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Proposed Amendments to the Toxic Substances Control Act (TSCA) in the 114th Congress: S. 697, S. 725, and a House Discussion Draft

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Summary

Enacted in 1976, the Toxic Substances Control Act (TSCA) is the primary federal law that governs the regulation of chemicals in commerce. TSCA authorizes the Environmental Protection Agency (EPA) to determine whether regulatory control of a chemical substance is necessary to protect against “unreasonable risks” to those who are potentially exposed or to the environment. For several years leading up to the 114th Congress, there have been various legislative proposals to amend Title I of TSCA to revise the chemical evaluation process and the criteria by which chemical substances would be regulated and to address certain other related purposes.

On April 28, 2015, the Senate Committee on Environment and Public Works reported the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697) for Senate floor consideration on a 15-5 vote. Another bill introduced in the Senate, the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act (S. 725), has not been reported out of committee. Additionally, on April 7, 2015, the House Committee on Energy and Commerce released a discussion draft titled the TSCA Modernization Act of 2015 (hereinafter referred to as the House discussion draft), which subsequently was the subject of a subcommittee hearing. S. 697, as reported, and S. 725 present fairly broad approaches to revising the evaluation process of chemical substances to determine whether regulatory control is warranted and would make various other changes to the TSCA framework, while the House discussion draft takes a more targeted approach in amending specific provisions of Title I of TSCA.

S. 697, as reported, S. 725, and the House discussion draft, similar to legislative proposals introduced regularly since 2005, would address many key issues regarding the federal role in regulating chemical substances. This report discusses selected issues that have received more attention and compares the current proposals’ differing approaches to revise Title I of TSCA. This report does not present a comprehensive analysis of all provisions of relevant legislation, nor is this report intended to provide a detailed analysis of precise language and its legal or regulatory interpretation. This report will be updated as necessary.

The following selected issues are described in more detail in the report and in the context of current TSCA, S. 697, as reported, S. 725, and the House discussion draft:

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

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Introduction

In 1976, President Ford signed into law the Toxic Substances Control Act (TSCA; P.L. 94-469), which authorized the U.S. Environmental Protection Agency (EPA) to identify and regulate toxic chemicals in U.S. commerce to prevent “unreasonable risk of injury to human health or the environment.”¹ 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 production, importation, processing, distribution, use, and disposal. EPA has authority to pursue a range of regulatory options to address risks from chemicals. Since 1976, Congress has added five other titles to TSCA and has also amended the original law, referred to as Title I, to target specific chemical concerns.² None of these additions and amendments addresses the core program under Title I of TSCA. Since 2005, a number of bills have been introduced to revise the chemical evaluation process for determining whether regulatory controls are warranted and to address certain other related purposes.³ These bills were not enacted, because there was and continues to be legislative debate on how to amend the evaluation process, regulatory criteria, and other elements of the law.⁴

Since the enactment of TSCA in 1976, more chemicals have continued to enter the U.S. market. A greater number of studies on chemical risks have been published, and scientific understanding of chemical risks has continued to evolve.⁵ Because relatively few chemicals have been evaluated and even fewer regulated under TSCA’s risk management provisions, proponents of amending Title I of TSCA argue that the current regulatory framework for chemical substances is not sufficiently protective of the public or the environment.⁶ Moreover, EPA’s evaluation of risks is ultimately dependent on the resources the agency has available.

¹ 15 U.S.C. §§ 2601-2629. 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 Jerry H. Yen.

Section 3(2) of TSCA (15 U.S.C. § 2602(2)) excludes certain chemical substances from regulation including pesticides, tobacco, 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, Section 9 of TSCA (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.

² The other specific chemical concerns include asbestos (Title II), indoor radon (Title III), lead (Title IV), environmental exposures in schools (Title V), and formaldehyde in composite wood products (Title VI).

³ 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 under the short title “Kid Safe Chemicals Act,” are examples of such legislation.

⁴ See, for example, 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, available at <http://energycommerce.house.gov/hearing/hr-tsc-modernization-act-2015> (hereinafter “House discussion draft hearing”); and U.S. Congress, Senate Committee on Environment and Public Works, *Frank R. Lautenberg Chemical Safety for the 21st Century Act*, 114th Cong., 1st sess., March 18, 2015, available at http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=60d1e265-cdac-7629-3385-2d72dd8fe3eb (hereinafter “S. 697 hearing”).

⁵ For example, there is greater scientific understanding of the properties of chemicals, the toxicological effects of chemicals, routes of exposure, and methods for assessing risk.

