the original Title I provisions and would make substantial additions to current law. Some key changes are summarized below.

Minimum Data Set Requirements

S. 847, as introduced, directs the EPA Administrator to establish varied or tiered minimum data set requirements for different chemical substances or categories of substances. Manufacturers would be given a specified period of time to produce and submit data meeting the minimum data

¹ For a summary of TSCA provisions and history, see CRS Report RL31905, *The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements*.

² For more information about issues revolving around TSCA, see CRS Report RL34118, *The Toxic Substances Control Act (TSCA): Implementation and New Challenges*.

³ U.S. Congress, Senate, Committee on Environment and Public Works, Subcommittee on Superfund, Toxics and Environmental Health, Hearing, "Assessing the Effectiveness of U.S. Chemical Safety Laws." February 3, 2011, http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=cd4fd6b9-802a-23ad-4d18-eac94d1414b3.

⁴ S. 906, which became P.L. 110-414.

requirements for chemicals that are already in commerce and for any new chemicals that they propose to manufacture. Data sets would have to be submitted within five years of the date of enactment of S. 847.

Current law does not routinely require submission of data for chemicals, but EPA has the authority to require data submission if it promulgates a rule based on a finding that a chemical “may present an unreasonable risk of injury to health or the environment” and the agency demonstrates a data need.

Prioritization of Chemicals

S. 847 directs the EPA Administrator to prioritize all chemicals already in commerce for evaluation and risk management by establishing a list that “contains the names of the chemical substances that ... warrant placement within 1 of 3 priority classes ... and identifies the priority class to which each listed chemical substance or category of chemical substance has been assigned by the Administrator.” Priority class 1 chemicals would be defined as those “... that the Administrator determines require immediate risk management.” The Administrator would be required to place between 20 and 30 chemicals in this category, and the data set for a high-priority chemical would have to be submitted within 18 months of its placement on the priority class 1 list. Priority class 2 chemicals would be defined as those “that the Administrator determines require safety standard determinations ... based on any more-than-theoretical concern, that there is uncertainty as to whether a chemical substance would satisfy the safety standard.” Priority class 3 chemicals would be defined as those “that the Administrator determines require no immediate action.”

Chemicals are not prioritized under current law.

Safety Standard and Burden of Proof

The Senate bill would establish a health-based safety standard for chemical use that protects vulnerable populations: manufacturers would be required to produce scientific data demonstrating “there is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance.” S. 847 would prohibit manufacture, processing, and distribution of any chemical substance for any use that had not been included in the safety determination issued for that chemical. Moreover, an exemption from a prohibition would be allowed for a particular use only if: it were “in the paramount interest of national security”; lack of the chemical use “would cause significant disruption in the national economy”; the use were essential or critical and there were no safer feasible alternative; or the chemical use, relative to alternatives, provided a benefit to health, the environment, or public safety.

In contrast, current law allows manufacture of and commerce in a chemical unless EPA promulgates a rule including a finding that a chemical presents or will present an “unreasonable risk” to human health or the environment. If EPA demonstrates that a risk associated with a chemical is unreasonable (relative to the benefits provided by the chemical and the estimated risks and benefits of any alternatives), the Agency is required to regulate, but only to the extent necessary to reduce that risk to a reasonable level and using “the least burdensome” restriction.

EPA Authority to Manage Risks

S. 847 would expedite regulatory action, relative to the process under current law, by authorizing EPA in some cases to issue administrative orders instead of rules (which must be promulgated under current law), exempting certain EPA decisions from judicial review, and removing certain TSCA requirements that are in addition to requirements specified in the Administrative Procedure Act (5 U.S.C. 553) for notice and comment rulemaking.

The scope of EPA oversight also would be expanded by S. 847. As introduced, the bill includes language that allows EPA to define various distinct forms of substances that are the same in terms of molecular identity but differ in structure and function, such as manufactured nanoscale forms of carbon and silver. The introduced bill also broadens the scope of environmental risks that EPA may manage to include risks found in the indoor environment; currently, TSCA applies only to chemicals in the ambient environment. S. 847 also would appear to more clearly authorize EPA control of risks posed by articles containing a substance.

The proposed amendments to TSCA would increase public access to information about EPA's decisions, as well as to some information about chemicals that currently is treated as confidential business information.

S. 847 would authorize EPA activities not currently authorized under TSCA to allow implementation of three international agreements pertaining to persistent organic pollutants and other hazardous chemicals. For example, the proposal would authorize EPA to regulate chemicals manufactured solely for export. The authority provided by the bill would be specific to three international agreements, rather than more generally authorizing regulatory activity to implement any ratified international agreement concerning chemicals. The bill would prohibit production and use of chemicals when it was inconsistent with U.S. obligations under any of the three international agreements after they had entered into force for the United States. For more information about these agreements, see CRS Report RS22379, *Persistent Organic Pollutants (POPs): Fact Sheet on Three International Agreements*.

State Preemption

The effect of TSCA on state and local chemical laws would be modified by S. 847, as introduced. Current law, TSCA Section 18, generally does not preempt state laws. However, if EPA requires testing of a chemical under section 4, no state may require testing of the same substance for similar purposes. Similarly, if EPA prescribes a rule or order under section 5 or 6, no state or political subdivision may have a requirement for the same substance to protect against the same risk unless the state or local requirement is identical to the federal requirement, is adopted under authority of another federal law, or generally prohibits the use of the substance in the state or political subdivision. TSCA authorizes states and political subdivisions to petition EPA, and authorizes EPA to grant petitions, by rule, to exempt a law in effect in a state or political subdivision under certain circumstances. A petition may be granted if compliance with the requirement would not cause activities involving the substance to be in violation of the EPA requirement, and the state or local requirement provides a significantly higher degree of protection from the risk than the EPA requirement does, but does not “unduly burden interstate commerce.” S. 847 would simplify this section of TSCA. An amended TSCA would not preempt laws relating to a chemical substance, mixture, or article unless compliance with both federal and the state or local law were impossible.

Miscellaneous Provisions

Several new provisions are included in S. 847. One provision, for example, would require definition and listing of localities with populations that are “disproportionately exposed” to toxic chemicals. EPA would be directed to develop an action plan to reduce exposure in such “hot spots.”

EPA would be required to establish a program to create market incentives for the development of safer alternatives to existing chemical substances that reduce or avoid the use and generation of hazardous substances. The program would be required to expedite review of a new chemical substance if an alternatives analysis indicated it was a safer alternative, and to recognize a substance or product determined by EPA to be a safer alternative.

Another provision would direct the EPA Administrator to coordinate with the Secretary of Health and Human Services to conduct a biomonitoring study to determine whether a chemical that research had indicated may be present in human biological substances and that may have adverse effects on human development in fact was present in pregnant women and infants. If the chemical were found to be present, manufacturers and processors would have to disclose to EPA, commercial customers, consumers, and the general public all known uses of the chemical and all articles in which the chemical was expected to be present.

Children’s environmental health also is addressed by the bill. It would establish a children’s environmental health research program at EPA and an advisory committee to provide independent advice relating to implementation of TSCA and protection of children’s health.

S. 847, as introduced, also establishes at least four research centers to encourage the development of safer alternatives to existing hazardous chemical substances. “Green chemistry and engineering” also would be promoted through grants.

Finally, S. 847 would direct EPA to minimize use of animals in toxicity testing. An advisory committee would be established to publish a list of testing methods that reduce use of animals. This provision aims to expedite development of so-called “alternative testing methods,” which have been under development for many years, but remain a minor component of toxicity testing programs.

Tables 1 through 6 summarize these and other selected provisions of S. 847.

Table I. Titles and Definitions in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced

Provision	15 U.S.C. 2601 et seq.	S. 847
Title	Toxic Substances Control Act (TSCA)	Safe Chemicals Act of 2011 (SCA)
Revised definitions	TSCA definitions are in alphabetical order in section 3 (15 U.S.C. 2602).	S. 847 section 4 would amend definitions in TSCA section 3.
<i>Chemical substance</i>	“[A]ny organic or inorganic substance of a particular molecular identity, including - (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical.” The term does not include any mixture, pesticide, tobacco, nuclear material, firearms, shells or cartridges for firearms, food, food additive, drug, cosmetic, or devices regulated by other specified federal laws. [TSCA 3(2)]	Proposed TSCA 3(5) is the same as 15 U.S.C. 2602(2), but also authorizes EPA to determine that “a variant of a chemical substance is a new chemical substance,” notwithstanding molecular identity.
<i>Distribute in commerce / Distribution in commerce</i>	“[T]o sell, or the sale of the substance, mixture, or article in commerce; to introduce or deliver for introduction into commerce, or the introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.” [TSCA 3(4)]	Would amend the TSCA 3(8) definition to include “to export or offer for export the substance, mixture, or article.”
<i>Environment</i>	“[I]ncludes water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.” [TSCA 3(5)]	Would amend the TSCA 3(10) definition to include “ambient” and “indoor air.”
<i>New chemical substance</i>	“[A]ny chemical substance which is not included in the chemical substance list compiled and published under section 2607(b) of this title, [corresponding to TSCA section 6(b)].” [TSCA 3(9)]	Proposed TSCA 3(15) revises the definition, eliminating reference to listing under 15 U.S.C. 2607(b) and instead referring to any chemical substance that does not have a submitted declaration under Proposed TSCA section 8(a).

Provision	15 U.S.C. 2601 et seq.	S. 847
<i>Standards for the development of test data</i>	A “prescription of (A) the - (i) health and environmental effects, and (ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment, for which test data for a chemical substance or mixture are to be developed and any analysis that is to be performed on such data, and (B) to the extent necessary to assure that data respecting such effects and characteristics are reliable and adequate (i) the manner in which such data are to be developed, (ii) the specification of any test protocol or methodology to be employed in the development of such data, and (iii) such other requirements as are necessary to provide such assurance.” [TSCA 3(12)]	This definition would be eliminated.
New definitions		
<i>Aggregate exposure</i>	No comparable definition.	Total exposure to a chemical substance regardless of the source of exposure, including activities involved in the manufacture, processing, distribution, use, or disposal of chemicals; contamination of food, air, water, soil, and house dust from current or prior uses or activity; accidental releases; permitted sources of pollution; nonpoint sources of pollution; documented background levels from natural and anthropogenic sources; and a mixture or article containing that chemical substance. The term would include exposure from a chemical substance that is not considered a chemical substance under TSCA solely because of its use as, or in, food, cosmetics, or medical devices. [Proposed TSCA 3(2)]
<i>Bioaccumulative</i>	No comparable definition.	As determined by the EPA Administrator, the ability to significantly accumulate in biota, or highly likely to accumulate in biota. [Proposed TSCA 3(3)]
<i>Chemical identity</i>	No comparable definition.	Each common and trade name, the most current internationally standardized name, the Chemical Abstracts Service registration number, and the molecular structure of a chemical substance, and for a mixture, the chemical identities and proportions of the components. [Proposed TSCA 3(4)]

