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# Proposed Amendments to the Toxic Substances Control Act (TSCA) in the 114th Congress: H.R. 2576 Compared with the Senate Substitute Amendment

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# Summary

This report compares H.R. 2576, the TSCA Modernization Act of 2015, as passed by the House on June 23, 2015, and the Senate's substitute amendment (S.Amdt. 2932) to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as passed by the Senate on December 17, 2015. The Senate amendment is based, in part, on S. 697, as reported by the Senate Committee on Environment and Public Works on April 28, 2015.

The House bill and the Senate amendment would amend Title I of the Toxic Substances Control Act (TSCA). Enacted in 1976, TSCA is the primary federal law that authorizes the regulation of commercial chemicals throughout their lifecycle from manufacture to disposal. TSCA authorizes the Environmental Protection Agency (EPA) to determine whether regulation of a chemical is necessary to provide protection against "unreasonable risk of injury to health or the environment." The Senate amendment, but not the House bill, would also amend the Mercury Export Ban Act of 2008 and add a provision to the Public Health Service Act regarding potential cancer clusters.

Over the 39-year history of TSCA, EPA, regulated entities, environmental and public health groups and others have observed significant challenges in implementing the statute. For example, concerns have been raised on whether the threshold to regulate a chemical under TSCA is too difficult for EPA to demonstrate and whether the agency is unnecessarily constrained by the requirement that it impose the "least burdensome requirement" to restrict a chemical. In addition, EPA has argued that limits in requesting test information have constrained its ability to assess risks of certain chemicals. Many have argued that these concerns have diminished public confidence in the "safety" of chemicals in commerce. Additionally, regulated entities and right-to-know advocates have raised concerns about the appropriate balance between disclosures of chemical information and confidentiality of business information submitted to EPA under TSCA. Regulated entities have also raised concerns that state and local governments are adopting different requirements with respect to particular chemicals and compliance may be difficult with this growing "patchwork" of requirements. They argue that there should be uniform regulation under TSCA nationally. However, certain states and others have expressed concerns regarding the role of preemption in limiting states' ability to regulate chemicals. Since 2005, these concerns and others led to the introduction of legislation that would amend TSCA in each Congress.

The first section of the report provides a brief background on TSCA. The second section provides a brief comparison between the House bill and the Senate amendment and also provides a background discussion of seven issues:

- Prioritization of chemicals for the evaluation of risks;
- Regulatory threshold for restricting a chemical;
- Regulatory options for restricting a chemical;
- Requirements for the development of test information;
- Preemption of state requirements;
- Confidentiality and disclosures of information; and
- Resources to administer TSCA.

Finally, **Table 1** presents a side-by-side comparison of the provisions of existing law, the House bill, and the Senate amendment. This report does not provide a comprehensive analysis of the potential effect of particular provisions. Ultimately, the outcome, if either the House bill or the Senate amendment were enacted, depends on implementation.

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# Introduction

This report presents a side-by-side comparison of H.R. 2576, the TSCA Modernization Act of 2015, as passed by the House on June 23, 2015,[1] and S.Amdt. 2932, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as passed by the Senate on December 17, 2015, as a substitute amendment to H.R. 2576.[2] (Hereafter in this report, the House-passed bill H.R. 2576 will be referred to as the "House bill," while the Senate amendment to H.R. 2576 will be referred to as the "Senate amendment.") Both the House bill and the Senate amendment would amend Title I of the Toxic Substances Control Act (TSCA).[3] The Senate amendment, but not the House bill, would also amend the Mercury Export Ban Act of 2008[4] and add a provision to the Public Health Service Act regarding potential cancer clusters.[5]

The first section of this report provides a brief background on Title I of TSCA. 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*, by (name redacted). The second section describes differences between the House bill and the Senate amendment and also presents background on selected issues that the legislation addresses. The final section includes **Table 1**, which presents a side-by-side comparison of the provisions of existing law, the House bill, and the Senate amendment.

# Title I of the Toxic Substances Control Act (TSCA)

In 1976, President Ford signed into law the Toxic Substances Control Act, which authorizes the U.S. Environmental Protection Agency (EPA) to identify and regulate chemicals in U.S. commerce that present an "unreasonable risk of injury to health or the environment."[6] Since 1976, Congress has added five other titles to TSCA and has amended the original law, referred to as Title I, to address specific chemical concerns.[7] None of these additions and amendments has altered the core program under Title I of TSCA. Neither the House bill nor the Senate amendment would amend the other titles (i.e., Titles II through VI) of TSCA.

[1] On June 3, 2015, the House Committee on Energy and Commerce reported the bill (H.Rept. 114-176).

[2] The Senate amendment is based on S. 697, as reported by the Senate Committee on Environment and Public Works on April 28, 2015, albeit with differences. On April 28, 2015, the Senate Committee on Environment and Public Works ordered that the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697) be reported for Senate floor consideration. On June 18, 2015, the committee filed the report (S.Rept. 114-67).

[3] P.L. 94-469 (1976), codified as amended at 15 U.S.C. 2601-2629.

[4] P.L. 110-414 (2008), in part, amended TSCA, and Section 5 of the statute codified at 42 U.S.C. 6939f.

[5] P.L. 78-410 (1944), codified as amended at 42 U.S.C. Chapter 6A.

[6] TSCA Section 3(2) (15 U.S.C. 2602(2)) excludes certain chemical substances from regulation, including pesticides, tobacco and tobacco products, certain radioactive materials, pistols, revolvers, firearms, shells, cartridges, food, food additives (including food contact substances, such as container components, that may be indirect food additives), drugs, cosmetics and personal care products, and medical devices. Additionally, TSCA Section 9 (15 U.S.C. 2608) limits EPA's authority to address unreasonable risks of chemical substances by directing the agency to determine, if unreasonable risks are identified, whether other statutes administered by EPA or another federal agency may adequately address such risks.

[7] The other specific chemical concerns include asbestos (Title II), indoor radon (Title III), lead-based paint (Title IV), environmental exposures in schools (Title V), and formaldehyde in composite wood products (Title VI). Title I was amended by the Mercury Export Ban Act of 2008 to address elemental mercury. 15 U.S.C. 2605(f) and 2611(c).

Among other things, Title I of TSCA requires EPA to compile and maintain a list of chemical substances manufactured or processed in the United States. This list is referred to as the TSCA Chemical Substance Inventory (or TSCA Inventory). EPA's initial compilation of the TSCA Inventory included over 62,000 chemical substances.[8] TSCA distinguishes between chemical substances that are on the inventory and those that are not. Any chemical substance listed on the inventory is considered by the agency as an "existing" chemical substance.[9] The statute defines any chemical substance not on the inventory as a "new chemical substance." Since EPA's publication of the initial TSCA inventory, the agency has added over 23,000 new chemical substances to the inventory.[10] Once a chemical substance is added to the TSCA inventory, it becomes an existing chemical substance for purposes of the statute.

In order to determine which chemicals warrant regulation under TSCA, EPA is authorized to evaluate risks that may arise from the entire commercial life-cycle of chemicals, including their manufacture,[11] processing, distribution, use, and disposal. Pursuant to TSCA Section 6, EPA has authority to pursue a range of regulatory options to address unreasonable risks from chemicals. These options vary in severity from a complete ban to a requirement that manufacturers notify distributors of unreasonable risks. Since the enactment of TSCA, EPA has regulated few chemicals under TSCA Section 6, including:

- chlorofluorocarbons used in aerosol propellants;[12]
- nitrosamines used in metalworking fluids (40 C.F.R. Part 747);
- hexavalent chromium used for certain water cooling towers (40 C.F.R. Part 749);
- new uses of asbestos (40 C.F.R. Part 763, Subpart I);
- dioxin-contaminated wastes;[13] and
- polychlorinated biphenyls (40 C.F.R. Part 761).

The agency has taken actions pursuant to other authorities in the statute. For example, EPA has:

- collected information on the risks, uses, and volumes in commerce of various chemicals to inform its evaluation of chemical risks (pursuant to TSCA Sections 4, 5, and 8);[14]
- evaluated various chemicals for risks (pursuant to TSCA Section 6);[15] and
- promulgated rules to require notification for significant new uses of certain chemical substances (pursuant to TSCA Section 5).[16]

[8] EPA, "About the TSCA Chemical Substance Inventory," updated October 26, 2015, http://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory.

[9] 15 U.S.C. 2602(9).

[10] As of October 26, 2015, EPA states that the TSCA inventory lists over 85,000 chemicals. EPA, "About the TSCA Chemical Substance Inventory," updated October 26, 2015, http://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory.

[11] TSCA Section 3(7) (15 U.S.C. 2602(7)) defines the term *manufacture* to include production and importation.

[12] TSCA regulation of chlorofluorocarbons used in aerosol propellants was superseded by regulations promulgated under the Clean Air Act.

[13] TSCA regulation of dioxin-contaminated wastes was superseded by regulations promulgated under the Solid Waste Disposal Act.

[14] 15 U.S.C. 2603, 2604, and 2607.

[15] 15 U.S.C. 2605.

[16] 15 U.S.C. 2604.

Since 2005, Members of Congress have introduced bills to revise the chemical evaluation process for determining whether regulatory actions are warranted and to address other related purposes.[17] Although the bills were not enacted, they generated debate on whether and how to amend the evaluation process, regulatory criteria, and other elements of the law.[18]

# H.R. 2576 and the Senate Substitute Amendment

The House bill would amend several provisions in TSCA, including:

- the authority for EPA to require testing of chemicals under TSCA Section 4;[19]
- the process by which EPA would evaluate risks of chemicals and regulate those found to present unreasonable risks under TSCA Section 6;[20]
- the procedures and standards under TSCA Section 14 for confidential treatment of certain information submitted to EPA under TSCA;[21]
- TSCA's relationship to state laws regulating chemicals under TSCA Section 18;[22] and
- the authority for EPA to collect fees under TSCA Section 26.[23]

The Senate amendment would amend the same provisions of TSCA listed above, albeit with differences. Additionally, the Senate amendment would amend:

- the process by which EPA reviews new chemical substances or significant new uses of chemicals under TSCA Section 5;[24]
- the recordkeeping and reporting requirements under TSCA Section 8;[25] and
- various other provisions.

The following sections provide a brief discussion of seven issues that have received attention in the debate to amend Title I of TSCA. The discussions include comparisons between how the House bill and Senate amendment would address each issue. These issues include:

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[17] Legislation to revise the chemical evaluation process under TSCA and for certain other related purposes dates back at least to the 109th Congress. S. 1391 and H.R. 4308, both introduced in 2005, are examples of such legislation.

[18] For recent examples of debate, see U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and the Economy, *H.R. ___, the TSCA Modernization Act of 2015*, 114th Cong., 1st sess., April 14, 2015, (Washington: GPO, 2015), https://www.gpo.gov/fdsys/pkg/CHRG-114hhrg95937/pdf/CHRG-114hhrg95937.pdf (hereinafter "House discussion draft hearing"); and U.S. Congress, Senate Committee on Environment and Public Works, *Legislative Hearing on the Frank R. Lautenberg Chemical Safety for the 21st Century Act (*S. 697*)*, 114th Cong., 1st sess., March 18, 2015, S. Hrg. 114-25 (Washington: GPO, 2015), https://www.gpo.gov/fdsys/pkg/CHRG-114shrg94985/pdf/CHRG-114shrg94985.pdf (hereinafter "S. 697 hearing").

[19] 15 U.S.C. 2603.

[20] 15 U.S.C. 2605.

[21] 15 U.S.C. 2613.

[22] 15 U.S.C. 2617. For more detailed information on preemption in TSCA, H.R. 2576 as passed by the House, and S. 697 as reported out of committee, see CRS Report R44066, *Preemption in Proposed Amendments to the Toxic Substances Control Act (TSCA): Side-by-Side Analysis of S. 697 and H.R. 2576*, by (name redacted) ; and CRS Legal Sidebar WSLG1269, *Toxic Substances Control Act (TSCA) Preemption and State Chemical Regulations Under Current Law*, by (name redacted) .

[23] 15 U.S.C. 2625.

[24] 15 U.S.C. 2604.

[25] 15 U.S.C. 2607.

- prioritization of existing chemical substances for the evaluation of risks;
- regulatory threshold criteria under which EPA would be authorized to restrict a chemical;
- regulatory options available to EPA in restricting a chemical found to warrant regulation;
- EPA's authority to require the development of new information regarding a chemical;
- preemption of state laws concerning the regulation of chemicals;
- disclosure and protection from disclosure of information submitted to EPA; and
- resources that may be available for EPA to administer the act.

## Prioritization of Chemicals for Evaluation of Risks

Determining which chemicals EPA may select before others to evaluate risks has been a long-standing issue given that the agency has finite resources to evaluate over 85,000 chemical substances listed on the TSCA inventory and continues to become aware of new chemical substances. EPA's evaluation of a chemical is intended to generate information that informs the agency's determination as to whether the regulatory threshold is met to restrict that chemical. Under TSCA, EPA has discretion over which chemicals on the TSCA inventory to evaluate for risks.[26] In 2012, EPA identified, as part of the agency's TSCA Work Plan, more than 1,200 substances that possibly warranted an evaluation based on certain prioritization criteria.[27] These substances were further screened based on hazard, exposure, and bioaccumulation potential, which led EPA to prioritize 90 substances for an evaluation of risks to human health or the environment.[28] Of the 90 prioritized chemical substances, EPA has assessed five, three of which were determined to present risks.[29] EPA continues to evaluate the other 85 substances.

For new chemical substances, TSCA Section 5 requires manufacturers to submit a premanufacture notice (PMN) to EPA 90 days prior to manufacturing the chemical substance, subject to certain exemptions.[30] During this time period, EPA has the opportunity to evaluate risks

[26] The substances that EPA may evaluate for risks include those on the initial inventory of known chemical substances reported to the agency under TSCA Section 8(a) after enactment of the law and those that manufacturers subsequently report to the agency in premanufacture notices (PMNs) under TSCA Section 5. Combined, these substances currently number more than 85,000. TSCA Section 3(7) (15 U.S.C. 2602(7)) defines the term *manufacture* to include production and importation. PMNs are therefore required for chemical substances not on the TSCA inventory that are to be imported into the United States. See EPA, "About the TSCA Chemical Substance Inventory," updated October 26, 2015, http://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory.

[27] EPA, Office of Pollution Prevention and Toxics, *TSCA Work Plan for Chemical Assessments: 2014 Update*, October 2014, p. 3, http://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

[28] Ibid.

[29] EPA, "Assessments for TSCA Work Plan Chemicals," updated March 3, 2016, http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals. EPA completed assessments for N-methylpyrrolidone (NMP) in paint and coating removal products; antimony trioxide (ATO) as a synergist in halogenated flame retardants; 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[γ]-2-benzopyran as a fragrance ingredient in commercial and consumer products; methylene chloride in paint and coating removal products; and trichloroethylene (TCE) as a degreaser, a spot-cleaner in dry cleaning, and a spray-on protective coating. For NMP, methylene chloride, and TCE, EPA has identified risks that have led the agency to consider pursuing a range of possible voluntary and regulatory actions.

[30] 15 U.S.C. 2604. TSCA Section 5(h) authorizes certain exemptions from the requirements of all or parts of TSCA (continued...)

of the new chemical substance and determine whether regulation may be warranted based on the PMN and any existing data concerning the environmental and health effects of the substance. According to EPA, from July 1979 through September 2015, the agency has received more than 39,000 PMNs and more than 15,000 PMN exemption applications.[31] EPA states that it has taken regulatory action on approximately 10% of the PMNs submitted.

Both the House bill and the Senate amendment would establish a process and criteria for EPA to prioritize existing chemical substances for evaluation, albeit with differences. The Senate amendment, and not the House bill, would amend TSCA Section 5 with regard to the evaluation of new chemical substances, although, in part, it would codify certain existing practices. For a comparison among existing law, the House bill, and the Senate amendment on this topic, see pages CRS-28 and CRS-36 in **Table 1**.

## Regulatory Threshold for Restricting a Chemical

In order for EPA to restrict a chemical under TSCA, the agency must first determine that the chemical presents or will present "an unreasonable risk of injury to [human] health or the environment." This phrase is used in multiple provisions of TSCA as the basis for whether certain actions may be warranted. Some stakeholders have argued that the existing regulatory threshold for restricting a chemical in TSCA—that the chemical presents or will present risks that are unreasonable—is difficult for EPA to demonstrate. A recurring issue of concern in the TSCA debate has been whether or how to amend the regulatory threshold to clarify the criteria and factors to be considered for determining whether certain chemicals warrant regulatory control.

TSCA does not define the "unreasonable risk" standard.[32] However, the "unreasonable risk" standard of TSCA has been interpreted at the circuit court level as, essentially, a multi-factor balancing test. In its 1991 decision, *Corrosion Proof Fittings v. EPA*, which struck down large parts of an asbestos ban under TSCA, the Fifth Circuit stated that "[i]n evaluating what is 'unreasonable,' the EPA is required to consider the costs of any proposed actions and to 'carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.'"[33] The court also quoted a Supreme Court case regarding "unreasonable risk" language in general, saying that "'unreasonable risk' statutes require 'a generalized balancing of costs and benefits.'"[34] The Fifth Circuit ruled that in its asbestos ban, EPA had "basically ignored the cost side of the TSCA equation" and that potentially "spending $200-$300 million to save approximately seven lives (approximately $30-$40 million per life) over thirteen years" was not reasonable under the "unreasonable risk" standard.[35] Thus, under TSCA's "unreasonable risk" standard, whether regulation of a chemical is warranted depends on not only the hazards of the chemical and the extent or likelihood of exposure to the chemical but

(...continued)

Section 5.

[31] EPA, "Statistics for the New Chemicals Review Program under TSCA," updated October 19, 2015, http://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.

[32] The interpretation of "unreasonable risk" is also influenced by the regulatory conditions for restricting a chemical substance, discussed below. In issuing rules to protect against unreasonable risk, EPA is directed to consider not only the hazards and exposures but also the benefits of the chemical, available alternatives to the chemical and the economic costs of restrictions. 15 U.S.C. 2605(c)(1).