⁶ For example, EPA has regulated six chemical substances under Section 6 of TSCA (15 U.S.C. § 2605). These substances include chlorofluorocarbons, nitrosamines in metalworking fluids, hexavalent chromium in certain water (continued...)

As states have enacted statutes to address specific chemical concerns not addressed by EPA under TSCA, there has been greater potential for the same chemical to be regulated differently among states and differently than the federal government.⁷ Manufacturers and processors of chemical substances have argued that compliance with different state regulations regarding the same chemical is not efficient given chemicals' movement through interstate commerce. Proponents of state regulations that differ from any federal requirements for the same chemicals, in turn, have argued that states can lead the way in trying alternative approaches and that states should be allowed to do so to protect their citizens. Non-governmental programs, such as voluntary measures to label products as sustainable or "non-toxic," have also emerged as an alternative approach to regulation.

This report tracks the legislative status in the 114th Congress of proposals to amend Title I of TSCA and includes a discussion of selected issues that have received more attention. This report does not present a comprehensive analysis of all provisions of relevant legislation, nor is this report intended to provide a detailed analysis of precise language and its legal or regulatory interpretation.

Legislative Status in the 114th Congress

In the 114th Congress, proposals have been offered in both chambers to amend Title I of TSCA.⁸ On March 10, 2015, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697) was introduced and referred to the Senate Committee on Environment and Public Works (Senate EPW). Two days later, the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act (S. 725) was introduced and also referred to Senate EPW. On March 18, 2015, Senate EPW held a hearing regarding S. 697.⁹ On April 28, 2015, Senate EPW marked up an amendment in the nature of a substitute for S. 697, which was ordered to be reported out of the committee for Senate floor consideration on a 15-5 vote.¹⁰

On April 7, 2015, the House Committee on Energy and Commerce, Subcommittee on Environment and the Economy announced a discussion draft that takes a narrower approach to amending Title I of TSCA than either Senate bill.¹¹ The discussion draft is called the TSCA

(...continued)

cooling towers, new uses of asbestos, dioxin-contaminated wastes, and polychlorinated biphenyls (PCBs).

⁷ For example, states including California, Maine, and Washington have enacted "green chemistry" statutes that authorize the regulation of chemical substances based on various criteria and regulatory processes. Also, many states have enacted chemical-specific restrictions.

⁸ S. 725 also proposes additional titles on the topic of "disease clusters," which are not discussed in this Report.

⁹ S. 697 hearing in footnote 4 above.

¹⁰ U.S. Congress, Senate Committee on Environment and Public Works, *Markup, Nomination, Consideration of GSA Resolutions*, 114th Cong., 1st sess., April 28, 2015, available at http://www.epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_id=3eae7787-b182-be85-c483-bdd391e4302b; and *S. 697 Compromise Amendment*, released April 28, 2015, available at <http://www.scribd.com/doc/263408687/S-697-Compromise-Amendment>.

¹¹ U.S. Congress, House Committee on Energy and Commerce, "Subcommittee to Review Bipartisan Draft of the TSCA Modernization Act," press release, April 7, 2015, available at <http://energycommerce.house.gov/press-release/shimkus-upton-pallone-back-effort-improve-chemical-safety>.

Modernization Act of 2015 and hereinafter referred to as the House discussion draft.¹² On April 14, 2015, the subcommittee held a hearing regarding the discussion draft.¹³

Selected Issues for Congress

Among the various issues regarding the federal role in regulating chemical substances under Title I of TSCA are the following:

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

The objective of this report is to compare approaches among S. 697, as ordered to be reported, S. 725, and the House discussion draft, dated April 7, 2015, in amending Title I of TSCA to address these key issues.

Prioritization of Chemical Substances for an Evaluation of Risks

Given that the evaluation of risks for the large number of chemicals in the marketplace is limited by finite resources, determining what criteria to use in selecting which chemicals to evaluate has been a perennial issue. Under existing law, EPA has discretion regarding which chemical substances to evaluate for risks and no affirmative mandate to review or evaluate chemicals. The substances that the agency may evaluate for risks include those on the initial inventory of known chemical substances reported to EPA under Section 8(a) of TSCA after enactment of the law¹⁴ and those that manufacturers subsequently reported to EPA in premanufacture notices (PMNs) under Section 5 of TSCA.¹⁵ These substances all together number over 83,000 chemical substances,

¹² 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 7, 2015, available at http://docs.house.gov/meetings/IF/IF18/20150414/103313/BILLS-114pjh-HR__TSCAModernizationActof2015.pdf.

¹³ House discussion draft hearing in footnote 4 above.