Provision	15 U.S.C. 2601 et seq.	S. 847
<i>Cumulative exposure</i>	No comparable definition.	The sum of aggregate exposure to each chemical substance that is known or suspected to contribute “appreciably to the risk of the same or a similar adverse effect.” [Proposed TSCA 3(7)]
<i>End consumer</i>	No comparable definition.	An “individual or other entity that purchases and uses or consumes a chemical substance (or mixture or article containing that chemical substance).” [Proposed TSCA 3(9)]
<i>Federal agency</i>	No comparable definition.	“[A]ny department, agency, or other independent agency or establishment of the Federal Government including any Government corporation, and the Government Printing Office.” [Proposed TSCA 3(11)]
<i>Persistent</i>	No comparable definition.	Determined by the EPA Administrator to significantly persist in one or more environmental media. [Proposed TSCA 3(16)]
<i>Person</i>	No comparable definition.	An “individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.” Includes “each Federal agency and any officer, agent, or employee of a Federal agency.” [Proposed TSCA 3(17)]
<i>Special substance characteristics</i>	No comparable definition.	Defines “special substance characteristic” to mean “such physical, chemical, or biological characteristic, other than molecular identity, that the Administrator determines, by order or rule, may significantly affect the risks posed by substances exhibiting that characteristic.” Allows consideration of size, shape, reactivity, and any other properties that may significantly affect risks posed. [Proposed TSCA 3(20)]

Provision	15 U.S.C. 2601 et seq.	S. 847
<i>Toxic</i>	No comparable definition.	Satisfies one of the following conditions: has a toxicological property meeting criteria for Category 1 or 2 for any toxicity endpoint established by the Globally Harmonized System for the Classification and Labeling of Hazardous Substances; “causes an adverse effect that has been demonstrated in humans or other exposed organisms”; or “the weight of evidence ... demonstrates the potential for an adverse effect in humans or other exposed organisms.” [Proposed TSCA 3(22)]
<i>Toxicological property</i>	No comparable definition.	“[A]ctual or potential toxicity or other adverse effects of a chemical substance or mixture, including actual or potential effects of exposure” on mortality, morbidity, reproduction, growth and development, the immune system, the endocrine system, brain or nervous system, other organ systems, or “any other biological functions in humans or nonhuman organisms.” [Proposed TSCA 3(23)]
<i>Vulnerable human population</i>	No comparable definition.	A “human population that is subject to a disproportionate exposure to, or the potential for a disproportionate adverse effect from exposure to, a chemical substance or mixture ...” and includes those who work with chemical substances and mixtures, individuals with preexisting medical conditions, the elderly, pregnant women, infants, children, adolescents, and “members of any other appropriate population identified by the Administrator.” [Proposed TSCA 3(25)]

Table 2. Testing in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced

Provision	15 U.S.C. 2601 et seq.	S. 847
Testing authorities and requirements	TSCA 4(a) [15 U.S.C. 2603(a)] directs the EPA Administrator to promulgate a rule requiring that testing be conducted on a substance or mixture to develop health and environmental effects data if: (1) the manufacture, processing, distribution, use, or disposal of the chemical “may present an unreasonable risk of injury to health or the environment,” or (2) the chemical is produced in very large volume and there is a potential for a substantial quantity to be released into the environment or for substantial or significant human exposure. In either case, EPA also must find that (a) existing data are insufficient to resolve the question of safety, and (b) testing is necessary to develop the data.	<p>S. 847, section 5, amends TSCA 4. Proposed TSCA 4(a) directs the EPA Administrator within one year of enactment of S. 847 to promulgate a rule establishing varied or tiered minimum data sets for different chemical substances or categories of substances. Data sets must encourage and facilitate use of alternative testing methods and strategies in accordance with section 30 and must include “the minimum amount of information necessary” for the conduct of a screening-level risk assessment of the substance or category of substances. The rule must require submission to EPA of such data by each manufacturer and processor of a new chemical substance and each manufacturer and processor of an existing chemical. Also requires updates of minimum data set submissions.</p> <p>Proposed TSCA 4(b) authorizes EPA to require, by rule or order, testing and submission of test results by a specified date “as necessary for making any determination or carrying out any provision” of TSCA. Authorizes EPA to require submission of a sample of any chemical for the purpose of conducting tests and making a determination or carrying out any provision of the act.</p>
Test rule requirements	TSCA 4(b) [15 U.S.C. 2603(b)] requires EPA in any test rule to identify the chemical substance or mixture for which testing is required, specify standards for the development of test data, and specify the period during which test results must be submitted.	Proposed TSCA 4(c) is similar to 15 U.S.C. 2603(b), but is applicable to EPA orders as well as rules.

Provision	15 U.S.C. 2601 et seq.	S. 847
Deadlines for initial data submission	No comparable provision.	Proposed TSCA 4(a) requires submission to EPA of the minimum data set for an existing chemical within 18 months of the date that EPA assigns the chemical to a priority class under section 6(a) or 5 years of the date of enactment of the SCA, whichever is earlier. Submission of the minimum data set is required for a new chemical at the time notice is provided to EPA [under revised TSCA section 5(a)] that a new chemical will be manufactured.
Persons required to submit data	TSCA 4(b) [15 U.S.C. 2603(b)] requires manufacturers and processors to conduct tests in response to a rule issued by EPA, but allows EPA to permit such persons to designate one person or a qualified third party to conduct such tests and submit data on their behalf.	Proposed TSCA 4(c) directs EPA to specify in any rule or order persons required to conduct tests and submit data, but allows designation of a single data provider, as is allowed under current law. In the event that a single data provider is designated, all parties remain individually liable for testing requirements
Failure to submit data	No comparable provision.	Proposed TSCA 4(a)(3) and 4(b)(3) authorize EPA to, by order, take any regulatory action authorized under section 6(c) if a manufacturer or processor fails to submit required data or a required chemical sample.
Data exemption	TSCA 4(c) [15 U.S.C. 2603(c)] allows manufacturers and processors to request an exemption, and directs EPA to grant an exemption if data would be duplicative. Provides for reimbursement by the exempted persons to manufacturers and processors who collected and submitted data. EPA is required to order a manufacturer or processor who is exempt to reimburse the entity that submitted data. Such an order is a final agency action for the purpose of judicial review.	Proposed TSCA 4(d) would have the same effect as TSCA, except exemptions could apply to orders as well as rules, and the bill does not provide that the EPA Administrator's order to reimburse is a final agency action for the purpose of judicial review.
Cessation of manufacture or processing	No comparable provision.	Proposed TSCA 4(b)(4) explicitly exempts from requirements any manufacturer or processor who has submitted a declaration of cessation of manufacture or processing of a chemical substance.

Provision	15 U.S.C. 2601 et seq.	S. 847
Contents of minimum data set	No comparable provision.	Proposed TSCA 4(a) directs EPA to include in the minimum data set information on characteristics, toxicological properties, exposure, and use of a chemical substance, information that the EPA anticipates will be necessary for the conduct of a screening-level risk assessment of the chemical. Allows EPA to provide for varied or tiered testing for different chemicals or categories of chemicals.
Prescribed data needs	TSCA 4(b) [15 U.S.C. 2603(b)] authorizes EPA to prescribe data development standards for effects which may present an unreasonable risk of injury to health or the environment and for characteristics of chemical substances and mixtures which may present such a risk, as well as for methodologies including epidemiological studies, serial or hierarchical tests, in vitro tests, and whole animal tests.	Proposed TSCA 4(c) authorizes EPA to prescribe data development standards for health and environmental information, including information pertaining to: any effect that may be considered in a safety standard determination; exposure, including presence in human tissues and fluids; and any characteristic of a chemical that may present an adverse effect. Also authorizes EPA to prescribe biomonitoring studies, in addition to methodologies already permitted under 15 U.S.C. 2603(b).
Petition for standards for development of test data	TSCA 4(g) [15 U.S.C. 2603(g)] authorizes manufacturers to petition EPA to prescribe standards for the development of test data for a new chemical.	This provision would be eliminated.
Alternatives to animal testing	No comparable provision. ^a	Requires that animal tests are consistent with provisions of Proposed TSCA section 30, promoting alternatives to animal testing.
Review and revision of data needs	TSCA 4(b) [15 U.S.C. 2603(b)] requires annual review and revision, if necessary, of standards for the development of data.	Proposed TSCA 4(c)(3)(C) changes the interval between required reviews and revisions, if necessary, from one to 3 years.
Rulemaking process	TSCA 4(b) [15 U.S.C. 2603(b)] directs EPA to issue test rules pursuant to 5 U.S.C. 553 (Administrative Procedure Act, procedures for informal notice and comment rulemaking). In addition, persons must be given an opportunity for oral presentation of data, views, or arguments and to make written submissions; a transcript must be made of oral presentations; and the EPA Administrator must publish findings required by TSCA 4(a)(1)(A) or (B).	Proposed TSCA 4(c) omits TSCA requirements for rulemaking that go beyond the notice and comment requirements of 5 U.S.C. 553. Proposed TSCA 4(b) authorizes EPA to issue orders in lieu of rules.

Provision	15 U.S.C. 2601 et seq.	S. 847
Public notice of receipt of data	TSCA 4(d) [15 U.S.C. 2603(d)] requires that EPA provide public notice of receipt of data and make data available for examination by any person (subject to section 14).	Proposed TSCA 4(e) is similar to 15 U.S.C. 2603(d) in requiring public notice of the receipt of data, but applies also to data submitted in accord with an EPA order, and requires that data be made “available on a publicly accessible Internet site.”
Interagency testing committee (ITC)	TSCA 4(e) [15 U.S.C. 2603(e)] establishes the ITC to advise the EPA Administrator regarding chemicals that should receive priority consideration for promulgation of a test rule [under subsection (a)].	Proposed TSCA 6(a)(5) establishes the Interagency Prioritization and Testing Committee, which is similar to the ITC in composition.
Committee recommendations for testing	TSCA 4(e) [15 U.S.C. 2603(e)] directs the ITC to establish a prioritized list of chemicals for the EPA Administrator to consider testing and to designate up to 50 chemicals on the list as the highest priority. In selecting chemicals, the committee is authorized to consider all relevant factors, including “the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment.” Priority attention is to be given to chemicals “known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects.”	Proposed TSCA 6(a)(5) changes the directive to the interagency committee with respect to the basis for recommendations for issuance of test rules or orders. The committee is directed to make recommendations for issuance of test rules or orders based on “all factors relevant to risk.” The committee also is to make recommendations for prioritization of chemical substances for risk assessment and management using the criteria established for each priority class under proposed TSCA 6(a)(2)(B), 6(a)(3)(B), and 6(a)(4)(B). Recommendations are to be updated annually, if necessary. The EPA Administrator is directed to provide reasonable opportunity to any interested person to file written comments on the recommendations. The Administrator is required to consider any comments received and to make them available to the public.
Prohibition of judicial review for committee recommendations	No comparable provision.	Proposed TSCA 6(a)(5) protects from judicial review recommendations by the Interagency Prioritization and Testing Committee.

