TSCA Reform: An Analysis of Key Provisions and Fundamental Shifts in the Amended TSCA

June 22, 2016

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg), which makes important changes to the Toxic Substances Control Act (TSCA). Lautenberg results in fundamental shifts in the requirements and approach under TSCA, while introducing important new concepts and approaches. It is our view that the body of changes, including the careful balancing of competing needs and interests and the deft and assiduous drafting, yield a statute that has been greatly strengthened in a way that addresses all or virtually all of the deficiencies and problems that have plagued TSCA over the years. Our one word review of the amendments is "Bravo" -- and now on the heels of this success comes the equally if not more difficult task to realize successful implementation of the amended TSCA. We wish to offer our thanks to all who labored tirelessly over many years to make the bill happen.

Lautenberg proposes to amend a number of the provisions of TSCA, including those relating to definitions, testing, review and regulation of new and existing chemicals (including for the latter, sequential prioritization, risk evaluation, and risk management steps, as required), information reporting, confidential business information (CBI), preemption, fees, and others. This report presents an initial overview, a more detailed discussion of the changes in Lautenberg relative to TSCA as they relate to these and other provisions, and a section that summarizes information on the timing of various activities under the bill as related to enactment and other important milestones. In addition, we have also included a **Note** in Section 5 of the Detailed Review portion of the report that discusses possible issues associated with the effective date of the law as currently drafted and offers our views on the question. The issue concerns the status of new chemical and significant new use (SNU) notifications currently pending before the U.S. Environmental Protection Agency (EPA), and new Section 5 notifications that could be submitted in the coming months.

This report is based on the "Rules Committee Print 114-54 Text of House Amendment to the Senate Amendment to H.R. 2576, TSCA Modernization Act of 2015," and reflects the changes in the "Amendment to Rules Committee Print 114-54 Offered by Mr. Shimkus of Illinois." In the review that follows, the Section references refer to those in the amended TSCA rather than as designated in Lautenberg.

The new program, not surprisingly, will face a variety of hurdles due to the challenge of deadlines, resources, and only a short (if any) honeymoon period. It might take a significant length of time before regulations, policies, and new procedures are "up and running" to implement fully the new legislation. That said, we again applaud not only the legislative crafting

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that went into the legislation but also the ability of this Congress, often unable to bridge partisan divides, to come to consensus on such an ambitious and important undertaking.

Overview

Section 3. Definitions. TSCA's definitions are retained intact and several new definitions are added. These include:

- *"Conditions of use"* serves as a centralizing concept under which EPA determines how a chemical is made, processed, used, and disposed of. The results of this EPA determination are then the focus of reviews conducted on new and existing chemicals.

- *"Potentially exposed or susceptible subpopulation"* which, as used in the text, serves to ensure that EPA, in conducting evaluations of unreasonable risk or in determining the need for and nature of control actions, considers and evaluates the risks presented to such populations when they are identified as relevant by EPA.

Section 4. Testing of Chemical Substances and Mixtures. Lautenberg provides additional, more flexible authority, including using orders and consent agreements in addition to test rules, that EPA can use to require development of new hazard or exposure information, including information needed to prioritize chemicals. In using the new authority, EPA must explain the basis and reasoning for the action. EPA is otherwise required to use tiered testing approaches, unless it can justify going directly to advanced testing.

Lautenberg also retains and expands the scope of TSCA Section 4(f) under which EPA is required to take expedited action when new information indicates that a chemical presents a significant risk to humans. TSCA had limited this provision to cases involving cancer, gene mutations, and birth defects, while the revision removes this limitation.

Lautenberg includes a new section that requires EPA to:

- Reduce and replace vertebrate animal testing when this can be scientifically justified; and

- Develop and implement a strategic plan to promote the use of alternative test methods that are not based on vertebrate animals.

Section 5. Manufacture and Processing Notices. Lautenberg retains much of TSCA Section 5 but makes important changes that strengthen the general approach. Part of this involves increasing EPA's obligations by explicitly requiring that the Agency review all new chemicals and SNUs and make one of three determinations and take required actions (as outlined below). In evaluating whether an unreasonable risk is presented by such cases, EPA, while it cannot

consider costs or other nonrisk factors, is required to consider potentially exposed or susceptible populations and the conditions of use. The bill seems to establish a fixed period of up to 180 days for EPA to review and take actions on new chemicals and SNUs. If this timeline is not met, while EPA is not relieved of the requirement to render a determination, the Agency is required to refund all applicable fees to the submitter.

