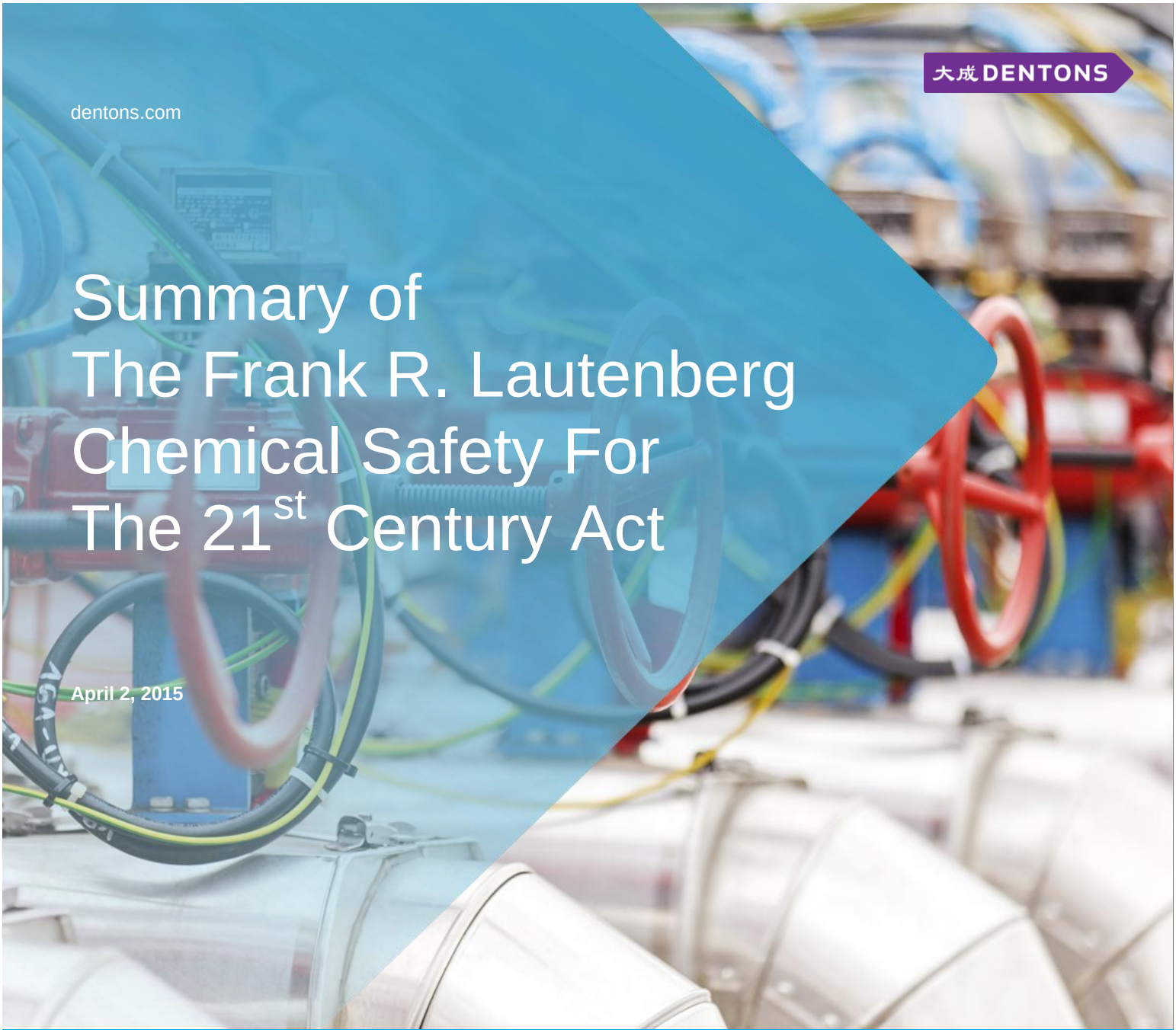

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Summary of The Frank R. Lautenberg Chemical Safety For The 21st Century Act

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Introduction

On March 10, 2015, United States Senators Tom Udall (D-NM) and David Vitter (R-LA) introduced the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("the bill"). With seventeen senators, including eight Democrats, cosponsoring the bill upon introduction, this bipartisan bill has a substantial chance of passing the U.S. Senate and, depending on the actions of the U.S. House of Representatives, being signed into law by the president.

The bill would overhaul the core provisions (title I) of the Toxic Substances Control Act ("TSCA"). The bill would require the Environmental Protection Agency ("EPA" or "the Agency") to identify all chemical substances that are "active" in U.S. commerce, screen and prioritize them for safety assessments and safety determinations, and impose restrictions or prohibitions on any uses of chemical substances that do not meet a purely risk-based safety standard.

The bill also would simplify EPA's authority to require companies to perform testing, enhance review of industry claims that information submitted to EPA should be kept confidential, and allow the Agency to assess new fees to pay for the implementation of new activities under TSCA.

Finally, the bill would limit the ability of state and local governments to establish or maintain chemical control laws after January 1, 2015 that duplicate or conflict with federal requirements under TSCA. Dentons' bill summary describes in detail the major changes that the bill would make to the existing TSCA.

TSCA § 3A – POLICIES, PROCEDURES, AND GUIDANCE

The bill establishes a new section 3A of TSCA entitled, "Policies, Procedures, and Guidance." Section 3A requires EPA to develop extensive new policies, procedures, and guidance, including rulemaking, under ambitious deadlines.

Section 3A establishes a deadline of two years following the bill's enactment for EPA to develop, following public notice and comment, any policies, procedures, and guidance that the Agency deems necessary to carry out sections 4 (testing), 4A (prioritization screening), 5 (new chemicals and significant new uses), and 6 (safety assessments and safety determinations) of TSCA. The Agency's new policies, procedures, and guidance must incorporate the following items, to the extent that they exist and are relevant: hazard, exposure, and risk assessment guidelines and methodologies; data evaluation and quality criteria; testing methodologies; and any other relevant guidelines and policies of EPA. Within five years of the bill's enactment and at least every five years thereafter, EPA must review and, if necessary and following public notice and comment, update the policies, procedures, and guidance developed under section 3A.

In addition, section 3A requires EPA, in making decisions under sections 4, 4A, 5, and 6 of TSCA, to consider reasonably available information about the hazards and exposures of chemical substances under their conditions of use. "Reasonably available information" includes three categories of information:

(1) information submitted to EPA either voluntarily or under a rule, order, consent agreement, or other TSCA requirement by manufacturers (including importers) or processors of a substance, the public, other federal departments or agencies, the governor of a state, or a state agency responsible for protecting health or the environment;

(2) information submitted to a government in any jurisdiction under a requirement related to protecting health or the environment; or

(3) information identified by EPA in an active search of publicly available or otherwise accessible information.

Section 3A also establishes a new federal advisory committee called the "Science Advisory Committee on Chemicals." The Committee will have representatives from science,

government, labor, public health, public interest, animal protection, industry, and other groups and will meet at least once every two years to give EPA independent advice and expert consultation regarding implementation of the core TSCA provisions (title I), as amended by the bill.

Lastly, section 3A requires EPA to develop extensive new policies, procedures, and guidance in three specific areas, as follows.

Use of Science

Section 3A requires EPA to establish new policies, procedures, and guidance on the use of science in making decisions under sections 4, 4A, 5, and 6 of TSCA. The new policies, procedures, and guidance must describe how EPA will ensure four outcomes:

(1) the Agency's decisions meet three criteria: (a) are based on information, procedures, measures, methods, and models used in a manner consistent with "the best available science" (not defined); (b) take into account the extent to which (i) assumptions and methods are clearly and completely described and documented, (ii) variability and uncertainty are evaluated and characterized, and (iii) information has been subject to independent verification and peer review; and (c) are based on the weight of the scientific evidence, in which EPA considers information in a "systematic and integrative framework" to assess relevance;

(2) if appropriate and practicable, peer review, standardized test design and methods, consistent data evaluation procedures, and good laboratory practices are "encouraged";

(3) a clear description of each individual or entity who funds the generation or assessment of information and the degree of his, her, or its control over the generation, assessment, or dissemination of the information is made available; and

(4) if appropriate, advice of the National Academy of Sciences regarding the hazards, exposures, and risks of chemical substances is considered.

Testing

Section 3A also requires EPA to establish new policies and procedures for testing under section 4 of TSCA. The new policies and procedures must do four things:

(1) address how and when actual or potential exposure will factor into a decision to require new testing;

(2) describe how EPA will determine when additional information is needed to implement TSCA;

(3) require EPA to consult with the National Institute for Occupational Safety and Health before requiring epidemiological studies of employees; and

(4) require EPA to consider reasonably available information of the following types, if appropriate and practicable, before adopting any requirement to perform tests on vertebrate animals: (a) toxicity information; (b) computational toxicology and bioinformatics; (c) high-throughput screening methods and their prediction models; and (d) scientifically reliable and relevant alternatives to animal tests that would provide equivalent information.

In addition, Section 3A requires EPA to adopt a tiered approach to testing under which the Agency uses the results of screening-level tests or assessments of available information to screen chemical substances or mixtures for potential adverse effects and to inform decisions about whether additional testing is necessary. Screening-level tests may include tests for hazard (e.g., in silico, in vitro, and in vivo tests), environmental and biological fate and transport, and measurements or modeling of actual or potential exposure, as appropriate.

Following screening, if EPA determines that additional testing is required to make a safety assessment or safety determination under section 6 of TSCA, the Agency may require advanced tests for potential health or environmental effects or exposure potential. Section 3A grants EPA the authority, however, to skip screening and proceed directly to advanced testing

when other available information justifies this action under new guidance that the Agency develops to address this specific situation.

Safety Assessments and Determinations

As soon as practicable after EPA designates a substance as "high priority" under section 4A of TSCA, section 3A requires EPA to inform the public about the schedule for completing the substance's safety assessment and safety determination under section 6 of TSCA. EPA may establish different schedules for different high-priority substances, but all schedules must comply with deadlines contained in section 6. Also, at the start of each year, EPA must identify the substances whose safety assessments and safety determinations the Agency will complete during that year.