[33] 947 F.2d 1201, 1222 (5th Cir. 1991) (quoting 15 U.S.C. 2601(c)).

[34] Ibid. (quoting American Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 510 n.30 (1981)).

[35] Ibid. at 1223.

also the costs of risk management and the benefits of various uses of the chemical. Since 1991, EPA has not promulgated a rule to restrict a chemical under TSCA Section 6.

Both the House bill and the Senate amendment would amend the regulatory threshold for restricting a chemical by modifying what constitutes "unreasonable risk." As an example, both the House bill and the Senate amendment would prohibit the consideration of cost and other non-risk factors when determining whether there are unreasonable risks associated with a chemical. However, whether more chemicals could be regulated under TSCA by amending the regulatory threshold would ultimately depend on implementation. For a comparison among existing law, the House bill, and the Senate amendment on this topic, see page CRS-31 in **Table 1**.

## Regulatory Options for Restricting a Chemical

If EPA were to determine that a chemical presents or will present "an unreasonable risk of injury to health or the environment," TSCA Section 6 directs the agency to promulgate a requirement to protect adequately against such risks using the "least burdensome requirement" while considering certain other factors. These include, among other factors, the approximate costs of the proposed regulation and the availability of alternatives to the chemical subject to regulatory control.[36] EPA may select the least burdensome requirement from options listed in the statute that vary in severity from a complete ban to a requirement that manufacturers or processors notify distributors, other people in possession of a chemical, and the general public of unreasonable risks. This provision implements the concept of balancing costs and benefits when determining what requirement to impose on a chemical determined to meet the regulatory threshold. Some stakeholders have argued that the limit on EPA to choose the least burdensome regulatory requirement that still adequately protects against unreasonable risk requires the agency to do lengthy analyses and may result in the promulgation of a regulation that is inadequately protective because of considerations of cost.

In *Corrosion Proof Fittings v. EPA*, the Fifth Circuit stated that EPA had not shown substantial evidence[37] that its total ban on most uses of asbestos was the least burdensome adequate alternative for all circumstances and product categories.[38] Thus, in practice, the "least burdensome" requirement imposes an additional standard on EPA beyond that imposed by the requirement that the agency conduct a cost-benefit analysis of the chosen alternative, because a rule cannot be upheld based only on its benefits outweighing its costs. In order to reject a less burdensome requirement in favor of a more burdensome one, the Fifth Circuit required EPA to show that each less burdensome requirement would not adequately protect against the unreasonable risk.[39] Some environment and public health groups have argued that it is unlikely another chemical could be regulated under TSCA if EPA was not able to regulate asbestos under the statute.

[36] 15 U.S.C. 2605.

[37] TSCA Section 19 (15 U.S.C. 2618(c)(1)(B)) provides that the standard of review for certain rules issued by EPA, including restrictions on new or existing chemicals, is that a reviewing court shall set aside such rules if it finds that the rule is not supported by substantial evidence in the rulemaking record. This standard applies in lieu of the standard under the Administrative Procedure Act (APA), which provides that a reviewing court shall set aside agency action that is arbitrary, capricious, an abuse of discretion, etc. (5 U.S.C. 706). Neither the House bill nor the Senate amendment would substantively change this standard of review.

[38] 947 F.2d 1201 (5th Cir. 1991). The Fifth Circuit did not strike down restrictions on new uses of asbestos.

[39] Ibid. at 1226, 1229. This interpretation of the "least burdensome" requirement has not been applied in other significant TSCA litigation challenging risk management rules since *Corrosion Proof Fittings v. EPA*.

Both the House bill and the Senate amendment would remove from TSCA the requirement that EPA promulgate the "least burdensome requirement" in order to restrict a chemical demonstrated by the agency to present unreasonable risks. In addition, the House bill and the Senate amendment would amend the process that EPA would undertake to select a regulatory option that would restrict a chemical determined to warrant regulation. For a comparison among existing law, the House bill, and the Senate amendment on this topic, see page CRS-31 in **Table 1**.

## Requirement for the Development of Test Information

EPA relies on scientific and technical information regarding chemical substances and mixtures to evaluate risks and determine if any risks are unreasonable. In order to obtain such information, TSCA Section 8 authorizes EPA to require reporting and recordkeeping of existing information on chemical substances and mixtures by manufacturers, processors, and distributors of chemical substances.[40] If the risks are insufficiently known from existing information and testing is necessary to develop new information about the risks, TSCA Section 4 mandates that EPA promulgate a rule to require manufacturers and processors to conduct testing if the agency finds (1) that the chemical substance may present unreasonable risks,[41] or (2) that "substantial quantities" are or will be produced either in a way that enters or may reasonably be anticipated to enter the environment, or in a way that "there is or may be significant or substantial human exposures."[42] To date, EPA has required additional testing for over 200 chemical substances.[43]

Some stakeholders have argued that limits on EPA's authority under TSCA to require the development of new information regarding the health and environmental effects of chemicals have hindered EPA's ability to assess the risks of chemicals.[44] EPA has argued that finding a chemical substance "may present an unreasonable risk of injury to health or the environment" in order to require the development of new information to determine whether a chemical substance presents an unreasonable risk is a "possible analytical catch-22."[45] Likely for this reason, EPA has generally required further testing based on the production volume of a chemical and the likelihood of exposure. Some stakeholders contend that the development of new information may take a lengthy amount of time and be costly to those required to develop the information.

Both the House bill and the Senate amendment would expand EPA's authority to require the development of test data, albeit with differences in the extent of that authority. As an example, the House bill would authorize EPA to require testing if the agency finds that testing of the chemical

[40] 15 U.S.C. 2607.

[41] This threshold finding has been held to be met when EPA "finds a more-than-theoretical basis for suspecting that the chemical substance in question presents an 'unreasonable risk of injury….'" Chemical Mfrs. Ass'n v. U.S. EPA, 859 F.2d 977, 979 (D.C. Cir. 1988).

[42] This threshold finding has been held to require EPA to "articulate the standards or criteria on the basis of which it found the quantities of [a chemical] entering the environment … to be 'substantial' and the human exposure potentially resulting to be 'substantial'" on a general or case-specific basis. Chemical Mfrs. Ass'n v. EPA, 899 F.2d 344, 360 (5th Cir. 1990). EPA thereafter published technical criteria that form the basis for EPA's policy for making exposure-based findings. EPA, "TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure," 58 *Federal Register* 28736-28749, May 14, 1993.

[43] Testimony of James Jones, EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, in U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and the Economy, *H.R. ___, the TSCA Modernization Act of 2015*, 114th Cong., 1st sess., April 14, 2015, (Washington: GPO, 2015), pp. 5-6 (pp. 9-10 of PDF), https://www.gpo.gov/fdsys/pkg/CHRG-114hhrg95937/pdf/CHRG-114hhrg95937.pdf.

[44] Ibid.

[45] Ibid.

is necessary to evaluate risks to determine whether regulation is warranted under TSCA. Compared to existing TSCA, this finding would be an additional finding that EPA could make to require testing. As another example, the Senate amendment would give EPA discretion to require testing that the agency determines is necessary for specific purposes related to evaluating risks of chemicals. For a comparison among existing law, the House bill, and the Senate amendment on this topic, see page CRS-18 in **Table 1**.

## Preemption of State Requirements[46]

With an increasing number and diversity of state chemical regulations providing a backdrop for TSCA amendment discussions at the federal level, the scope of TSCA preemption has been a long-standing issue. Under the Supremacy Clause of the U.S. Constitution, conflicting state law and policy must yield to the exercise of Congress's enumerated powers.[47] When it acts, Congress can preempt state action within a field entirely, allow states to take different actions, or permit state action to any degree in between. Current TSCA preemption is not at either end of the spectrum; it gives EPA a primary role in management of chemicals but leaves states some ability to set their own chemical requirements under certain circumstances.

Specifically, TSCA Section 18 provides that states are generally preempted from taking action to manage risk from a chemical if EPA has taken action on a similar risk presented by that chemical, although states may apply for waivers.[48] For state requirements other than duplicative testing requirements, a number of exceptions to preemption apply. State requirements that are identical to federal requirements are not preempted, allowing states to co-enforce the federal requirements by adopting them as their own law.[49] States are also authorized to regulate disposal, establish or continue in effect any chemical requirement adopted under the authority of any other federal law, and prohibit use of a chemical within the state (except for its upstream use in manufacture or processing of other chemicals).[50]

In the TSCA amendment context, advocates for broader federal preemption claim that a uniform national regulatory framework with regard to chemicals can provide sufficient protection from chemical risks. They assert that absent preemption, states may implement varying and even conflicting regulations, leading to increased compliance costs, reduced economies of scale, and economic repercussions across industry supply chains and throughout interstate commerce.[51] On the other hand, opponents of preemption argue that the federal regulation should set a minimum standard but that states should be able to experiment with different policies and implement more

[46] For more on this topic, see CRS Report R44066, *Preemption in Proposed Amendments to the Toxic Substances Control Act (TSCA): Side-by-Side Analysis of S. 697 and H.R. 2576*, by (name redacted) and CRS Legal Sidebar WSLG1269, *Toxic Substances Control Act (TSCA) Preemption and State Chemical Regulations Under Current Law*, by (name redacted) .

[47] U.S. Constitution, Article VI, clause 2. Note that local as well as state laws are subject to federal preemption. Also, while this report discusses statutory preemption provisions, it should be noted that under the Supremacy Clause, state law can be preempted either because the federal law is intended to be comprehensive and occupies the field or because the state law conflicts with a federal law, even if the federal law does not expressly preempt the state law. Conflict preemption could occur either because compliance with both the state rule and the federal rule would be impossible or because the state rule would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Whether a certain state action is preempted by federal law is a question of congressional intent.

[48] 15 U.S.C. 2617.

[49] 15 U.S.C. 2617(a)(2)(B).

[50] Ibid.

[51] See, for example, S. 697 hearing in footnote 16 above.

stringent requirements than those EPA sets in order to protect the safety and welfare of their citizens.[52]

Both the House bill and the Senate amendment would retain the general structure of TSCA preemption, in which certain EPA actions regarding a specific chemical will preempt state chemical regulations for that same chemical, subject to exceptions and waivers. Both would add some exceptions to preemption and would align the preempting EPA actions with the amended regulatory framework but with some differences between their approaches. For a comparison among existing law, the House bill, and the Senate amendment on this topic, see pages CRS-42 through CRS-46 in **Table 1**.

## Confidentiality and Disclosures of Information

TSCA requires chemical manufacturers, processors, and distributors to submit certain information to EPA regarding their chemicals.[53] This information can include detailed chemical structures, production volumes, and health and safety data. Thus, another issue of concern in amending TSCA is how to balance the goals of, on the one hand, public access to chemical information and, on the other, protection of information that if disclosed could compromise the submitter's competitiveness.

TSCA Section 14 prohibits disclosure of information reported to or obtained by EPA that is exempt from disclosure under the Freedom of Information Act (FOIA) as "trade secrets and commercial or financial information obtained from a person and privileged or confidential,"[54] with certain exceptions.[55] Under the terms of TSCA, wrongful disclosure by EPA employees or contractors is a criminal act.[56] Confidential business information (CBI) protection under TSCA does not prohibit disclosure of any health and safety study, but any data within any such study that would disclose manufacturing processes or proprietary mixture compositions would remain protected.[57]

Many items of information—including chemical identities—have been protected by EPA as CBI on the TSCA Inventory, in health and safety studies, and in other situations.[58] TSCA Section 14 contains several exceptions requiring disclosure of CBI, including if EPA determines that disclosure is "necessary to protect health or the environment against an unreasonable risk of injury."[59] If EPA makes this determination, or if EPA finds that information that has been designated as CBI does not meet the standard for protection, EPA must provide notice to the information submitter prior to disclosing the information.[60]

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[52] Ibid.

[53] See 15 U.S.C. 2604(d)(1), 2607(a)(2) (requiring information on new and existing chemicals to the extent such information is known or reasonably ascertainable), 2607(d)-(e) (requiring submission to EPA of health and safety studies and of substantial risk allegations), and 2603 (authorizing EPA to require development of new information).

[54] 5 U.S.C. 552(b)(4).

[55] 15 U.S.C. 2613.

[56] 15 U.S.C. 2613(d).

[57] 15 U.S.C. 2613(b).

[58] EPA, "About Confidential Business Information (CBI) Claims and Their Reviews Under TSCA," updated September 15, 2015, http://www.epa.gov/tsca-cbi/about-confidential-business-information-cbi-claims-and-their-reviews-under-tsca.

[59] 15 U.S.C. 2613(a)(3).

[60] 15 U.S.C. 2613(c)(2).

Procedurally, to obtain CBI protection for information that the submitter believes is entitled to confidential treatment, the submitter is required only to designate the information as CBI.[61] Neither substantiation nor EPA review of confidentiality claims is expressly required under current TSCA. CBI protection also continues indefinitely, unless EPA determines that the information no longer qualifies for protection under the FOIA exemption and gives the submitter the required prior notice.[62] Since 2010, EPA has increased its review of confidentiality claims, particularly relating to chemical identities in health and safety studies.[63] The agency has also issued a "CBI Declassification Challenge" asking industry to withdraw CBI claims voluntarily and has engaged in other initiatives to increase public access to non-confidential information.[64]

Both the House bill and the Senate amendment would expand the requirements for substantiation of confidentiality claims and add certain circumstances (such as emergencies) when confidential information may be disclosed, with some differences. The House bill and the Senate amendment also take somewhat differing approaches to protecting chemical identities in health and safety studies. For a comparison among existing law, the House bill, and the Senate amendment on this topic, see pages CRS-20 through CRS-27 in **Table 1**.

## Resources to Administer TSCA

The level of resources and staffing available to EPA is one key factor that affects the pace and thoroughness for evaluating chemicals under TSCA. An issue for Congress is whether to continue funding EPA's activities under TSCA through discretionary appropriations or to establish dedicated sources of funding that are supplemental to and not subject to discretionary appropriations.

Under TSCA Section 29, appropriations for Title I were authorized through FY1983. Congress has continued to fund EPA's implementation of TSCA through annual appropriations pursuant to the program or "organic" authorities of TSCA that do not have a sunset date and do not expire unless otherwise amended.[65] Additionally, TSCA Section 26(b) authorizes EPA to assess fees on chemical manufacturers (including importers) or processors.[66] The authorization for EPA to assess these fees does not have a sunset date. EPA's authority to collect fees is statutorily limited to a maximum of $2,500 for the following actions required under TSCA Section 5:

- Each PMN that a manufacturer of a new chemical substance is required to submit to EPA, and
- Each notice that a manufacturer or processor is required to submit to EPA for a significant new use of a chemical substance.[67]

TSCA Section 26(b) currently provides an exception for small businesses under which these fees are limited to a maximum of $100. Furthermore, TSCA Section 26(b) authorizes EPA to assess fees within these statutory caps for the costs of evaluating testing data that a manufacturer or

[61] 15 U.S.C. 2613(c)(1).

[62] 15 U.S.C. 2613(c)(2).

[63] See footnote 58.

[64] EPA, "Voluntary Challenge To Declassify Confidential Business Information (CBI)," updated September 15, 2015, http://www.epa.gov/tsca-cbi/voluntary-challenge-declassify-confidential-business-information-cbi.

[65] 15 U.S.C. 2628.

[66] 15 U.S.C. 2625(b).

[67] 15 U.S.C. 2604.

processor of a chemical substance may be required to submit to the agency under TSCA Section 4.[68] Under TSCA, there is no dedicated account for fees collected under Section 26(b). As such, these fees are treated as miscellaneous receipts and deposited into the General Fund of the U.S. Treasury as required by the Miscellaneous Receipts Act.[69] The availability of fees collected under TSCA for obligation by EPA is subject to annual appropriations.

Both the House bill and the Senate amendment would amend TSCA Section 26(b) with regard to the authority to collect fees. The House bill and the Senate amendment differ in terms of what activities EPA would be authorized to collect a fee from manufacturers or processors and certain other limitations to overall fee collection authority. For either the House bill or the Senate amendment, collected fees would only be made available to EPA subject to the discretionary appropriations process. For a comparison among existing law, the House bill, and the Senate amendment on this topic, see pages CRS-47 through CRS-48 in **Table 1**.

# Side-by-Side Comparison of Provisions by Topic

**Table 1** of this report presents a side-by-side comparison of existing law, the House bill, and the Senate amendment. The table includes a discussion of each provision of the House bill and the Senate amendment, although it does not provide comprehensive analysis of the potential effects of particular provisions in the House bill or the Senate amendment. Existing law in the table is presented to the extent that such law would be amended by either the House bill or the Senate amendment. The table organizes the provisions of the House bill and the Senate amendment under 10 subheadings selected by CRS that reflect the following elements of TSCA:

I. Short title, intent, and definitions (page CRS-12);
II. Policies, procedures, and guidance; and advisory committee (page CRS-13);
III. Recordkeeping, reporting, chemical inventory, and development of new information (page CRS-15);
IV. Confidential treatment and public disclosure of information (page CRS-20);
V. Addressing risks of existing chemical substances and mixtures (page CRS-28);
VI. Addressing risks of new chemical substances and significant new uses of chemical substances (page CRS-36);
VII. Judicial review and enforcement (page CRS-39);
VIII. Relationship to state law (page CRS-42);
IX. Resources to implement TSCA (page CRS-47); and
X. Other provisions (page CRS-49).

[68] 15 U.S.C. 2603. As a matter of implementation, the regulations that EPA has promulgated to assess fees under TSCA apply to PMNs and notices of significant new uses required under TSCA Section 5 but not to the evaluation of testing data that may be required under TSCA Section 4.

[69] 31 U.S.C. 3302(b).