Provision	15 U.S.C. 2601 et seq.	S. 847
Required agency actions	TSCA 4(f) [15 U.S.C. 2603(f)] requires the EPA Administrator to respond within 180 days to new information indicating “that there may be a reasonable basis to conclude that a chemical substance or mixture presents or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects.” Requires EPA to “initiate appropriate action under section 5, 6, or 7 to prevent or reduce to a sufficient extent such risk or publish in the <i>Federal Register</i> a finding that such risk is not unreasonable.” A finding that a risk is not unreasonable is a final agency action for purposes of judicial review.	This provision would be eliminated, but proposed TSCA 6(a)(2) directs the Administrator to assign a chemical substance to priority class I if “the chemical substance is, or is degraded and metabolized into, a persistent, bioaccumulative, and toxic substance with the potential for widespread exposure to humans or other organisms.” “As soon as practicable, but not later than 18 months after the date on which a chemical substance is assigned to priority class I,” EPA must impose conditions on its manufacturing, processing, use, distribution in commerce, and disposal that are determined to be necessary to achieve “the greatest practicable reductions in human or environmental exposure” to the chemical substance. Proposed TSCA 6(a)(2)(E) directs EPA to promptly revise the priority I list of chemicals whenever the addition or removal of a chemical substance from the list is warranted.
Requests from other federal agencies	No comparable provision.	Proposed TSCA 4(f) authorizes any federal agency to request that EPA seek information unavailable to that other agency which it has determined would assist it in carrying out its duties or exercising its authority. Requires EPA within 60 days to collect and provide such information to the requesting agency, collect information under TSCA 8, issue a rule or order to develop the data, or publish in the <i>Federal Register</i> the reason for not taking any of these actions.
Certification of data submitted	No comparable provision.	Proposed TSCA 4(g) requires that each submission of information under a rule or order be accompanied by a certification of the accuracy, reliability, and completeness (to the extent reasonably ascertainable) of the information provided. Such certification must be signed by a responsible official of the manufacturer or processor.
<p>a. However, EPA has stated that it “is committed to examining alternative test methods that reduce the number of animals needed for testing, reduce pain and suffering of test animals, and whenever possible, replace animals in testing with validated in vitro (non-animal) test systems. EPA has released guidance on this issue ...” (U.S. EPA, “Fact Sheet on Animal Welfare,” April 2001, EPA 745-F-99-003, http://www.epa.gov/HPV/pubs/general/anfacs.pdf).</p>		

Table 3. Notices in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced

Provision	15 U.S.C. 2601 et seq.	S. 847
Notices concerning new chemicals or uses	TSCA 5(a)(1) [15 U.S.C. 2604(a)(1)] prohibits manufacture of a new chemical and prohibits manufacture or processing of any chemical for a use which is a significant new use unless notice is submitted to EPA 90 days prior to such manufacture or processing.	<p>Proposed TSCA 5(a)(1)-(3) treats new chemicals in a similar manner to current law, but also requires notice prior to processing for a new chemical. For an existing chemical that has met the safety standard, requires notice prior to manufacture or processing for a new use, at new production volume, or in a manner other than specified in the safety determination.</p> <p>No notice is required for an existing chemical for which EPA has not yet made a safety determination, when manufacture or process would be for a new use or at a significantly increased volume, but in such cases, proposed TSCA 5(a)(2) requires submission of a new or updated declaration as required under proposed TSCA 8(a).</p>
New use determination	TSCA 5(a)(2) [15 U.S.C. 2604(a)(2)] directs EPA to designate a significant new use of an existing chemical by promulgating a rule after considering “all relevant factors, including – (A) the projected volume of manufacturing and processing of a chemical substance, (B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance, (C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and (D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.”	Prior to a safety standard determination for an existing chemical, proposed TSCA 5(a) designates a use to be a new use if at the time of enactment of S. 847 that use was not ongoing, or if manufacture or processing of the substance would be at a significantly increased volume. After a safety standard determination has been made for an existing chemical, a new use is any use, production volume, or manner other than those the EPA Administrator specified in the safety standard determination.
Special substance characteristics	No comparable provision.	Proposed TSCA 5(a)(6) directs the EPA Administrator to determine by order or rule that a variant of a chemical substance exhibiting one or more “special substance characteristics” [such as size or reactivity, as defined in proposed TSCA 3(20)] is a new use or a new chemical substance.

Provision	15 U.S.C. 2601 et seq.	S. 847
Notice content	TSCA 5(d) [15 U.S.C. 2604(d)] requires that notices contain the information required by TSCA 8(a)(2)(A)-(D), (F), and (G). [See “Reporting and record keeping” below.]	Proposed TSCA 5(c) requires a notice to include the declaration made under proposed TSCA 8(a)(2), the minimum data set established under TSCA 4(a), and a statement that the chemical will meet the applicable safety standard.
Certification	No comparable provision.	Proposed TSCA 5(e) requires that each submission of information under a rule or order be accompanied by a certification of the accuracy, reliability, and completeness (to the extent reasonably ascertainable) of the information provided. Such certification must be signed by a responsible official of the manufacturer or processor.
Submission of test data with notice	TSCA 5(b) [15 U.S.C. 2604(b)] requires persons who propose to manufacture a new chemical or to manufacture or process a chemical for a significant new use to submit with such notice any test data that are required by rule under TSCA 4(a). If no test data are required under TSCA 4(a), but the chemical has been listed under TSCA 5(b)(4), indicating that the EPA Administrator has determined that it “presents or may present an unreasonable risk,” manufacturers and processors must submit data showing that manufacture, processing, distribution in commerce, use, and disposal (in the case of a new chemical or mixture), or the new use (in the case of a significant new use), “will not present an unreasonable risk of injury to health or the environment.”	At the time a manufacturer or processor notifies EPA that it plans to manufacture or process a chemical substance that is new, proposed TSCA 5(b) requires submission of: any data required for that chemical substance under a section 4(b) test rule or order; the section 8(a) declaration; and the minimum data set established under proposed section 4(a). When providing notice to EPA regarding a new use of a chemical for which the EPA Administrator previously has made the safety determination, manufacturers must provide an update for the minimum data set. With respect to a new use of a chemical which has not been evaluated for safety, manufacturers must submit to EPA a new or updated declaration under proposed TSCA 8(a).
Public availability of data	TSCA 5(b)(3) [15 U.S.C. 2604(b)(3)] directs EPA to make such data publicly available, subject to protections for confidential business information in section 14.	Proposed TSCA 5(b)(2) requires EPA to make data available on a publicly accessible Internet site, subject to proposed TSCA 14.
EPA’s response to notice	No comparable provision, but EPA has 90 days to decide whether the chemical or chemical use may present an unreasonable risk of injury to health or the environment.	Proposed TSCA 5(a)(4) requires EPA to determine within 180 days after receiving notice and data whether it has been established that the chemical substance or mixture meets the safety standard under proposed TSCA section 6(b).

Provision	15 U.S.C. 2601 et seq.	S. 847
Extension of the notice period	TSCA 5(c) [15 U.S.C. 2604(c)] authorizes EPA to extend the period between notice and manufacture for additional periods of up to a total of 90 days “for good cause.”	Authorizes EPA to extend the determination deadline for periods not to exceed one year.
Publication of notice	TSCA 5(d) [15 U.S.C. 2604(d)(1)] requires notice to be available for examination by interested persons, subject to disclosure restrictions at TSCA 14 [15 U.S.C. 2613]. [See “Disclosure of data” section below.] Directs EPA to publish a notice identifying the chemical, listing the intended uses, and describing the nature of tests performed and data that were developed pursuant to a rule.	Proposed TSCA 5(b)(3)-(4) is similar to current law [TSCA 5(d)(1)], but specifies that EPA must make notices available on a publicly accessible Internet site and requires disclosure of the availability of the minimum data set. In addition, requires EPA to make available on the internet monthly a list of chemical substances for which notice has been received. [Also, see “Disclosure of data” section below.]
“Manufacture” and “process”	TSCA 5(i) [15 U.S.C. 2604(i)] defines “manufacture” and “process” as used in TSCA section 5 to mean manufacturing and processing for commercial purposes.	Proposed TSCA 5(f) provides the same definition as current law.

Provision	15 U.S.C. 2601 et seq.	S. 847
Safety determination for new chemical or new use	No specific provision, but TSCA requires an EPA finding that manufacture, processing, distribution in commerce, use, and disposal of a chemical “may present an unreasonable risk of injury to health or the environment,” when the agency issues a test rule under TSCA 4(a). Similarly, EPA must find that a chemical substance “presents an unreasonable risk” before EPA can issue a rule to ensure that risks are adequately regulated.	<p>Proposed TSCA 5(a) prohibits manufacture and processing of a chemical for which notice is required unless the EPA Administrator finds either: 1) that the manufacturers and processors have established that the chemical meets the safety standard under proposed TSCA 6(b), or 2) that the new chemical substance or its metabolite or degradation product is not, and is not expected to be—manufactured in a volume of more than one million pounds annually or released into the environment in a volume of more than 100,000 pounds annually; a known, probable, or suspected reproductive, developmental, neurological, or immunological toxicant, carcinogen, mutagen, or endocrine disruptor, or has other toxicological properties of concern; persistent and bioaccumulative; found in human cord blood, or otherwise found in human blood, fluids, or tissue, unless it is naturally present at the level commonly found in that medium; or found in food, drinking water, ambient or indoor air, residential soil, or house dust, unless it is naturally present at the level commonly found in that medium.</p> <p>With respect to a new use of a chemical for which the EPA Administrator previously has made the safety determination, manufacturers must provide evidence that permits the EPA Administrator to amend the safety determination.</p> <p>With respect to a new use of a chemical for which the EPA Administrator has not yet made a safety standard determination, manufacturers must provide the declaration described in proposed 8(a).</p>

Provision	15 U.S.C. 2601 et seq.	S. 847
Protection against unreasonable risks	TSCA 5(f) [15 U.S.C. 2604(f)] directs EPA to control an unreasonable risk posed by a new chemical or a significant new use of a chemical in the interim between the expiration of the notification period and the effective date of a rule that is being developed to control such risk. EPA is directed to issue a proposed rule or an order. If the EPA Administrator issues a proposed rule, it is effective on the date it is issued.	This provision would be eliminated. S. 847 requires risk management prior to production and distribution.
Regulation pending development of information	TSCA 5(e) [15 U.S.C. 2604(e)] authorizes the EPA Administrator to issue a proposed order to prohibit or limit manufacture, processing, distribution in commerce, use, or disposal of a new chemical or significant new use in the event that the EPA Administrator determines that: the information available “is insufficient to permit a reasoned evaluation of the health and environmental effects” of the chemical; and either the chemical may present an unreasonable risk, or it will be produced in substantial quantities and “may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance.” If EPA makes such a determination but no order is issued or objections are filed to the order, then EPA must apply to the District Court to prohibit or limit activities with respect to the chemical, unless EPA finds on the basis of the objections that the determination cannot be made.	This provision would be eliminated. Proposed TSCA 5(a) requires submission of data and a safety determination prior to production and distribution of a new chemical or of an existing chemical for a new use.
Statement of reasons for not taking action	If EPA does not take action with respect to a chemical covered by a test rule [under TSCA 4(a)], a significant new use rule [under TSCA 5(a)(1)(B)], or listed under TSCA 5(b)(4), then TSCA 5(g) directs the EPA Administrator to publish a statement of reasons for not taking action.	This provision would be eliminated.