If EPA wants to prohibit or otherwise restrict an article on the basis of a chemical substance's presence in the article, section 3A requires EPA to have evidence of "significant exposure" (not defined) to the chemical substance from the article. Section 3A also requires EPA to promulgate by notice-and-comment rulemaking new policies and procedures that the Agency will use to carry out section 6 of TSCA. At a minimum, EPA's new policies and procedures (rules) must do six things:

(1) describe (a) how EPA will identify informational needs and seek information from the public; (b) the information, including draft safety assessments, that interested persons, entities, and states may submit to EPA; and (c) the criteria that EPA will use to evaluate information;

(2) require EPA (a) to define the scope of safety assessments and safety determinations conducted under section 6, including the hazards, exposures, conditions of use, and potentially exposed and susceptible populations that the Agency expects to consider; (b) to explain the basis for the scope of safety assessments and safety determinations; (c) to accept comments on the scope of safety assessments and safety determinations; (d) to identify the items in (a) to (c) of this paragraph that the Agency has considered in a final safety assessment; and (e) explain the basis for the Agency's consideration of these items;

(3) describe how EPA will consider “aggregate exposures” (not defined) or significant subsets of exposures to a chemical substance under the conditions of use and explain the basis for the Agency’s consideration of these issues in a final safety assessment;

(4) require each safety assessment and safety determination to include a description of the weight of the scientific evidence and a summary of the information about the substance’s health and environmental impacts that EPA used, including available mechanistic, animal toxicity, and epidemiological studies;

(5) establish a timely and transparent process for determining whether new information submitted or obtained after the date of a final safety assessment or safety determination warrants reconsideration; and

(6) require EPA to consider the extent of federal regulation under other U.S. laws when relevant information is provided or made available to the Agency.

In addition, section 3A requires EPA to develop guidance within one year of the bill’s enactment to assist interested persons in developing draft safety assessments and other information for submission to EPA, which the Agency may consider or disregard at its discretion. At a minimum, the new guidance must address the quality of information submitted by interested persons and the process that they must follow in developing a draft safety assessment for consideration by EPA.

Lastly, section 3A requires EPA to make specific information about safety assessments and safety determinations available to the public:

(1) a nontechnical summary and the final version of each safety assessment and safety determination;

(2) each proposed safety assessment and safety determination, with notice and opportunity for comment; and

(3) in each final safety assessment and safety determination, a list of the studies considered by EPA and a list of the policies, procedures, and guidance that the Agency followed.

TSCA § 4 – TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

The bill makes it easier for EPA to require test data. The bill grants this expanded authority by first changing the standard for when testing can be required. Under the bill, EPA may require manufacturers, including importers, and processors to conduct testing if the Agency needs new data in order to do any of the following: make any decision under section 5 ("New Chemicals and Significant New Uses") or 6 ("Safety Assessments and Safety Determinations") of TSCA; to determine whether an export-only substance or mixture under section 12(a)(1) of TSCA meets the safety standard while the substance is present in the United States; or to implement another federal statute. EPA also may require test data to facilitate the prioritization screening process under new section 4A of TSCA, but EPA cannot establish a minimum required data set for this purpose.

In addition, the bill expands the manner in which EPA may require testing, permitting the Agency to require test data development by promulgating a rule, entering into a testing consent agreement, or simply issuing an order. If EPA issues an order, however, the Agency must provide a justification for doing so instead of promulgating a rule or entering into a testing consent agreement.

Any testing rule, order, or consent agreement must identify the chemical substance concerned, the persons required to conduct the testing, the applicable testing protocols, and when the data are due to EPA. In selecting test procedures and deadlines, EPA must consider the cost of different test methods and the availability of research facilities. The Agency also must explain its need for the test data and why available information is insufficient. Subject to section 14 ("Confidential Information") of TSCA, EPA will make all testing agreements and orders and all test data and other information submitted under section 4 available to the public, but the bill does not mandate a specific method of publication.

Animal Testing

The bill adds new requirements for EPA to minimize testing on vertebrate animals. EPA must accomplish this goal by encouraging the following: use of integrated and tiered testing strategies; "best available science" (although this term is not defined); test methods that reduce the use of animals but still provide high-quality information; grouping of chemicals, so that one test is used for multiple substances; and formation of industry consortia, to avoid duplicative testing. EPA also must fund research to reduce animal testing.

In addition, EPA must develop and take public comments on a strategic plan to promote the development and implementation of testing strategies that reduce the use of vertebrate animals. The Agency will then use the strategic plan to develop testing requirements. To ensure that EPA takes steps toward reducing animal testing, the bill requires EPA to submit a report to Congress every five years that describes the Agency's progress in reducing animal testing and its goals for developing and adopting alternative test methods.

Reimbursement of Testing Costs

Under the bill, as with current TSCA, EPA can require test data from manufacturers, including importers, and processors. Persons required to submit test data can agree to do so jointly. Unchanged in the bill is that one person may seek an exemption from testing based on another person's commitment to submit the required data. In such case, EPA will order payment of "fair and equitable reimbursement" to the data submitter. If the parties cannot agree on the amount of compensation due to the submitter, reimbursement is determined by arbitration.

The bill may have far-reaching implications on the reimbursement of testing costs. Under TSCA, the amount of reimbursement must be based on the effect on the parties' competitive positions and their market shares. The EPA regulations that implement existing section 4 of TSCA apply a fixed reimbursement formula under which the parties' shares of data development costs equal their respective shares of the total production volume of the test chemical or mixture.

The bill removes from TSCA all guidance regarding factors, including market share, that should be considered in allocating testing costs. Although the bill does not require EPA to amend its existing section 4 reimbursement rules, the bill provides the Agency more options for allocating testing costs, if the parties cannot agree on the amount of reimbursement due. It is unclear whether EPA will change the production-based reimbursement formula based on the new bill's provisions.

The bill also affects reimbursement by dramatically shortening the reimbursement period. TSCA requires reimbursement from a manufacturer, including an importer, or processor who relies on data generated by others and who manufactures, including imports, or processes the relevant substance during the reimbursement period. The reimbursement period is currently at least five years after the last data item is submitted but can be longer in some instances. Under the bill, however, the reimbursement period is only 180 days from the date on which the studies are due.

Lastly, the bill designates existing subsection 4(f) as 4(g) and amends it to require EPA to take appropriate action under section 5, 6, or 7, if the Agency receives information about a chemical substance or mixture under section 4 that indicates a significant risk of harm from any effect.

TSCA § 4A – PRIORITIZATION SCREENING

The bill establishes a new section 4A of TSCA entitled, "Prioritization Screening." In brief, section 4A requires EPA to establish by notice-and-comment rulemaking and then carry out under ambitious deadlines a new "prioritization screening process" for designating existing substances that EPA has separately determined to be "active" under section 8 of TSCA as either a high priority or a low priority for safety assessment and safety determination under section 6 of TSCA.

Within a year of the bill's enactment, EPA must establish by rule a risk-based screening process and explicit criteria for identifying existing chemical substances as either "high-priority substances" or "low-priority substances" for purposes of safety assessment and safety

determination under section 6 of TSCA. For this purpose, EPA must consider existing substances that the Agency has designated as “active” under section 8 of TSCA. EPA may consider substances on an interim list of active substances established by section 8 and also may consider substances that it deems “inactive” under section 8 in two situations:

(1) EPA has never taken action to ban or phase out the substance, and it has the potential for high hazard and widespread exposure; or

(2) EPA has taken action to phase out or ban the substance, but the action does not address the potential for residual high hazards or widespread exposures.

Within 180 days after the effective date of EPA’s rulemaking to establish a risk-based screening process and screening criteria, the Agency must start the prioritization screening process and make every effort to complete it “in a timely manner,” including consideration of EPA’s ability to schedule and complete safety assessments and safety determinations under section 6 in a timely manner. EPA has the authority to screen categories of chemical substances to ensure efficiency and timeliness. In addition, within 90 days after receiving information that a substance has complied with a test rule, order, or consent agreement issued under section 4 of TSCA for the purpose of determining a substance’s priority under section 4A, EPA must designate the substance as a high- or low-priority substance.

EPA must publish an annual goal for the number of substances to be screened and prioritized under section 4A. At least once a year, EPA must publish a list of substances being considered in the screening prioritization process and their current status, including any deferred decisions. The list also must identify high-priority and low-priority substances and the bases for their designations. At least every five years, EPA also must review its experience with the prioritization screening process and make any modifications needed to improve efficiency and effectiveness in light of the Agency’s available resources.

Prioritization Screening Criteria

EPA's prioritization screening criteria must take eight factors into account:

(1) the recommendations of state governors and state agencies charged with protecting health or the environment from chemical substances appropriate for screening;

(2) the hazard and exposure potential of the substance or category, including specific scientific classifications and designations by "authoritative government entities" (not defined);

(3) the substance's conditions of use or significant changes in them;

(4) evidence and "indicators" of the substance's exposure potential to humans or the environment, including potentially exposed or susceptible populations;

(5) the volume of a substance manufactured or processed;

(6) whether the volume of a substance reported under section 8(a) of TSCA (for example, the Chemical Data Reporting Rule) has significantly increased or decreased during the period beginning on the date of a previous section 8(a) report or the date on which a section 5 premanufacture notice or significant new use notice was filed for the substance;

(7) the availability of hazard and exposure information required for conducting a safety assessment or safety determination for a substance, with limited availability being a sufficient basis for but not mandating a substance's designation as high priority; and

(8) the extent of federal and state regulation of the substance or the extent of the impact of state regulation of the substance on the United States (unclear what the latter "extent" includes), with existing federal or state regulation of any uses evaluated in the section 4A screening prioritization process being a factor in designating the substance as low priority.

Prioritization Screening Process

EPA's prioritization screening process must do four things:

(1) identify the chemical substances that the Agency considers for prioritization;

(2) invite interested persons to supply information about substances under consideration;

(3) apply the required screening criteria; and

(4) identify a chemical substance as a high- or low-priority substance using available information, unless the Agency defers a decision in order to obtain and evaluate additional information needed to make the decision.

In each prioritization screening decision, EPA must integrate the hazard and exposure information available to the Agency.