**Table 1. Side-by-Side Comparison of Existing Law, H.R. 2576 as Passed by the House, and the Senate Substitute Amendment to H.R. 2576 as Passed by the Senate in the 114th Congress**

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| **I. Short title, intent, and definitions** | | | |
| Short title | Not applicable. | Section 1 of the House bill provides that it may be cited as the "TSCA Modernization Act of 2015." | Section 1 of the Senate amendment provides that it may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act." |
| Intent | TSCA Section 2(c) [15 U.S.C. 2601(c)] states the intent of Congress that EPA shall carry out TSCA in a reasonable and prudent manner, and consider the environmental, economic, and social impact of TSCA actions. These provisions, particularly Section 2(c), have been used by courts in interpreting other provisions of TSCA.[a] | TSCA Section 2 would not be amended. | Section 2 of the Senate amendment would add to TSCA Section 2's congressional intent statement "as provided under this Act" language, reflecting the new limitations the amendments would impose on EPA's consideration of the economic and social impacts of certain TSCA actions.<br>Section 2 of the Senate amendment would also add a new paragraph to TSCA Section 2(c) specifying that (1) EPA shall protect various populations and the environment from risks of harmful exposures and shall ensure availability of emergency response information, and (2) the amendments shall not displace common law rights and remedies. These additions are mirrored in certain other provisions, as discussed below. |
| Definitions | TSCA Section 3 [15 U.S.C. 2602] defines 14 terms for purposes of the statute: Administrator, chemical substance, commerce, distribute in commerce, environment, health and safety study, manufacture, mixture, new chemical substance, process, processor, standards for the development of test data, state, and United States. | Existing definitions in TSCA Section 3 would not be amended. Section 2 of the House bill would add definitions for two terms: "intended conditions of use" and "potentially exposed subpopulation." These terms are discussed below in the context of their uses in the House bill. | Existing definitions in TSCA Section 3 would not be amended. Section 3 of the Senate amendment would add definitions for five terms: "conditions of use," "potentially exposed or susceptible population," "safety assessment," "safety determination," and "safety standard." These terms are discussed below in the context of their uses in the Senate amendment. |

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| **II. Policies, procedures, and guidance; and advisory committee** | | | |
| Scientific standards and use of information | No comparable provision in TSCA.[a] | Section 8(3) of the House bill would add new TSCA Section 26(h)-(i) to require EPA to consider—when making decisions based on science under amended TSCA Sections 4, 5, and 6—enumerated factors, as applicable. These factors are (1) soundness of scientific and technical methodology used to generate information; (2) relevancy of information; (3) clarity and completeness in documenting the generation of information; (4) variability and uncertainty in information; and (5) extent of independent verification or peer review of the information or of the methodology.[b] Furthermore, EPA is required to make decisions under amended TSCA Sections 4, 5, and 6 based on the "weight of the scientific evidence."<br><br>Amended TSCA Section 4 is discussed below under subheading III, amended TSCA Section 5 under subheading VI, and amended TSCA Section 6 under subheading V. | Section 4 of the Senate amendment would add new TSCA Section 3A(c) to direct that EPA policies, procedures, and "guidance" on the use of science in making decisions under amended TSCA Section 4, 5, and 6 and new TSCA Section 4A "ensure" that EPA decisions (1) are based on information and methodology that are consistent with the "best available science;" (2) take into account the extent to which there is clarity and completeness in documenting the generation of information, variability and uncertainty, and independent verification and peer review; and (3) are based on the "weight of the scientific evidence." Additionally, EPA policies, procedures, and guidance are to "ensure" that funding sources of information are clearly described and that, if appropriate, the recommendations in reports of the National Academy of Sciences relevant to chemical risk assessment are considered.[c] For purposes of new TSCA Section 3A, the term "guidance" would be defined in new TSCA Section 3A(a) to include any "significant" written guidance of general applicability prepared by EPA.<br><br>Section 4 of the Senate amendment would also add new TSCA Section 3A(f) to require EPA to take into consideration various sources of information relating to a chemical substance that is reasonably available to the agency in carrying out amended TSCA Sections 4, 5, and 6 and new TSCA Section 4A.<br><br>Amended TSCA Section 4 is discussed below under subheading III, amended TSCA Section 5 under subheading VI, and new TSCA Section 4A and amended TSCA Section 6 under subheading V. |

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| Development of policies, procedures, and guidance to implement TSCA | No comparable provision in TSCA.[d] | Section 8(3) of the House bill would add new TSCA Section 26(k) to direct EPA to develop any policies, procedures, and guidance for implementing the new purposes of the bill within two years of enactment. Within five years of enactment and at least once every five years thereafter, EPA would be directed to review the adequacy of the policies, procedures, and guidance, and, if necessary, revise them to reflect new scientific developments or understandings. | Section 4 of the Senate amendment would add new TSCA Section 3A(b) to direct EPA, within two years of enactment, to develop, with notice and public comment, any policies, procedures, and "guidance"—including those required by new TSCA Section 3A—for implementing purposes of amended TSCA Section 4, 5, and 6 and new TSCA Section 4A. As discussed in the previous row, the term "guidance" would be defined in new TSCA Section 3A(a) to include certain "significant" guidance. Section 4 of the Senate amendment would add new TSCA Section 3A(d) to direct that policies, procedures, and guidance under new TSCA Section 3A(b) incorporate existing relevant policies, procedures, and guidance as appropriate. Section 4 of the Senate amendment would add new TSCA Section 3A(e) to direct EPA, within five years of enactment and at least once every five years thereafter, to review the adequacy of any policies, procedures, and guidance developed under the section and, if necessary, after notice and public comment, revise them to reflect new scientific developments or understandings.<br><br>Section 4 of the Senate amendment would add new TSCA Section 3A(g) to require EPA to establish policies, procedures, and guidance for testing under amended TSCA Section 4.[e] Section 4 of the Senate amendment would also add new TSCA Section 3(h) to require EPA, through rulemaking, to establish policies and procedures for implementing amended TSCA Section 6 that, at a minimum, describe how EPA would gather, receive, and evaluate information and require certain content in each draft and final "safety assessment" and "safety determination."[f] Within one year of enactment, EPA would also be required to develop guidance to assist interested persons in developing their own draft safety assessments and other information for consideration by EPA. |

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| Establishment of an EPA advisory committee | No comparable provision in TSCA.<br>However, Section 8 of the Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA; 42 U.S.C. 4365) established a "science advisory board" that may provide independent scientific and technical advice to EPA regarding any proposed criteria document, standard, limitation, or regulation of the agency.[g] The Federal Advisory Committee Act (FACA; 5 U.S.C. Appendix) generally governs the operations of federal advisory committees, including the EPA Science Advisory Board.[h] | No comparable provision. | Section 4 of the Senate amendment would add new TSCA Section 3A(j) to direct EPA to establish, within one year of enactment, a Science Advisory Committee on Chemicals with the sole purpose of providing independent scientific and technical advice regarding implementation of the Senate amendment's provisions. Section 4 of the Senate amendment would establish certain requirements for the committee's membership and frequency of meetings. FACA would govern all proceedings and meetings of this committee, and the Senate amendment would not amend ERDDAA or FACA. |
| **III. Recordkeeping, reporting, chemical inventory, and development of new information** | | | |
| Recordkeeping and reporting requirements under TSCA | TSCA Section 8(a) [15 U.S.C. 2607] directs EPA to promulgate various recordkeeping and reporting requirements for manufacturers and processors of chemical substances and mixtures for purposes of enforcing requirements under TSCA.[a] EPA is prohibited from requiring recordkeeping or reporting with respect to changes in the proportions of mixture components unless the agency finds that it is necessary for enforcing requirements under TSCA.<br>EPA has discretion to promulgate certain recordkeeping and reporting requirements for small manufacturers and processors of chemical substances and mixtures that are found to warrant additional testing or regulation.[b] EPA, after consultation with the Small Business Administration (SBA), is directed to promulgate a rule establishing standards for determining whether an entity qualifies as a small manufacturer or processor for these purposes. The standards are codified in 40 C.F.R. 704.3. | Section 9(e) of the House bill would make conforming amendments to TSCA Section 8(a) to reflect proposed changes elsewhere in the House bill. | Section 10(1) of the Senate amendment would amend TSCA Section 8(a) in two ways. First, Section 10(1) of the Senate amendment would direct EPA, after consultation with SBA, to periodically review and, if necessary, after notice and public comment, revise standards for determining which entities qualify as a small manufacturer or processor for purposes of recordkeeping and reporting requirements. Initial review of these standards would be directed within 180 days of enactment and then at least once every 10 years thereafter. Second, Section 10(1) of the Senate amendment would add a new paragraph to TSCA Section 8(a) to direct EPA, within two years of enactment, to promulgate recordkeeping and reporting requirements for manufacturers and processors for purposes of implementing the amended TSCA. EPA would be authorized to modify, as appropriate, rules promulgated before the enactment of the Senate amendment. EPA would also be authorized to impose different recordkeeping and reporting requirements on manufacturers and processors and would be required to include the level of detail necessary to be reported. |

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| Inventory of chemical substances | TSCA Section 8(b) [15 U.S.C. 2607(b)] directs EPA to compile, keep current, and publish a list of each non-exempt chemical substance manufactured (defined to include imported) or processed for commercial purposes in the United States. This list is referred to as the TSCA inventory. New chemical substances for which a notice is received under TSCA Section 5 [15 U.S.C. 2604] are to be included on the inventory when manufactured or processed in the United States. EPA reports that the existing TSCA inventory includes at least 85,000 chemical substances.[c] EPA has also developed guidance on nomenclature conventions for purposes of identifying chemical substances. | TSCA Section 8(b) would not be amended. | Section 10(2) of the Senate amendment would add paragraphs to TSCA Section 8(b) to require EPA to use certain nomenclature conventions described in existing guidance for purposes of identifying substances on the inventory. Additionally, Section 10(2) of the Senate amendment would establish a process for EPA to divide substances on the TSCA inventory into those that are "active substances" or "inactive substances," which would both be new terms defined in TSCA Section 8(f). In order to inform EPA's division of the inventory, the agency would be directed, within one year of enactment, to promulgate a rule that requires manufacturers and processors to notify EPA, within 180 days after the rule is promulgated, which chemical substances on the inventory have been manufactured or processed during the timeframe within 10 years prior to enactment. EPA would be required to designate chemical substances for which a notice was received as active substances on the TSCA inventory. EPA would also be required to designate chemical substances for which no notice was received as inactive substances on the TSCA inventory. EPA would also be required to maintain and keep current designations of active substances and inactive substances on the TSCA inventory. Any person who intends to manufacture or process a chemical substance that is designated as an inactive substance would be required to notify EPA of this intention, and the agency would be required to redesignate this chemical substance as an active substance. Additionally, EPA would be required to designate chemical substances that were most recently reported under 40 C.F.R. Part 711 prior to enactment as the interim list of active substances for purposes of prioritization under new TSCA Section 4A. |

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| Confidential inventory | The inventory required under TSCA Section 8(b), as described above, includes a portion in which the confidentiality of certain chemical identities is maintained in accordance with procedures for protecting confidential information (40 C.F.R. Part 2). | No comparable provision. | As part of the overall process to divide substances on the TSCA inventory as "active" and "inactive," Section 10(2) of the Senate amendment would add paragraphs to TSCA Section 8(b) to require manufacturers and processors submitting active substance notices to indicate whether they seek to maintain any existing claim for confidentiality protection of specific chemical identities and to substantiate such claims (unless recently substantiated). The certifications would differ somewhat from the data-related confidentiality certifications (see below, subheading VI). Section 10(2) of the Senate amendment would require EPA to establish, by rule, a plan and a timeline for reviewing all such claims within five to seven years—and to review claims when an inactive substance changes to active status—as well as to "encourage" withdrawal or substantiation of claims for inactive substances. |
| Substantial risk notification requirement under TSCA | TSCA Section 8(e) [15 U.S.C. 2607(e)] requires any manufacturer, processor, or distributor of a chemical substance or mixture to notify EPA immediately of information obtained that reasonably supports the conclusion that such chemical substance or mixture presents a substantial risk of injury to health or the environment unless the notifier has knowledge that the agency has been adequately informed of such information.[d] | TSCA Section 8(e) would not be amended. | Section 10(3) of the Senate amendment would add new provisions to TSCA Section 8(e) to explicitly authorize any person to submit to EPA information that reasonably supports the conclusion that a chemical substance or mixture presents, will present, or does not present substantial risks. Section 10(3) of the Senate amendment would not amend the requirement for manufacturers, importers, processors, and distributors to notify EPA immediately of substantial risk information. |

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| Authority to require testing of chemical substances and mixtures to evaluate risks | TSCA Section 4(a) [15 U.S.C. 2603(a)] directs EPA to require manufacturers or processors of a chemical substance or mixture to test for whether there may be adverse health or environmental effects from that substance or mixture if the agency makes certain findings. In order to require testing, the agency may find that (1) there may be unreasonable risks from a substance or mixture and that the risks are insufficiently known or (2) substantial quantities of a chemical substance or mixture are being or will be produced in a way that either substantial quantities may enter the environment or there may be "significant or substantial human exposure" for which the risks are also insufficiently known. Additionally, EPA may require testing of mixtures if effects cannot be determined by the testing of substances that comprise the mixture. Section 4 authorizes EPA to require testing through rulemaking that is subject to the Administrative Procedure Act (5 U.S.C. 553) and additional requirements specified in TSCA Section 4. Exceptions from testing requirements are provided for instances when the information requested has already been developed or is being developed by another entity. Section 4(c) establishes a process for determining reimbursement of testing costs to the entity developing the required information by those for which an exception from testing requirements is made. EPA regulations establishing the procedures for test rules are codified in 40 C.F.R. Part 790. These regulations also provide for enforceable consent agreements, but Section 4 does not explicitly address such agreements. EPA regulation treats violations of enforceable consent agreements as subject to enforcement of orders (40 C.F.R. 790.65). | Section 3 of the House bill would generally retain the current framework under TSCA Section 4(a) for EPA to require testing based on the same findings as current law. In addition to the findings under current law, EPA would also be authorized to require testing if the agency finds that testing of a chemical substance is necessary to conduct a risk evaluation to determine whether regulation is warranted under TSCA. In addition to existing authority for EPA to promulgate a rule to require testing, EPA would also be expressly authorized to issue administrative orders and enter into consent agreements for purposes of requiring testing.<br>Section 9(a) of the House bill would make conforming amendments to TSCA Section 4 to reflect proposed changes elsewhere in the bill. | Section 5 of the Senate amendment would generally amend and restructure TSCA Section 4(a)-(e) and strike Section 4(g) (relating to certain petitions).[e] Section 5 of the Senate amendment would eliminate TSCA's current requirements for certain findings in order to require testing. Section 5 would amend TSCA Section 4(a) to give EPA discretion to require testing that the agency determines is necessary for specific purposes. The purposes include (1) prioritization of existing chemical substances for evaluation under new TSCA Section 4A (with certain limitations); (2) evaluation of existing and new chemical substances under amended TSCA Sections 5 and 6; (3) implementation of a requirement imposed in a consent agreement or order that prohibits or restricts a new chemical substance under new TSCA Section 5(c)(4) and 6(d)(3); (4) evaluation of chemical substances, mixtures, and articles manufactured or processed solely for export under amended TSCA Section 12; or (5) response to requests by another "implementing authority" under another federal law, to meet that authority's regulatory testing needs. In addition to existing authority for EPA to promulgate a rule to require testing, EPA would also be expressly authorized to issue administrative orders and enter into consent agreements for purposes of requiring testing, subject to certain requirements and procedures as would be amended by the bill, including certain explanatory statements. Section 5 of the Senate amendment would also amend TSCA Section 4(d) regarding procedures for determining fair and equitable reimbursement among entities required to conduct testing. |

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| Interagency committee for purposes of recommending testing of priority chemical substances and mixtures | TSCA Section 4(e) [15 U.S.C. 2603(e)] authorizes EPA to establish an interagency committee for purposes of recommending a list of priority chemical substances and mixtures to EPA for the agency to determine whether promulgation of a test rule is warranted.[f] The committee is authorized to designate a subset of chemical substances and mixtures, no more than 50 at any one time, from this list that warrant higher priority for testing. Such designation identifies those chemical substances and mixtures for which EPA is to determine whether the agency may find that a test rule is required under Section 4(a) within 12 months of its designation. EPA is required to publish reasons for not initiating a rulemaking for those designated chemical substances and mixtures that the agency does not find to require testing. The recommendations of the committee are not binding on EPA. | TSCA Section 4(e) would not be amended. | Section 5 of the Senate amendment would amend TSCA Section 4(e) with new language, thereby repealing the establishment of the interagency committee. As discussed above, under amended TSCA Section 4(a), EPA may require testing that the agency determines to be necessary for purposes of "implementing authority" requests under another federal law, to meet the regulatory testing needs of that authority. |
| Use of vertebrate animals for testing chemical substances and mixtures under TSCA | No comparable provision in TSCA.<br>However, the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-2 et seq.) directs the National Institute of Environmental Health Sciences to establish the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) for purposes of establishing guidelines, recommendations, and regulations that promote the use of new or revised scientifically valid toxicological tests while reducing, refining, or replacing animal tests.[g] EPA is a member of ICCVAM. | No comparable provision. | Section 5 of the Senate amendment would amend TSCA Section 4(c) to direct EPA to minimize, to the extent practicable, the use of vertebrate animals when requiring the development of new information under TSCA. Within two years of enactment, EPA would be directed to develop a strategic plan to promote alternative testing methods not based on vertebrate animals and fund research that is intended to help minimize the use of vertebrate animals in testing. EPA would be authorized to adapt or waive testing requirements based on certain considerations regarding the use of vertebrate animals. Additionally, Section 5 of the Senate amendment would address the use of vertebrate animals in voluntary testing for purposes of TSCA. The ICCVAM Authorization Act of 2000 would not be amended. |