¹⁴ 15 U.S.C. § 2607(a). The initial inventory included approximately 62,000 chemicals, which were not subject to the 90-day prior notice requirement described below for new chemicals. See U.S. EPA, TSCA Chemical Substance Inventory: Basic Information, updated March 13, 2014, available at <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/basic.html>.

¹⁵ 15 U.S.C. § 2604. Note that manufacture is defined to include import. TSCA § 3(7), 15 U.S.C. § 2602(7).

although not all of them are necessarily still in U.S. commerce.¹⁶ In 2012, as part of EPA's TSCA Work Plan, the agency identified more than 1,200 substances that possibly warranted an evaluation based on certain prioritization criteria.¹⁷ These substances were further screened based on hazard, exposure, and bioaccumulation potential, which led EPA to prioritize 90 substances for an evaluation of risks.¹⁸ Of the 90 prioritized chemical substances, EPA has assessed 5, 3 of which were determined to present risks.¹⁹

For new chemicals, Section 5 of TSCA requires manufacturers to submit a PMN to EPA 90 days prior to manufacturing the chemical substance, subject to certain exemptions.²⁰ During this time period, before the chemical substance is manufactured, EPA has the opportunity to evaluate risks of the new chemical substance and determine whether regulation may be warranted based on the PMN. According to EPA, from July 1979 to September 2010, the agency has received more than 36,000 PMNs and more than 13,000 PMN exemption applications.²¹ Additionally, EPA reports that the agency has taken more than 4,400 regulatory actions on PMNs received under Section 5.²² Such regulatory actions include, for example, consent orders, use restrictions, and testing agreements.

S. 697 and S. 725 would direct EPA to prioritize existing chemical substances in multiple steps for evaluation of risks.²³ Further, S. 697 would allow manufacturers and processors to request that EPA prioritize certain substances for an evaluation, although EPA would have discretion to grant only a limited number of such requests, subject to public notice and opportunity for comment. In contrast to the multi-step prioritization processes set forth by S. 697 and S. 725, the House discussion draft would direct EPA to evaluate risks of those chemicals that the agency identified as warranting an evaluation due to a potential for unreasonable risk arising from the combination of hazards and exposures under the intended conditions of use for the chemical and those chemicals for which a manufacturer requested an evaluation.

S. 697 and S. 725 would establish a process that includes dividing the inventory of chemical substances into those that are reported to be currently in the marketplace (i.e., active substances) and those that are not (i.e., inactive substances), prioritizing the inventory of substances for

¹⁶ U.S. EPA, Summary of the Toxic Substances Control Act, updated March 9, 2015, available at <http://www2.epa.gov/laws-regulations/summary-toxic-substances-control-act>.

¹⁷ U.S. EPA, Office of Pollution Prevention and Toxics, *TSCA Work Plan for Chemical Assessments: 2014 Update*, October 2014, p. 3, available at http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Work_Plan_Chemicals_2014_Update-final.pdf.

¹⁸ U.S. EPA, Office of Pollution Prevention and Toxics, *TSCA Work Plan for Chemical Assessments: 2014 Update*, October 2014, p. 3, available at http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Work_Plan_Chemicals_2014_Update-final.pdf.

¹⁹ U.S. EPA, "Assessments for TSCA Work Plan Chemicals," updated April 29, 2015, available at <http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html>. 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 (HHCB) 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. The NMP, methylene chloride, and TCE assessments identified risks.

²⁰ 15 U.S.C. § 2604.

²¹ U.S. EPA, "Summary of Accomplishments," updated April 3, 2013, available at <http://www.epa.gov/oppt/newchems/pubs/accomplishments.htm>.

²² *Ibid.*

²³ See generally Section 6 of S. 697 and Section 105 of S. 725.

evaluations based on various factors, conducting risk-based safety evaluations, and taking regulatory action based on the result of each evaluation. However, S. 697 and S. 725 differ in the factors used to prioritize substances. Additionally, S. 697 and S. 725 would establish this process with varying deadlines for evaluating chemical substances and, if necessary, for taking regulatory actions.