Identifying High- and Low-Priority Substances

Section 4A requires EPA to identify as a high-priority substance any substance that has the potential for high hazard *and* widespread exposure in relation to other chemical substances. EPA may designate as high priority a substance that has the potential for high hazard or widespread exposure in relation to other chemical substances. EPA also may designate as high priority a substance that it deems "inactive" under section 8, if the Agency determines that the inactive substance "warrants" a safety assessment and safety determination, although the bill provides no criteria for making this decision.

Conversely, EPA must designate as a low-priority substance a substance for which the Agency has sufficient information to conclude that the substance is likely to meet the safety standard, i.e., no unreasonable risk of harm to health or the environment will result from exposure to the substance under the intended, known, and reasonably foreseeable conditions of use, taking into account the risk of harm to the general population and to relevant susceptible populations identified by EPA, and ignoring cost or other "nonrisk" factors.

In all cases, EPA must publish its proposed prioritization screening decisions for public comment. EPA's prioritization screening decisions do not affect the import, manufacture,

processing, distribution in commerce, use, or disposal of chemical substances or the regulation of these activities except as provided by TSCA's preemption provisions (section 18).

If EPA needs additional information in order to prioritize a substance, the Agency may defer the prioritization screening decision for a reasonable period of time. The deferral period must be sufficient to allow interested parties to submit and EPA to review the additional information or to require development of the additional information under a testing rule, order, or consent agreement under section 4 of TSCA.

Upon the receipt of new information, EPA may but is not required to revise its prior designation of a substance as either high or low priority. In addition, if EPA initially identifies a substance as high priority due to a lack of relevant information, the Agency must reconsider its prioritization screening decision upon receiving the relevant information.

Prioritization Screening Following State Action

After the bill's enactment into law, a state must notify EPA if the state takes or proposes to take action to prohibit or restrict the import, manufacture, processing, distribution in commerce, or use of any substance that EPA has identified as a high-priority substance. EPA must make the notice public, subject to section 14 of TSCA and applicable state law regarding the confidentiality of information provided to the state or EPA. The notice requirement does not preempt any state law, and a state's failure to notify EPA is not a violation of TSCA.

Upon receiving the notice, EPA may request information from the state, including the following: scientific evidence about hazards, exposures, and risks of the substance under its conditions of use that the state's action or proposal is intended to address; any state or local conditions that justify the state's action or proposal; the legal basis for the state's action or proposal; and any other information relevant to the state's action or proposal, including information about any alternatives to the substance that the state considered. For any substance about which EPA receives a notice from a state, EPA must make a prioritization screening decision if the Agency

determines that the substance is likely to have a significant impact on health, the environment, or interstate commerce or has been prohibited or restricted in two or more states.

Industry Requests for Safety Assessments and Determinations

EPA's prioritization screening process must allow importers, manufacturers, and processors of a chemical substance that EPA has designated as "active" under section 8 but has not yet designated as a high-priority substance or included in the prioritization screening process to request a safety assessment of and safety determination for the substance under section 6, upon the payment of a fee provided in section 26 of TSCA. EPA must explain to submitters how to make a request and how the Agency will decide whether to grant any request.

EPA must give the public notice and opportunity to comment on the requests for safety assessments and safety determinations made by industry. The Agency also must make a decision regarding any request within 180 days of receiving it. If EPA grants an industry request, the Agency must adhere to applicable deadlines but cannot expedite the safety assessment or safety determination and also cannot give the substance any other "special treatment."

In granting requests, EPA must give preference to chemical substances for which one or more states has acted to ban or restrict the import, manufacture, processing, distribution in commerce, or use of the substance when the state-imposed ban or restriction has the potential to significantly impact interstate commerce, health, or the environment. EPA also must limit the number of substances undergoing safety assessments and safety determinations as a result of requests from importers, manufacturers, and processors to 15 percent of the total and allocate resources to industry requests in proportion to the percentage that the industry requests represent.

While EPA is conducting a safety assessment and safety determination pursuant to an industry request, the chemical substance is not considered to be designated as a high-priority substance by EPA. As a result, a state may ban or restrict the import, manufacture,

processing, distribution in commerce, or use of the substance, although TSCA's preemption provisions (section 18) would nullify any state ban or restriction enacted after January 1, 2015 that conflicts with EPA's *final* safety determination for the substance. In addition, EPA does not add the substance to or remove it from the Agency's list of high-priority substances.

List of High- and Low-Priority Substances

Before EPA's rulemaking to establish a risk-based screening process and screening criteria but not later than 180 days after the bill's enactment, the Agency also must publish an initial list of high-priority and low-priority substances ("List") and may initiate new or continue ongoing safety assessments and safety determinations for high-priority substances on the List. The initial List must contain at least 10 high-priority substances, at least five of which EPA must draw from its October 2014 TSCA Work Plan, and at least 10 low-priority substances. Thereafter, to the extent possible, EPA must draw at least half of the high-priority substances that the Agency identifies from the October 2014 TSCA Work Plan and any updates to it, until EPA has designated all Work Plan chemicals as either high-priority or low-priority substances.

Three years after the bill's enactment, EPA must add additional high-priority substances to the List to ensure that the Agency has completed or is conducting safety assessments and safety determinations for at least 20 high-priority substances under section 6 of TSCA. In addition, EPA must add additional low-priority substances to ensure that the Agency has designated at least 20 low-priority substances. As soon as practicable and not later than five years following the bill's enactment, EPA must add additional high-priority and low-priority substances to the List to ensure that the Agency has completed or is conducting safety assessments and safety determinations for at least 25 high-priority substances and has designated at least 25 low-priority substances.

When EPA has completed a safety determination under section 6, the Agency must remove the substance from the List. EPA must add at least one high-priority substance to the List for

each one removed, until the Agency has completed a safety assessment and safety determination for all high-priority substances.

TSCA § 5 – NEW CHEMICALS AND SIGNIFICANT NEW USES

The bill makes substantial changes to section 5 of TSCA without eliminating the existing premanufacture notice ("PMN") and significant new use notice ("SNUN") requirements or the exemptions from them. Although the bill does change EPA's process and standards for reviewing PMNs and SNUNs, the bill does not significantly change the informational requirements for PMNs or SNUNs, and the possible outcomes will be familiar to current submitters of PMNs and SNUNs. In addition, the bill codifies the notice of commencement requirement currently found only in EPA's TSCA regulations at 40 C.F.R. § 720.102.

Reorganization of Section 5

The bill deletes existing subsection 5(b) ("Submission of Test Data") in its entirety and puts existing subsection 5(a) ("In General") in its place, after renumbering it as subsection 5(b) and giving it a new name: "Notices." In addition, the bill renumbers existing subsection 5(i) ("Definition") as subsection 5(a) and moves it to the start of section 5.

The bill then deletes existing subsection 5(c) ("Extension of Notice Period") in its entirety and puts existing subsection 5(d) ("Content of Notice; Publication in the Federal Register") in its place, after renumbering it as subsection 5(c). In addition, the bill amends the renumbered subsection to codify the existing informational requirements for PMNs and SNUNs in EPA's TSCA regulations at 40 C.F.R. §§ 720.45 and 720.50 and to add a new requirement for "information regarding conditions of use and reasonably anticipated exposures."

The bill also deletes existing subsections 5(e) ("Regulation Pending Development of Information"), 5(f) ("Protection Against Unreasonable Risks"), and 5(g) ("Statement of Reasons for not Taking Action") and replaces them with new subsections numbered 5(d) to 5(g). The bill does not change existing subsection 5(h) ("Exemptions"), which is good news for those already

familiar with the existing PMN and SNUN exemptions and the large body of EPA guidance about them.

Review Process for Notices

The bill establishes a new process and standard for reviewing and disposing of PMNs and SNUNs, although the possible outcomes of the process will be familiar to current submitters of PMNs and SNUNs. Within 90 days of a PMN's or SNUN's submission, EPA must conduct an initial review, develop a profile of the PMN or SNUN substance and its potential for exposure to humans and the environment, and make one of three required determinations based on the information provided in the PMN or SNUN or any other relevant information available to the Agency:

(1) the PMN or SNUN substance is likely to meet the safety standard, i.e., no unreasonable risk of harm to health or the environment will result from exposure to the substance under the intended, known, and reasonably foreseeable conditions of use, taking into account the risk of harm to the general population and to relevant susceptible populations identified by EPA, and ignoring cost or other "nonrisk" factors.

(2) the PMN or SNUN substance is not likely to meet the safety standard; or

(3) EPA needs additional information in order to decide whether the PMN or SNUN substance is likely to meet the safety standard.

(New section 3A of TSCA requires EPA to develop and publish for comment the criteria that the Agency will use to determine whether a PMN or SNUN substance is likely to meet the safety standard.) For good cause, EPA can extend the initial review period for additional periods of time that total 90 days or fewer, excluding any extension of the review period that EPA and the PMN or SNUN submitter agree to in the context of the submitter's developing and the Agency's reviewing additional, needed information about the PMN or SNUN substance.

Possible Outcomes for Notices

Under the bill, there are three possible outcomes for a PMN or SNUN: EPA determines that the substance is likely to meet the safety standard, that the substance is not likely to meet the safety standard, or that the Agency needs additional information in order to make a determination.

Likely to Meet the Safety Standard

If EPA determines that the PMN or SNUN substance is likely to meet the safety standard, the submitter may freely commence commercial manufacture, including import, of the PMN substance or commercial manufacture, including import, or processing of the SNUN substance, as appropriate.

Not Likely to Meet the Safety Standard

If EPA determines that the PMN or SNUN substance is not likely to meet the safety standard, however, EPA must, before the end of the review period, prohibit the substance or restrict the substance to ensure that it is likely to meet the safety standard. Such a prohibition or restriction can be by consent agreement or order before the end of the review period. No one may manufacture, including import, the PMN substance or manufacture, including import, or process the SNUN substance until the end of the review period and except in compliance with the consent agreement or order.

In addition, within 90 days after issuing a consent agreement or order, EPA must consider whether to issue a significant new use rule ("SNUR") that identifies as a new use any manufacture, including import, processing, distribution in commerce, use, or disposal of the substance that does not comply with the consent agreement or order. Then, EPA must either initiate rulemaking to promulgate the SNUR or publish the Agency's reasons for not initiating a SNUR.