Provision	15 U.S.C. 2601 et seq.	S. 847
Exemptions from notice requirements		
<i>General authority</i>	TSCA 5(h)(4) [15 U.S.C. 2604(h)(4)] authorizes EPA upon application and by rule to exempt a manufacturer of a new chemical substance from notification and data requirements, if the EPA Administrator determines it will not “present an unreasonable risk of injury to health or the environment.” Any such rule must be promulgated in accord with TSCA section 6(c)(2) and (3) (see below).	This provision would be eliminated.
<i>Intermediate production chemicals</i>	TSCA 5(h)(5) [15 U.S.C. 2604(h)(5)] authorizes exemptions upon application for production-related (temporary, so-called “intermediate”) chemicals when no human or environmental exposure will occur.	Proposed TSCA 5(d)(4) is the same as current law.
<i>Test marketing</i>	TSCA 5(h)(1) [15 U.S.C. 2604(h)(1)] authorizes EPA to exempt any person from notification or data requirements so as to permit manufacture or processing for test marketing purposes, if the person applies for such exemption and demonstrates the chemical will not present an “unreasonable risk.”	Proposed TSCA 5(d)(1) is similar to current law but a person must show that it “will not endanger human health or the environment.” “Test marketing” is defined in proposed TSCA 5(f) to exclude provision of a chemical or article containing a chemical to an end consumer.
<i>Equivalent chemicals and duplicative data</i>	TSCA 5(h)(2) [15 U.S.C. 2604(h)(2)] allows manufacturers and processors of new chemicals or chemicals with significant new uses that are on the priority list but are not subject to a TSCA 4(b) data submission requirement to request from EPA an exemption from the TSCA 5(b) requirement that they submit data showing that manufacture, processing, distribution in commerce, use, and disposal of the chemical substance, or the significant new use, will not present an unreasonable risk. Directs EPA to grant such exemption if the chemical is equivalent to a substance for which data has been submitted and data would be duplicative. Provides for reimbursement by the exempted persons to manufacturers and processors who collected and submitted data. EPA is required to order a manufacturer or processor who is exempt to reimburse the entity that submitted data. Such an order is a final agency action for the purpose of judicial review.	Proposed TSCA 5(d)(2) allows manufacturers and processors of new chemicals or chemicals with new uses to request, and EPA to grant, full or partial exemption from data submission requirements if the chemical is equivalent to a chemical substance for which data have been submitted and submission would be duplicative of data previously submitted to EPA. Provides for reimbursement by the exempted persons to those who collected and submitted data in the same manner as current law.

Provision	15 U.S.C. 2601 et seq.	S. 847
<i>Small quantities</i>	TSCA 5(h)(3) [15 U.S.C. 2604(h)(3)] exempts from notification and data requirements manufacturing and processing of small quantities for purposes of scientific experimentation or chemical research on, or analysis of, such substances or another substance, including product development.	Proposed TSCA 5(d)(3) is the same as current law.
<i>EPA response to exemption requests</i>	TSCA 5(h)(6) [15 U.S.C. 2604(h)(6)] requires EPA to publish notices of, and request comments on, requests for exemptions that the agency receives. EPA must issue an approval or disapproval within 45 days.	Proposed TSCA 5(d)(5) is the same as current law.

Provision	15 U.S.C. 2601 et seq.	S. 847
Chemicals of concern list (priority list)	<p>TSCA 5(b)(4) [15 U.S.C. 2604(b)(4)] authorizes EPA to “by rule, compile and keep current a list of chemical substances with respect to which the EPA Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.” In listing decisions the EPA Administrator is directed to consider “all relevant factors, including – (I) the effects of the chemical substance to health and the magnitude of human exposure to such substance; and (II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.” Any rule listing a chemical must identify “uses that the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.”</p> <p>Any rulemaking under this provision must be promulgated pursuant to the procedures specified in the Administrative Procedure Act (5 U.S.C. 553) providing for notice and public comment, and must provide opportunity for oral and written presentation of data, views, or arguments. In addition, a transcript must be kept of any oral presentation and the EPA Administrator must make and publish with the rule the finding that an activity related to the chemical “presents or may present an unreasonable risk of injury to health or the environment.”</p>	<p>This provision would be eliminated, but proposed TSCA 6(a) directs EPA by order to establish a list that “contains the names of the chemical substances that ... warrant placement within 1 of 3 priority classes ... and identifies the priority class to which each listed chemical substance or category of chemical substance has been assigned by the EPA Administrator.”</p> <p>EPA must give due consideration in listing decisions to recommendations provided by the Interagency Prioritization and Testing Committee.</p> <p>Proposed TSCA 6(a)(6) prohibits judicial review of EPA’s decisions about listing, including any EPA response to a petition to list a particular chemical substance.</p>

Provision	15 U.S.C. 2601 et seq.	S. 847
Priority class 1	No comparable provision.	<p>Priority class 1 chemicals are those “that the Administrator determines require immediate risk management.” A chemical must be assigned to priority class 1 if it “is, or is degraded and metabolized into, a persistent, bioaccumulative, and toxic substance with the potential for widespread exposure to humans or other organisms.” Proposed TSCA 6(a)(2)(C) requires that at least 20 but no more than 30 chemicals be assigned to priority class 1 within one year of enactment of S. 847. Proposed TSCA 6(a)(2)(E) directs the EPA Administrator to revise the list whenever the EPA Administrator determines that addition or removal of a chemical substance is warranted, but a substance only may be removed “if the Administrator finds that such substance meets the safety standard under subsection (b).”</p>
Priority class 2	No comparable provision.	<p>Priority class 2 chemicals are those “that the Administrator determines require safety standard determinations ... based on any more-than-theoretical concern, that there is uncertainty as to whether a chemical substance would satisfy the safety standard in a determination made under “ proposed TSCA 6(b). The timing of additions to the priority class 2 list of chemicals should be “expeditious” but “shall not exceed the rate at which the Administrator reasonably anticipates completing safety determinations under subsection (b).” The EPA Administrator is required to first assign to priority class 2 those chemicals “that present the greater risks to human health or the environment.” Proposed TSCA 6(a)(3)(C) prohibits removal of a chemical from the list until the EPA Administrator has made a safety determination for that chemical.</p>

Provision	15 U.S.C. 2601 et seq.	S. 847
Priority class 3	No comparable provision.	Priority class 3 chemicals are those “that the Administrator determines require no immediate action.” A chemical is to be assigned to this list if it has intrinsic properties that pose no risk of adverse effects to human health or the environment under existing, proposed, or anticipated levels of exposure or production or patterns of use. The EPA Administrator is directed to “promptly revise the list under paragraph (1) whenever the Administrator determines that the addition or removal of a chemical substance from priority class 3 is warranted.”

Table 4. Restrictions in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced

Provision	15 U.S.C. 2601 et seq.	S. 847
Regulation	<p>TSCA 6(a) [15 U.S.C. 2605(a)] directs EPA by rule to apply one or more requirements “to the extent necessary to protect adequately against” an “unreasonable risk” “using the least burdensome requirements,” if EPA finds that “there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture ... presents or will present an unreasonable risk of injury to health or the environment.” Specifies various regulatory options. Authorizes regulations to: prohibit or limit the amount of substance manufactured, processed, or distributed in commerce, generally or for a specific use; require labeling, recordkeeping, provision of notice to distributors and to the public of unreasonable risk of injury, or replacement or repurchase of a substance; and specify methods of disposal.</p> <p>TSCA 6(c) [15 U.S.C. 2605(c)] specifies procedures for rulemaking that allow for informal hearings and requires EPA to publish a statement describing the health and environmental effects, level of exposure, benefits of the substance, and “reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.” Requires that EPA’s decisions be based on the rulemaking record. Directs EPA to promulgate needed rules under other environmental laws, unless it is in the public interest to issue rules under TSCA.</p>	<p>S. 847 does not require rulemaking, but section 7 would authorize EPA to specify allowed uses of any substance that meets the safety standard and to impose conditions on its manufacture, processing, use, distribution in commerce, or disposal to “ensure the safety standard is met.” Many of the conditions that EPA is authorized to impose are the same as the regulatory options listed in current law, but S. 847 also would authorize EPA to impose a requirement that the manufacturers and processors of a chemical substance or mixture or article containing it develop a risk reduction management plan to achieve a risk reduction specified by the EPA Administrator. The bill, as introduced, does not authorize the option of requiring manufacturers or processors to give notice of unreasonable risk of injury to distributors or the public or to replace or repurchase a substance.</p> <p>In addition, S. 847 differs from current law in that the bill does not authorize limiting conditions to specified geographic areas, nor does it prohibit requiring a person to take an action that would be in violation of a law or requirement of a state or political subdivision. [Proposed TSCA 6(b) and (c)]</p>

Provision	15 U.S.C. 2601 et seq.	S. 847
Safety standard	No comparable provision, but in general terms, the standard embedded in TSCA is that EPA should protect against “unreasonable risk,” a standard that appears to require risk assessment but allows balancing of risks and benefits.	Proposed TSCA 6(b)(1)(C) directs the EPA Administrator to base a determination of whether a chemical meets its safety standard “solely on considerations of human health and the environment, including the health of vulnerable human populations.” To the extent practicable, the EPA Administrator is required to incorporate “any available scientific information relating to the effect of cumulative exposure ... on human health and the environment.” For a chemical to meet the safety standard, the EPA Administrator must find that “there is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance.”
General process for safety determinations	No comparable provision.	<p>Proposed TSCA 6(b)(1) requires that EPA produce a risk assessment addressing health and environmental impacts in support of any determination that a manufacturer or processor of a chemical substance has met the applicable safety standard. Risk assessments must be transparent and understandable to the public and to risk managers.</p> <p>No risk assessment is required when EPA determines that the safety standard has not been met, and such determination is not subject to judicial review.</p> <p>Proposed TSCA 6(b)(1) also establishes that manufacturers and processors of a chemical substance are responsible for providing sufficient information for the EPA Administrator to determine whether the substance meets the applicable safety standard, and that the EPA Administrator has the responsibility of determining within 180 days of data submission whether the manufacturers and processors have met the applicable safety standard.</p>

Provision	15 U.S.C. 2601 et seq.	S. 847
Scientific standards for data assessment	No comparable provision.	Proposed TSCA 6(b)(1)(C) requires the EPA Administrator to “use the best available science” in conducting a risk assessment considering the recommendations of the National Academy of Sciences in the report entitled “Science and Decisions.” Every 5 years, the EPA Administrator is required to review the methodology and may revise it “to reflect new scientific developments or understandings.”
Safety of chemicals for export	No comparable provision.	Proposed TSCA directs EPA to consider risks that a chemical manufactured in whole or in part for export may pose in the United States during production and distribution in commerce, including in imported products containing the substance.
Safety determinations for existing chemicals		
<i>EPA’s determination</i>	No comparable provision.	Within 1 year after receipt of a data submission, EPA is directed to determine, by order, whether the manufacturers and processors of the substance have established that the substance meets the safety standard.
<i>Failure to submit data</i>	No comparable provision.	If data are not submitted, proposed TSCA 6(b)(2) authorizes EPA to take any action authorized under subsection (c).
<i>Failure by EPA to meet required deadline</i>	No comparable provision.	If EPA fails to meet the deadline for a safety determination, proposed TSCA 6(b)(2) provides that manufacturers and processors are required to provide to EPA, the public, their employees, and customers written notice that a determination by EPA of the safety of the chemical is pending.
<i>Resubmission</i>	No comparable provision.	Proposed TSCA 6(b)(2) provides that within 30 months of assignment of a chemical to priority class 2 under proposed TSCA 6(a), manufacturers must submit updated information for any previously submitted minimum dataset. In addition, requires that at least every 15 years, manufacturers and processors of each chemical substance submit an updated minimum dataset and indicate whether the substance and specified uses meet the safety standard.