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| **IV. Confidential treatment and public disclosure of information** | | | |
| Information protected from disclosure | TSCA Section 14 [15 U.S.C. 2613(a)] operates in conjunction with the Freedom of Information Act (FOIA; 5 U.S.C. 552). TSCA Section 14(a) clarifies that information reported to or obtained by EPA under TSCA that is exempt from the public disclosure requirements of FOIA as "trade secrets and commercial or financial information obtained from a person and privileged or confidential" (5 U.S.C. 552(b)(4)) cannot be disclosed by EPA or any representative of EPA, with certain exceptions described below.<br>EPA's general regulations on public information and confidential business information (40 C.F.R. Part 2) generally apply to information submitted under TSCA (40 C.F.R. 2.306). | Section 6 of the House bill would maintain TSCA Section 14(a) confidentiality protections for trade secrets and confidential business information. | Section 14 of the Senate amendment would maintain TSCA Section 14(a) confidentiality protections for trade secrets and confidential business information, slightly rearranged, "so long as the requirements of subsection (d) [of amended TSCA Section 14; for example, required certifications] are met."[a] Section 14 of the Senate amendment would also amend TSCA Section 14(b) to list categories of information "presumed to be protected from disclosure." These would include, for example, specific information describing manufacturing or processing, marketing and sales information, and, in general, the specific chemical identity of a new chemical substance claimed as confidential before it is first offered for commercial distribution. Time limits on protection (see below) would not apply to TSCA Section 14(b) information. |

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| Procedures and standards for designating or asserting confidentiality | TSCA Section 14(c)(1) [15 U.S.C. 2613(c)(1)] allows but does not require a manufacturer, processor, or distributor, when submitting information under TSCA to EPA, to designate in writing the information the submitter believes is entitled to confidential treatment. | Section 6 of the House bill would amend TSCA Section 14(c)(1)(A) to require a manufacturer, processor, or distributor, when submitting information under TSCA to EPA, to designate in writing the information the submitter believes is entitled to confidential treatment. It would require each designation to include a justification and a certification by the submitter that the information is not otherwise publicly available. | Section 14 of the Senate amendment would amend TSCA Section 14(d) to require any person seeking to protect from disclosure any information submitted under TSCA to EPA to assert a confidentiality claim at the time of submission. It would require each assertion to include a certification, by an authorized official of the submitter, that certain statements of justification and supporting information required to assert or substantiate a confidentiality claim are true. Section 14 of the Senate amendment would also require claims for protection of specific chemical identity of substances to include "structurally descriptive generic names" for the substances meeting certain conditions. EPA would be tasked with assigning a "unique identifier" to each generically named substance. For submitted information not presumed to be protected from disclosure under amended TSCA Section 14(b), Section 14 of the Senate amendment would require the submitter to provide further substantiation for confidentiality claims, pursuant to rules and guidance to be developed by EPA. |

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| Penalties for wrongful disclosure of confidential information | TSCA Section 14(d) [15 U.S.C. 2613(d)] sets forth criminal penalties for wrongful disclosure of information by current or former federal officers or employees, or contractors or their employees. Knowing and willful disclosure of protected information to any person not entitled to receive it is a misdemeanor. TSCA Section 14(d) provides that a person who commits such a misdemeanor shall be subject to a fine of up to $5,000 and/or imprisonment for up to one year. However, under the Sentencing Reform Act of 1984, as amended by the Criminal Fines Improvement Act of 1987 (18 U.S.C. 3571), all criminal fines are subject to certain uniform levels, modifying all fines imposed in the *U.S. Code*, including those imposed by TSCA. As a result of those two laws, the current maximum fine for an individual who has committed a misdemeanor under TSCA Section 14(d) is $100,000. TSCA Section 14(d) also provides that the penalties apply in lieu of 18 U.S.C. 1905 (which also requires removal from employment for public officers/employees). | TSCA Section 14(d) would not be amended.<br>Section 6 of the House bill would add new TSCA Section 14(f) prohibiting any person receiving information under one of the TSCA Section 14(a) exceptions (as discussed below) from using the information for any purpose not specified in the exception and from disclosing the information to any unauthorized person. | Section 14 of the Senate amendment would amend the penalties in a new TSCA Section 14(h), changing the fine from "not more than $5,000" to "fined under title 18." 18 U.S.C. 3571 applies higher fines for misdemeanors that result in death and for violations by organizations. 18 U.S.C. 3571 also provides for alternative fines based on pecuniary gain by the offender or pecuniary loss by another person caused by the violation. |

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| EPA review of confidentiality claims; time limits on protection from disclosure and renewal of claims | There are no provisions in TSCA requiring a confidentiality designation to include any justification of the designation or providing for the expiration of the information's confidentiality protection.[b] | The House bill would not modify EPA's review of confidentiality claims; it appears that EPA could continue to apply its current policy authorizing review of business information confidentiality under certain circumstances.<br>Section 6 of the House bill would amend TSCA Section 14(c)(1)(B) to provide that designations of confidentiality made after enactment of the House bill would expire after 10 years, after which EPA would make the information public—unless the submitter had reasserted the claim in writing, including (at least) all of the elements required for the initial designation. Section 6 of the House bill would add new TSCA Section 14(c)(1)(C) to require EPA to notify the submitter at least 60 days prior to such expiration. It is uncertain from the bill's language whether this renewal would be one time only or would be required every 10 years. | Section 14 of the Senate amendment would add new TSCA Section 14(g) to require EPA to review a data submitter's confidentiality claim within 90 days of the submission and give reasons for denial or modification of the claim. The "failure of [EPA] to make a decision regarding a claim" by the deadline would not be a basis for denying or eliminating the claim. EPA would have to review all claims for confidential treatment of the identity of chemical substances offered for commercial distribution and at least 25% of other confidentiality claims.<br>Section 14 of the Senate amendment would add new TSCA Section 14(f)(1) to require EPA to protect from disclosure confidential information submitted after enactment of the Senate amendment (other than information presumed to be protected under amended TSCA Section 14(b)) for 10 years and to notify the submitter 60 days before the expiration of that period. Certain procedures would apply to extension requests. The number of confidentiality extensions would be unlimited.<br>Section 14 of the Senate amendment would add new TSCA Section 14(f)(2) to authorize EPA, in its discretion, to require a submitter claiming protection to withdraw, reassert, or resubstantiate confidentiality claims in limited circumstances. Section 14 of the Senate amendment would *require* EPA to review confidentiality claims (1) if it had a reasonable basis to believe the information does not qualify, (2) in connection with FOIA requests, or (3) for any chemical substance found not to meet the safety standard. Approval after review would begin a 10-year protection period. A savings clause would bar EPA from requiring substantiation except as provided. |

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| Circumstances when confidential information may be disclosed | TSCA Section 14(a) [15 U.S.C. 2613(a)] sets forth exceptions to protection from disclosure, the first three of which are mandatory. Information is to be made available (1) to any officer or employee of the United States, in connection with official duties for the protection of health or the environment or specific law enforcement purposes; (2) to federal contractors and their employees for work in connection with TSCA, under certain conditions; (3) when EPA determines it "necessary to protect health or the environment against an unreasonable risk of injury"; or (4) at EPA's discretion, in any proceeding under TSCA, preserving confidentiality to the extent practicable.<br>TSCA Section 14(e) clarifies that all information obtained by EPA under TSCA shall be made available upon written request to any duly authorized congressional committee. | Section 6 of the House bill would retain TSCA Section 14(a)'s four current exceptions to protection from disclosure and also (1) authorize disclosure to a state, local, or tribal government official upon their request for the purpose of administration or enforcement (but not development) of a law; and (2) mandate disclosure upon request to a health or environmental professional employed by a federal or state agency in response to an environmental release or to a treating physician or other health care professional to assist in individuals' diagnoses or treatments. Rather than requiring confidentiality agreements in specific situations, Section 6 of the House bill would prohibit recipients from using the information for any purpose not specified in the exception and from disclosing the information to any unauthorized person, as noted above.<br>TSCA Section 14(e) would not be amended. | Section 14 of the Senate amendment would restructure and expand the exceptions to protection from disclosure by replacing TSCA Section 14(e). It would generally maintain the current exceptions and would add the following mandatory disclosures:<br>(1) To a state or locality—tribes are not mentioned—upon their request for the purpose of development, administration, or enforcement of a law, subject to confidentiality agreements meeting certain criteria;<br>(2) To a health or environmental professional employed by a federal or state agency or treating health care professional in a non-emergency situation, upon a written statement of need and agreement to sign a confidentiality agreement, subject to certain conditions;<br>(3) In emergencies, upon request, to a treating health care or poison control professional, public health or environmental official, or first responder, subject to certain conditions, including a statement of need and signed confidentiality agreement (not necessarily prior to disclosure);<br>(4) Similar to current TSCA Section 14(e), for requests from any duly authorized congressional committees; and<br>(5) If required to be made public under any other provision of federal law.<br>For disclosures to a health or environmental professional or in an emergency, as described in (2) and (3) above, EPA would be required to consult with the Centers for Disease Control and Prevention (CDC) on an access system for the information disclosed. |

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| Procedures for disclosure of information designated as confidential | TSCA Section 14(c)(2) [15 U.S.C. 2613(c)(2)] sets forth notice procedures if EPA proposes to release information designated as confidential (other than health and safety studies, as discussed below). EPA may not release such information until 30 days after the information's submitter has received notice, in writing by certified mail, of EPA's intended release. This notice period is shortened to 15 days if EPA deems disclosure "necessary to protect health or the environment against an unreasonable risk" (or 24 hours if the risk is imminent). Notice requirements generally do not apply to disclosures to federal employees or contractors, or to disclosures in proceedings under TSCA. | The House bill would not make substantive changes to the proposed release notice procedures of TSCA Section 14(c)(2) except to clarify that (1) they are distinct from the notice required before expiration of the 10-year protection period, and (2) the procedures do not apply to disclosures to government health or environmental professionals or treating health care professionals who are provided information upon their request under the circumstances described above.<br>Section 6 of the House bill would add new TSCA Section 14(g) savings clause clarifying that nothing in amended TSCA Section 14 shall be construed to affect the applicability of state or federal rules of evidence or procedures in any judicial proceeding. This is similar to the savings clause in the preemption provisions in amended TSCA Section 18 (see below). | Section 14 of the Senate amendment would generally prohibit EPA from releasing information asserted as confidential (other than, e.g., to EPA employees and contractors) until 30 days after the submitter has received notice, in writing by certified mail, of EPA's intended release. This notice period would be shortened to 15 days for congressional requests or if EPA deems it necessary to protect health or the environment against an unreasonable risk (no prior notification is required if the release is to protect against imminent and substantial harm). EPA would be required to notify "as soon as practicable" after disclosure to a health or environmental professional or in an emergency under the circumstances set forth, respectively, in exceptions (2) and (3) in the preceding row. For chemical substances subject to a ban or phase-out under TSCA, Section 14 of the Senate amendment would authorize requests for nondisclosure, with "a rebuttable presumption that the public interest in [disclosure] outweighs the proprietary interest in maintaining the protection," subject to certain conditions for EPA determinations and appeals. |

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| Information that may be disclosed; health and safety studies | TSCA Section 14(b) [15 U.S.C. 2613(b)] provides that TSCA's confidentiality protections do not extend to health and safety studies or related data submitted to EPA under TSCA for chemical substances and mixtures that have been offered for commercial distribution or in certain other circumstances. However, this exclusion does not authorize "the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, … the portion of the mixture comprised by any of the chemical substances in the mixture." Some chemical identities in health and safety studies have been protected as confidential under this exclusion.[c]<br>There is no specific provision regarding other information that may be disclosed, but information that is outside the FOIA (b)(4) [5 U.S.C. 552(b)(4)] exemption for trade secrets and confidential business information is outside the scope of protection from disclosure under TSCA Section 14. (Other FOIA exemptions could still apply.) | Section 6(2) of the House bill would retain TSCA Section 14(b)'s provision that TSCA's confidentiality protections do not extend to health and safety studies or related data but expands the exception to this provision: In addition to protecting data disclosing processes or mixture portions, Section 6(2) of the House bill would also protect "data that disclose formulas (including molecular structures) of a chemical substance or mixture" if otherwise confidential. This provision could include confidential chemical identities.<br>There would continue to be no specific provision regarding other information that may be disclosed. | Section 14 of the Senate amendment would amend TSCA Section 14(c) to expressly articulate information not protected from disclosure pursuant to TSCA. Amended TSCA Section 14(c) would retain without substantive change TSCA's provision that confidentiality protections do not extend to health and safety studies or related data. It would address chemical identities, whether in health and safety studies or not, in a separate paragraph on "other information not protected from disclosure." For information submitted after enactment, information not protected from disclosure would include "the specific identity of a chemical substance as of the date on which the chemical substance is first offered for commercial distribution" unless the person submitting the information meets the substantiation and other requirements of amended TSCA Section 14(d). Information not protected from disclosure would also include safety assessments, safety determinations, and certain types of general information. If EPA promulgates a rule establishing a ban or phase-out of a chemical substance, then any confidentiality protection for information on that chemical substance would no longer apply, subject to applicable notification and appeal provisions. |

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| Requirements for public disclosure | TSCA has no general requirement for public disclosure or dissemination of non-confidential information.[d] | Section 6 of the House bill would amend TSCA Section 14(c)(1)(B) to require EPA to make public all information submitted to the agency for which the 10-year protection period (described above) has expired without renewal.<br>Additionally, Section 8 of the House bill would add new TSCA Section 26(j) to require EPA to make available to the public all EPA notices, determinations, findings, rules, and orders under TSCA. | Sections 4, 5, and 7 of the Senate amendment contain provisions that would require EPA to make available to the public certain information relating to safety assessments and safety determinations, testing or other information submitted or orders or agreements issued under amended TSCA Section 4, and new chemical information submitted or issued under amended TSCA Section 5, subject to the protections of TSCA amended Section 14. Information from states on state chemical restrictions would also have to be made publicly available, subject to amended TSCA Section 14 and any applicable state law. Section 14 of the Senate amendment would also require EPA to promptly make public information for which a claim for confidentiality is withdrawn or information on a chemical substance subject to a ban or phase-out rule if EPA determines the information is not protected from disclosure. |

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| **V. Addressing risks of existing chemical substances and mixtures** | | | |
| Prioritization of existing chemical substances and mixtures for evaluation of risks | No comparable provision in TSCA.<br>As a practical matter, EPA has discretion regarding which chemical substances and mixtures to prioritize for the evaluation of risks to determine whether regulation is warranted.[a] | Section 4 of the House bill would add new TSCA Section 6(b)(3) to establish three principal mechanisms to select existing chemical substances for risk evaluation.[b] Section 4 of the House bill would require EPA to conduct and publish risk evaluations on chemical substances (1) that the agency has determined may present an unreasonable risk because of potential hazard and potential route of exposure under the "intended conditions of use" (defined in Section 2 of the House bill), or (2) for which a manufacturer has requested a risk evaluation, subject to fees (discussed below under subheading IX). Third, EPA would be authorized and not required to conduct risk evaluations for substances listed in EPA's TSCA Work Plan[c] on the date of enactment without having to make a determination regarding potential hazard and potential route of exposure, as discussed above.<br>Section 4 of the House bill also sets forth separate provisions in new TSCA Section 6(i) to address chemical substances that are "persistent, bioaccumulative, and toxic." These provisions are discussed below under this subheading. | Section 6 of the bill would add new TSCA Section 4A to establish a risk-based screening process for EPA to prioritize existing chemical substances on the TSCA inventory for evaluation to determine whether regulation is warranted. EPA would be directed to promulgate a rule to establish the process and criteria for prioritization within one year of enactment. The rule would be required to contain a number of procedures (including various public notice and certain public comment requirements), preferences, and criteria.[d] For example, EPA would have to prioritize at a specified rate all substances identified by EPA on the TSCA Work Plan[e]; to use certain approaches for certain substances, such as metals[f] or inactive substances; and to consider state input. (States would be required to notify EPA of their proposed restrictions on chemical substances not prioritized.) EPA would also be required to prioritize a chemical substance within 90 days after receiving information on that substance required under TSCA Section 4. Based on the process, preferences, and criteria, chemical substances would be listed as high priority or low priority for evaluation or needing additional information for prioritization. Chemical substances would be removed from the high priority list as their evaluations are completed and replaced on the list by at least one other chemical. EPA would have to make "every effort" to prioritize all active substances "in a timely manner."<br>The process would also include input from manufacturers or processors who may request EPA to evaluate a particular chemical substance as an "additional priority," subject to fees. Such requests would be subject to notice and public comment, and EPA would be required to grant or deny them within 180 days under set criteria and limits. |

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| Evaluation of existing chemical substances and mixtures | TSCA Section 6 [15 U.S.C. 2605] authorizes EPA to evaluate chemical substances or mixtures to find whether regulation is warranted. EPA is authorized to make a finding that there is a reasonable basis to conclude that the manufacture, processing, distribution, use, or disposal of a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. "Unreasonable risk" has been interpreted by the Fifth Circuit Court of Appeals to encompass economic and practical considerations.[g]<br><br>Additionally, TSCA Section 4(f) [15 U.S.C. 2603(f)] requires EPA to initiate "appropriate" action under TSCA Sections 5, 6, or 7 to reduce risk from a chemical substance or mixture for which test data or other information indicates there may be a reasonable basis to conclude that the chemical substance or mixture presents a significant risk of serious or widespread harm from cancer, gene mutations, or birth defects or to publish reasons for finding that such risk is not unreasonable. EPA is required to initiate the action or publish the reasons within 180 days after receiving the information; EPA may extend this deadline up to 90 days for good cause. | Section 4(b) of the House bill would amend TSCA Section 6(b) to require EPA to conduct risk evaluations "without consideration of cost or other non-risk factors" to determine whether a chemical substance[h] presents or will present an unreasonable risk under amended TSCA Section 6(a). EPA would be directed to evaluate chemical substances that meet criteria described in the row above to determine whether they present unreasonable risk under their "intended conditions of use" and thus whether regulation is warranted.<br><br>Sections 4 and 8 of the House bill would direct EPA to conduct risk evaluations in accordance with certain requirements that pertain to timing, use of science, and consideration of risks to "potentially exposed subpopulations" (defined in Section 2 of the House bill).<br><br>Relatedly, Section 4(e) of the House bill would add new TSCA Section 6(g) to prohibit EPA from considering costs or other non-risk factors when deciding whether to initiate a rulemaking under amended TSCA Section 6(a).<br><br>TSCA Section 4(f) would not be amended. | Section 3 of the Senate amendment would add several new definitions to TSCA Section 3 that would effectively prohibit EPA from considering cost or other non-risk factors in making a "safety determination" as to whether a chemical substance meets the "safety standard." Section 3 would also define "safety standard" as a standard that "ensures, without taking into consideration cost or other non-risk factors," no "unreasonable risk."<br><br>Section 8 of the Senate amendment would amend TSCA Section 6(a) and (c) to direct EPA to conduct a "safety assessment" (also defined by Section 3 of the Senate amendment) and make a safety determination of high-priority substances to determine whether regulation is warranted.[i] For each safety determination, EPA would be required to determine whether a chemical substance meets or does not meet the safety standard or whether additional information is necessary to make such determination. The scope of the safety determination would be limited to the "conditions of use" and risks that would be evaluated include those to "potentially exposed or susceptible populations," defined in Section 3 of the Senate amendment. Section 8 of the Senate amendment would amend TSCA Section 6(b) to encourage continuation of prior-initiated assessments and policies and use of existing information. Other considerations pertaining to use of science and other topics would be guided by policies and guidance required to be issued by EPA under new TSCA Section 3A. A determination that a substance meets the safety standard would be required to be issued by order and would be a final agency action subject to judicial review.<br><br>Section 5 of the Senate amendment would amend TSCA Section 4(f) to encompass *any* serious or widespread harm and make certain other conforming changes. |