The bill authorizes EPA to impose a variety of prohibitions and restrictions under a consent agreement or order for a PMN or SNUR substance:

(1) a requirement that the substance be marked with or accompanied by prescribed warnings and instructions regarding use, distribution in commerce, or disposal, which will not however preempt failure-to-warn claims under federal or state law;

(2) a requirement that manufacturers or processors keep records of their manufacturing or processing processes or, subject to section 4 of TSCA, monitor or conduct tests reasonably necessary to address potential risks of manufacturing, including importing, processing, distributing in commerce, using, or disposing of the substance;

(3) a restriction on the quantity of the substance that may be manufactured, including imported, processed, or distributed in commerce, in general or for a specific use;

(4) a prohibition or other restriction of the manufacture, including import, processing, or distribution in commerce of the substance for a significant new use, any method of using the substance commercially, or any method of disposing of the substance; and

(5) a prohibition or other restriction on the manufacture, including import, processing, or distribution in commerce of the substance, in general or for a specific use.

Before adopting any prohibition or other restriction to address workplace exposures to chemical substances, EPA must consult with the United States Occupational Health and Safety Administration ("OSHA").

More Information Needed

If EPA determines that it needs more information to decide whether a PMN or SNUN substance is likely to meet the safety standard, the Agency must give the PMN or SNUN submitter an opportunity to provide the additional information. In addition, EPA may agree with the submitter to extend the review period for a reasonable time that permits the submitter to

develop and the Agency to review the additional information needed. EPA also may require development of the additional information by a testing rule, consent agreement, or order under section 4 of TSCA.

If and when EPA obtains the additional information needed, the Agency must promptly determine whether the PMN or SNUN substance is likely to meet the safety standard. If EPA does not obtain the additional information for any reason, the Agency must prohibit or restrict the substance by consent agreement or order before the end of the review period, to ensure that the substance is likely to meet the safety standard, and no one may import, manufacture, or process the substance, as applicable, until the end of the review period and except in compliance with the consent agreement or order.

Notice of Commencement

In the case of any PMN substance, the submitter must file a notice of commencement ("NOC") with EPA within 30 days of starting commercial manufacture, including importation, of the substance, whether or not there is a consent agreement or order for the PMN substance. At any time after receiving an NOC for or new information about a substance, EPA may put the substance into the prioritization screening process under section 4A of TSCA.

TSCA § 6 – SAFETY ASSESSMENTS AND SAFETY DETERMINATIONS

The bill keeps the two chemical-specific provisions of existing section 6 of TSCA with a minor change but deletes and replaces all remaining provisions. Specifically, the bill retains subsections 6(e) ("Polychlorinated Biphenyls") and 6(f) ("Mercury"), renumbers them as subsections 6(g) and 6(h), respectively, deletes paragraph 6(g)(4) (relating to rulemaking for polychlorinated biphenyls), and renumbers paragraph 6(g)(5) as 6(g)(4). The bill then replaces the rest of existing section 6 with new subsections numbered 6(a) to 6(f).

The new provisions establish a novel system under which EPA will systematically conduct safety assessments and safety determinations of chemical substances that the Agency has both identified as active in U.S. commerce under section 8 of TSCA and prioritized

(designated) for a safety assessment and a safety determination under new section 4A of TSCA. EPA will restrict substances that do not meet a new safety standard for their intended, known, and reasonably foreseeable uses until the uses do meet the safety standard. EPA will phase out or ban any specific uses that cannot meet the safety standard even with the imposition of restrictions.

EPA will use a risk-benefit test to choose which restrictions to impose on any substance's use that does not meet the safety standard but not to determine whether the use itself meets the safety standard in the first instance. In other words, EPA will not preserve a substance that cannot be used safely on the basis of any risk-benefit analysis. In limited exigencies, however, a qualified substance can obtain a time-limited exemption from a restriction, phase out, or prohibition of specific uses.

Terms Added to TSCA § 3

For purposes of the safety assessments and safety determinations required by section 6 of TSCA, the bill adds five new terms to existing section 3 ("Definitions") of TSCA, as follows.

Safety Assessment

The bill defines "safety assessment" broadly as "an assessment of the risk posed by a chemical substance under the conditions of use, integrating hazard, use, and exposure information regarding the chemical substance." In addition, section 3A of TSCA requires EPA to specify in new policies and procedures developed by notice-and-comment rulemaking the scope, basis, content, use, publication, and interested persons' participation in both draft and final safety assessments. Accordingly, the bill leaves the substance of what a safety assessment is to future rulemaking by EPA.

Safety Determination

The bill defines "safety determination" in general terms as "a determination by the Administrator [of EPA] as to whether a chemical substance meets the safety standard under

the conditions of use." Additionally, section 3A of TSCA requires EPA to specify in new policies and procedures developed by notice-and-comment rulemaking the scope, basis, content, use, publication, and interested persons' participation in safety determinations. Thus, the bill also leaves the substance of what a safety determination is to future EPA rules.

Safety Standard

For purposes of safety determinations, the bill defines the applicable "safety standard" as follows:

> a standard that ensures, without taking into consideration cost or other nonrisk factors, that no unreasonable risk of harm to health or the environment will result from exposure to a chemical substance under the conditions of use, including no unreasonable risk of harm to the general population; or any potentially exposed or susceptible population that the Administrator [of EPA] has identified as relevant to the safety assessment and safety determination for a chemical substance.

(Emphasis added.) Therefore, in considering whether exposure to a substance under the conditions of use will result in an unreasonable risk of harm, EPA cannot consider cost or other non-risk factors. In other words, the Agency cannot consider the benefits of the use or the cost of restricting, phasing out, or banning the substance in deciding whether it risks harm or whether any risk of harm is unreasonable. "Unreasonable risk of harm" is not, however, otherwise defined or explained in the bill.

Conditions of Use

For both safety assessments and safety determinations, the bill defines "the conditions of use" as "the intended, known, or reasonably foreseeable circumstances [under which] the Administrator determines [that] a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of." Without our editorial remarks in square brackets,

however, the definition is ungrammatical and, thus, a good candidate for correction during the legislative process.

Potentially Exposed or Susceptible Population

Lastly, for purposes of the safety standard used in safety determinations, the bill defines "potentially exposed or susceptible population" as follows:

> [One] or more groups of individuals within the general population who may be differentially exposed to chemical substances under the conditions of use or susceptible to greater adverse health consequences from chemical exposures than the general population and that when identified by the Administrator [of EPA] may include such groups as infants, children, pregnant women, workers, and the elderly.

In its future rules to develop the policies and procedures required by section 3A for implementing section 6 of TSCA, EPA will have to elaborate upon this concept for the purpose of conducting safety determinations.

Requirement and Deadlines for Safety Assessments and Determinations

Section 6 requires EPA to conduct a safety assessment and a safety determination for each chemical substance that the Agency has designated as a high-priority substance under section 4A of TSCA. Within six months after designating a substance as a high-priority substance, EPA must define the scope of the safety assessment and the safety determination to be conducted, including the hazards, exposures, conditions of use, and potentially exposed and susceptible populations that the Agency expects to consider. Based on the results of the safety determination, EPA must impose any restrictions required by subsection 6(d) of TSCA.

EPA must complete a safety assessment and safety determination within three years after designating a chemical substance as a high-priority substance. Within two years after

completing the safety determination for the substance, EPA must promulgate a final rule containing any restrictions required by subsection 6(d) of TSCA. The bill allows EPA to extend either of these deadlines for a given substance following an "adequate public justification," so long as any extensions do not exceed two years in the aggregate. Therefore, the bill allows from five to seven years to elapse between EPA's designating a substance as a high-priority substance under section 4A of TSCA and the Agency's restricting, phasing out, or banning by rule, as appropriate, any uses of the substance that do not meet the safety standard.

Prior and Ongoing EPA Actions

While EPA is developing the new policies, procedures, and guidance required by section 3A of TSCA for using science, testing under section 4, and conducting safety assessments and safety determinations under section 6 and while the Agency also is developing the policies and procedures required by section 4A of TSCA for implementing the prioritization screening process, the bill does not stop EPA from either initiating a safety assessment or safety determination or continuing with one initiated before the bill is enacted into law. In addition, the bill does not require EPA to revise or withdraw any safety assessment, safety determination, or rule on the basis that it was completed before EPA developed a relevant policy, procedure, or guidance document under section 3A or 4A of TSCA, which the bill does not allow to invalidate the previously completed EPA action. To the extent possible, however, the bill does require EPA to integrate the new policies, procedures, and guidance developed under sections 3A and 4A of TSCA into any ongoing safety assessments and safety determinations.

Safety Determinations

Section 6 requires EPA to make a safety determination based on available information, including any draft safety assessments submitted by interested persons. EPA must make one of three determinations: that the substance meets the safety standard, that the substance does not meet the safety standard, or that the Agency needs additional information in order to make a determination.

Section 3A of TSCA requires EPA to publish each proposed safety assessment and safety determination, with notice and for comment. Section 3A also requires EPA to publish a nontechnical summary and the final version of each safety assessment and safety determination, including a list of the studies that the Agency considered and a list of the policies, procedures, and guidance that EPA followed.

Meets the Safety Standard

For purposes of judicial review, EPA's determination that a substance meets the safety standard, including the underlying safety assessment, is a final agency action as of the date on which the Agency publishes the final safety determination, as required by section 3A of TSCA. EPA's final safety determination preempts state laws and actions to the extent provided by section 18 of TSCA.

Does Not Meet the Safety Standard

If EPA determines that the substance does not meet the safety standard, the Agency must initiate rulemaking to restrict the uses until they meet the safety standard. If restricted uses cannot meet the safety standard, then EPA's rulemaking must phase out or ban the substance, as appropriate. Section 6 provides detailed instructions for the required rulemaking, which we discuss below. For purposes of judicial review, EPA's rule restricting, phasing out, or banning a substance, including the underlying safety assessment and safety determination, is a final agency action as of the date on which the Agency promulgates the final rule. EPA's final rule preempts state laws and actions to the extent provided by section 18 of TSCA.

More Information Needed

If EPA determines that it needs additional information in order to make a safety assessment or safety determination, the Agency must give interested persons an opportunity to provide the needed information. In addition, EPA may require development of the additional information by a testing rule, consent agreement, or order under section 4 of TSCA.