Under S. 697, EPA would be required to “make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner” and to publish an annual goal. EPA would have to designate at least 25 chemicals as high priority and begin safety assessment on them within five years after enactment of S. 697.²⁴ Safety evaluations and determinations would have to be completed within three years after a chemical’s designation as a high-priority substance and a rule promulgated within two years after a negative safety determination, subject to limited extensions. The prioritization and evaluation procedures proposed by S. 725 are generally comparable to those under S. 697, with some differences. S. 725 would impose some tighter deadlines on EPA for prioritization, evaluation, and repopulation of the priority lists than S. 697. For example, EPA would have to designate at least 90 chemicals as high-priority and begin safety assessment on them by five-and-a-half years after enactment.²⁵ Certain other conditions and procedures for listing as high or low priority and for conducting evaluations would also differ in some respects from S. 697, and S. 725 does not include any provision for manufacturers to request prioritization or assessment. The House discussion draft would require risk evaluations to be published within 180 days after a manufacturer’s request for an evaluation or within three years after EPA made a finding of potential for unreasonable risk.²⁶ The House discussion draft would not impose deadlines regarding the pace of those EPA findings or limits on manufacturer requests, except that they are paid for fully by the requesters.

For new chemical substances and significant new uses,²⁷ S. 697 and S. 725 would amend TSCA Section 5 to establish a process for EPA to review a notice and information submitted by manufacturers and processors and to determine whether regulatory action is warranted based on the result of the review.²⁸ For new chemicals, both Senate bills would direct EPA to conduct an initial review and render a determination within 90 days of receiving a notice and information that the substance is likely or not likely to attain the safety standard or that additional information is necessary to make such a determination. Once the manufacture of a new chemical has commenced and that chemical is added to the TSCA Inventory, it would presumably be subject to the same prioritization, safety assessment, and safety determination procedures and conditions for

²⁴ Section 6 of S. 697 would require an initial high- and low-priority list each containing at least 10 substances. By three years after enactment, additional substances would have to be added to each list to ensure at least 20 had undergone or were undergoing safety assessment, and by five years, at least 25.

²⁵ Section 105 of S. 725 would require EPA to develop an initial high-priority list within six months of enactment containing at least 15 substances, and to add at least an additional 15 one year after the initial list, plus at least an additional 15 for each of the following four years. Upon removing a substance from the high-priority list after its safety determination, EPA would be required to add at least three substances to repopulate the list, when fees are in place. In addition, safety evaluations and determinations would also have to be completed within two, rather than three, years after a chemical’s designation as a high-priority substance.

²⁶ See generally Section 4 of the House discussion draft.

²⁷ Under Section 5(a)(2) of TSCA (15 U.S.C. § 2604(a)(2)), EPA may determine that a use of a chemical substance constitutes a significant new use following consideration of all relevant factors. The manufacture and processing of a substance for a use that is considered a significant new use are subject to notice requirements 90 days prior to manufacture or processing of a substance for that use. S. 697 and S. 725 would not amend this provision.

²⁸ See generally Section 7 of S. 697 and Section 106 of S. 725.

existing chemical substances as proposed by S. 697 or S. 725. The House discussion draft would not amend TSCA Section 5, which would leave in place the current process for EPA to have the initial opportunity to evaluate risks of new chemicals based on when a notice is submitted.²⁹

Regulatory Threshold for Restricting a Chemical Substance

TSCA establishes a standard for regulation of chemical substances based on a threshold of whether the chemical would present “an unreasonable risk of injury to [human] health or the environment.” This phrase is used in multiple provisions of TSCA as the basis of whether certain actions may be warranted, particularly with respect to various regulatory controls under Section 5³⁰ regarding new chemicals and Section 6³¹ regarding existing chemicals. Some have argued that the current regulatory threshold for restricting a chemical substance in TSCA, that the chemical presents or will present risks that are unreasonable, is difficult for EPA to show and subject to interpretation. A persistent issue 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 substances warrant regulatory control.

Under current TSCA, the “unreasonable risk” standard is not defined.³² However, the “unreasonable risk” standard of TSCA has been interpreted by courts as, essentially, a multi-factor balancing test. In its influential 1991 decision, *Corrosion Proof Fittings v. EPA*, which struck down large parts of an asbestos ban under TSCA, the Fifth Circuit interpreted TSCA’s “unreasonable risk” standard, stating 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 the “unreasonable risk” standard in current TSCA, whether regulation of a substance is warranted depends not only on the hazards of the chemical and the extent or likelihood of exposure to the chemical but also on the costs of risk management and the benefits of the chemical for various uses.

S. 697 would establish a statutory definition for the term “safety standard” that is based on the regulatory threshold of “unreasonable risk of injury to health or the environment” in current

²⁹ 15 U.S.C. § 2604.

³⁰ *Ibid.*

³¹ 15 U.S.C. § 2605.

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.