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| Pace of prioritization and evaluation of existing chemical substances and mixtures | No comparable provision in TSCA. | Section 4 of the House bill would add new paragraphs to TSCA Section 6(b) to require EPA to initiate 10 or more risk evaluations in each fiscal year (excluding requests from manufacturers) subject to the availability of appropriations.<br>EPA would also be required to conduct and publish risk evaluations that the agency initiates within three years of determining that the chemical substance warrants evaluation. The agency would be required to complete manufacturer-requested evaluations within two years after granting the request. These deadlines would be subject to extension if EPA determines additional information is necessary to make a risk evaluation determination up to 90 days after receipt of the required information or two years after the deadline being extended. Additionally, EPA would be required to publish a preliminary determination of no unreasonable risk at least 30 days prior to finalizing such determination. The final determination would be considered a final agency action subject to judicial review. | Section 6 of the Senate amendment would add new TSCA Section 4A(a) directing EPA to publish an initial list of at least 10 high-priority substances and at least 10 low-priority substances within 180 days after enactment (that is, prior to the deadline for EPA's publication of a rule to establish the process and criteria for subsequent prioritization). Section 6 of the Senate amendment would require EPA to add chemical substances to the priority lists described above sufficient to have initiated at least 20 safety assessments of high-priority substances by three years after enactment (and to have listed 20 low-priority chemical substances) and at least 25 by five years after enactment. Generally at least half of high-priority substances would be drawn from the TSCA Work Plan until all Work Plan chemical substances were designated. EPA would also be required to designate high-priority substances consistent with the agency's ability to complete safety assessments and safety determinations in accordance with the statutory deadlines and to publish an annual goal for prioritization.<br>Section 8 of the Senate amendment would amend TSCA Section 6(a) to require EPA to complete risk assessments within three years of prioritization, subject to limited extension up to one year where required information has not been received. Manufacturer- or processor-requested risk assessments could not be expedited or otherwise favored. Section 4 of the Senate amendment would add new TSCA Section 3A(h) to require EPA to publish an annual plan, including certain mandatory elements, for safety assessments and safety determinations. |

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| Regulatory actions to address unreasonable risks | If EPA were to find that a chemical substance or mixture warranted regulation due to unreasonable risks, TSCA Section 6(a) [15 U.S.C. 2605] directs the agency to promulgate a rule using the "least burdensome" requirement to adequately address such risks pursuant to certain procedures and requirements in rulemaking.[i] TSCA Section 6 identifies seven regulatory options that range in severity from a labeling requirement to an outright ban.<br><br>EPA is required to consider the effects and exposure of the chemical substance found to warrant regulation, benefits of the substance, and any consequences from regulation. Additionally, EPA is required to determine whether another federal law may adequately address the identified risks (see discussion below on "Relationship to other federal laws not administered by EPA" and "Relationship to other federal laws administered by EPA").<br><br>TSCA Section 6(b) authorizes EPA to issue quality control orders under certain conditions. TSCA Section 6(c) sets forth required statements and procedures, including informal hearings. TSCA Section 6(d) addresses effective dates for rules under TSCA Section 6(a). | If EPA were to determine that a chemical substance or mixture presented an unreasonable risk based on the evaluation of risks, TSCA Section 6(a), as would be amended by Section 4 of the House bill, would require EPA to promulgate, by rule, a restriction on the substance or mixture so that it would no longer present unreasonable risks, including those risks to "potentially exposed subpopulations." Section 4(a) of the House bill would strike language requiring EPA to protect against unreasonable risks using the "least burdensome requirement." EPA would be required to determine that the restrictions are "cost effective" unless the agency was to determine that additional or different requirements were necessary to protect against the identified risks. Section 4 of the House bill would require EPA to make a determination on the availability of alternatives as a substitute to the chemical substance subject to the proposed restriction. EPA would be required to apply restrictions to articles containing a chemical substance that are subject to a proposed restriction only to the extent necessary to protect against the risks being addressed. The deadline for the final rule would be two years after the publication of the risk evaluation. Any restriction would be required to have a reasonable transition period. Additionally, Section 4 of the House bill would repeal the authority of EPA to issue quality control orders under TSCA Section 6(b) and the provisions on informal hearings under TSCA Section 6(c).<br><br>Section 9(c) of the House bill would make conforming amendments to TSCA Section 6 to reflect proposed changes elsewhere in the bill. | If EPA were to find that a chemical substance warranted regulation based on a safety determination, TSCA Section 6, as would be amended by Section 8 of the Senate amendment, would require EPA to promulgate, by rule, a restriction on the substance so that the safety standard (defined to include no unreasonable risks to "potentially exposed or susceptible subpopulations") would be met. Section 8 of the Senate amendment would slightly reword the regulatory options and add specific requirements for a ban or phase-out. Restrictions would no longer need to be the least burdensome requirement. EPA would have discretion in determining whether restrictions would apply to mixtures containing a substance found to warrant regulation. There would be certain rulemaking requirements and mandatory considerations, such as alternatives to the chemical substance that warrants regulation. EPA would be required to apply restrictions to articles containing a chemical substance subject to a proposed restriction, only to the extent necessary to address risks from exposure to that substance in articles. The deadline for the final rule would be two years after the safety determination, subject to extension up to two years and the condition that the aggregate length of all extensions of deadlines for the safety assessment and safety determination for a chemical substance does not exceed two years. Rules would have to include dates by which compliance is mandatory, as soon as practicable but generally within four years.<br><br>Additionally, Section 8 of the Senate amendment would repeal EPA authority to issue quality control orders under TSCA Section 6(b) and the provisions on informal hearings. |

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| Exemptions from regulatory actions | No comparable provision in TSCA. | Section 4(c) of the House bill would amend TSCA Section 6(c) to require EPA to exempt "replacement parts" *designed* prior to the publication of the rule unless the agency finds that such parts contribute significantly to the risks being addressed.[k]<br>Additionally, Section 4(e) of the House bill would add new TSCA Section 6(h) giving EPA discretion to exempt critical uses from any restriction pursuant to certain procedures and requirements. | Section 8 of the Senate amendment would direct EPA to exempt "replacement parts" that are *manufactured* prior to the publication of the rule, unless the agency finds that such parts contribute significantly to the risks being addressed.[l]<br>EPA would have discretion to exempt from regulation, by rule, certain uses that the agency determines would compromise national security, disrupt the national economy, or provide substantial benefit or public safety over an alternative, although there would be additional considerations and conditions for any proposed exemption to a ban or a phase-out. |
| Chemical substances that are persistent, bioaccumulative, and toxic (PBT) | No comparable provision in TSCA. | Section 4 of the House bill would add TSCA Section 6(i) to require expedited action for chemical substances that are "persistent, bioaccumulative, and toxic" (PBT) and not metals, metal compounds, or polychlorinated biphenyls (PCBs) subject to TSCA Section 6(e). EPA would be directed to publish an initial list of PBTs within nine months after enactment; within two years after enactment, EPA would be required to confirm and designate as PBT chemicals of concern those that, with respect to persistence and bioaccumulation, score high for one and either high or moderate for the other, pursuant to EPA's February 2012 "TSCA Work Plan Chemicals Method Document"[m] and for which exposure is likely to the general population or to a "potentially exposed subpopulation" identified by EPA. Upon such designation, EPA would be directed to promulgate a rule within two years to reduce likely exposure to the designated substance to the extent practicable. However, if, within 90 days after EPA publishes the initial list of PBTs, the agency were to make a finding that a risk evaluation is warranted or a manufacturer were to request a risk evaluation for a chemical substance, these provisions would not apply to that chemical substance. | Section 6 of the Senate amendment would, in new TSCA Section 4A, direct EPA to give preference in prioritization to (among others) chemical substances that, with respect to persistence and bioaccumulation, score high for one and either high or moderate for the other, pursuant to EPA's February 2012 "TSCA Work Plan Chemicals Methods Document."[n]<br>For such substances, Section 7 of the Senate amendment would add new TSCA Section 5(d)(4)(D), and Section 8 of the Senate amendment would amend TSCA 6(d)(2)(B) to direct EPA, in selecting among regulatory actions to address unreasonable risk, to reduce exposure to the maximum extent practicable. |

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| Regulatory actions to address imminently hazardous chemical substances and mixtures | TSCA Section 7 [15 U.S.C. 2606] authorizes EPA to file a civil action in a federal district court to address an "imminently hazardous chemical substance or mixture," which is defined in Section 7(f) as a chemical substance or mixture that presents an "imminent and unreasonable risk of substantial or widespread injury to health or the environment." Imminent risks are considered as those risks that are likely to result in serious or widespread injury before a Section 6 rule may be promulgated to protect against such risk. EPA may file for seizure of such substance, mixture, or article containing such substance or mixture or for other relief. | Section 9(d) of the House bill would make conforming amendments to TSCA Section 7 to reflect proposed changes elsewhere in the bill. | Section 9 of the Senate amendment would amend TSCA Section 7 to authorize EPA to file a civil action to address a chemical substance or mixture for which risks are imminent but not necessarily unreasonable and make certain conforming amendments. |

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| Relationship to other federal laws not administered by EPA | TSCA Section 9(a) [15 U.S.C. 2608] directs EPA to take certain actions if the agency has reasonable basis to conclude that the manufacture, processing, distribution, use or disposal of a chemical substance or mixture presents or may present unreasonable risk and determines that such risk may be prevented or reduced to a sufficient extent by action taken under a federal law not administered by the agency. If such determination were made, EPA is directed to report (1) a description of the unreasonable risk and (2) activities that EPA believes to present such risk to the federal agency that administers the other federal law. Additionally, EPA is required to request that the other federal agency determine if the risk may be addressed to a sufficient extent by action taken under other federal law and to issue an order declaring whether or not the activities described by EPA present such risk within an amount of time that EPA specifies in the request, although the amount of time may not be less than 90 days from when the request was made. EPA is prohibited from taking action under TSCA Section 6 or 7 with respect to the unreasonable risk reported to the other federal agency if such agency issues an order declaring that activities described by EPA do not present unreasonable risk or initiates action under another federal law to protect against such risk described by the report. If EPA has already initiated action under TSCA Section 6 or 7 with respect to an unreasonable risk reported to another federal agency, that agency is required to consult with EPA before taking action under other federal law for the purpose of avoiding duplication of federal action against such risk. | Section 9(f) of the House bill would make conforming amendments to TSCA Section 9(a) to reflect proposed changes elsewhere in the bill. | Section 11 of the Senate amendment would amend TSCA Section 9 to direct EPA to take certain actions if (1) EPA were to report to another federal agency that administers other federal law regarding unreasonable risks and (2) that agency does not respond or take action within an amount of time that EPA specifies in its request. If the aforementioned conditions are met, EPA would be required to (1) complete the safety assessment and safety determination for the chemical substance that is the subject of the report under amended TSCA Section 6 if such assessment and determination has not been completed, (2) initiate action under amended TSCA Section 6(d) with respect to the risk if the chemical substance that is the subject of the report is determined not to meet the safety standard, or (3) take any action authorized or required under amended TSCA Section 7, as appropriate. Section 11 of the Senate amendment further clarifies that EPA would not be relieved of any obligation to complete a safety assessment and safety determination or take any required action under amended TSCA Section 6(d) or 7 to address risks that are not identified in a report issued by the agency.<br><br>Additionally, Section 11 of the Senate amendment would add new TSCA Section 9(e) to direct EPA to make information related to exposures or releases of a chemical substance that may be prevented or reduced under another federal law to the relevant federal agency or EPA office. |

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| Relationship to other federal laws administered by EPA | TSCA Section 9(b) [15 U.S.C. 2608(b)] requires EPA to coordinate actions taken under TSCA with actions taken under other federal laws administered by the agency. If EPA determines that a risk associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under other federal law, EPA is required to take action under that other federal law unless the agency determines it is in the public interest to take action under TSCA. | Section 5 of the House bill would add a new paragraph to TSCA Section 9(b) to require EPA to consider the relevant risks, and compare the estimated costs and efficiencies, of an EPA action under TSCA and an action taken under another federal law that the agency administers if the agency has determined that it is in the public interest to take action under TSCA. | TSCA Section 9(b) would not be amended. |

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| **VI. Addressing risks of new chemical substances and significant new uses of chemical substances** | | | |
| Premanufacture notices (PMNs) of new chemical substances and significant new use notices (SNUNs) of chemical substances | TSCA Section 5 [15 U.S.C. 2604] establishes a framework in which EPA is authorized to evaluate new chemical substances and "significant new uses" of a chemical substance to determine whether regulation may be warranted prior to such substances and uses entering commerce. EPA evaluations are based on required notification from (1) manufacturers of new chemical substances and (2) manufacturers and processors of chemical substances that are intended for a use that the agency has determined, through a significant new use rule (SNUR), to be a significant new use. Notification for a new chemical substance is commonly referred to as a PMN, whereas notification for a significant new use is commonly referred to as a SNUN. PMNs and SNUNs are required to be submitted at least 90 days prior to the new chemical substance entering commerce or the manufacture or processing of a chemical substance for a significant new use, respectively, subject to extension by EPA for good cause. Section 5(b) addresses testing for new chemical substances and significant new uses and authorizes EPA to compile a list of chemical substances that present or may present unreasonable risk. Section 5(h) provides certain exemptions from notification for circumstances in which there is likely to be less risk. Existing EPA regulation generally does not require notification for importation of an article that contains a new chemical substance or a chemical substance that would otherwise require notification by a SNUR (40 C.F.R. 720.22).[a] | Section 9(b) of the House bill would make conforming amendments to TSCA Section 5 to reflect proposed changes elsewhere in the bill. | Section 7 of the Senate amendment would restructure TSCA Section 5.[b] Section 7 of the Senate amendment would amend TSCA Section 5(b) to authorize EPA to require notification for importing or processing of a chemical substance as part of an article or category of articles that would otherwise require notification based on a SNUR if the agency makes a finding in the SNUR that there is "reasonable potential for exposure" from importation and processing that warrants notification.<br>Section 7 of the Senate amendment would also amend TSCA Section 5(c) to codify existing EPA regulations (40 C.F.R. 720.45 and 720.50) regarding the content required in a PMN or SNUN and require that such notices include all known or reasonably ascertainable information regarding conditions of use and reasonably anticipated exposures.<br>Additionally, Section 7 of the Senate amendment would make certain conforming amendments to TSCA Section 5(h) to reflect proposed changes elsewhere in the Senate amendment. |

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| Review of PMNs and SNUNs | Under TSCA Section 5 [15 U.S.C. 2604], EPA is not required to review the information required in PMNs or SNUNs. In practice, the agency prioritizes its reviews based on the likelihood of unreasonable risk to determine if regulation may be warranted. If EPA does not take regulatory action on a chemical substance that is the subject of a notice, the manufacturer or processor submitting that notice may initiate manufacture or processing of that chemical substance. | Section 9(b) of the House bill would make conforming amendments to TSCA Section 5 to reflect proposed changes elsewhere in the bill. | Section 7 of the Senate amendment would amend TSCA Section 5(d) to direct EPA to conduct initial reviews of PMNs and SNUNs that are submitted to the agency within 90 days of receipt of the notice and make a determination on whether regulation would be warranted or that additional information is necessary to make such determination. Regulation would be warranted if the substance or significant new use is "not likely to meet the safety standard." (Section 3 of the Senate amendment would define "safety standard" as a standard that "ensures, without taking into consideration cost or other non-risk factors" no "unreasonable risk.") Generally, EPA would be authorized to extend the review period by an additional 90 days. If EPA were to find that a new chemical substance or significant new use was "likely to meet the safety standard," manufacturing of the new chemical substance or manufacturing or processing of the chemical substance for the significant new use could commence before the end of the 90-day review period. |