In all cases, EPA must establish a deadline for submission of the additional information needed. In addition, EPA may defer a safety assessment and safety determination for a reasonable period of time until after receipt of the additional information, so long as the Agency completes the safety assessment and safety determination within three years or within five years following an extension of up to two years based on "adequate public justification."

Section 6 contemplates that interested persons will submit any information needed for safety assessments or safety determinations or that EPA will require development of the information under section 4 of TSCA. In either case, when EPA obtains the additional information needed, the Agency must promptly determine whether the substance meets the safety standard.

Rulemaking to Restrict, Phase Out, or Ban Substances

When EPA determines that a chemical substance does not meet the safety standard, the Agency must promulgate a rule that restricts uses to the extent necessary to ensure that they meet the safety standard. The rule may include both mixtures and, subject to section 3A(h)(3) and section 6(d)(3)(G), articles that contain the substance and also may exempt replacement parts for articles manufactured prior to the rule's compliance deadline. The rule's compliance date must be "as soon as practicable," but EPA may vary compliance deadlines for different groups of affected people. Before EPA prohibits or restricts workplace exposure to substances, the Agency must consult with OSHA.

The bill authorizes EPA to impose a variety of prohibitions and restrictions in the rule:

(1) a requirement that the substance be marked with or accompanied by prescribed warnings and instructions regarding use, distribution in commerce, or disposal, which will not, however, preempt failure-to-warn claims under federal or state law;

(2) a requirement that manufacturers or processors keep records of their manufacturing or processing processes, describe and apply relevant quality control procedures used to

manufacture or process the substance, or monitor or conduct tests reasonably necessary to ensure compliance with the rule itself;

(3) a restriction on the quantity of the substance that may be manufactured, including imported, processed, or distributed in commerce;

(4) a requirement to ban or phase out or any other rule regarding the manufacture, including import, processing, or distribution in commerce of the substance for a particular use, for a particular use at a concentration above a level specified by EPA, or for all uses;

(5) a restriction on the quantity of the substance that may be manufactured, including imported, processed, or distributed in commerce for a particular use or for a particular use at a concentration above a level specified by EPA;

(6) a requirement to ban, phase out, or otherwise restrict any method of using the substance commercially;

(7) a requirement to ban, phase out, or otherwise restrict any method of disposing of the substance or articles that contain it; and

(8) a requirement that manufacturers, including importers, or processors of the substance notify those who distribute the substance in commerce and, to the extent reasonably ascertainable, others who possess the substance about EPA's determination that the substance does not meet the safety standard.

Cost-Benefit Analysis

In deciding which restrictions or prohibitions to impose by rule on a substance that has failed to meet the safety standard, EPA must consider to the extent practicable reasonably available information about the quantifiable and not quantifiable costs and benefits of the proposed regulatory action and of the one or more other primary regulatory actions that the Agency has considered. As part of the analysis, EPA must review any one or more technically and

economically feasible alternatives to the substance that the Agency considers relevant to the rulemaking. EPA must include its cost-benefit analysis in the proposed rule to restrict, prohibit, or phase out the substance that has failed to meet the safety standard. In the final rule, EPA must explain how the Agency used the analysis.

Exemptions

EPA may temporarily exempt one or more uses of a substance from the restrictions or prohibitions contained in the rule, with conditions, if the Agency makes either of two findings:

(1) compliance with the rule will harm national security, cause a significant disruption in the national economy due to the substance's unavailability, or interfere with a critical or essential use for which no technically and economically feasible safer alternative is available, taking hazard and exposure into account; or

(2) the use of the substance as compared to reasonably available alternatives provides a substantial benefit to health, the environment, or public safety.

EPA must include its exemption analysis in the proposed rule to restrict, prohibit, or phase out the substance that has failed to meet the safety standard. In the final rule, EPA must explain how the Agency used the analysis.

When EPA's rule imposes a phase out or ban, the Agency must consider certain factors when deciding whether to grant any exemption. Specifically, EPA must consider to the extent practicable reasonably available information about the quantifiable and not quantifiable costs and benefits of the one or more technically and economically feasible alternatives to the substance that are mostly likely to be used in its place, if EPA promulgates the rule.

If EPA exempts any use of a substance from the rule, the Agency must include reasonable recordkeeping, monitoring, and reporting requirements that EPA deems necessary to protect health and the environment while achieving the purposes of the exemption. In addition, EPA must establish in the rule that contains any exemption a reasonable time limit on it, which the

Agency will determine on a case-by-case basis. In issuing exemptions and establishing time limits for them, EPA must consider factors that the Agency has found relevant to fostering innovation and developing alternatives that meet the safety standard.

The bill gives EPA the authority to cancel, modify, or extend any extension by rule, if the Agency finds that the action is warranted on the basis of reasonably available information and after "adequate public justification." In the case of an exemption from a rule imposing a phase out or ban, however, any renewal cannot exceed five years.

Immediately Effective Proposed Rules

When EPA proposes a rule to restrict or prohibit a substance that has failed to meet the safety standard, the Agency can declare the proposed rule to be effective upon publication in the *Federal Register*. This provision resembles existing section 5(f)(2) TSCA, which EPA has used only a handful of times, all in 1984, for section 6 rules ultimately codified in 40 C.F.R. pt. 747, subpt. B. EPA may publish an immediately effective proposed rule if the Agency makes two findings:

(1) the manufacture, including import, processing, distribution in commerce, use, or disposal of the substance or mixture in question is likely to result in an unreasonable risk of serious or widespread harm to health or the environment before the final rule takes effect, and an immediately effective proposed rule is necessary to protect the public interest; and

(2) in the case of a proposed rule to prohibit the manufacture, including import, processing, distribution in commerce, use, or disposal of the substance or mixture due to an unreasonable risk of serious or widespread harm to health or the environment, a federal court has granted relief with respect to the risk under section 7 of TSCA ("Imminent Hazards").

TSCA § 8 – REPORTING AND RETENTION OF INFORMATION

The bill does not make any changes to existing subsections 8(c) ("Records" of significant adverse reactions to health or the environment) or 8(d) (reporting of "Health and Safety

Studies"), and the bill makes only modest changes to existing subsections 8(e) ("Notice to Administrator of Substantial Risks") and 8(f) ("Definitions"). Specifically, the bill reorganizes existing subsection 8(e) as a paragraph numbered 8(e)(1) and then adds a new paragraph after it numbered 8(e)(2), which gives anyone the option to submit to EPA information supporting the conclusion that a chemical substance or mixture presents, will present, or does not present a substantial risk of harm to health or the environment, but the bill does not otherwise alter existing subsection 8(e). In addition, the bill adds two new terms, namely, "active substance" and "inactive substance," to existing subsection 8(f) but does otherwise change it.

The bill's most significant changes are to existing subsections 8(a) ("Reports") and 8(b) ("Inventory"). In brief, the bill adds new paragraphs numbered (4) and (5) to existing subsection 8(a). The new paragraphs require EPA to promulgate new recordkeeping and reporting rules and to develop related reporting guidance for manufacturers, including importers, processors, and other persons likely to have "relevant" information, so that the Agency has the information that it needs to carry out sections 4 and 6 of TSCA.

In addition, the bill adds new paragraphs numbered (3) to (9) to existing subsection 8(b). The new paragraphs codify specific nomenclature conventions used with the TSCA Chemical Substance Inventory ("TSCA Inventory") and also require EPA to establish and carry out a new program to identify the chemical substances that are active in U.S. commerce, so that the Agency may then screen and prioritize them under section 4A of TSCA for safety assessments and safety determinations under section 6 of TSCA. The new paragraphs also require EPA to review within five years of the bill's enactment all claims of confidentiality for chemical identities included in the confidential portion of the TSCA Inventory.

New Recordkeeping and Reporting Rules

The bill creates new paragraphs (4) and (5) under existing subsection 8(a) ("Reports") of TSCA. The new paragraphs require EPA to promulgate new recordkeeping and reporting rules

within two years of the bill's enactment, "so that [EPA] has the information necessary to carry out sections 4 and 6." For this purpose, the bill authorizes EPA to modify any preexisting TSCA rules, for example, the Preliminary Assessment Information Rule and the Chemical Data Reporting Rule, "as appropriate."

Required recordkeeping and reporting must include information "known or reasonably ascertainable by the person making the report." In addition, EPA's new rules must include the level of detail that persons must report, and the Agency must separately develop guidance relating to the information that persons must report under the new rules.

EPA's new rules must require reporting by "processors," but the Agency must minimize the impact of the new rules on "small" manufacturers and processors. EPA also must minimize the potential for duplicative reporting generally, and the Agency may but is not required to impose different recordkeeping and reporting requirements on manufacturers (including importers) and processors under the new rules.

In addition, the bill directs EPA to apply "any reporting obligations" in the new rules to "those persons likely to have information relevant to the effective implementation" of title I of TSCA. Therefore, while EPA's new reporting and recordkeeping rules will clearly apply to manufacturers, including importers, and processors, including small businesses, it is unclear whether the bill makes anyone else who may have "relevant information" subject to reporting under EPA's new rules, for example, distributors, users, or persons who dispose of chemical substances.

Inventory Nomenclature

The bill creates a new paragraph (3) under existing subsection 8(b) ("Inventory") of TSCA. Paragraph (3) addresses technical issues regarding how chemical substances are named or otherwise described for purposes of inclusion in the TSCA Inventory.

The bill maintains the TSCA Inventory descriptions for Class 2 chemical substances that exist on the date of the bill's enactment. A "Class 2" substance is one whose composition cannot be easily represented by a definite chemical structural diagram. The bill also maintains indefinitely the use of the Soap and Detergent Association Nomenclature System originally published in 1978, during EPA's compilation of the initial TSCA Inventory, and republished with the 1985 edition of the TSCA Inventory. In addition, the bill codifies EPA's longstanding policy that other chemical substances created during the manufacture of the complex chemical substances ("statutory mixtures") described by six categorical listings on the TSCA Inventory are themselves automatically included in the TSCA Inventory.