Provision	15 U.S.C. 2601 et seq.	S. 847
Redetermination	No comparable provision.	EPA may initiate a redetermination of whether a chemical meets the safety standard if new information raises a question in that regard, on the receipt of a renewal submission, or 15 years following the previous determination.
Petition for redetermination	No comparable provision.	Authorizes any person to petition the EPA Administrator for a redetermination. The Administrator must decide whether to make the requested redetermination and publish the decision and its basis in the <i>Federal Register</i> within 180 days.
Restrictions on substances that do not meet the safety standard	No comparable provision, but TSCA 6(a) directs EPA by rule to apply one or more requirements (such as labeling or banning particular uses) “to the extent necessary to protect adequately against” an “unreasonable risk” “using the least burdensome requirements,” if the EPA Administrator finds that “there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment.”	Proposed TSCA 6(b)(3) prohibits manufacture, processing, and distribution in commerce of a chemical substance, mixture, or article if EPA makes a safety determination and does not determine that a substance meets the safety standard. Such prohibition is effective immediately for a new chemical or after one year for any other chemical.
Use restrictions for substances meeting the safety standard	No comparable provision.	Proposed TSCA 6(b) prohibits manufacture, processing, and distribution in commerce of a chemical substance, mixture, or article for any use not specified in the safety determination if EPA determines that the chemical and its specified uses meet the safety standard.
Effective date of Section 6 rules	TSCA 6(d) [15 U.S.C. 2605(d)] directs EPA to make such rules effective “as soon as feasible,” and allows EPA to make a proposed rule effective upon publication until the effective date of the final rule if there is an unreasonable risk of serious or widespread injury to health or the environment and a court has granted relief under section 7.	Proposed TSCA 6(i) directs EPA to specify a date on which a rule or order shall take effect and that such date should be “as soon as feasible.”

Provision	15 U.S.C. 2601 et seq.	S. 847
Quality control	TSCA 6(b) [15 U.S.C. 2605(b)] authorizes EPA to review and regulate a manufacturer's or processor's quality control procedures if there is "a reasonable basis to conclude" that the manner of manufacturing or processing "unintentionally causes a chemical ... to present or which will cause it to present an unreasonable risk of injury to health or the environment." EPA also is authorized to order the manufacturer or processor to provide notice to its customers of such risk and to replace or repurchase the substance as is necessary to adequately protect health or the environment. Requires any determination that a chemical presents an unreasonable risk to be made on the record after opportunity for hearing.	Proposed TSCA 6(d) is similar to current law but applies when there is "a reasonable basis to conclude" that the manner of manufacturing or processing "may present a substantial endangerment to human health or the environment." Does not require such determination to be made on the record after opportunity for hearing.
Resale of used articles	No comparable provision.	Proposed TSCA 6(e)(3) provides that restrictions established under sections 4(a)(3), 4(b)(3), 6(b)(2)(A)(iv), 6(b)(3), 8(b)(6), or 8(c)(3) do not apply to resale of an article subject to a restriction under proposed TSCA 6(b) if the article has previously been used.
Delay of effective date of restrictions	No comparable provision.	Proposed TSCA 6(e)(4) authorizes EPA to order delay in the effective date of a restriction for 3 years for retail sales to an end consumer of a chemical substance, mixture, or article subject to a restriction under sections 4(a)(3), 4(b)(3), 6(b)(2)(A)(iv), 6(b)(3), 8(b)(6), 8(c)(3), or 29, if necessary and appropriate, if it "will not present a substantial endangerment to human health or the environment." EPA authority does not extend to any retailer who has failed to comply with an order requesting information under proposed TSCA section 8.

Provision	15 U.S.C. 2601 et seq.	S. 847
Exemptions from prohibitions and other restrictions	No comparable provision.	Proposed TSCA 6(e) authorizes EPA to grant, by order, exemptions (and renewals of exemptions) to restrictions proposed to be established under sections 4(a)(3), 4(b)(3), 6(b)(2)(A)(iv), 6(b)(3), 8(b)(6), 8(c)(3), and 29 for particular uses. Exemptions and renewals may be granted for up to 5 years, if manufacturers and processors “have established by clear and convincing evidence that the uses to be exempted meet the exemption criteria.” Those criteria are: 1) that the exemption is in the paramount interest of national security; 2) lack of availability would cause significant disruption in the national economy; or 3) the use is a critical or essential use for which there is no safer feasible alternative, or the specified use compared to available alternatives provides a net benefit to human health, the environment, or public safety. The manufacturer or processor must notify customers and the public of any exemptions granted. EPA is directed to impose any condition on a granted exemption that is necessary to ensure the protection of human health and the environment.
Certification of the quality of submitted information	No comparable provision.	Proposed TSCA 6(h) requires that each submission of information under a rule or order be accompanied by a certification of the accuracy, reliability, and completeness (to the extent reasonably ascertainable) of the information provided. Such certification must be signed by a responsible official of the manufacturer or processor.
Mercury	15 U.S.C. 2605(f) prohibits federal agencies from conveying, selling, or distributing elemental mercury to any federal agency, state or local government, or private entity, except to facilitate storage at a federal agency.	Proposed TSCA 6(g) is the same as current law.

Provision	15 U.S.C. 2601 et seq.	S. 847
Polychlorinated biphenyls (PCBs)	TSCA 6(e) [15 U.S.C. 2605(e)] directs EPA to prescribe methods of disposal for PCBs and to require PCBs to be marked with clear and adequate warnings and instructions regarding processing, distribution in commerce, use, or disposal. Prohibits use of any PCB other than “in a totally enclosed manner,” unless EPA finds that such activity “will not present an unreasonable risk of injury to health or the environment.” Prohibits manufacture, processing, and distribution in commerce. Authorizes any person to petition for an exemption and authorizes EPA to grant such exemption if EPA finds that an unreasonable risk would not result, and “good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk ... and which may be substituted for such [PCB].” Requires use of rulemaking procedure in TSCA 6(c).	Proposed TSCA 6(f) is similar to existing law but authorizes the EPA Administrator to act by order or rule, and to grant exemptions from the general prohibitions on manufacturing, processing, distribution in commerce, or use when such activities “will not present a substantial endangerment to health or the environment” rather than when activities “will not present an unreasonable risk.”
Imminent hazards <i>Relief</i>	Authorizes an appropriate district court to grant relief necessary to protect health or the environment from unreasonable risk.	Similar to current law, but authorizes district court to grant relief necessary to protect health or the environment from “the risk associated with the activity involved in the civil action.”

Provision	15 U.S.C. 2601 et seq.	S. 847
<i>Civil actions</i>	<p>TSCA 7(a) [15 U.S.C. 2606(a)] authorizes EPA to begin a civil action: for seizure of “an imminently hazardous” chemical substance, mixture, or article; for relief against any person who manufactures, processes, distributes in commerce, or uses, or disposes of such chemical or article; or for both seizure and relief. Requires EPA to commence such civil action if the agency has not made a rule under TSCA 6(a) effective immediately. Requires that EPA “where appropriate, concurrently with the filing of an action ... initiate a proceeding for the promulgation of a rule” under TSCA 6(a). Defines “imminently hazardous chemical substance or mixture” to mean a chemical that “presents an imminent and unreasonable risk of serious or widespread injury to health or the environment.”</p>	<p>Similar to current law, but authorizes EPA civil action against a person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance or mixture, or any article containing a chemical substance or mixture, or who contributes to any of those activities, when a chemical, mixture, or article “may present an imminent and substantial endangerment to health or the environment, as determined by the Administrator.” Does not require EPA to commence action if the agency has not made a rule effective immediately concerning the chemical. Also authorizes EPA to issue orders to protect health or the environment from a chemical substance or mixture or article containing such substance or mixture that may present an imminent and substantial endangerment to health or the environment.</p> <p>Would eliminate authority concurrently to initiate a proceeding for the promulgation of a rule under TSCA 6(a) [15 U.S.C. 2605(a)]. Also would eliminate the definition for “imminently hazardous chemical substance or mixture.”</p>

Table 5. Reporting Requirements in Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced

Provision	15 U.S.C. 2601 et seq.	S. 847
EPA authority to require reporting and record keeping	TSCA 8(a) [15 U.S.C. 2607(a)] authorizes EPA, to the extent necessary for the effective enforcement of the law, to promulgate rules requiring maintenance of records and submission of reports to EPA by persons who manufacture or process or who propose to manufacture or process a chemical substance. Prohibits a rule requiring maintenance of records or submission of reports with respect to changes in the proportions of the components of a mixture unless necessary for effective enforcement.	Proposed TSCA 8(b) authorizes EPA by rule or order to require any person who manufactures, processes, distributes in commerce, uses, or disposes of a chemical substance to maintain records of and report any information that would assist the EPA Administrator in administering TSCA.
Declaration	No comparable provision	Proposed TSCA 8(a) requires each manufacturer and processor of a chemical substance to submit a declaration of current manufacturing or processing for each substance, mixture, or article manufactured or processed. Each declaration must be accompanied by certification of its accuracy, reliability, and comprehensiveness.
Failure to submit declaration	No comparable provision.	EPA may by order prohibit manufacture, processing, or distribution of any substance if a manufacturer or processor violates EPA requirements for submitting or updating a declaration.