TSCA and the addition of some qualifiers.³⁶ First, S. 697 would establish the regulatory threshold based on whether the “conditions of use” of a chemical substance would attain the safety standard.³⁷ Additionally, S. 697 would explicitly reference “potentially exposed or susceptible populations” among the general population with respect to an evaluation of risks.³⁸ Also, in the qualifier departing most significantly from current TSCA, S. 697 would expressly prohibit the consideration of “cost and other nonrisk factors” in evaluating risks.

Similar to S. 697, S. 725 would likewise define a “safety standard” against which chemical risks would be measured.³⁹ However, under S. 725, the safety standard would be one that “ensures with reasonable certainty, without taking into consideration cost or other non-risk factors, that no harm to human health or the environment will result from exposure to a chemical substance under the intended or reasonably foreseeable conditions of use, including no harm to the general population or to any potentially exposed or susceptible subpopulation.”⁴⁰ This “reasonable certainty [of] no harm” language parallels the standard used to evaluate, for example, pesticides residues in or on food.⁴¹

In contrast to S. 697 and S. 725, the House discussion draft would retain the language of the regulatory threshold based on “unreasonable risk” in current TSCA but would add certain requirements for EPA’s risk evaluation process to determine risks. Some examples of the requirements for evaluating risks include assessing risks to “potentially exposed populations” and not considering information on “cost and other factors not directly related to health or the environment” in evaluating risks.

³⁶ Section 3 of S. 697.

³⁷ Section 3 of S. 697 would add a definition to TSCA for “conditions of use,” which is defined as the “intended, known, or reasonably foreseeable circumstances the [EPA] Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.”

³⁸ Section 3 of S. 697 would add a definition to TSCA for “potentially exposed or susceptible population,” which is defined as “1 or more groups (A) of individuals within the general population who may be (i) differentially exposed to chemical substances under the conditions of use; or (ii) susceptible to greater adverse health consequences from chemical exposures than the general population;” and (B) that when identified by the [EPA] Administrator may include such groups as infants, children, pregnant women, workers, and the elderly.”

³⁹ Section 102 of S. 697.

⁴⁰ Section 102 of S. 725 would add a definition to TSCA for “intended or reasonably foreseeable conditions of use,” which is defined as “circumstances under which a chemical substance is intended, reasonably known, or reasonably anticipated to be manufactured, processed, distributed in commerce, used, disposed of, and released into the environment, including reasonably foreseeable but unintended exposure conditions from unplanned releases into the environment.”

Additionally, Section 102 of S. 725 would add a definition to TSCA for “potentially exposed or susceptible population,” which means “a group or groups of individuals within the general population who may be (A) differentially exposed to chemical substances under the intended or reasonably foreseeable conditions of use; or (B) more susceptible to adverse health consequences from chemical exposures than the general population, which when identified by the [EPA] Administrator may include such groups as infants, children, pregnant women, workers, and the elderly.”

⁴¹ Federal Food, Drug, and Cosmetic Act § 408(b)(2)(A)(ii), (b)(2)(C)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii), (b)(2)(C)(ii) (“As used in this section, the term ‘safe’, with respect to a tolerance for a pesticide chemical residue, means that the [EPA] Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue...”, including “no harm... to infants and children”).

Regulatory Options for Restricting a Chemical Substance

Some statutes that authorize regulatory controls such as TSCA include the concept of balancing costs and benefits. Title I of TSCA acknowledges this balance through various references. As an example, if EPA were to determine that a chemical substance presents or will present “an unreasonable risk of injury to health or the environment,” Section 6 of TSCA directs the agency to promulgate a requirement to protect adequately against such risks using the least burdensome requirement while considering certain other factors, for example, the approximate costs of the proposed regulation and the availability of alternatives to the chemical subject to regulatory control.⁴² The regulatory requirements that EPA may choose vary in severity from a total ban to a requirement that manufacturers notify distributors of unreasonable risks. Some have argued that the limit on EPA to choose the least burdensome regulatory requirement that still adequately protects from unreasonable risk subjects the agency to lengthy analyses.

In *Corrosion Proof Fittings v. EPA*, the Fifth Circuit stated that EPA had not shown substantial evidence⁴³ that its total ban on most ongoing uses of asbestos was the least burdensome adequate alternative for all circumstances and product categories.⁴⁴ Thus, in practice, the “least burdensome” requirement imposes an additional standard on EPA beyond that imposed by the requirement that EPA 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 has required EPA to show that each less burdensome requirement would not adequately protect against the unreasonable risk.⁴⁵

S. 697, S. 725, and the House discussion draft would eliminate the requirement that EPA choose the least burdensome regulatory option to restrict a chemical substance that warrants regulation.⁴⁶ Rather, S. 697 and S. 725 would direct EPA to choose a regulatory option that is “necessary” for the chemical substance to meet the safety standard, subject to consideration of other factors such as costs and alternative regulations. In contrast, the House discussion draft would amend the factors that EPA would be required to consider to promulgate a restriction on a chemical substance and would require rules to be, by EPA’s determination, “cost-effective.”