The bill also addresses the situation in which current EPA guidance allows for multiple TSCA Inventory naming conventions. In such case, EPA must maintain the multiple naming conventions while it develops new guidance that establishes the equivalence of the multiple naming conventions for chemical substances listed on the TSCA Inventory. EPA also must allow persons to use the new guidance when determining whether a chemical substance is listed on the TSCA Inventory.

Notification of Active Substances

The biggest single change to existing section 8 of TSCA is the addition of paragraphs numbered (4) to (9) to existing subsection 8(b) ("Inventory"). The new paragraphs establish a program under which EPA will designate all chemical substances on the TSCA Inventory as either "active substances" or "inactive substances" and thereafter will maintain and keep current the designations of active substances and inactive substances on the TSCA Inventory.

Within a year of the bill's enactment, EPA must promulgate a rule under which manufacturers, including importers, and processors must notify the Agency of the chemical substances on the TSCA Inventory that they have manufactured, including imported, or processed during the ten years immediately preceding the bill's enactment. Notices are due to EPA within 180 days of

the rule's effective date. EPA must then designate as "active substances" the chemical substances for which it receives notices under the rule.

The bill preserves the confidential and non-confidential (i.e., public) portions of the TSCA Inventory. If a person submits a notice for a substance listed on the confidential portion, however, he or she must tell EPA whether the identity of the chemical substance continues to be confidential. If so, the notifier must substantiate the claim of confidentiality under section 14 of TSCA. If a person submits a notice for a substance listed on the public portion of the TSCA Inventory, however, EPA will not allow the person to make a new claim of confidentiality for the identity of the substance.

Maintenance of Active and Inactive Substances

Based on the submission of manufacturer, including importer, and processor notices, EPA will compile an "initial" list of active substances, make an initial designation of the substances on the TSCA Inventory that are active substances, and designate all remaining substances on the TSCA Inventory as inactive substances. Even before then, however, the bill requires EPA to create an "interim" list of active substances composed of all chemical substances reported under the Chemical Data Reporting Rule during the reporting period that immediately precedes the bill's enactment. The interim list of active substances allows EPA to begin the screening prioritization process under section 4A of TSCA even before the Agency has collected manufacturer and processor notices and compiled an initial list of active substances.

EPA must maintain and keep current the designations of the active substances and inactive substances included in the TSCA Inventory. For this purpose, "active substance" includes not only any substance for which EPA receives a manufacturer, including importer, or processor notice, but also any PMN substance that EPA adds to the TSCA Inventory following the receipt of an NOC under section 5 of TSCA and any inactive substance for which EPA later receives a notice that someone intends to manufacture, including import, or process it. In turn, an "inactive substance" is any substance on the TSCA Inventory that is not an active substance.

The bill requires EPA to update the list of active substances and the corresponding designations on the TSCA Inventory as soon as practicable after the Agency publishes the data from any reporting under the Chemical Data Reporting Rule or the recordkeeping and reporting rules to be promulgated under new paragraph 8(a)(4) of TSCA (see the subsection of this summary above entitled “New Recordkeeping and Reporting Rules”).

For all active and inactive substances on the non-confidential (public) portion of the TSCA Inventory, EPA must publish the specific chemical identity. For each substance on the confidential portion of the TSCA Inventory for which EPA has received and approved a claim of confidentiality for the chemical identity, the Agency must publish the EPA Accession Number, the generic chemical name, and the PMN Number.

Changing from Inactive to Active Substance

For inactive substances, the bill requires manufacturers, including importers, and processors to notify EPA if they intend to start and before they do start any non-exempt commercial manufacture, including import, or processing. For this purpose, the bill implies that EPA will compile, maintain, and update a separate list of inactive substances in addition to maintaining designations of the inactive substances on the TSCA Inventory. If the inactive substance is listed on the confidential portion of the TSCA Inventory and the notifier wants to maintain the chemical identity as confidential, he or she must assert a claim of confidentiality in the notice and substantiate the claim within 30 days after filing the notice with EPA. If the inactive substance is listed on the public portion of the TSCA Inventory, however, EPA will not allow the notifier to make a new claim of confidentiality for the chemical identity.

When EPA receives the notice, the Agency will designate the substance in question as an active substance and will approve, modify, or deny any related claim of confidentiality for the chemical identity. In addition, EPA will put the substance into the prioritization screening process that the Agency will carry out under section 4A of TSCA.

If EPA grants a claim of confidentiality for the identity of the notified substance, the Agency will protect the confidential chemical identity from disclosure for 10 years, unless the claimant withdraws his or her claim of confidentiality or EPA becomes aware that the claimant can no longer substantiate the claim. In the latter case, EPA must notify the claimant under section 14(g)(2) of TSCA before the Agency moves the previously confidential chemical identity to the non-confidential portion of the TSCA Inventory or otherwise makes the chemical identity public.

Review of Confidential Chemical Identities

Within a year after compiling an initial list of active substances based on the submission of manufacturer and processor notices, EPA must promulgate yet another rule that establishes a plan to review the claims of confidentiality for all active substances listed on the confidential portion of the TSCA Inventory.

Under the review plan, EPA will require manufacturers, including importers, and processors to substantiate their claims of confidentiality for chemical identities on the confidential portion of the TSCA Inventory, unless they have done so within the five years immediately preceding the Agency's request for substantiation. EPA also will encourage but not require manufacturers, including importers, and processors to review and either withdraw or substantiate claims of confidentiality for inactive substances listed on the confidential portion of the TSCA Inventory.

Under the review plan, EPA will review each substantiation submitted and either approve, modify, or deny it. If a person can lawfully rely on a previously submitted substantiation instead of providing a new one, then EPA will review the previously submitted substantiation, too, and approve, modify, or deny it, if the Agency did not previously review it.

For any claim of confidentiality that EPA approves under the review plan, the Agency will protect the confidential chemical identity from disclosure for 10 years, unless the claimant withdraws his or her claim of confidentiality or EPA becomes aware that the claimant can no longer substantiate the claim. In the latter case, EPA must notify the claimant under section

14(g)(2) of TSCA before the Agency moves the previously confidential chemical identity to the non-confidential portion of the TSCA Inventory or otherwise makes the chemical identity public.

EPA must complete all reviews under the review plan within five years after compiling the initial list of active substances based on the submission of manufacturer, including importer, and processor notices. In addition, the bill requires EPA to publish annual goals for completing reviews of confidentiality claims under the review plan. EPA may extend the original five-year deadline by up to two years with an "adequate public explanation," if the Agency's resources are inadequate to review the number of confidentiality claims involved.

TSCA § 12 – EXPORTS

The bill maintains existing paragraph 12(a)(1)'s exemption from TSCA for substances that are manufactured, including imported, and labeled solely for export, but the bill strikes existing paragraph 12(a)(2)'s disqualification from the export-only exemption and replaces the current disqualification with a new one. Under new paragraph 12(a)(2), export-only chemical substances remain subject to TSCA when EPA has determined under section 5 or 6 of TSCA that the substances are not likely to meet or do not in fact meet the safety standard, as applicable. This disqualification varies from the existing one, which applies to mixtures and articles in addition to substances and which requires EPA to find that the substance, mixture, or article presents an unreasonable risk of injury within the United States. Under the bill, EPA can determine that an exported mixture or article that contains a disqualified substance is subject to TSCA, or the Agency can establish a concentration of the disqualified substance in the exported mixture or article at which the mixture or article is not exempt from TSCA. In addition, the bill allows EPA to require testing under section 4 to determine whether export-only substances meet the safety standard within the United States.

The bill also amends existing subsection 12(b), regarding when a person must notify EPA of an intended export and when the Agency must in turn notify the country of import. The bill maintains the requirement that exporters notify EPA of exports of a chemical substance or

mixture for which test data is required as well as the Agency's obligation to notify the country of import of the availability of the testing information.

The bill updates the export notice requirement for substances that are subject to orders or rules. Under the bill, a person must notify EPA of an export of a chemical substance or a mixture containing the substance, if EPA finds that the substance is not likely to meet or does not in fact meet the safety standard under sections 5 or 6 of TSCA and if the Agency has restricted or prohibited the substance under section 5 or 6 or proposed to do so. Additionally, a person must notify EPA when he or she exports a substance or mixture subject to any TSCA prohibition or restriction under a rule, order, or consent agreement, whether or not EPA has evaluated the substance against the safety standard. For these export notices, the bill maintains the current TSCA requirement that EPA notify the country of import of the determination, rule, order, or consent agreement that restricts or prohibits the substance in the United States.

Finally, a person must notify EPA when he or she exports a chemical substance for which the United States is obligated by treaty to provide a notice to the country of import. This requirement is new and seems to anticipate eventual obligations under the Rotterdam Convention on Prior Informed Consent, a treaty that the United States has signed but not yet ratified. Should the United States ratify the treaty, EPA would then be obligated to provide the country of import with the prior notice that the treaty requires.

The bill requires EPA to promulgate regulations implementing export notice requirements. The rules may include exemptions. Despite that the bill only requires export notices for certain substances and mixtures that contain them, EPA's regulations can extend the export notice requirements to articles that contain substances that trigger export notice requirements.

Lastly, the bill removes the one-time requirement that EPA publish and submit a report to Congress regarding mercury compounds, because EPA fulfilled this requirement in 2009.

TSCA § 13 – IMPORTS

The bill amends existing section 13 of TSCA regarding imports by reflecting the already effective transfer of power from the Secretary of the Treasury to the Secretary of Homeland Security ("USCBP"). Additionally, the bill adds two new reasons why USCBP may deny an imported chemical substance, mixture, or article entry into the United States: (1) EPA's finding under section 6 of TSCA that the chemical substance or mixture does not meet the safety standard followed by the Agency's banning the substance by rule, and (2) an imported chemical substance's absence from the TSCA Inventory without an exemption from the section 5 PMN requirement. The bill retains the current process for managing imports that are denied entry.

The bill adds two new subsections to existing section 13 of TSCA. The first new subsection primarily enacts into law a policy that has previously existed only in EPA's TSCA regulations. As is already required by rule, a person who imports a chemical substance or mixture subject to TSCA must certify that the shipment complies with TSCA. The bill changes, however, which sections of TSCA are covered by the import certification.