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| Regulatory action to address unreasonable risks of new chemical substances and significant new uses of chemical substances | TSCA Section 5 [15 U.S.C. 2604] provides three mechanisms through which EPA can take regulatory action to address unreasonable risks of a new chemical substance or a significant new use of a chemical substance. These mechanisms include administrative orders, rulemakings, and judicial orders. Section 5(e) authorizes EPA to issue an administrative order based on determinations that (1) there may be unreasonable risks from a substance and that the risks are insufficiently known, or (2) substantial quantities of a chemical substance are being or will be produced in a way that either substantial quantities may enter the environment or there may be "significant or substantial human exposure" for which the risks are also insufficiently known. In practice, such orders are generally negotiated as a consent order with the manufacturer or processor and are sometimes followed by SNURs. Section 5(e) also authorizes EPA to apply for a judicial order under certain conditions. Additionally, Section 5(f) authorizes EPA to issue an administrative order, pursue rulemaking under Section 6, or apply for a judicial order to address unreasonable risks. | TSCA Section 5(e) and (f) would not be amended. Section 4 of the House bill would amend TSCA Section 6, as discussed above. | Section 7 of the Senate amendment would amend TSCA Section 5(d) to authorize EPA to issue an administrative order or enter into a consent agreement to restrict new chemical substances or significant new uses of chemical substances that EPA determines not to meet the "safety standard" or determines that additional information would be necessary to make a determination. (Section 3 of the Senate amendment would define "safety standard" as a standard that "ensures, without taking into consideration cost or other non-risk factors" no "unreasonable risk.") Section 7 of the Senate amendment would also require EPA, within 90 days after a consent agreement or order under TSCA Section 5 as would be amended, to consider whether to promulgate a SNUR and initiate rulemaking or publish reasons for not doing so. |
| Notice of commencement | Pursuant to TSCA Section 8(b) [15 U.S.C. 2607(b)], new chemical substances for which a notice is received under TSCA Section 5 [15 U.S.C. 2604] are to be included on the TSCA inventory by EPA when manufactured or processed for commercial purposes in the United States, as discussed above under subheading III.[c] | No comparable provision. | Section 7 of the Senate amendment would amend TSCA Section 5(e) to codify existing EPA regulation that requires manufacturers to submit a SNUN within 30 days after commencing manufacture of a new chemical substance.<br>Section 7 of the Senate amendment would amend TSCA Section 5(f) to authorize EPA to prioritize chemical substances for evaluation of risks under new TSCA Section 4A any time after a notice of commencement or new information has been received by the agency. |

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| **VII. Judicial review and enforcement** | | | |
| Judicial review of EPA actions | TSCA Section 19(a) [15 U.S.C. 2618(a)] allows any person to file a petition for judicial review of a rule to require testing under Section 4, a SNUR under Section 5, risk protection requirements under Section 6(a) or 6(e), or a reporting or recordkeeping rule under Section 8 (or rules under other titles of TSCA). Petitions must be filed in a federal court of appeals within 60 days after the rule's promulgation. Section 19(a) also provides for judicial review of quality control orders under Section 6(b)(1) in federal courts of appeals. Section 19(a) incorporates 28 U.S.C. 2112 procedural requirements relating to filing the rulemaking record and defines "rulemaking record." TSCA Section 19(b) governs applications for additional submissions and presentations.<br>Under TSCA Section 19(c), the standard of review for rules other than SNURs is that "the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record (as defined …) taken as a whole," rather than the usual "arbitrary or capricious" standard under the Administrative Procedure Act (APA; 5 U.S.C. 706(2)(E)). Section 19(c) also offers grounds for striking down a Section 6 rule based on certain deficiencies in informal hearings. The APA otherwise applies.<br>TSCA Section 4(f) also provides that a finding by EPA that a risk is not unreasonable, after the receipt of certain "significant risk of serious or widespread harm" information under that subsection, is "an agency action for purposes of judicial review." | Section 9(j) of the House bill would expand TSCA Section 19(a) to authorize challenges to testing orders (in addition to rules) under amended TSCA Section 4 and amend TSCA Section 19(b)-(c) to reflect the addition of such orders to TSCA Section 19(a). The House bill would not amend the standard of review, except to make a conforming amendment to extend the application of the "substantial evidence" standard to challenges to testing orders as well as to testing rules.<br>Additionally, Section 9(j) of the House bill would make conforming amendments to TSCA Section 19 to reflect proposed changes elsewhere in the bill. | Section 18 of the Senate amendment would amend TSCA Section 19(a) to authorize challenges to safety determination orders under amended TSCA Section 6(c)(1)(A) finding a chemical substance to meet the safety standard. It would not authorize challenges to testing orders. However, Section 18 of the Senate amendment would also state that except as otherwise provided, federal courts of appeals shall have exclusive jurisdiction of any action to obtain judicial review of any order (other than in enforcement proceedings) issued under Title I of TSCA if any federal district court would have had jurisdiction. This could potentially include testing orders. Section 18 of the Senate amendment would change TSCA Section 19(a)'s references to rules under specific provisions of Sections 4, 5, 6, or 8 to "a rule under this title."<br>Section 18 of the Senate amendment would add a paragraph to TSCA Section 19(a) dealing specifically with civil actions to challenge low-priority decisions. The implications of the use of the term "civil action" rather than "petition" are not entirely clear.<br>Section 18 of the Senate amendment would remove the definition of "rulemaking record" and slightly reword the standard of review under TSCA Section 19(c) to read that "… if the court finds that the rule is not supported by substantial evidence (including any matter) in the rulemaking record, taken as a whole." Section 18 of the Senate amendment would make certain conforming and streamlining revisions but would not update TSCA Section 19(b)-(c) to reference orders in addition to rules, except that the safety standard would apply to positive safety determination orders under amended TSCA Section 6(c)(1)(A). |

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| Penalties | Under TSCA Section 16(a) [15 U.S.C. 2615(a)], any person who violates Section 15 or 409 (in TSCA Title IV) shall be liable for a civil penalty up to $25,000 per violation. Each day a violation continues is a separate violation. Section 16(a) provides procedures for notice, hearing, judicial review, and recovery for non-payment. (The Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note and 31 U.S.C. 3701 note) requires agencies to issue regulations adjusting for inflation the statutory civil monetary penalty limits under the laws they administer. The adjusted limit for civil penalties under TSCA is $37,500 per violation (40 C.F.R. 19.4).<br><br>TSCA Section 16(b) sets forth criminal penalties for knowing or willful violations, providing that in addition to or in lieu of any civil penalty, such a violator shall be subject, upon conviction, to a fine of up to $25,000 for each day of violation and/or imprisonment for up to one year. However, under the Sentencing Reform Act of 1984, as amended by the Criminal Fines Improvement Act of 1987 (18 U.S.C. 3571), all criminal fines are subject to certain uniform levels, modifying all fines imposed in the *U.S. Code*, including those imposed by TSCA. As a result of those two laws, the current maximum fine for an individual who has committed a TSCA misdemeanor that does not result in death is $100,000, and an individual who has committed a TSCA misdemeanor that does result in death or a TSCA felony could be subject to a fine of up to $250,000. Likewise, under current law, an organization could be forced to pay a maximum fine of $200,000 if guilty of a TSCA misdemeanor and a maximum fine of $500,000 for a TSCA misdemeanor resulting in death or a TSCA felony. | TSCA Section 16 would not be amended. | Section 16 of the Senate amendment would increase the civil penalty cap under TSCA Section 16(a) from $25,000 to $37,500, reflecting the current adjusted civil monetary penalty cap, and change "violation of section 15 or 409" to "violation of this Act."<br><br>Section 16 of the Senate amendment would also double the criminal penalty cap under TSCA Section 16(b) from $25,000 per day to $50,000 per day. Section 16 of the Senate amendment would add a new paragraph to TSCA Section 16(b) regarding knowing or willful criminal violations placing an individual in imminent danger of death or serious bodily injury. In such cases, an individual violator would be subject on conviction to a fine of not more than $250,000 total and/or imprisonment for not more than 15 years, and an organization would be subject on conviction to a fine of up to $1 million per violation.[a] For prosecution of these violations, Section 16 of the Senate amendment would incorporate various procedural and definitional provisions in Clean Air Act Section 113(c)(5) [42 U.S.C. 7413(c)(5)]—for example, regarding affirmative defenses and what constitutes knowledge and "serious" injury.[b] |

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| Citizen civil actions | TSCA Section 20 [15 U.S.C. 2619] allows any person to commence a civil action in certain federal district courts (1) to restrain alleged TSCA violations, or (2) to compel EPA to perform a nondiscretionary duty under TSCA. Section 20 also sets forth certain other provisions governing such civil actions, including certain requirements to give notice to EPA and, if applicable, to the alleged violator prior to commencing action. | Section 9(k) of the House bill would make conforming amendments to TSCA Section 20 to reflect proposed changes elsewhere in the bill. | Section 19 of the Senate amendment would make certain conforming amendments to TSCA Section 20. |
| Citizen petitions | TSCA Section 21 [15 U.S.C. 2620] allows any person to petition EPA to initiate a proceeding for issuance, amendment, or repeal of certain rules or orders and sets forth certain procedures. | Section 9(l) of the House bill would make conforming amendments to TSCA Section 21 to reflect proposed changes elsewhere in the bill. | Section 20 of the Senate amendment would make certain conforming amendments to TSCA Section 21. |

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| **VIII. Relationship to state law** | | | |
| Preemption general framework | Under the Supremacy Clause of the U.S. Constitution,[a] state or local (hereinafter "state" will be used to refer collectively to both state and local) law and policy must yield to the exercise of Congress's powers if Congress so intends.[b] Under TSCA Section 18(a)(1) [15 U.S.C. 2617(a)(1)], there is no preemption of state regulation of chemical substances, mixtures, or articles containing chemical substances or mixtures unless EPA takes certain preemptive actions described in Section 18(a)(2). Where EPA has taken such actions, any preemption is chemical-specific. Exceptions to preemption may apply, or EPA may grant waivers by rule.<br>Section 18(a)(2) provides for preemption of state requirements as follows:<br>(A) An EPA test rule under Section 4 will preempt a state testing requirement for the same chemical substance or mixture for similar purposes.<br>(B) An EPA rule or order under Section 5 or 6 (other than a regulation of disposal of a chemical substance or mixture) that is designed to protect against a risk of injury to health or the environment associated with a chemical substance or mixture will preempt a non-identical state requirement that is applicable to that chemical substance or mixture and is designed to protect against the same risk.<br>There has been little preemption of state law under TSCA, in part because EPA has issued few Section 6 rules.[c] | The House bill would retain TSCA's general framework whereby enumerated EPA actions preempt state chemical requirements for particular chemical substances or mixtures unless an exception or waiver applies.<br>Section 7 of the House bill would modify and add to the circumstances in which state requirements are preempted (unless an exception or waiver applies):<br>(A) An EPA order or consent agreement, as well as rule, under TSCA Section 4 would preempt a state testing requirement for the same chemical substance or mixture for similar purposes.<br>(B) An EPA final determination under amended TSCA Section 6(b) that a chemical substance will not present an unreasonable risk under the "intended condition of use" would preempt a state requirement designed to protect against exposure to the chemical substance under those intended conditions of use.<br>(C) An EPA rule or order under TSCA Section 5 or 6, designed to protect against a risk of injury to health or the environment associated with a chemical substance or mixture, would preempt, from its effective date, a state requirement that applies to that substance or mixture (or to an article because the article contains the substance) and is (i) designed to protect against exposure to the substance under either the intended conditions of use considered by EPA in its risk evaluation or uses identified in a PMN or SNUN, or (ii) for an EPA requirement under new TSCA Section 6(i) (i.e., expedited action for chemical substances that are persistent, bioaccumulative, and toxic, designed to protect against a risk considered by EPA in imposing such requirement. | The Senate amendment would retain TSCA's general framework whereby enumerated EPA actions preempt state chemical requirements for particular chemicals unless an exception or waiver applies, but it would generally restructure TSCA Section 18.[d]<br>Section 17 of the Senate amendment would modify and add to the circumstances in which state requirements would be preempted (from the effective date of the EPA action in each case):<br>(A) An EPA order or consent agreement, as well as rule, under TSCA Section 4 would preempt a state information development requirement for the same chemical substance reasonably likely to produce the same information.<br>(B)(i) An EPA safety determination finding a chemical substance to meet the safety standard, or (ii) an EPA rule issued under amended TSCA Section 6(d) on the basis of an EPA safety determination, finding the chemical not to meet the safety standard, would preempt a state chemical restriction to the extent of the scope of the safety assessment and determination.<br>(C) A SNUR for a chemical would preempt a state requirement for the notification of the uses in the SNUR.<br>Section 17 would also set forth temporary preemption of new state requirements. While a high-priority (not manufacturer-requested "additional priority") substance is under evaluation—from scoping until either publication of the determination or the deadline for such publication, whichever is earlier—states would be preempted from establishing a *new* prohibition or restriction on the manufacture, processing, distribution in commerce, or use of that substance. |

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| Exceptions to preemption based on nature of state requirement | TSCA Section 18 [15 U.S.C. 2617] does not provide exceptions to preemption by EPA test rules, but there are several exceptions to preemption by EPA rules or orders under Sections 5 or 6:<br>(i) state requirements identical to those prescribed by EPA;<br>(ii) state requirements adopted under the authority of the Clean Air Act or any other federal law; or<br>(iii) prohibitions on the use of a chemical substance or mixture in the state (other than its use in the manufacture or processing of other substances or mixtures).<br>A parenthetical provides that Section 6 rules imposing disposal requirements will not preempt state disposal-related requirements. | Section 7 of the House bill would generally expand the exceptions to preemption but would not add exceptions to preemption by EPA test rules. For chemical substances or mixtures found to not present an unreasonable risk or for which EPA has issued a risk protection rule or order under amended TSCA Section 5 or 6, exceptions would include state requirements:<br>(i) adopted under the authority of a federal law;<br>(ii) adopted to protect air or water quality or related to waste treatment or disposal, except if an EPA action under TSCA "actually conflicts" with the state requirement; and<br>(iii) identical to those prescribed by EPA, for EPA rules under TSCA Section 5 or 6. A state could not assess a penalty for a violation for which EPA had assessed a penalty under TSCA. If a state assessed a penalty, EPA could not assess a penalty for that violation in an amount that would cause the total penalties assessed to exceed TSCA's penalty caps. | Section 17 of the Senate amendment would set forth exceptions to preemption in new subsections (d) and (e) of TSCA Section 18. For *all* bases of preemption, exceptions would include state requirements, standards, determinations, etc.:<br>(i) adopted or authorized under the authority of, or adopted to satisfy or obtain authorization or approval under, any other federal law;<br>(ii) implementing a reporting, monitoring, disclosure, or other information obligation not otherwise required by EPA or under any other federal law;<br>(iii) adopted under a state or local law related to water quality, air quality, or waste treatment or disposal, except to the extent that the state or local action or requirement imposes a restriction and either (a) addresses the same hazards and exposures, under the same conditions of use, as EPA included in the chemical's safety determination, but is inconsistent with the EPA action, or (b) would cause a violation of (i.e., narrower than "conflicts with") the applicable EPA action; or<br>(iv) identical to a requirement prescribed by EPA. The state could not have more stringent penalties or sanctions than EPA for the requirement and could not assess a penalty for a violation for which EPA had assessed an "adequate" penalty under TSCA. If a state assessed a penalty, EPA could not assess a penalty for that violation in an amount that would cause the total penalties to exceed TSCA's penalty caps. |

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| Exceptions to preemption to preserve certain existing state requirements | Not applicable. | Section 7 of the House bill would add new TSCA Section 18(c)(1) allowing a state to continue to enforce (A) any action taken, or requirement that has taken effect, before August 1, 2015, under the authority of a state (not local) chemical restriction law; and (B) any action taken, or requirement that has taken effect, pursuant to a state law that was in effect on August 31, 2003. Exception (B) in this subsection appears not to include, for example, future actions or requirements under California's Proposition 65 or existing state green chemistry laws. Neither (A) nor (B) would apply if an EPA action or determination under TSCA "actually conflicts with the [state] action.…" | Section 17 of the Senate amendment would amend TSCA Section 18(e) to allow a state (A) to continue to enforce any action taken before August 1, 2015, under the authority of a state or local chemical restriction law; and (B) to proceed without preemption with any action taken, without time limitation, pursuant to a state law that was in effect on August 31, 2003. Exception (B) appears to preserve, for example, future actions or requirements under California's Proposition 65 but not later state green chemistry laws. Nothing in amended TSCA Section 18 could be construed as modifying the preemptive effect of any EPA rules or orders existing before enactment of the Senate amendment. For the few chemical substances for which Section 6 rules have been issued, current TSCA Section 18 would govern unless and until the chemical substance is designated as high-priority or an additional priority. |

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| Waivers or exemptions from preemption | Under TSCA Section 18(b) [15 U.S.C. 2617(b)], EPA has discretion to grant, by rule, an application of a state to exempt a state requirement from preemption by an EPA rule or order under TSCA Sections 5 or 6 if certain conditions are met:<br>(1) compliance with the state requirement would not cause a violation of the otherwise preempting EPA requirement;<br>(2) the state requirement provides a significantly higher degree of protection from the risk than the EPA requirement; and<br>(3) the state requirement does not unduly burden interstate commerce through difficulties in marketing, distribution, or other factors.<br>EPA could impose conditions in the rule. There are no specific provisions for judicial review, so presumably the APA would apply. (It appears that no TSCA preemption waivers have been issued.) | TSCA Section 18(b) would not be amended. | Section 17 of the Senate amendment sets forth two types of waivers from preemption in new TSCA Section 18(f). First, the EPA Administrator (non-delegable) would have discretion to grant, by rule, an application of a state to exempt a state statute or administrative action from preemption if he or she determines that (A) compelling conditions warrant the waiver to protect health or the environment; (B) compliance with the state requirement would not unduly burden interstate commerce or cause a violation of any federal requirement; and (C) the state requirement is designed to address a chemical risk, under the conditions of use that (in the Administrator's judgment) the state identified consistent with various scientific and evidentiary standards. EPA could impose conditions on the waivers. Second, the Administrator would be required to grant an application of a state to exempt, from the temporary preemption applicable during EPA's evaluation, a new state statute or action relating to the effects of exposure to a chemical under the conditions of use if he or she determines the state "has a concern about the chemical … based in peer-reviewed science" and meets conditions similar to (B) above.<br>New TSCA Section 18(f) would require the Administrator to make a determination on a discretionary waiver within 180 days and on a required waiver within 110 days. For the latter, if the Administrator missed the deadline, the application would be automatically approved. Notice and public comment would be required for all waiver applications, except those for required waivers that had been automatically approved. Decision on waiver applications would be considered final agency action, subject to judicial review. Amended TSCA Section 19 would add expediting provisions for actions brought to compel a decision by EPA on required waivers. |