Provision	15 U.S.C. 2601 et seq.	S. 847
Information required to be submitted	TSCA 8(a) authorizes collection of information including: trade name or common name, chemical identity, categories of use, amount of each chemical manufactured or processed, byproducts resulting from such manufacture or processing, "all existing data concerning the environmental and health effects," number of individuals exposed, and, in the initial report, the manner of disposal.	<p>Proposed TSCA 8(a) requires the declaration to state: the chemical identity and substance characteristics; name and location of each facility where the substance is manufactured or processed or from which it is distributed; a list and copies of health and safety studies that are reasonably ascertainable; and all other information not previously submitted to EPA regarding the physical, chemical, and toxicological properties of the substance, its annual production volume and known uses, exposure and fate information, and the name and location of each facility to which the substance is sent for processing, distribution, or use. Or, the declaration may say that all production, importation, processing, and export of a substance has ceased or will cease within 180 days.</p> <p>Declarations must be updated and submitted at least every 3 years, and immediately when new information becomes available regarding a physical, chemical, or toxicological property or use of, or exposure to, the substance.</p>
Inventory	TSCA 8(b) [15 U.S.C. 2607(b)] directs EPA to compile, keep current, and publish an inventory of each chemical manufactured or processed in the United States. New chemicals are to be listed when manufacture or processing begins. The list should exclude chemicals produced in small quantities for purposes of scientific experimentation, analysis, or research. Authorizes EPA to list chemicals by category rather than individually.	Proposed TSCA 8(c) is the same as TSCA 8(b), except that it omits the authority in current law to list chemicals by category rather than individually.

Provision	15 U.S.C. 2601 et seq.	S. 847
Small quantities for research and development	TSCA 8(a)(3) [15 U.S.C. 2607(a)(3)] explicitly authorizes EPA to require reporting from small manufacturers and processors of chemical substances or mixtures subject to a rule proposed or promulgated under TSCA 4, 5(b)(4), or 6 or an order under TSCA 5(e) or with respect to which relief has been granted under TSCA 5 or 6. Reporting also may be required once under TSCA 8(b) for the original inventory (see above) from processors and manufacturers who are small (as determined by the EPA Administrator after consultation with the Small Business Administration). TSCA 8(b) [15 U.S.C. 2607(b)] directs EPA to limit record keeping and reporting requirements for those who manufacture or process a chemical in small quantities solely for purposes of scientific experimentation or analysis of a chemical substance.	Proposed TSCA 8(b)(2) authorizes EPA to define by rule manufacture, processing, distribution in commerce, use, or disposal of a chemical substance in small quantities solely for purposes of research, and to issue a rule or order under this subsection only if EPA determines maintenance of records or submission of reports is necessary for effective enforcement of the law.
Public access	No comparable provision.	Proposed TSCA 8(d) directs EPA to establish an electronic database of information relating to the toxicity and use of and exposure to chemical substances. It is required to include descriptions of “all significant decisions made by the Administrator” and significant information submitted under TSCA Title I.
Records of significant adverse reactions	TSCA 8(c) [15 U.S.C. 2607(c)] requires all manufacturers and processors to keep records of all reports of significant adverse reactions to health or the environment alleged to have resulted from exposure to a chemical substance or mixture.	Proposed TSCA 8(e) is similar to TSCA but does not apply to mixtures. For chemical substances, it also requires submission of such records to EPA.
Information from other federal agencies	No comparable provision.	Proposed TSCA 8(f) requires each federal agency and institution to submit to EPA a synopsis of the data and records in its control that may be useful to EPA in carrying out TSCA Title I. Such synopsis shall be updated and resubmitted at least once every 3 years. On request by the EPA Administrator, federal agencies are directed to submit information relating to hazard, use, exposure, or risk of a chemical substance (or mixture or article containing that chemical substance).

Provision	15 U.S.C. 2601 et seq.	S. 847
Health and safety studies	TSCA 8(d) [15 U.S.C. 2607(d)] directs EPA to require manufacturers, processors, and distributors to submit lists and copies of health and safety studies for each chemical manufactured or processed.	Requires submission of such studies as part of the declaration under proposed TSCA 8(a).
Substantial risk notice	TSCA 8(e) [15 U.S.C. 2607(e)] requires manufacturers, processors, and distributors who obtain information “which reasonably supports the conclusion” that a chemical substance or mixture “presents a substantial risk of injury to health or the environment” to inform EPA.	Proposed TSCA 8(g) is the same as current TSCA 8(e).
Certification	No comparable provision.	Proposed TSCA 8(h) requires that each submission of information under a rule or order be accompanied by a certification of the accuracy, reliability, and completeness (to the extent reasonably ascertainable) of the information provided. Such certification must be signed by a responsible official of the manufacturer or processor.
“Manufacture” and “process”	TSCA 8(f) [15 U.S.C. 2607(f)] defines “manufacture” and “process” to mean manufacture or process for commercial purposes.	Proposed TSCA 8(i) is the same as current TSCA 8(f).

Table 6. Other Selected Provisions of TSCA (15 U.S.C. 2601 et seq.) and the Safe Chemicals Act (S. 847), as Introduced

Provision	15 U.S.C. 2601 et seq.	S. 847
Action under laws administered by other federal agencies	If EPA has a reasonable basis to conclude that activities with respect to a chemical substance or mixture present or will present an unreasonable risk, and EPA determines that such risk may be prevented or reduced to a sufficient extent by action taken under a federal law not administered by EPA, then TSCA 9(a) [15 U.S.C. 2608(a)] directs EPA to submit to the agency which administers such law a report describing the risk and activities that present such risks. The EPA report must request that the other federal agency 1) tell EPA whether the risk may be prevented or reduced under the law the agency administers, and 2) issue an order declaring whether the activities present a risk. If EPA makes a report and the other agency either 1) issues an order declaring that the activities do not present the risk, or 2) initiates action to protect against such risk, then EPA may not take regulatory action under TSCA 6 or 7.	Proposed TSCA 9(a) is similar to current law, but does not apply to mixtures and the criterion for EPA action differs. If the EPA Administrator determines “that the manufacture, processing, distribution in commerce, use, or disposal of a chemical ... does not meet a safety standard ... or requires conditions or restrictions” to do so, and “that action may be taken under a Federal law not administered by the Administrator” then EPA must submit a report to the other agency describing the activities that prevent the chemical from meeting the safety standard or restrictions or conditions required to meet the safety standard. The report must request that the other agency 1) determine whether action may be taken under a Federal law administered by the agency, and if so, 2) initiate such action and provide a timetable for action, and 3) respond to EPA’s report. If the other agency initiates civil action under Federal law within 90 days or a shorter timeframe specified in the report, EPA may not take action under proposed TSCA with respect to the civil action except under TSCA 7. If the other agency determines that action cannot be taken under its authorities; does not initiate action or complete action within the timeframe provided; or fails to respond, then EPA may, by order, initiate action to ensure compliance with a safety standard.
Occupational safety and health	TSCA 9(c) states that any EPA exercise of authority under TSCA is deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.	Same as current law. In addition, S. 847 directs EPA to ensure that any EPA actions to address workplace exposures “are consistent with the industrial hygiene hierarchy of controls.”
Coordination	TSCA 9(d) directs EPA to consult and coordinate with appropriate federal agency heads to achieve “maximum enforcement” “... while imposing the least burdens of duplicative requirements” on those being regulated.	Strikes the requirement that coordination for the purpose of enforcement should impose the least burdens of duplicative requirements.

Provision	15 U.S.C. 2601 et seq.	S. 847
Inspections	TSCA 11 [15 U.S.C. 2610] authorizes EPA to inspect premises in which chemicals are manufactured, processed, stored, or held before or after distribution in commerce and any conveyance used to transport chemicals in commerce. Limits inspections by requiring presentation of appropriate credentials and written notice to the person in charge of the premises or conveyance to be inspected on each occasion of inspection. Requires inspections to begin and end with reasonable promptness and to “be conducted at reasonable times, within reasonable limits, and in a reasonable manner.” Prohibits inspection of financial, sales, pricing, personnel, or research data, unless they are described specifically in the required written notice.	Proposed TSCA 11(a) and (b) are similar to current TSCA 11 but also apply to premises and conveyances handling articles subject to TSCA. Inspections are not limited by requiring presentation of credentials or provision of written notice. Authorizes EPA to inspect any place where records relating to compliance with the law are held and to inspect and obtain samples of any chemicals, containers, or labeling. Does not prohibit inspection of any data.
Subpoenas and warrants	TSCA 11(c) [15 U.S.C. 2610(c)] authorizes EPA to require by subpoena attendance and testimony of witnesses, production of reports, documents, answers to questions, and other information. Authorizes district courts to order compliance in the event of contumacy, failure, or refusal to obey.	Proposed TSCA 11(c) authorizes EPA to require attendance, testimony, and production of documents, items, answers to questions and other information deemed necessary. In the event that “there is reason to believe that the provisions” of the law have been violated, proposed TSCA 11(d) empowers EPA to obtain and to execute warrants authorizing entry, inspection, and copying of records, or seizures of any chemical in violation.
Exports		
<i>Exclusion from requirements</i>	TSCA 12(a) [15 U.S.C. 2611(a)] excludes chemical products manufactured for export (other than elemental mercury) from TSCA requirements except for reporting and record keeping requirements in Section 8. This exclusion applies as long as the products are labeled for export only and their manufacture, processing, and distribution do not pose an unreasonable risk within the United States. EPA may require testing to allow assessment of the risk within the United States.	Proposed TSCA 12 would eliminate the current exclusion from requirements for chemicals manufactured, processed, or distributed in commerce solely for the purpose of export.
<i>Mercury</i>	TSCA 12(c) [15 U.S.C. 2611(c)] prohibits the export of elemental mercury (but not of coal containing mercury). Authorizes exemptions from this prohibition for essential uses.	Same as current law.

Provision	15 U.S.C. 2601 et seq.	S. 847
<i>Notice of export</i>	TSCA 12(b) [15 U.S.C. 2611(b)] requires anyone who exports or intends to export a substance that is subject to a test rule or order under section 4 or a proposed or final rule under section 5 or 6, or for which action is pending or relief has been granted under section 5 or 7, to notify EPA of such exportation or intent, and EPA must then notify the countries that will be receiving the substance that data are available or that restrictions are in place in the United States for such substance.	Proposed TSCA 12(a) is similar to current TSCA 12(b), but excludes from requirements those who “intend” to export, and applies only to exports of chemicals subject to data submission requirements under proposed TSCA 5 or 6(b), or for which action has been taken under TSCA 6 or 7. Also, S. 847 allows exporters 30 days from the date of export for providing notice to EPA, and specifies that EPA must provide notice to countries “promptly thereafter.” Requires exporters to notify EPA, and EPA to notify receiving countries, of any change in the status of a chemical. EPA also must notify receiving countries that it has received new data or if there is any change in risk management action taken under section 6 or 7. Requires EPA to maintain copies of current notices provided to other governments and to make them available to the public electronically.
Imports	TSCA 13 [15 U.S.C. 2612] directs the Secretary of the Treasury to refuse entry into the United States of chemicals that fail to comply with a rule under TSCA or that are in violation of TSCA.	Proposed TSCA 13 is similar to current law but transfers authority to the Secretary of the Department of Homeland Security. In addition, a new paragraph (3) in proposed TSCA 13(a) explicitly subjects to TSCA requirements chemical substances and mixtures imported as part of an article, except “as the Administrator may provide by rule under this Act, or as the Secretary of Homeland Security may provide by rule.”