Requirement for the Development of Test Information

EPA relies on scientific and technical information regarding chemical substances to evaluate risks and determine if any risks are unreasonable. In order to obtain such information, Section 8 of TSCA authorizes EPA to require reporting and record keeping of existing information on

⁴² 15 U.S.C. § 2605.

⁴³ Section 19 of TSCA (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 S. 697 nor the House discussion draft would substantively change this standard of review, but S. 725 would apply the APA standard for judicial review.

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

⁴⁵ *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*.

⁴⁶ See generally Section 8 of S. 697, Section 107 of S. 725, and Section 4 of the House discussion draft.

chemicals by manufacturers, processors, and distributors of chemical substances.⁴⁷ If the risks are insufficiently known from existing information and testing is necessary to develop new information about the risks, Section 4 of TSCA mandates that EPA promulgate a rule to require manufacturers and processors to conduct testing if the agency is able to render one of the following two threshold findings.⁴⁸ The threshold findings are either (1) that the chemical substance may present unreasonable risks,⁴⁹ 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.”⁵⁰ To date, EPA has required additional testing for over 200 chemical substances.⁵¹

Some 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 limited EPA’s ability to assess the risks of chemicals. 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.”⁵² Instead, EPA generally has made the other finding, which is based on the production volume of a chemical and the likelihood of exposure. However, the development of new information may take a lengthy amount of time and be costly to those who are required to develop the information.

Whereas Section 4 of TSCA currently mandates that EPA require testing based on certain conditions for which the agency renders a finding, S. 697, S. 725, and the House discussion draft would give EPA discretion to require testing for specific purposes.⁵³ Subject to procedures as would be amended by S. 697, S. 725, or the House discussion draft, EPA would have discretion to require testing by promulgating a rule, issuing an order, or entering into a testing consent agreement in requiring the development of new information.

Preemption of State Requirements

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

⁴⁷ 15 U.S.C. § 2607.

⁴⁸ 15 U.S.C. § 2603.

⁴⁹ 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)

⁵⁰ 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. U.S. 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.

⁵¹ Testimony of EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention James Jones, 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, available at <http://docs.house.gov/meetings/IF/IF18/20150414/103313/HHRG-114-IF18-Wstate-JonesJ-20150414.pdf>.

⁵² *Ibid.*

⁵³ See generally Section 5 of S. 697, Section 104 of S. 725, and Section 3 of the House discussion draft.

long-standing issue.⁵⁴ Under the Supremacy Clause of the U.S. Constitution, conflicting state law and policy must yield to the exercise of Congress's enumerated powers.⁵⁵ 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 extreme 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, Section 18 of TSCA provides that states are generally preempted from taking action to manage risk from a chemical substance if EPA has taken action on a similar risk presented by that chemical, although states may apply for waivers.⁵⁶ 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.⁵⁷ States are also authorized to regulate disposal, to establish or continue in effect any chemical requirement adopted under the authority of any other federal law, and to prohibit use of a chemical within the state (except for its upstream use in manufacture or processing of other chemicals).⁵⁸

In the TSCA amendment context, advocates for broader federal preemption claim that a uniform national regulatory framework with regard to chemical substances 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.⁵⁹ 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 to implement more stringent requirements than those EPA sets in order to protect the safety and welfare of their citizens.⁶⁰

S. 697 would make a number of changes to TSCA preemption and the state-federal relationship in the field of chemical management. As under current TSCA, states could act without preemption if EPA had taken no action with respect to a chemical. However, S. 697 would modify the EPA actions triggering preemption, the scope of state laws that would be preempted, and the waiver provisions. A state would be prohibited from restricting the manufacture, processing, sale or distribution in commerce, or use of a chemical that EPA either had found to meet the safety standard or had restricted by rule on the basis that it did not meet the safety standard, within the

⁵⁴ For more information on this topic, please see CRS General Distribution Memorandum, *The Toxic Substances Control Act (TSCA): Preemption in Current Law and Recent Legislation*, by Alexandra M. Wyatt, available from the author.

⁵⁵ U.S. CONST. art. VI, cl. 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 because it 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.

⁵⁶ 15 U.S.C. § 2617.