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| Preemption savings clauses: limitations on effects of TSCA on common law and other actions | No comparable provision in TSCA.<br>TSCA does not restrict evidentiary uses of EPA actions under TSCA, although the relevance or evidentiary weight—if any—of EPA actions in a particular case would depend on applicable law and on the facts of that case.<br>TSCA Section 18 also does not expressly preempt or affect lawsuits regarding chemical exposures under common law. Nonetheless, courts could interpret preempted "requirements" to include state common law.[e] | Section 7 of the House bill would add new paragraphs in TSCA Section 18(c) to provide that nothing in TSCA Title I as amended, nor any risk evaluation or requirement under that title, shall be construed to "preempt or otherwise affect" federal or state tort law or law governing the interpretation of contracts of any state. This would include any statutory or common law remedy for civil relief, including for civil damages, as well as any cause of action for injury based on any legal theory relating to tort law.[f]<br>New TSCA Section 18(c) would also state the intent of Congress that nothing in amended TSCA, and no requirement under that title (this provision does not expressly address risk evaluations), be interpreted as influencing the disposition of any civil action for damages in a state court or the authority of any court to make a determination in an adjudicatory proceeding under applicable state law on the admissibility of evidence unless a provision of this title actually conflicts with the state court action. For purposes of TSCA Title I, the term "requirements" would not include civil tort actions for damages under state law. | Section 17 of the Senate amendment would add new TSCA Section 18(g)(1) to provide that nothing in TSCA as amended—and no scientific assessment, safety determination, or requirement under it—shall be construed to "preempt, displace, or supplant" federal or state common law rights or statutes creating a remedy for civil relief, including for civil damages, or a penalty for criminal conduct. Nothing in amended TSCA would preempt or preclude any cause of action for injury based on any legal theory of liability under any state law, maritime law, or federal common law or statutory theory.[g]<br>TSCA Section 18(g)(2) would also provide that nothing in amended TSCA—no safety determination, scientific assessment, or requirement pursuant to amended TSCA—shall be interpreted as dispositive in any civil action. Amended TSCA would also not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable state or federal law with respect to the admission into evidence, or any other use, of amended TSCA and any safety determination, scientific assessment, or requirement thereunder. |
| Preemptive effect of pre-enactment EPA actions | Not applicable. | Section 7(c) of the House bill would state that nothing in the House bill shall be construed as changing the preemptive effect of a rule promulgated or order issued by EPA under TSCA either prior to enactment of the House bill or at any time under TSCA Section 6(e) [15 U.S.C. 2605(e)] (regarding polychlorinated biphenyls (PCBs)). | Section 17 of the Senate amendment would state that nothing in amended TSCA Section 18 shall be construed as changing the preemptive effect of any rule promulgated or order issued under TSCA prior to the enactment of the Senate amendment. For chemicals for which any rule or order was promulgated under TSCA Section 6 prior to enactment of the Senate amendment (including Section 6(e) regarding PCBs), the pre-amendment version of TSCA Section 18 would govern the preemptive effect of any additional rule or order after that date as well, unless the latter rule or order follows a designation of that chemical as a high-priority substance or as an additional priority. |

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| Grants to states addressing unreasonable risks not being addressed by EPA | TSCA Section 28 [15 U.S.C. 2627] authorizes EPA to award grants to states that have programs approved by the agency to address unreasonable risks associated with a chemical substance or mixture that the agency is unable or is not likely to address. Grant awards are limited to 75% of the establishment and operation costs of a state program. Section 28 provides criteria for EPA approval of a state program and authorizes states to use such grants only for the establishment and operation of such program. Section 28 established an annual reporting requirement on EPA to report to Congress grant awards to states for fiscal years that have since passed. Section 28 also authorized appropriations of $1.5 million for the purpose of awarding grants most recently for FY1982 and FY1983. Although authorization of such appropriations has expired, Congress has continued to provide TSCA grant funding to states through annual discretionary appropriations.[h] | TSCA Section 28 would not be amended. | Section 25 of the Senate amendment would repeal the annual reporting requirement and the authorization of appropriations for awarding grants for fiscal years that have since expired. EPA authority to award grants to states under TSCA Section 28 would be retained. |
| **IX. Resources to implement TSCA** | | | |
| Authorization of appropriations | TSCA Section 29 [15 U.S.C. 2628] authorized appropriations ($58.65 million for FY1982 and $62.00 million for FY1983) for the implementation of TSCA not including development and evaluation of test methods under TSCA Section 27, grants to state programs under TSCA Section 28, and certain research, development, and monitoring authorities under TSCA Section 10. Although authorization of appropriations has expired, Congress has continued to fund EPA's implementation of TSCA through annual discretionary appropriations.[a] | TSCA Section 29 would not be amended. | Section 26 of the Senate amendment would repeal TSCA Section 29. |

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| Fees | TSCA Section 26(b) [15 U.S.C. 2625(b)] authorizes EPA to assess fees for the following actions. EPA may assess fees for the costs of evaluating (1) each PMN under TSCA Section 5, (2) each SNUN under TSCA Section 5, and (3) testing data that a manufacturer or processor of a chemical substance or mixture may be required to submit to the agency under TSCA Section 4. Fees are limited to a maximum of $2,500, and an exception is provided for a "small business concern" up to a maximum of $100. EPA, after consultation with the Small Business Administration, is directed by rule to prescribe standards for determining a small business concern for purposes of collecting fees under TSCA. The standard is codified in 40 C.F.R. 700.43. The availability of fees collected under TSCA for obligation by EPA are subject to annual discretionary appropriations. Fees without a dedicated account, such as these TSCA fees, are generally treated as miscellaneous receipts and deposited into the General Fund of the U.S. Treasury as required by the Miscellaneous Receipts Act (31 U.S.C. 3302(b)).[b] | Section 8(1) of the House bill would amend TSCA Section 26(b) to strike the existing statutory caps on fees that EPA may assess. The agency would be limited to assessing fees that are "sufficient and not more than reasonably necessary." In addition to the same notices and testing data for which EPA may assess fees under TSCA Section 4 and 5, the agency would be authorized to assess fees from manufacturers who request the agency to conduct a risk evaluation of a chemical substance. Section 8(2) of the House bill would establish a revolving fund of the U.S. Treasury to be known as the "TSCA Service Fee Fund." EPA would be directed to deposit collected fees into the TSCA Service Fee Fund. The availability of fees in the TSCA Service Fee Fund for obligation by EPA would be subject to annual discretionary appropriations. Section 8(2) of the House bill would also subject the TSCA Service Fee Fund to certain accounting and auditing requirements. | Section 23 of the Senate amendment would replace TSCA Section 26(b) with new language. Within one year of enactment, EPA would be directed to promulgate a rule to collect a fee from manufacturers or processors who submit certain notices, requests for exemptions, or information to the agency or who manufacture or process a substance that is subject to a safety assessment and a safety determination. Fees could be used only to defray costs associated with certain agency activities to implement TSCA. Section 23 of the Senate amendment would establish a limit on the amount that could be collected annually, which would be set at the lower of 25% of the cost for EPA to conduct relevant activities or up to $25 million, adjustable after consultation with parties potentially subject to the fees. Fees from manufacturers or processors would be set to defray the full annual costs of conducting safety assessments and safety determinations that are requested or 50% annual costs of conducting safety assessments and safety determinations that are requested for substances already on the TSCA Work Plan. Section 23 of the Senate amendment would establish a fund of the U.S. Treasury to be known as the "TSCA Implementation Fund." EPA would be directed to deposit collected fees into the TSCA Implementation Fund. The availability of fees in the TSCA Implementation Fund for obligation by EPA would be subject to annual discretionary appropriations. Authorization to collect fees would be contingent upon minimum appropriations that are equivalent or greater than that appropriated in FY2014 for EPA's Chemical Risk Review and Reduction program project. Section 23 would also subject the TSCA Implementation Fund to certain auditing requirements. The authority for EPA to collect fees would terminate 10 years after enactment unless otherwise reauthorized by Congress. |

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| **X. Other Provisions** | | | |
| Export recordkeeping, reporting, and notification requirements | TSCA Section 12 [15 U.S.C. 2611] provides that TSCA requirements (other than recordkeeping or reporting requirements under TSCA Section 8) do not apply to chemical substances, mixtures, or articles containing a chemical substance or mixture intended for export only and marked as such unless there is an exception.<br>If EPA finds that the chemical substance, mixture, or article intended only for export will present unreasonable risks in the United States, then the agency may require testing of such substance or mixture pursuant to TSCA Section 4.<br>If EPA has required testing on a chemical substance or mixture under TSCA Sections 4 or 5(b) that is intended for export only, then the exporter is required to notify EPA about the export activity. EPA, in turn, is required to notify the government of the country to which the chemical substance or mixture is being exported of the availability of testing data submitted to the agency.<br>If EPA has issued an order under TSCA Section 5 or proposed or promulgated a rule under TSCA Sections 5 or 6 on a chemical substance or mixture intended for export only, or if relief has been granted under TSCA Sections 5 or 7 on a chemical substance or mixture intended for export only, then the exporter is required to notify EPA about the export activity. EPA, in turn, is required to notify the government of the country to which the chemical substance or mixture is being exported of the regulatory action.<br>An exception from not being subject to TSCA (other than TSCA Section 8) is also made for export of elemental mercury, discussed below. | TSCA Section 12 would not be amended. | Section 13 of the Senate amendment would amend TSCA Section 12 with regard to exceptions for which a chemical substance may be subject to TSCA requirements in addition to recordkeeping and reporting requirements under TSCA Section 8. EPA would be authorized to require testing under amended TSCA Section 4 on any chemical substance (including a new chemical substance) for which the agency has made a determination of unreasonable risk without accounting for cost or other non-risk factors. EPA would be authorized to determine whether mixtures or articles containing a chemical substance that is for export only and for which TSCA requirements apply may be subject to TSCA requirements in addition to TSCA Section 8 requirements or establish a threshold concentration in a mixture or an article for which TSCA requirements may apply in addition to TSCA Section 8 requirements.<br>Section 13 of the Senate amendment would amend the circumstances in which an exporter of a chemical substance or mixture must notify EPA of an export to a foreign country. These circumstances are similar to those in current TSCA, although, in addition, an exporter is required to notify EPA of export of a chemical substance for which the United States is obligated by treaty to provide notification. EPA would be directed to promulgate rules to require notification by exporters, include in the rule any exemption that EPA determines to be appropriate, and indicate whether, or to what extent, the rule would apply to articles containing a chemical substance or mixture. EPA would still be required to notify the government of the country to which a chemical substance or mixture is being exported of certain information. |

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| Employment effects | TSCA Section 24 [15 U.S.C. 2623] requires EPA to evaluate on a continuing basis the potential effects on employment of the issuance of a rule or order under TSCA Sections 4, 5, or 6 or a requirement under TSCA Sections 5 or 6. Additionally, TSCA Section 24 establishes a process in which EPA is required to conduct an investigation and, upon request by any interested person, hold public hearings in investigating certain employer actions that allegedly result from a rule or order under TSCA Sections 4, 5, or 6 or a requirement under TSCA Sections 5 or 6 if requested by any employee. Public hearings are to be held in accordance with TSCA Section 6(c)(3) and other requirements. Upon completion of an investigation, EPA is required to publicize its findings and recommendations. | TSCA Section 24 would not be amended. | Section 21 of the Senate amendment would require that hearings be held in accordance with "applicable requirements" of TSCA rather than with TSCA Section 6(c)(3), which would be amended by the Senate amendment. |
| Studies | TSCA Section 25 [15 U.S.C. 2624] required EPA and the Council on Environmental Quality to conduct certain studies by a date that has since passed. | TSCA Section 25 would not be amended. | Section 22 of the Senate amendment would repeal TSCA Section 25. |

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| Sustainable chemistry research | TSCA Section 10 [15 U.S.C. 2609] authorizes EPA, in consultation and cooperation with the Department of Health and Human Services (HHS) and other federal agencies and departments, to enter into contracts and to award grants for purposes of research, development, and monitoring under TSCA. Under Section 10, EPA has provided financial assistance to eligible projects that relate to "sustainable chemistry."[a]<br><br>Additionally, Section 509 of the National Science Foundation Authorization Act of 2010 (42 U.S.C. 1862p-3) directs the National Science Foundation (NSF) to establish a Green Chemistry Basic Research grant program to provide funding for "green chemistry research, education, and technology transfer." | TSCA Section 10 and Section 509 of the National Science Foundation Authorization Act of 2010 would not be amended. | Section 12 of the Senate amendment would make a conforming amendment to TSCA Section 10. Section 509 of the National Science Foundation Authorization Act of 2010 would not be amended.<br><br>Section 24(a) of the Senate amendment would add new subsections to TSCA Section 27 to direct the Office of Science and Technology Policy to establish, within 180 days of enactment, an interagency entity under the National Science and Technology Council with the responsibility to coordinate federal programs and activities in support of "sustainable chemistry." This entity would be co-chaired by the NSF director and EPA assistant administrator for the Office of Research and Development and would be required to (1) develop a working definition of "sustainable chemistry," (2) oversee the establishment of an interagency Sustainable Chemistry Initiative to promote and coordinate certain activities related to sustainable chemistry, (3) submit to certain congressional committees a national strategy on federal support for sustainable chemistry within two years of enactment, (4) submit to certain congressional committees an implementation plan based on findings of the national strategy and other assessments within three years of enactment, and (5) consult and coordinate with stakeholders on these activities. Additionally, the entity would be required to work through federal agencies involved in the entity to support the establishment of partnerships between various organizations with regard to sustainable chemistry research and training.<br><br>Section 24(b) of the Senate amendment would expressly direct NSF to continue carrying out the Green Chemistry Basic Research program authorized under Section 509 of the National Science Foundation Authorization Act of 2010, subject to the availability of appropriated funds. |

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| TSCA implementation reports | TSCA Section 30 [15 U.S.C. 2629] establishes an annual reporting requirement for EPA to report to the President and Congress regarding aspects of the statute's implementation. However, Section 3003 of P.L. 104-66, the Federal Reports Elimination and Sunset Act of 1995 [31 U.S.C. 1113 note] terminated this reporting requirement and other requirements under other laws.[b] | Section 9(o) of the House bill would make conforming amendments to TSCA Section 30 to reflect proposed changes elsewhere in the bill.[c] However, the House bill would not alter the termination of reporting requirements pursuant to Section 3003 of P.L. 104-66.<br>Additionally, Section 8(3) of the House bill would add new TSCA Section 26(l) to establish a requirement for EPA to report to certain congressional committees regarding (1) the agency's capacity to conduct and publish risk evaluations that are initiated by the agency and resources necessary to initiate the minimum number of risk evaluations that are required; (2) the agency's capacity to conduct and publish risk evaluations that are requested by manufacturers (including requested risk evaluations for substances that are already on TSCA Work Plan), the likely demand for such risk evaluations, and anticipated schedule for accommodating such demand; (3) the agency's capacity to promulgate rules for those chemical substances found to warrant regulation based on a risk evaluation; and (4) the agency's efforts to increase capacities to conduct risk evaluations. The initial report is to be submitted within six months after enactment. The report is to be updated and resubmitted not less than once every five years. | Section 27 of the Senate amendment would amend the content of the annual reporting requirement under TSCA Section 30. However, the Senate amendment would not alter the termination of reporting requirements pursuant to Section 3003 of P.L. 104-66. |
| Effective date | TSCA Section 31 [15 U.S.C. 2601 note] made provisions of the statute effective on January 1, 1977 (except for a two-year delay for TSCA Section 4(f), requiring EPA action upon receipt of information suggesting significant risk of serious or widespread harm to humans from cancer, gene mutations, or birth defects). | TSCA Section 31 would not be amended, nor does the House bill include a provision specifying an effective date. Where no statutory provision specifies otherwise, a statute takes effect on its date of enactment.[d] | Section 28 of the Senate amendment would eliminate the reference to a delayed effective date for TSCA Section 4(f) and would specify that "the act" should not be interpreted to apply retroactively to any state, federal, or maritime legal actions commenced prior to the effective date of the Senate amendment, which would be its date of enactment. |