Provision	15 U.S.C. 2601 et seq.	S. 847
Disclosure of data	<p>TSCA 14 [15 U.S.C. 2613] provides broad protection of proprietary confidential information about chemicals in commerce. Disclosure by EPA employees of such information generally is not permitted, except to other federal employees or when relevant in any proceeding under TSCA. Disclosure of information is required when “necessary to protect health or the environment against an unreasonable risk of injury to health or the environment.”</p> <p>Manufacturers, processors, or distributors in commerce may designate data that they believe is entitled to confidential treatment. If EPA proposes to release such data the EPA Administrator must notify the manufacturer, processor, or distributor who designated the data.</p>	<p>Proposed TSCA 14 requires conformance to the standards of the Freedom of Information Act (FOIA). Like current law, S. 847 prohibits disclosure of proprietary confidential information by EPA employees except to other federal agencies and EPA contractors, but it specifically directs EPA to disclose information upon request to a state, tribal, or municipal government for the purpose of administration or enforcement of a law if an agreement ensures that the recipient government will take appropriate steps to maintain the confidentiality of the information in accordance with proposed TSCA 14 and 40 CFR 350.19, which directs EPA to provide confidential information to states if EPA receives a written request from a governor and the state agrees to safeguard the information with procedures equivalent to those used by EPA and the governor agrees to disclose the information only to employees. Directs EPA to release information if it is necessary to protect health or the environment against “an imminent and substantial endangerment” to health or the environment. Requires those designating data as confidential to justify such claims and to certify that the information is not otherwise publicly available. The EPA Administrator is required to by order develop standards for justifying claims and necessary documentation and within one year of enactment, to identify by rule the types of information for which EPA shall not specify prospectively the term of confidentiality. Requests must be reviewed by EPA within 90 days. If approved, submitted information will be protected from disclosure for up to 5 years.</p>
Health and safety information	<p>Disclosure of health and safety information is not prohibited when it relates to a chemical which has been offered for commercial distribution, or for which testing is being required under section 4, or for which notification is required under section 5, unless data disclosure would reveal a chemical process or chemical proportion in a mixture.</p>	<p>Proposed TSCA 14 specifies data that are not to be protected, including the health and safety data allowed to be disclosed by current law, the identity of a chemical, any safety standard determination, and information “indicating the presence of a chemical in a consumer article intended for use or reasonably expected to be used by children or to which children can otherwise be reasonably expected to be exposed.”</p>
Penalties for disclosure and inappropriate designation	<p>TSCA 14(d) provides that knowing and willful disclosure of protected information by a federal employee may result in a fine of up to \$5,000 or imprisonment for up to one year, or both.</p>	<p>Proposed TSCA 14(f) is the same as current TSCA 14(d).</p>

Provision	15 U.S.C. 2601 et seq.	S. 847
Risk information for workers	No comparable provision.	Proposed TSCA 14(h) requires EPA to provide standards for and facilitate sharing with each certified or recognized bargaining agent information regarding chemical identity, safety standard determination, and health and safety data that pertains to substances that workers may come into contact with or otherwise be exposed to during the course of work.
Prohibited Acts	TSCA 15 [15 U.S.C. 2614] prohibits any person from failing or refusing to comply with rules, orders, or other requirements of TSCA, using for commercial purposes a chemical substance or mixture that was known to be manufactured, processed, or distributed in commerce in violation of the law, failing or refusing to establish and maintain records, submit reports, notices, or other information, or to permit access to or copying of records, or failing or refusing to permit entry or inspection.	Proposed TSCA 15 is similar to current law and prohibits all the same actions, but also prohibits manufacturing, processing, distributing in commerce, or disposing of a chemical or article or using an article that was known to have been manufactured, processed, or distributed in commerce in violation of the law. S. 847 also prohibits failing or refusing to establish and maintain “accurate and complete” records, reports, notices, information, disclosures, declarations, certifications, or other information. Prohibits submitting information “that is materially false, in whole or in part,” or falsifying or concealing “any material fact.” Prohibits taking any action prohibited by proposed TSCA.
Penalties	<p>TSCA 16 [15 U.S.C. 2615] authorizes civil penalties, not to exceed \$25,000 per violation per day, and affords the defendant an opportunity to request a hearing before an order is issued and to petition for judicial review of an order after it is issued with the U.S. Court of Appeals for the District of Columbia Circuit or for any other circuit in which the person resides or transacts business.</p> <p>Criminal penalties of up to \$25,000 per day of violation or up to one year of imprisonment, or both, also are authorized for knowing or willful violations.</p>	<p>Proposed TSCA 16 increases the maximum civil penalty per violation per day to \$37,500 and authorizes EPA to commence a civil action in an appropriate U.S. district court to assess penalties. Changes the court in which a person may file a petition for judicial review to eliminate jurisdiction in any federal circuit court, instead vesting jurisdiction in the appropriate district court for the district in which the person resides or transacts business.</p> <p>Removes criminal sanctions for “willfully” violating any provision of TSCA, as proposed, but increases the maximum penalty for “knowing” violations to \$50,000 per day of violation or up to 5 years of imprisonment, or both. Adds a provision that any person who knowingly violates any provision of the law and “who knows at the time that he thereby places another person in imminent danger of death or serious bodily injury to any person shall upon conviction be subject to a fine of not more than \$250,000 or imprisonment of not more than 15 years, or both.” A person who is not an individual is subject to a fine of not more than \$1,000,000.</p>

Provision	15 U.S.C. 2601 et seq.	S. 847
Seizure	TSCA 17 [15 U.S.C. 2616] makes substances produced in violation of Title IV (Lead Exposure Reduction) liable to be proceeded against, by process of libel, for seizure and condemnation in any district where the substance is found.	Proposed TSCA 17 is similar to current law but S. 847 applies to “articles” rather than “products” and to any articles, substances, or mixtures, that are subject to any title of TSCA.
Enforcement	<p>TSCA 17 [15 U.S.C. 2616] provides jurisdiction to district courts over civil actions to restrain any violation or any person from taking any action prohibited, to compel the taking of any action required, or to direct any manufacturer or processor in violation of section 5 or 6 or of Title IV (or a rule or order under those provisions): to give notice to distributors and to others in possession of the substance, to give public notice of risk, and to replace or repurchase the substance.</p> <p>Authorizes civil actions brought in the U.S. district court for the judicial district wherein any violation occurred or where the defendant is found or transacts business.</p>	<p>Proposed TSCA 17 authorizes the EPA Administrator to commence a civil action in the appropriate district court to compel compliance of any person with any provision of TSCA or any rule or order promulgated pursuant to TSCA. Authorizes EPA to seek civil or criminal penalties, enjoin any violation, or order compliance, through an administrative proceeding, with any provision of TSCA or with any rule or order issued under it.</p> <p>Gives district courts jurisdiction over civil actions to seek penalties or enjoin violations in the U.S. district court for the judicial district wherein any violation occurred or where the defendant is found or transacts business. Gives jurisdiction over civil actions ordering compliance to the U.S. district court for the judicial district where the defendant is found or transacts business.</p>
Preemption of state law	TSCA 18 [15 U.S.C. 2617] does not preempt state laws, with two exceptions: 1) when EPA requires testing of a chemical under section 4, no state may require testing of the same substance for similar purposes; and 2) if EPA prescribes a rule or order under section 5 or 6 to protect against a risk, no state or political subdivision may have a requirement for such substance to protect against such risk unless it is identical to the EPA requirement, is adopted under authority of the Clean Air Act or another federal law, or prohibits the use of such substance in such state or political subdivision (other than use in manufacture or processing of other substances or mixtures).	Proposed TSCA 18 does not preempt laws of states or political subdivisions relating to a chemical substance, mixture, or article unless compliance with both the law of the state or political subdivision and federal law is impossible.

Provision	15 U.S.C. 2601 et seq.	S. 847
Exemption from state or local law preemption	TSCA 18 [15 U.S.C. 2617] authorizes EPA, upon application by a state or political subdivision, by rule to exempt a law in effect in the state or political subdivision, if compliance with the requirement would not cause activities involving the substance to be in violation of the EPA requirement, and the requirement of the state or political subdivision provides a significantly higher degree of protection from the risk than the EPA requirement does and does not “unduly burden interstate commerce.”	No comparable provision. (Since state laws are not preempted, there is no need for an exemption.)
Standard for judicial review	TSCA 19 [15 U.S.C. 2618] authorizes any person to file a petition with the U.S. Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which the person’s principal place of business is located, for judicial review of rules promulgated under TSCA sections 4(a), 5(a)(2), 5(b)(4), 6(a), 6(e), or 8 within 60 days of issuance. The appropriate district court is directed to set aside specified rules if they are not supported by “substantial evidence in the rulemaking record ... taken as a whole,” which is defined in TSCA 19(a)(3).	Similar to current law, but TSCA 19, as proposed, authorizes filing a petition for judicial review of any rule or order issued under TSCA, as proposed, rather than only specified rules, and would eliminate the directive in current law to the court (to set aside a rule not supported by substantial evidence in the rulemaking record taken as a whole).
Citizen suits	TSCA 20 [15 U.S.C. 2619] authorizes civil suits by any person against any person in violation of TSCA or rules or orders promulgated under specified sections of TSCA. It also authorizes suits against EPA to compel performance of nondiscretionary actions under TSCA.	Proposed TSCA 20 is similar to current law, but authorizes suits against any person in violation of rules or orders promulgated under any provision of TSCA, as proposed.
Citizen petitions	TSCA 21 [15 U.S.C. 2620] provides the public with the right to petition EPA to initiate rulemaking or repeal of specified rules. Requires the EPA Administrator to grant or deny the petition within 90 days of its filing.	Proposed TSCA 21 is similar to current law, but authorizes petitions for EPA to initiate any action authorized under the law.
Employment effects	TSCA 24 [15 U.S.C. 2623] directs the EPA Administrator to continually evaluate the potential effects of specified rules, orders, and requirements under specified TSCA provisions on employment.	Proposed TSCA 24 is similar to current law, but directs the EPA Administrator to evaluate potential effects of the law as a whole, rather than specific provisions, and reporting is to be “periodic,” rather than continual.