The import certification currently covers sections 5, 6, and 7 of TSCA, but the bill's certification covers rules, orders, and agreements under sections 5 and 6 of TSCA and requires that the substance or mixture is either listed on the TSCA Inventory or is exempt from the section 5 PMN requirement. The bill also limits the certification requirement to a statement that reflects the importer's best knowledge after reasonable inquiry. For this purpose, a "reasonable inquiry" includes good-faith reliance on a safety data sheet, a statement by the supplier that specifically identifies the imported chemical substance, or a certification by the supplier that the imported substance or mixture complies with TSCA to the extent required by the import certification.

To assist with import certifications, the bill requires EPA to provide publicly accessible, understandable information about the identity of a chemical substance or mixture subject to a

rule under TSCA. The bill also permits EPA to require an import certification for articles containing a chemical substance or mixture subject to a rule under section 5 or 6 of TSCA, but the rule needs to clearly identify the articles subject to the import certification requirement. In deciding to require an import certification for an article, EPA must consider whether the certification will be useful in enforcing the underlying section 5 or 6 rule, the potential risk of exposure to the regulated substance from the article, the concentration of the regulated substance in the article, the impact that an import certification requirement would have on U.S. commerce, and the frequency of required import certification.

The second new subsection that the bill adds to existing section 13 of TSCA requires the importer of a chemical substance to notify USCBP when an imported chemical substance or chemical substance in a mixture is a high-priority substance, is a substance for which a treaty requires the United States to provide export notices, or is a substance that has failed to meet the safety standard under section 6 of TSCA.

Finally, the bill permits USCBP, with EPA, to modify the application of any of the section 13 requirements above.

TSCA § 14 – CONFIDENTIAL INFORMATION

The bill strikes all of existing section 14 of TSCA, which addresses the public disclosure of information reported to or otherwise obtained by EPA under TSCA, and replaces the stricken text with new provisions that address the same subject matter. Much of the “new” language is, however, a restatement of the language in the current section 14 of TSCA but with different paragraph breaks and subheadings, to conform with Congress’s drafting standards since 1976.

As in existing section 14 of TSCA, the bill generally prohibits disclosure of trade secrets and commercial or financial information that is privileged or confidential. The bill adds a new presumption of protection from disclosure for certain categories of information under specific conditions. The presumptively protected categories include the following: specific information

about processes for manufacturing or processing chemical substances, mixtures, or articles; specific information about the use, function, or application of a chemical substance or mixture in a process, mixture, or product; details of the full composition of a mixture, including the portion of the mixture comprised by any chemical substance in the mixture; specific import or production volumes; information that identifies a supplier or customer; marketing and sales information; and chemical identities prior to commercialization.

The bill requires EPA to disclose certain categories of information currently addressed in existing section 14 of TSCA, including health and safety studies. The bill also requires EPA to disclose new categories of information: safety assessments and determinations carried out under section 6; general information on processes used in the manufacture or processing of a chemical substance, mixture, or article containing a chemical substance; general descriptions of industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance; general information describing production volume; and information on banned or phased-out chemicals.

In addition, the bill adds a requirement to TSCA that a person who seeks to protect information against public disclosure must both assert and substantiate a claim of confidentiality. For information in a category that the bill presumes to be protected against disclosure, the submitter does not have to *substantiate* a claim of confidentiality, but he or she must still *assert* a claim at the time of submission, if he or she wants protection.

The bill establishes nine situations in which EPA must disclose otherwise protected information, subject to limitations. Examples include sharing with state officials, federal contractors doing TSCA-related work for EPA, and medical professionals dealing with chemical exposure and disclosure whenever the Agency finds it necessary to protect public health or the environment. In some cases, EPA's disclosure of otherwise protected information involves procedural requirements.

The bill requires EPA to protect eligible information against disclosure for an initial period of 10 years, unless the claimant withdraws the claim of confidentiality or EPA discovers that the claimant can no longer satisfy the substantiation criteria. In the latter case, EPA must notify the claimant under section 14(g)(2) of TSCA before the Agency discloses the information. The bill allows EPA to extend the initial period of protection for additional 10-year periods, with no limit on the number of extensions, so long as the information in question continues to meet all applicable criteria for protection.

In general, if EPA denies or modifies a claim seeking protection for information against disclosure, the Agency must notify the claimant before releasing information covered by the original claim for protection. No notice is required, however, for disclosures to federal employees or contractors or to anyone in a long list of federal, state, and local officials involved in responding to emergencies. Likewise, notice to a claimant is not required when EPA determines that disclosure of information is relevant in a proceeding under TSCA or when the Agency must disclose or otherwise make the information public under any other federal law.

Under the bill, a person who receives a notice from EPA that denies or modifies a claim to protect information against disclosure may bring an action in federal court to restrain the Agency's disclosure of the information. Judicial review is, however, contingent on receiving a notice from EPA. Therefore, the *exemptions* from the notice requirement discussed above are important. For example, EPA's denial or modification of a claim for protection on the basis that disclosure is necessary to protect human health or the environment would require notice to the claimant and allow judicial review while a denial or modification based on the Agency's determination that disclosure of information is relevant in a proceeding under TSCA would not require any notice or permit judicial review.

Finally, EPA *may* require substantiation or resubstantiation of a previously asserted claim to protect any information against disclosure if EPA identifies the substance involved as a high-priority substance under section 4A of TSCA or as an inactive substance under section 8 of TSCA. EPA *must* require substantiation or resubstantiation of claims in the following situations:

in response to a Freedom of Information Act ("FOIA") request, when FOIA protects the information against disclosure; when EPA learns that the information no longer meets FOIA's requirements for protection against disclosure under FOIA; and when EPA determines that a chemical substance does not meet the safety standard under section 6 of TSCA. In addition, when the bill is enacted, EPA must initiate a program to review then-existing claims to protect information against disclosure. Under the program, EPA must review the following: (1) *all* existing claims for specific chemical identities, excluding the identities of substances not yet offered for commercial distribution, for example, in a PMN for which no NOC has been filed; and (2) at least 25 percent of claims for all other information submitted to the Agency under TSCA.

TSCA § 16 – PENALTIES

The bill increases the civil penalty for violations of TSCA from $25,000 to $37,500 and also increases the monetary penalty for criminal violations from $25,000 to $50,000. In addition, the bill adds new penalties for any person or entity who knowingly or willfully commits a TSCA violation while also knowing that the violation will place another person in "imminent danger of death or serious bodily injury," which the bill does not define. Under the bill's new penalties for imminent endangerment, conviction of an individual can result in a fine of up to $250,000 and imprisonment for up to 15 years, and conviction of an entity can result in a fine of up to $1,000,000.

TSCA § 18 – PREEMPTION

As amended by the bill, section 18 of TSCA addresses when federal actions under TSCA preempt requirements of state and local governments related to chemical substances. The bill focuses mostly on preemption of state and local actions that occur after January 1, 2015. Subsection 18(e) states that nothing in TSCA preempts or otherwise affects any action taken "before January 1, 2015 under the authority of a State law that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use or disposal of a chemical substance." An even broader grandfathering provision also in subsection 18(e) protects "any

action taken pursuant to a State law that was in effect on August 31, 2003." EPA has testified to Congress that this provision would preserve California's "Proposition 65" in its entirety.

For state and local actions taken *after* January 1, 2015, however, state and local governments are prohibited from enforcing existing or establishing new requirements that conflict with or duplicate EPA's requirements under TSCA, specifically, testing and SNUN requirements, findings that chemical substances meet the safety standard under section 6 of TSCA, and rules prohibiting or restricting the manufacture, processing, distribution in commerce, or use of chemical substances that do not meet the safety standard.

The timing of federal preemption has been an important issue in the debate over TSCA modernization. The preemptive effect of most EPA actions begins when the action is completed. For example, preemption of duplicative state and local testing requirements begins when EPA issues a test rule or order or enters into a testing consent agreement under section 4 of TSCA. Likewise, preemption of *existing* state and local restrictions begins when EPA publishes a determination under section 6 that a chemical substance has met the safety standard or when a final rule under section 6 of TSCA takes effect and restricts or prohibits use of a substance that does not meet the safety standard.

However, preemption of *new* state and local restrictions of a chemical substance begins at the time EPA starts a safety assessment for the substance under section 6 of TSCA. This leaves a period of time during which EPA has initiated but not yet completed a safety assessment and safety determination for an active substance under section 6 of TSCA, but states and local governments may not establish new laws or actions that restrict or prohibit the substance.

EPA's designation of a substance as a low-priority substance under section 4A of TSCA does not preempt any state or local laws or actions. In addition, the bill expressly shields the following state and local laws and actions against any preemption by TSCA:

(1) state and local laws and actions that are adopted under the authority of or authorized to comply with any other federal law;

(2) state and local laws and actions that require reporting, monitoring, or information collection not otherwise required by EPA under TSCA or any other federal law; and

(3) state and local laws and actions that are related to water quality, air quality, or waste, with qualifications.

Finally, in order to address "compelling State or local conditions," the bill gives EPA the authority to grant waivers to state and local governments, upon application and under certain other conditions, for state and local laws and actions that TSCA would otherwise preempt. The bill allows any person to obtain judicial review of EPA's final decision on a given state or local government's waiver application. The bill also allows the governor of a state or a state agency responsible for protecting health or the environment to obtain judicial review of any EPA decision to designate a chemical substance as a low-priority substance under section 4A of TSCA.

TSCA § 19 – JUDICIAL REVIEW

Most of the changes that the bill makes to existing section 19 of TSCA amend or remove cross-references to other sections of TSCA, to reflect renumbering and other changes made by the bill. The bill amends TSCA's existing provisions for judicial review in three potentially meaningful ways.

First, the bill appears to expand the list of orders over which the federal courts of appeals have exclusive jurisdiction. The bill gives the federal courts of appeals jurisdiction over all EPA orders issued under TSCA, whereas section 19 of TSCA currently gives the federal courts of appeals jurisdiction solely over quality control orders issued by EPA under existing section 6(b)(1) of TSCA.

Second, the bill eliminates the definition of "rulemaking record." This deletion may have little practical effect, to the extent that the definition reflects rules that federal courts already use to determine the scope of any rulemaking record. Regardless, deletion of the definition with its specific criteria for a rulemaking record under TSCA frees a federal court to determine the scope of the rulemaking record in accordance with principles of administrative law established under applicable federal case law and federal statutes other than TSCA itself.