⁵⁷ 15 U.S.C. § 2617(a)(2)(B).

⁵⁸ *Ibid.*

⁵⁹ See, for example, S. 697 hearing in footnote 4 above.

⁶⁰ *Ibid.*

scope of uses addressed by EPA.⁶¹ Moreover, states would be prohibited from establishing new restrictions on chemicals listed by EPA as high priority chemicals for safety assessment if the state restrictions fell within the scope of uses or conditions to be considered in EPA's planned safety assessment.⁶² S. 697 would generally retain the preemption exceptions provided by current TSCA, except for TSCA's current exception allowing states to prohibit use of chemicals, which would be removed. Other exceptions to preemption would be added, including to allow states to establish or enforce some requirements adopted under the authority of state environmental laws.⁶³ Certain state actions taken before August 2015, and past or future state actions under the authority of state laws that were in effect as of 2003, would not be subject to preemption.⁶⁴

S. 725, in contrast, would eliminate TSCA's current preemption provisions. While state laws could be found to be implicitly preempted if they conflicted with federal requirements, S. 725 would generally allow states to impose and enforce different regulations or requirements for chemicals.⁶⁵

The House discussion draft would make the fewest substantive changes to TSCA preemption. The House discussion draft would provide for the preemption of state laws designed to protect against exposure to a chemical substance that EPA had determined not to present an unreasonable risk.⁶⁶ The House discussion draft generally would maintain preemption of state requirements for chemicals on the basis of EPA risk management actions for such chemicals but would not except state prohibitions on use of such chemicals.⁶⁷

Confidentiality and Disclosures of Information

TSCA requires chemical manufacturers, processors, and distributors to submit certain information to EPA regarding their chemicals.⁶⁸ This information can include detailed chemical structures, production volumes, and health and safety data. Thus, another issue for TSCA amendment is how to balance the goals of public access to chemical information, on the one hand, and protection of information, which, if disclosed, could compromise the submitter's competitiveness, on the other.

Section 14 of TSCA 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,"⁶⁹ with certain exceptions.⁷⁰ Under the terms of TSCA, wrongful disclosure by EPA employees or

⁶¹ Section 17 of S. 697 would replace subsections (a) and (b) of TSCA Section 18 with new subsections (a) through (g). The preemption of existing state laws would be set forth in new Section 18(a).

⁶² Section 17 of S. 697 would set forth preemption of new state laws in an amended Section 18(b) of TSCA.

⁶³ Section 17 of S. 697 would describe the exceptions in amended subsections (c) through (e) of TSCA Section 18.

⁶⁴ *Ibid.*

⁶⁵ Section 117 of S. 725 would replace TSCA Section 18.

⁶⁶ Section 8 of the House discussion draft would replace TSCA Section 18(b) with new subsections (b) and (c).

⁶⁷ *Ibid.*

⁶⁸ 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).

⁶⁹ 5 U.S.C. § 552(b)(4).

⁷⁰ 15 U.S.C. § 2613.

contractors is a criminal act.⁷¹ Confidential business information (CBI) protection under TSCA does not prohibit disclosure of any health and safety study, except that any data within any such study that would disclose manufacturing processes or proprietary mixture compositions would remain protected.⁷² Many items of information—including chemical identities—have been protected by EPA as trade secrets on the TSCA Inventory, in health and safety studies, and in other situations.⁷³ 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.”⁷⁴ 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.⁷⁵

Procedurally, to obtain CBI protection for information that the submitter believes is entitled to confidential treatment, the submitter is only required to designate the information as CBI.⁷⁶ Neither substantiation nor EPA review of confidentiality claims is expressly required under current TSCA. CBI protection also lasts indefinitely, unless EPA decides the information no longer qualifies for protection under the FOIA exemption and gives the submitter the required prior notice.⁷⁷ However, since 2010, EPA has increased its review of confidentiality claims, particularly relating to chemical identities in health and safety studies.⁷⁸ 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.⁷⁹

S. 697, S. 725, and the House discussion draft would retain current TSCA’s basic framework requiring protection of information that falls within the FOIA trade secrets exemption. The three proposals, however, would require or authorize EPA to disclose CBI in additional circumstances, including in response to requests from state, local, or tribal officials for enforcement purposes; requests from certain federal or state professionals in response to an environmental release; or requests from health care professionals to assist in diagnoses or treatments of patients.⁸⁰ The Senate bills would make more extensive revisions and additions to Section 14 of TSCA than the House discussion draft, with more detailed procedural requirements for information submitters and more review requirements for EPA.⁸¹ They would also enumerate certain categories of information presumed protected from disclosure, including specific chemical identity prior to the

⁷¹ 15 U.S.C. § 2613(d).