Provision	15 U.S.C. 2601 et seq.	S. 847
Administration	<p>TSCA 26(a) [15 U.S.C. 2625(a)] authorizes federal agencies, upon request from EPA, to provide services, personnel, facilities, and information to EPA to assist in implementation of TSCA.</p> <p>TSCA 26(b) [15 U.S.C. 2625(b)] authorizes EPA to collect fees from persons required to submit data under section 4 or 5 to defray the cost to EPA of administering the Act. Such fees may not exceed \$2,500, or in the case of a small business \$100.</p> <p>TSCA 26(c) [15 U.S.C. 2625(c)] authorizes EPA to impose regulatory controls on categories of chemicals, rather than on a case-by-case basis. Prohibits regulation of a group based solely on the fact that it consists of new chemical substances.</p> <p>TSCA 26(d) [15 U.S.C. 2625(d)] directs EPA to establish an office to assist the regulated community.</p> <p>TSCA 26(e) [15 U.S.C. 2625(e)] requires that EPA establish a procedure to ensure disclosure of financial interests in the regulated community by EPA employees.</p> <p>TSCA 26(f) [15 U.S.C. 2625(f)] provides that final orders issued under TSCA must contain a statement of basis and purpose.</p> <p>TSCA 26(g) [15 U.S.C. 2625(g)] requires appointment of an Assistant Administrator for Toxic Substances.</p>	<p>Proposed TSCA 26 is similar to current law, except for proposed subsections (b) and (c) and a new subsection (h).</p> <p>Proposed TSCA 26(b) authorizes collection of fees from any data submitter (not just those submitting under section 4 or 5) to defray the cost of administering TSCA. It removes the restrictions in the original TSCA 26(b) on the amount of such fees.</p> <p>Proposed TSCA 26(c) also authorizes the EPA Administrator to take an action with respect to a mixture if such action is authorized or required under any provision of the Act with respect to a chemical substance, if the Administrator determines it is “reasonable and efficient” to do so.</p> <p>New TSCA 26(h) authorizes the EPA Administrator to issue orders and prescribe regulations as necessary to carry out the law.</p>
State programs	<p>TSCA 28 [15 U.S.C. 2627] authorizes grants to states to establish and operate programs to prevent or eliminate unreasonable risks to health or the environment which EPA is unable or is not likely to address under TSCA.</p>	<p>Proposed TSCA 28 is similar to current law, but grants are authorized to prevent or eliminate any risks that EPA has not addressed. In addition, EPA is directed to establish a process to coordinate with the states “to share data and priorities relating to the management of chemical substances” under TSCA, as proposed, and under state programs.</p>

Provision	15 U.S.C. 2601 et seq.	S. 847
Children's environmental health research	No comparable provision.	New TSCA 29(a) would establish a Children's Environmental Health Research Program at EPA and authorize the EPA Administrator to enter into contracts and make grants to conduct research that will "further understanding of the vulnerability of children to chemical substances and mixtures." Proposed TSCA 29(b) establishes an Interagency Science Advisory Board on Children's Health Research and makes it subject to the Administrative Procedure Act and Chapter 7 of Title 5 of the U.S. Code, which pertains to judicial review. The purpose of the Board is to provide independent advice upon request of the EPA Administrator or Congress relating to the implementation of the proposed TSCA "with respect to protecting children's health and research." The committee members would include representatives of the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, the National Toxicology Program, the National Cancer Institute, the National Tribal Science Council, and not fewer than 3 centers of children's health at leading institutions of higher education.
Monitoring exposures	No comparable provision.	New TSCA 29(c) would direct EPA to coordinate with the Secretary of Health and Human Services (HHS) to conduct a biomonitoring study to determine the presence of a chemical in human biological media in pregnant women and infants, if research has indicated that it may be present and may have adverse effects on development. Study results must be published. If the study finds that the chemical is present in human biological media, manufacturers and processors must disclose to EPA, commercial customers, consumers, and the public all known uses of the chemical and all articles in which the chemical is expected to be present.

Provision	15 U.S.C. 2601 et seq.	S. 847
Animal-based testing	No comparable provision. ^a	New TSCA 30 would direct the EPA Administrator to minimize the use of animals in testing of chemical substances or mixtures. Establishes an Interagency Science Advisory Board on Alternative Testing Methods subject to Title 5, Chapter 5, Subchapter 11 and Chapter 7. The Board is directed to provide independent advice and peer review to the EPA Administrator and Congress and to publish a list of testing methods that reduce the use of animals in testing under proposed TSCA 4. Directs the EPA Administrator in consultation with the Board to develop a strategic plan, biennially report to Congress on progress in implementing this section, and fund and carry out research, development, performance assessment, and translational studies to accelerate the development of test methods and strategies for use in safety standard determinations under proposed TSCA 6(b). Authorizes the EPA Administrator, on request of a manufacturer or processor, to adapt or waive animal-based testing of a chemical substance or mixture under specific conditions.
Safer alternatives	No comparable provision. ^b	New TSCA 31(a) would establish a program to create market incentives for the development of safer alternatives to existing chemical substances that reduce or avoid the use and generation of hazardous substances. Requires that the program include expedited review of new chemical substances for which an alternatives analysis indicates it is a safer alternative, and recognition for a substance or product determined by EPA to be a safer alternative.
Green chemistry and green engineering	No comparable provision. ^b	New TSCA 31(b) would direct the EPA Administrator to establish a network of at least four green chemistry and engineering centers in various U.S. regions. New TSCA 31(c) would direct EPA to make grants to promote and support research, development, and adoption of safer alternatives. New TSCA 31(d) would create a program to facilitate the development of a workforce that produces safer alternatives to existing chemical substances.

Provision	15 U.S.C. 2601 et seq.	S. 847
International cooperation	No comparable provision.	New TSCA 32 would direct the EPA Administrator to cooperate with the Secretary of State and the head of any other appropriate federal agency “with international efforts as appropriate” to develop a common protocol or electronic database relating to chemical substances or to develop safer alternatives for chemical substances.
Reliable information and advice	No comparable provision.	New TSCA 33 would direct EPA by order to establish and implement procedures to ensure data reliability by annually inspecting laboratories and performing an annual data audit. Requires that EPA establish a registry of studies. Provides the EPA Administrator with access to all records of health and safety studies initiated in response to requirements of Title I, and requires each submitter of a research study conducted by a third party to disclose the sources of any funding used to conduct or publish the study.
Hot spots	No comparable provision.	As proposed, a new TSCA 34 requires that EPA promulgate a rule to establish criteria to identify any locality that is disproportionately exposed. Defines “disproportionate exposure” to mean residential population exposure to one or more toxic chemical substances and mixtures at levels that are significantly greater than the average exposure in the United States. Directs EPA, within 120 days of promulgation of the rule, to identify localities subject to such exposure using data in EPA’s National Air Toxic Assessment Database and other available data, and providing an opportunity for public nominations of localities. Requires EPA to publish a list of such localities, and to update it at least once every 5 years. The locations on the list are not subject to judicial review. Publication of a list is a nondiscretionary duty and subject to judicial review. Requires the EPA Administrator to develop and publish an action plan that includes an identification of the chemicals that contribute to the disproportionate exposure, and a description of actions to be taken to reduce exposure. Directs EPA to report annually to Congress.

Provision	15 U.S.C. 2601 et seq.	S. 847
Federal agencies subject to TSCA	No comparable provision.	<p>New TSCA 35 would provide that all federal agencies are subject to the provisions of TSCA, as proposed, and expressly waive any immunity otherwise applicable to the United States. However, no agent, employee, or officer of the United States is personally liable for any civil penalty under TSCA with respect to any act or omission within the scope of the official duties of that person. Such persons are subject to any criminal sanction under proposed TSCA. The President is authorized to grant an exemption for any federal agency from compliance with any requirement of TSCA, as proposed, if “the President determines it is in the paramount interest of the United States.” An exemption may be granted due to lack of appropriation if the President specifically requested such appropriation and Congress failed to make available such requested appropriation. Directs the President annually to report to Congress all exemptions granted during the previous year.</p> <p>Authorizes enforcement action against any federal agency, as well as voluntary resolution or settlement set forth in a consent order.</p>
International agreements	No comparable provision	<p>New TSCA 36 would provide authority for EPA to implement three international agreements: the Stockholm Convention on Persistent Organic Pollutants (Stockholm Convention), the Aarhus Protocol to the Convention on Long-Range Transboundary Air Pollution (LRTAP Protocol), and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (PIC Convention). Directs the EPA Administrator to implement and support implementation of the provisions of the three agreements that have entered into force for the United States. Prohibits manufacture, processing, distribution in commerce, use, disposal, or any other action with respect to a covered chemical, mixture, or substance that is part of an article in a manner inconsistent with applicable international obligations. Directs EPA to provide timely public notice and opportunity to comment on: a chemical proposed for listing, a recommendation made to list a chemical on any Annex in advance of any meeting of the Parties at which the recommendation is to be considered, and any decision by the Meeting of the Parties to list a chemical.</p>

Provision	15 U.S.C. 2601 et seq.	S. 847
		Authorizes the EPA Administrator to prescribe regulations to carry out provisions of the three agreements or to ensure compliance with obligations under them. Prohibitions and other requirements shall be enforced in the same way as final rules or orders under proposed TSCA 6.
Authorization of appropriations	TSCA 29 [15 U.S.C. 2628] authorizes appropriations for implementation of specific TSCA provisions for 1982 and 1983. Prohibits expenditures of appropriated funds to construct laboratories.	New TSCA 39 (but identified as section 38 in the new Table of Contents) would authorize “such sums as are necessary” to carry out the law for 2011 through 2018, with no restriction on how those funds might be used.
<p>a. However, EPA has stated that it “is committed to examining alternative test methods that reduce the number of animals needed for testing, reduce pain and suffering of test animals, and whenever possible, replace animals in testing with validated in vitro (non-animal) test systems. EPA has released guidance on this issue. ...” U.S. EPA, “Fact Sheet on Animal Welfare,” April 2001, EPA 745-F-99-003, http://www.epa.gov/HPV/pubs/general/anfacs.pdf.</p> <p>b. Although there is no explicit authority in TSCA, EPA does promote green chemistry (http://www.epa.gov/greenchemistry/), safer products (http://www.epa.gov/dfe/product_label_consumer.html), green engineering (http://www.epa.gov/oppt/greenengineering/pubs/whats_ge.html), and other “green” initiatives.</p>		

Author Contact Information

(name redacted)
Specialist in Environmental Policy
/redacted/@crs.loc.gov, 7-....

EveryCRSReport.com

The Congressional Research Service (CRS) is a federal legislative branch agency, housed inside the Library of Congress, charged with providing the United States Congress non-partisan advice on issues that may come before Congress.

EveryCRSReport.com republishes CRS reports that are available to all Congressional staff. The reports are not classified, and Members of Congress routinely make individual reports available to the public.

Prior to our republication, we redacted names, phone numbers and email addresses of analysts who produced the reports. We also added this page to the report. We have not intentionally made any other changes to any report published on EveryCRSReport.com.

CRS reports, as a work of the United States government, are not subject to copyright protection in the United States. Any CRS report may be reproduced and distributed in its entirety without permission from CRS. However, as a CRS report may include copyrighted images or material from a third party, you may need to obtain permission of the copyright holder if you wish to copy or otherwise use copyrighted material.

Information in a CRS report should not be relied upon for purposes other than public understanding of information that has been provided by CRS to members of Congress in connection with CRS' institutional role.

EveryCRSReport.com is not a government website and is not affiliated with CRS. We do not claim copyright on any CRS report we have republished.