Lastly, the bill eliminates a provision in existing section 19 of TSCA under which a federal court must set aside an EPA rule that restricts or prohibits a chemical substance under existing section (6)(a) of TSCA if the Agency limited cross-examination or the presentation of certain evidence or arguments against the rule.

TSCA § 21 – CITIZENS' PETITIONS

The bill makes modest revisions to TSCA's citizen petition process that largely reflect the bill's other changes to TSCA. In substantive terms, the bill continues to allow any person to petition EPA for the issuance, amendment, or repeal of any rule promulgated under section 4 ("Testing of Chemical Substances and Mixtures"), 6 ("Safety Assessments and Safety Determinations"), or 8 ("Reporting and Retention of Information") of TSCA, but the bill significantly expands the scope of these underlying sections, which means that the potential scope of citizens' petitions expands correspondingly. The bill also slightly amends the right of any person to petition the Agency for the issuance, amendment, or repeal of an order: Instead of an order under existing subsection 5(e) or section 6(b)(2) of TSCA, which the bill removes and replaces, the bill allows a person to petition EPA for the issuance, amendment, or repeal of an order under section 4 or subsection 5(d) of TSCA.

New section 4 of TSCA authorizes EPA to order the development of any "new" information needed for the following purposes: to make any decision under section 5 ("New Chemicals and Significant New Uses") or 6 ("Safety Assessments and Safety Determinations") of TSCA; to prioritize an active substance under section 4A of TSCA for a safety assessment and safety

determination under section 6 of TSCA; to determine whether an export-only substance or mixture under section 12(a)(1) of TSCA meets the safety standard while the substance is present in the United States; and to implement another federal statute. Subsection 5(d) of TSCA authorizes EPA to order the development of any "additional" information needed by the Agency to review a PMN or SNUN and to issue orders that restrict or prohibit PMN and SNUN substances. Accordingly, EPA's authority to issue orders under section 4 and subsection 5(d) overlaps slightly, as regards the Agency's ability to order the development of new or additional information for the purpose of reviewing PMNs and SNUNs.

In procedural terms, the bill preserves a petitioner's right to a de novo review in federal district court of EPA's denial of a petition, but the bill amends the current procedural requirements. Specifically, the federal district court must order EPA to grant the petition when the petitioner shows the following "by a preponderance of the evidence":

(1) for a petition that requests a rule or order under section 4 of TSCA, the information available to EPA is insufficient for the Agency to act under section 4, 4A, 5, or 6(d) of TSCA;

(2) for a petition that requests an order under section 5(d) of TSCA, there is a reasonable basis to conclude that the PMN or SNUN substance is not likely to meet the safety standard;

(3) for a petition that requests a rule under subsection 6(d) of TSCA, there is a reasonable basis to conclude that the active substance will not meet the safety standard; or

(4) for a petition that requests a rule under section 8 of TSCA, there is a reasonable basis to conclude that the rule is necessary to protect public health or the environment or to ensure that the active substance meets the safety standard.

In addition, the bill continues to authorize a federal district court in a de novo review of a petition to defer an order that EPA grant the petition, if the court makes two findings: (1) the extent of the risk to health or the environment alleged by the petitioner is less than the extent

of risks to health or the environment with respect to which EPA is taking action under TSCA; and (2) EPA has insufficient resources to take the action requested by the petitioner.

TSCA § 26 – ADMINISTRATION

The bill makes one significant alteration and one addition to existing section 26 of TSCA: The bill replaces existing subsection 26(b) ("Fees") of TSCA with new text and adds a new subsection 26(h) entitled "Prior Actions." The bill leaves intact the remainder of existing section 26 of TSCA.

Under existing section 26(b) of TSCA, EPA is authorized to promulgate a rule that requires the payment of a reasonable fee from any person required to submit data under section 4 or 5 of TSCA, to defray the cost of administering these requirements. Subsection 26(b) establishes a fee limit of $100 for "small business concerns" and $2,500 for everyone else. For this purpose, EPA must define "small business concern" by rule, following consultation with the U.S. Small Business Administration ("SBA"), which the Agency has done. In setting fees, EPA must consider covered persons' ability to pay and the Agency's own costs to review data. Fee-sharing is permitted when testing costs also are shared.

The bill significantly changes TSCA's existing fee provisions. The bill requires EPA to promulgate rules within one year of the bill's enactment that require the payment of "reasonable" fees for the submission of any PMN, SNUN, or exemption request under section 5 of TSCA. EPA's new rule also must apply reasonable fees to a manufacturer, including an importer, or processor who does any of the following:

(1) notifies an existing chemical substance as active or changes its status from inactive to active under subsection 8(b) of TSCA;

(2) reports information under EPA's new section 8(a) recordkeeping and reporting rules, which will collect information that the Agency needs to carry out sections 4 and 6 of TSCA; or

(3) manufactures or processes a chemical substance subject to a safety assessment and safety determination under section 6 of TSCA.

The bill limits EPA's use of fees to the following activities:

(1) collecting, processing, reviewing, providing access to, and protecting information on chemical substances under TSCA;

(2) reviewing and making determinations about PMNs and SNUNs and imposing restrictions on PMN and SNUN substances under section 5(d) of TSCA;

(3) prioritizing active substances under section 4A of TSCA;

(4) conducting safety assessments and safety determinations for active substances under section 6 of TSCA; and

(5) conducting rulemaking under section 6(d) of TSCA to restrict or prohibit active substances that do not meet the safety standard.

Where possible, EPA must collect a fee before conducting the fee-supported activity. In addition, EPA cannot collect "excess" fees or retain a "significant amount" of unused fees. As in existing subsection 26(b) of TSCA, the bill requires EPA to consider the cost of fee-supported activities when setting fees for them and to establish lower fees overall for small businesses, in consultation with SBA.

The bill explains at length how EPA must set and adjust fees. In particular, the bill requires EPA to set fees at a level that defrays 25 percent of the Agency's costs to conduct fee-supported activities and that does not exceed $18 million in any fiscal year, excluding any fees that EPA collects for industry requests under subsection 4A(c) for EPA to conduct safety assessments and safety determinations under section 6 of TSCA. EPA's fee structure also must reflect "an appropriate balance" between manufacturers, including importers, and processors and allow fee payments by consortia. For an industry request under subsection

4A(c) that EPA conduct a safety assessment and safety determination under section 6 of TSCA for an active substance without having designated it as either high- or low-priority under section 4A of TSCA, the fee must fully cover the cost of the eventual safety assessment and safety determination.

Before establishing or amending the fee schedule, EPA must consult and meet with manufacturers and processors. Every three years, EPA must review and adjust its fees, as needed and in consultation with affected parties, to ensure that the Agency's funds are sufficient to conduct fee-supported activities and to account for inflation. EPA also must adjust fees, for example, by reductions or waivers, where appropriate to reduce a burden on manufacturing, including importing, or processing or to remove barriers to innovation or when collecting a fee would cost more than the fee itself. In addition, EPA must refund a PMN or SNUN processing fee under section 5 of TSCA, if the PMN or SNUN is refused or withdrawn before the Agency performs "substantial" work on it.

The bill establishes a "TSCA Implementation Fund" in which EPA will deposit fees. The bill makes the collection and availability of fees subject to Congress's annual appropriations process but also allows the fees to be available from one fiscal year to the next, rather than disappearing with each new fiscal year. Under the bill, EPA can use the fees solely to defray the cost of fee-supported TSCA activities, but this use of fees is exempt from any fiscal year limitation on federal government spending. Also, notwithstanding any other provision of subsection 26(b) of TSCA, EPA cannot assess TSCA fees in a given fiscal year, unless Congress funds EPA's Office of Pollution Prevention and Toxics ("OPPT") with at least the amount of money appropriated for fiscal year 2015.

The bill requires EPA's Inspector General to audit the TSCA Implementation Fund each year. The audit must review the following: the fees collected and disbursed under TSCA; EPA's compliance with deadlines under section 6 of TSCA; the amounts budgeted, appropriated, collected from fees, and disbursed to meet the requirements of sections 4, 4A, 5, 6, 8, and 14 of TSCA; and the reasonableness of overhead costs allocated to carrying out fee-supported

TSCA activities. EPA's Inspector General will report its findings and recommendations to the Administrator of EPA and to Congress.

The bill states that the authority granted by section 26 of TSCA will expire at the end of the fiscal year that is 10 years after the bill's enactment, unless Congress reauthorizes section 26. If the intent of the bill is to limit only EPA's authority to collect and disburse fees under subsection 26(b), however, then the bill is overbroad, because its expiration clause encompasses all of section 26, including longstanding TSCA provisions that do not obviously need reauthorization by Congress, for example, EPA's authority to regulate categories of chemical substances or mixtures under TSCA (current subsection 26(c)), the Administrator of EPA's authority to establish OPPT (current subsection 26(d)), and "known financial interest" disclosure requirements for officers and employees of EPA and the U.S. Department of Health and Human Services (current subsection 26(e)).

Lastly, the bill adds a new savings clause, subsection 26(h), to existing section 26 of TSCA. Subsection 26(h) explains that nothing in the bill eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established under TSCA before the bill's enactment. After the bill's enactment, however, it is foreseeable, even likely, that EPA will amend, repeal, or replace many existing rules, orders, and regulations under the current TSCA, including but not limited to the following: EPA's provisional, chemical fate, environmental effects, and health effects testing guidelines under section 4, which the Agency may amend or replace in order to comply with new section 3A of TSCA; section 5(e) consent orders and section 5(a)(2) SNURs for specific chemical substances, which EPA may amend, for example, to extend current consent order restrictions and new uses to substances in articles following safety assessments and safety determinations under new section 6 of TSCA; the section 8(a) Preliminary Assessment Information Rule, which EPA may repeal if the rule is obsolete following the Agency's promulgation of new recordkeeping and reporting rules under new section 8 of TSCA; the section 8(a) Chemical Data Reporting Rule, which EPA may expand in order to comply with new section 8's requirement for new recordkeeping and reporting rules; and the

section 12(b) export notice regulations, which EPA may amend to reflect the bill's changes to existing section 12 of TSCA.