⁷² 15 U.S.C. § 2613(b).

⁷³ U.S. EPA, “Declassifying Confidentiality Claims to Increase Access to Chemical Information,” updated January 8, 2015, available at <http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html>.

⁷⁴ 15 U.S.C. § 2613(a)(3).

⁷⁵ 15 U.S.C. § 2613(c)(2).

⁷⁶ 15 U.S.C. § 2613(c)(1).

⁷⁷ 15 U.S.C. § 2613(c)(2).

⁷⁸ See U.S. EPA, footnote 64 above.

⁷⁹ U.S. EPA, “Increasing Transparency in TSCA,” updated January 8, 2015, available at <http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html>.

⁸⁰ See generally Section 14 of S. 697 and Section 114 of S. 725, which would replace current TSCA Section 14 and would enumerate disclosure circumstances in a new TSCA Section 14(e); and Section 7(1) of the House discussion draft, which would add specific new disclosure circumstances to those now contained in TSCA Section 14(a).

⁸¹ See generally Section 14 of S. 697 and Section 114 of S. 725, replacing current TSCA Section 14(c) with new procedures that would be set forth in new subsections (d) and (f)-(g) of TSCA Section 14.

date a chemical is first offered for commercial distribution.⁸² All three proposals would require submitters to substantiate, and periodically resubstantiate, confidentiality claims.⁸³

Resources to Administer TSCA

In implementing Title I of TSCA, the pace and thoroughness with which EPA can evaluate chemical risks often depends on the resources made available to the agency. 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 in addition to and not subject to discretionary appropriations.

While Section 29 of current TSCA authorized appropriations for Title I of TSCA 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.⁸⁴ Additionally, Section 26(b) of TSCA authorizes EPA to assess fees on chemical manufacturers, importers, or processors.⁸⁵ EPA's authority to collect fees is statutorily limited to a maximum of \$2,500 for the following actions required under Section 5 of the statute:

- each PMN that a manufacturer or importer of a new chemical substance is required to submit to EPA, and
- each notice that a manufacturer, importer, or processor is required to submit to EPA for a significant new use of a chemical substance.⁸⁶

Section 26(b) also provides an exception for small businesses under which these fees are limited to a maximum of \$100. Furthermore, Section 26(b) authorizes EPA to assess fees within these statutory caps for the costs of evaluating testing data that a manufacturer, importer, or processor of a chemical substance may be required to submit to the agency under Section 4 of the statute.⁸⁷

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.⁸⁸ The availability of fees collected under TSCA for obligation by EPA is subject to annual appropriations.

S. 697 and S. 725 would repeal the expired authorization of appropriations under Section 29 of TSCA, whereas the House discussion draft would not make changes to Section 29.⁸⁹ With regard

⁸² See Section 14 of S. 697 and Section 114 of S. 725, revising TSCA Section 14(b).

⁸³ Section 14 of S. 697, Section 114 of S. 725, and Section 7(3) of the House discussion draft would replace TSCA Section 14(c)(1).

⁸⁴ 15 U.S.C. § 2628.

⁸⁵ 15 U.S.C. § 2625(b).

⁸⁶ 15 U.S.C. § 2604.

⁸⁷ 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 Section 5 of the statute, but not to the evaluation of testing data that may be required under Section 4.

⁸⁸ 31 U.S.C. § 3302(b).

⁸⁹ See generally Section 25 of S. 697 and Section 124 of S. 725.

to the authority to collect fees, S. 697 and S. 725 would replace Section 26(b) with new language, whereas the House discussion draft would make targeted amendments to Section 26(b).⁹⁰ As an example, the House discussion draft would eliminate the statutory limit on collecting fees under current TSCA. In contrast, S. 697 would authorize the collection of fees to accompany certain submissions of information to EPA regarding chemicals that the agency would be directed to evaluate. The collected fees would be deposited in a dedicated fund to defray the costs of evaluating the information submitted to the agency, although the availability of the monies in the fund to EPA would be conditional on a certain level of discretionary appropriations made available to the agency. S. 725 would authorize EPA to collect fees from chemical manufacturers for various purposes. As is currently done under TSCA, the receipts from collected fees would presumably be deposited as miscellaneous receipts into the General Fund of the U.S. Treasury, to be made available subject to discretionary appropriations.

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⁹⁰ See generally Section 22 of S. 697, Section 121 of S. 725, and Section 9 of the House discussion draft.