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| Specific chemical concerns: mercury | TSCA Section 6(f) [15 U.S.C. 2605(f)] prohibits the conveyance, sale, and distribution of elemental mercury that is owned by federal agencies, effective October 14, 2008, unless it is only for purposes of facilitating storage or involves coal.[e] TSCA Section 12(c) [15 U.S.C. 2611(c)] prohibits export of elemental mercury, effective January 1, 2013, unless it is exempted as an "essential use." Any person residing in the United States may petition EPA for such exemption, and EPA may grant by rule, after notice and public comment, an exemption for a specified use at a foreign facility if the agency were to make certain findings that are specified in statute. Essential use exemptions are limited to three years in duration and 10 metric tons of elemental mercury and are subject to terms and conditions specified by EPA.<br>Section 5 of the Mercury Export Ban Act of 2008 (42 U.S.C. 6939f) directs the Department of Energy (DOE) to designate a facility (excluding DOE Oak Ridge Reservation facilities) for the acceptance of elemental mercury generated within the United States for long-term management and storage by January 1, 2010, and to have this facility be operational to accept custody of elemental mercury by January 1, 2013.[f] Section 5 authorizes DOE to collect certain fees from those who deliver elemental mercury at the time of delivery to the designated facility and also establishes an annual reporting requirement for DOE to certain congressional committees on all costs associated with the long-term management and storage of elemental mercury. Section 5 requires DOE, in consultation with EPA and states, to establish, by October 1, 2009, guidance that includes procedures and standards for the receipt, management, and long-term storage of elemental mercury. Other provisions of Section 5 address indemnification of those who deliver elemental mercury and applicability of other law. | TSCA Section 6(f) and 12(c), and Section 5 of the Mercury Export Ban Act of 2008 would not be amended. | Section 29 of the Senate amendment would amend Section 5 of the Mercury Export Ban Act of 2008 to extend the deadline for a DOE-designated facility to accept elemental mercury generated within the United States for long-term management and storage from January 1, 2013, to January 1, 2019. DOE would be required to adjust fees for generators temporarily accumulating elemental mercury if the designated facility were not operational by January 1, 2019. If such facility were not operational by January 1, 2020, DOE would be directed to immediately accept the conveyance of title to all elemental mercury that has accumulated in certain facilities, deliver the accumulated mercury to the designated facility once it becomes operational, pay any applicable federal permitting costs, and store or pay for storage of accumulated mercury until the designated facility is operational. Additionally, DOE would be required, after consultation with EPA and states, to develop guidance on the management and short-term storage of elemental mercury by January 1, 2017. Section 29 of the Senate amendment would also make certain conforming amendments to Section 5 of the Mercury Export Ban Act of 2008.<br>Section 29 of the Senate amendment would also add new TSCA Section 8(b)(10) to direct EPA to gather and publish information regarding the supply, use, and trade of elemental mercury and certain mercury compounds in the United States by April 1, 2017. Section 29 of the Senate amendment would also amend TSCA Section 12(c)(3) to expand the prohibition on export of elemental mercury to include certain mercury compounds, effective January 1, 2020, and report to Congress regarding exports of calomel for disposal within five years of enactment. TSCA Section 6(f) would be redesignated as new TSCA Section 6(i). |

| Purpose | Existing Law: the Toxic Substances Control Act (TSCA) and Other Provisions | H.R. 2576, the TSCA Modernization Act of 2015, as Passed by the House on Jun. 23, 2015 ("House bill") | Senate Substitute Amendment to H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, as Passed by the Senate on Dec. 17, 2015 ("Senate amendment") |
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| Identification and investigation of potential cancer clusters | No comparable provision in TSCA.<br>The federal role in addressing potential cancer clusters is limited and primarily involves providing technical advice if requested by those who are investigating potential cancer clusters locally.[g]<br>In addition, Section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act (42 U.S.C. 9604(i)) established the Agency for Toxic Substances and Disease Registry primarily to assess potential health risks that may include those related to cancer at geographic-specific sites due to the release of a hazardous substance into the environment. | No comparable provision. | Section 30 of the Senate amendment (captioned "Trevor's Law") would add a new Section 399V-6 to the Public Health Service Act (42 U.S.C. Chapter 6A) to authorize a greater federal role in addressing potential cancer clusters.[h] HHS would be directed to develop criteria for designating potential "cancer clusters" based on certain considerations. The term "cancer cluster" is defined in this section. HHS, in consultation with the Council of State and Territorial Epidemiologists and state health officials, would be directed to develop, publish, and periodically update guidelines for investigating potential cancer clusters. Section 30 of the Senate amendment states that such guidelines "shall ... require" use of the criteria and the "best available science" and rely on a "weight of the scientific evidence"; it appears potentially unclear from the language of the Senate amendment to whom or in what manner the guidelines would apply. HHS, in consultation with state health officials, would be directed to consider whether it is appropriate to investigate a potential cancer cluster and would be authorized to prioritize investigations based on the availability of resources. Section 30 would establish certain requirements for HHS in investigating potential cancer clusters. Although it appears that Section 30 would not expressly authorize HHS to investigate potential cancer clusters—other than to provide assistance to state officials and to consult with community members—these requirements may provide HHS implicit authority to investigate potential cancer clusters. |

**Source:** Prepared by CRS based on Title I of TSCA (15 U.S.C. 2601-2629); the Mercury Export Ban Act of 2008 (P.L. 110-414); H.R. 2576, as passed by the House on June 23, 2015; and H.R. 2576, as passed with an amendment in the nature of a substitute (S.Amdt. 2932) by the Senate on December 17, 2015.

**Notes, Section I:**

a. See, for example, Nat'l Ass'n of Home Builders v. EPA, 682 F.3d 1032, 1039 (D.C. Cir. 2012); Chemical Mfrs. Ass'n v. EPA, 899 F.2d 344, 348 (5th Cir. 1990).

**Notes, Section II:**

a. EPA has issued various policy and guidance documents regarding its standards for science and data. See, for example, EPA, "Test Guidelines for Pesticides and Toxic Substances," http://www2.epa.gov/test-guidelines-pesticides-and-toxic-substances.

b. These factors are similar to general assessment factors for evaluating the quality of scientific and technical information described by EPA. EPA Science Policy Council, *A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information*, June 2003, http://www.epa.gov/sites/production/files/2015-01/documents/assess2.pdf.

c. There are several examples of such reports providing advice regarding assessing the hazards, exposures, and risks of chemical substances. The Senate amendment would also encompass any future National Academy of Sciences (NAS) reports meeting this description. See NAS, Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, *Science and Decisions: Advancing Risk Assessment* (National Academies Press, 2009); NAS, Committee on Toxicity and Assessment of Environmental Agents, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (National Academies Press, 2007).

d. In order to implement TSCA, EPA has developed various non-binding policies, procedures, and guidance. See, for example, EPA, "Risk Assessment Guidelines," http://www2.epa.gov/risk/risk-assessment-guidelines.

e. The policies, procedures, and guidance under new TSCA Section 3A(g) are to (1) address how and when the exposure or potential exposure would factor into decisions to require new testing, although EPA would be prohibited from interpreting lack of exposure information as an indication of actual lack of exposure or lack of exposure potential, and (2) describe the manner in which EPA will determine that additional information is necessary to implement new purposes of the amended TSCA.

f. Among other content, each draft and final safety assessment and safety determination would be required to include a description of the scope of the assessment and determination, the basis for such scope, the manner in which "aggregate exposures" were considered, the "weight of the scientific evidence" of risk, and information regarding the impact on health and the environment that was used to make the assessment or determination.

g. For more information on the EPA Science Advisory Board, see EPA, "EPA Science Advisory Board (SAB)," http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommittees/BOARD.

h. For more information on FACA, see CRS Report R44253, *Federal Advisory Committees: An Introduction and Overview*, by (name redacted) .

**Notes, Section III:**

a. See, for example, EPA, "Chemical Data Reporting under the Toxic Substances Control Act," http://www.epa.gov/chemical-data-reporting.

b. Specifically, EPA may require reporting or recordkeeping for any chemical substance or mixture that is the subject of a rule proposed or promulgated under TSCA Sections 4, 5(b)(4), or 6, an order in effect under TSCA Section 5(e), or relief granted pursuant to a civil action brought under TSCA Sections 5 or 7.

c. See EPA, "TSCA Chemical Substance Inventory," http://www2.epa.gov/tsca-inventory.

d. EPA guidance clarifies that this requirement is considered met if notification is completed within 30 days of obtaining information regarding substantial risks. EPA, "TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance," 68 *Federal Register* 33129-33140, June 3, 2003.

e. Section 5 of the Senate amendment would also make a conforming amendment to Section 104(i)(5)(A) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(5)(A)).

f. EPA, "Interagency Testing Committee," http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca/interagency-testing-committee.

g. National Toxicology Program, "About ICCVAM," http://ntp.niehs.nih.gov/pubhealth/evalatm/iccvam/index.html.

**Notes, Section IV:**

a. TSCA Section 14(a), which would not be amended by the House bill, does not appear to preclude EPA from maintaining confidentiality of information even where a claim for that information was not properly made if EPA determines on its own that the information falls within the FOIA exemption. In comparison, the Senate amendment would appear to disallow EPA from treating as confidential information for which no claim or an inadequate claim was made pursuant to amended TSCA Section 14(d), although the exemptions provided by FOIA may still apply. In the case of an inadequate claim, pre-release notification procedures would apparently apply.

b. However, EPA's general regulations on treatment of confidential business information provide certain procedures for agency review whenever EPA "desires to determine whether business information in its possession is entitled to confidential treatment, even though no request for release of the information has been received." 40 C.F.R. 2.204-2.205, 2.208, 2.306; see also EPA, "About Confidential Business Information (CBI) Claims and their Reviews under TSCA," http://www2.epa.gov/tsca-cbi/about-confidential-business-information-cbi-claims-and-their-reviews-under-tsca. ("While CBI claims under the Toxic Substances Control Act (TSCA) will be honored by the Agency initially as long as there is compliance with procedural requirements, the Agency retains an ability to review, and potentially disallow the claims if they do not meet the substantive criteria in the statute.")

c. See EPA, "Claims of Confidentiality of Certain Chemical Identities Contained in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the Toxic Substances Control Act, 75 *Federal Register* 29754-29757, May 27, 2010: "Chemical identify has been claimed as confidential in a significant number of health and safety submissions" p. 29756).

d. However, it contains various provisions for publication of certain items, including the TSCA inventory under Section 8, subject to the protections of Section 14. Moreover, pursuant to 40 C.F.R. 2.100 and several executive orders, EPA routinely provides some non-confidential information to the public as part of its regular activities. See, for example, Executive Office of the President, "Freedom of Information Act; Policies and Guidance (Memorandum of January 21, 2009)," 74 *Federal Register* 4683-4684, January 26, 2009; Executive Office of the President, "Making Open and Machine Readable the New Default for Government Information, (Executive Order 13642 of May 9, 2013)," 78 *Federal Register* 28111-28113, May 14, 2013.

**Notes, Section V:**

a. According to EPA, the agency developed the TSCA Work Plan to help prioritize existing chemical substances for the evaluation of risks. In October 2014, EPA updated the TSCA Work Plan list of chemical substances. The updated plan contains 90 chemical substances. EPA, "Assessments for TSCA Work Plan Chemicals," http://www2.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals; and EPA, *TSCA Work Plan for Chemical Assessments: 2014 Update*, October 2014, http://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

b. Note that the House bill would not amend TSCA Section 6(a)'s reference to "chemical substance or mixture," but in other instances in Section 4 of the House bill it refers to risk evaluation and other topics pertaining to a "chemical substance."

c. See table note a about the TSCA Work Plan.

d. "Preferences" under the Senate amendment relate to persistence and bioaccumulation and to carcinogenicity and high acute and chronic toxicity. Seven paragraphs of "criteria" are provided, including, for example, information availability on the substance and storage of the substance near sources of drinking water. Designation as high priority must also account for relatively significant hazard and exposure.

e. See table note a about the TSCA Work Plan. Specifically, Section 6 of the Senate amendment would require at least five of the initial list of high-priority substances, and at least 50% of all substances subsequently identified by EPA as high-priority substances, to be drawn from the TSCA Work Plan until all Work Plan chemicals have been designated. In addition, Section 6 of the Senate amendment would require EPA to give prioritization screening preference to, among other chemical substances, those listed in the TSCA Work Plan and subsequent updates that are known human carcinogens and have high acute and chronic toxicity.

f. See EPA Office of the Science Advisor, Risk Assessment Forum, *Framework for Metals Risk Assessment*, EPA 120/R-07/001, March 2007, http://www.epa.gov/sites/production/files/2013-09/documents/metals-risk-assessment-final.pdf.

g. See Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991).

h. Note that the House bill would not amend TSCA Section 6(a)'s reference to "chemical substance or mixture," but in other instances in Section 4 of the House bill it refers to risk evaluation and other topics pertaining to a "chemical substance."

i. Among other proposed changes, Section 8 of the Senate amendment would retitle the section heading of TSCA Section 6 from "Regulation of hazardous chemical substances and mixtures" to "Safety assessments and safety determinations."

j. Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1215-1218 (5th Cir. 1991) (interpreting "least burdensome" and other requirements for TSCA Section 6 rules). Since 1976, EPA has promulgated rules imposing restrictions to protect against risk of injury to health or the environment on certain existing chemical substances under TSCA Section 6. See EPA, TSCA Chemical Substance Inventory, 2014 version, http://www.epa.gov/tsca-inventory/how-access-tsca-inventory (search "regulatory flags" in inventory file).

k. The term "replacement parts" is not explicitly defined in the language and would appear to apply to a potentially broad spectrum of replacement parts across many industry sectors. The full implications of an exemption on replacement parts would likely be determined only through implementation. One apparent implication of this exemption is that a replacement part containing a regulated chemical substance would otherwise be allowed in commerce.

l. Ibid.

m. See EPA Office of Pollution Prevention and Toxics, *TSCA Work Plan Chemicals: Methods Document*, February 2012, http://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.

n. Ibid.

**Notes, Section VI:**

a. See EPA, "Significant New Use Rule for Hexabromocyclododecane and 1,2,5,6,9,10-Hexabromocyclododecane [HBCD]: Final Rule," 80 *Federal Register* 57293-57302, September 23, 2015 (providing that the standard exemption for persons importing or processing a chemical substance as part of an article does not apply to importers and processors of HBCD as part of a textile article).

b. Among other proposed changes, Section 7 of the Senate amendment would retitle the section heading of TSCA Section 5 from "Manufacturing and processing notices" to "New chemicals and significant new uses."

c. Existing EPA regulation requires manufacturers of new chemical substances to submit, within 30 days, a notice of commencement informing the agency when manufacture has begun (40 C.F.R. 720.102). EPA adds a new chemical substance that is the subject of a PMN to the TSCA inventory upon receiving the NOC.

**Notes, Section VII:**

a. It appears that the $250,000 cap on criminal fines against individuals in cases of imminent danger may not necessarily apply to civil violations, which could exceed that figure after five days of violation.

b. It is unclear from the wording of Section 16 of the Senate amendment whether the violator must be knowing or willful regarding only the violation, or also the imminent danger, to fall within the new paragraph. Clean Air Act Section 113(c)(5)(B)-(F) [42 U.S.C. 7413(c)(5)(B)-(F)] provides rules for determining whether a defendant who is an individual knew that the violation placed another person in imminent danger of death or serious bodily injury.

**Notes, Section VIII:**

a. U.S. Const. art. VI, cl. 2.

b. See generally U.S. Congress, Senate, "Article VI: Prior Debts, National Supremacy, and Oaths of Office," in *The Constitution of the United States of America: Analysis and Interpretation*, Interim Edition: Analysis of Cases Decided by the Supreme Court of the United States to July 1, 2014, prepared by the Congressional Research Service, Library of Congress ((name redacted), Editor -in-Chief, (name redacted), Managing Editor), 112th Cong., 2nd sess., S. Doc. 112-9 (Washington: GPO, 2014), pp. 986-1005, http://www.gpo.gov/fdsys/pkg/GPO-CONAN-REV-2014/pdf/GPO-CONAN-REV-2014-9-7.pdf.

c. For more information on preemption under TSCA, see CRS Legal Sidebar WSLG1269, *Toxic Substances Control Act (TSCA) Preemption and State Chemical Regulations Under Current Law*, by (name redacted) .

d. Section 17 of the Senate amendment would generally restructure TSCA Section 18. Scope of preemption would be governed by amended TSCA Section 18(a)-(b). Among other changes, Section 17 of the Senate amendment would change the section heading from "Preemption" to "State-Federal Relationship." It would remove current TSCA Section 18(a)(1). However, this would appear to have little substantive effect.

e. See, for example, Riegel v. Medtronic, Inc., 552 U.S. 312, 324 (2008) ("Absent other indication, reference to a State's 'requirements' includes its common-law duties."). Thus, it is possible, for example, that a defendant's compliance with TSCA could provide a viable preemption defense to a lawsuit if the common law or statutory requirement forming the basis for the lawsuit were designed to protect against the same risk as an EPA rule or order under TSCA Section 5 or 6. See Anderson v. Hackett, 646 F. Supp. 2d 1041, 1053 (S.D. Ill. 2009) (stating in dicta that a showing by the defendant chemical manufacturers that they had complied with EPA's polychlorinated biphenyl (PCB) regulations under TSCA "may provide them a defense to Plaintiffs' action" seeking damages and medical monitoring for alleged releases of PCB-containing oil).

f. Examples of such theories provided by the bill's language include, for example, negligence, strict liability, products liability, or failure to warn.

g. Ibid.

h. Congress has appropriated these funds within the EPA State and Tribal Assistance Grants appropriations account and other accounts of the agency that preceded the establishment of that account in FY1996. For the President's FY2016 budget request, see the "Toxics Substances Compliance Categorical Grant" program activity within the State and Tribal Assistance Grants account presented in the EPA FY2016 "Justification of Appropriation Estimates for the Committee on Appropriations," p. 800 (p. 812 of the PDF), http://www2.epa.gov/planandbudget/fy-2016-congressional-justification.

**Notes, Section IX:**

a. Congress has appropriated these funds within the EPA Environmental Programs and Management appropriations account and other accounts of the agency that preceded the establishment of that account in FY1996. For the President's FY2016 budget request, see the "Chemical Risk Review and Reduction" program activity within the Environmental Programs and Management account presented in ibid., p. 485 (p. 497 of the PDF.

b. See Office of Management and Budget, *Appendix, Budget of the United States Government, Fiscal Year 2016,* p. 1137 (p. 1141 of PDF), https://www.whitehouse.gov/sites/default/files/omb/budget/fy2016/assets/appendix.pdf.

**Notes, Section X:**

a. For the President's FY2016 budget request, see the "Pollution Prevention Categorical Grants" program activity within the State and Tribal Assistance Grants account presented in the EPA FY2016 "Justification of Appropriation Estimates for the Committee on Appropriations," beginning on p. 788 (p. 800 of the PDF), http://www2.epa.gov/planandbudget/fy-2016-congressional-justification.

b. See note codified under TSCA Section 30 [15 U.S.C. 2629 note].

c. Additionally, Section 9(g), (m), and (n) would make conforming amendments to TSCA Section 11, 24, and 27, respectively, to reflect proposed changes elsewhere in the bill.

d. See Gozlon-Peretz v. United States, 498 U.S. 395, 404 (1991) (citations omitted) ("It is well established that, absent a clear direction by Congress to the contrary, a law takes effect on the date of its enactment.").

e. The Mercury Export Ban Act of 2008 (P.L. 110-414; 122 Stat. 4341) added TSCA Section 6(f) and 12(c).

f. For information on status of designating a facility, see DOE, "Long-Term Management and Storage of Elemental Mercury," http://energy.gov/em/services/waste-management/waste-and-materials-disposition-information/long-term-management-and.

g. The Centers for Disease Control and Prevention (CDC), an agency under HHS, and the Council of State and Territorial Epidemiologists have developed and published guidelines on investigating potential cancer clusters. These guidelines include criteria for defining a potential cancer cluster and recommendations on investigating potential cancer clusters. See CDC, "Investigating Suspected Cancer Clusters and Responding to Community Concerns: Guidelines from CDC and the Council of State and Territorial Epidemiologists," *Morbidity and Mortality Weekly Report*, September 27, 2013, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6208a1.htm.

h. Section 30 of the Senate amendment would entitle Section 399V-6 of the Public Health Service Act with the section heading "Designation and investigation of potential cancer clusters."

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