Regarding the requirement that EPA make a determination and take required actions on all new chemicals and SNUs, the three alternative determinations available to EPA under Lautenberg are as follows:

- First, that the new chemical or SNU *presents* an unreasonable risk of injury to health or the environment in which case EPA is required to regulate under Section 5(f) and must then also promulgate a Significant New Use Rule (SNUR) or explain why not.

- The second alternative consists of a series of "or" statements, as follows:

  - The information available on the case is insufficient to permit a reasoned evaluation of the chemical, *or*

  - In the absence of sufficient information, the substance *may present* an unreasonable risk, *or*

  - That the substance will be produced in *substantial quantities* and it either enters or may be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure.

  If any of these determinations is satisfied, EPA is required to issue an order under Section 5(e) and to either implement a SNUR or explain why it is not taking this step.

  We note that the language for the second alternative is somewhat similar to that in TSCA Section 5(e) *except* that in TSCA, the first italicized "or" is an "and" (also nonrisk factors or potentially exposed or susceptible subpopulations are not discussed in TSCA). The effect of the change from "and" to "or" is to substantially broaden the scope and effect of the provision and allow EPA regulatory action based merely on a lack of information.

- Third, that the new chemical or SNU is *not likely to present* an unreasonable risk, in which case, the notifier can commence manufacture/processing forthwith once the determination has been made

notwithstanding any remaining portion of the applicable review period. EPA is also required to publish a statement of its finding.

Two prominent examples of issues under TSCA Section 5 that received attention over recent years are the use by EPA of SNURs to trigger notifications for the import or processing of chemicals in articles, and the attempt by EPA to use TSCA Section 5(b)(4) to create a so-called *chemicals of concern* list. Regarding the first, Lautenberg tightens the SNUR requirements for articles such that EPA must find that the potential for exposure through the article justifies the SNU notification. Interestingly, and somewhat surprisingly, Lautenberg retained the *chemicals of concern* provision and even simplified the procedural requirements for creating such a list.

Finally, Lautenberg retains the exemptions provisions at TSCA Section 5(h) with conforming changes, and also simplified the procedures for implementing exemption rules under Section 5(h)(4) (existing examples include the low volume and polymer exemptions).

Also as discussed in more detail in the **Note** under Section 5 in the Detailed Review portion of the report below, insofar as Lautenberg as it currently stands does not include a provision regarding its effective date and unless the bill is amended prior to ultimate passage, it appears that the new notification process and regulatory requirements created by the amendments to TSCA Section 5 will take effect immediately upon signature by the President, on June 22, 2016. While Lautenberg does not include detailed provisions governing the disposition of pending or voluntarily suspended Section 5 notices (these would include Premanufacture Notifications (PMN) and Significant New Use Notifications (SNUN), as well as exemption requests under Section 5(h)(4)), it is our view that there are some provisions in amended TSCA Section 26(p) that would appear to afford EPA discretion to take needed actions on such cases using the provisions of existing TSCA Section 5 for some period after enactment. Because these transitional provisions only govern "prior actions," it is doubtful they would allow EPA to utilize the existing TSCA Section 5 provisions for any Section 5 notice that is submitted after enactment. In addition, for this reason, and given that the bill has now been signed by the President, parties should plan accordingly with regard to Section 5 notices that would be submitted thereafter. Our thinking is explained in more detail below.

Section 6. Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures. Lautenberg significantly revises TSCA Section 6 by adding prioritization and risk evaluation steps to the process, deleting the problematic "least burdensome requirement" language in TSCA Section 6(a), and includes aggressive timelines for completion of the key steps in the process, including prioritizations, risk evaluations, and risk management actions. The bill also simplifies the procedural requirements in TSCA for promulgation of risk management rules while adding new requirements and providing for certain exemptions from such rules.

Prioritizations. Lautenberg includes numeric goals, certain preferences, and deadlines for completion of prioritizations. It requires that EPA implement a risk-based screening process that includes considerations such as hazard and exposure potential, persistence and bioaccumulation,

and storage near significant sources of drinking water. The screening process applies criteria (developed by rule) for designating high- and low-priority chemicals for the risk evaluation step and the process period for a given chemical is limited to a maximum of 12 months, including opportunities for submission of information and comments by the public. Under the process:

- EPA must designate chemicals as high-priority if it concludes, without consideration of costs or other nonrisk factors, that the substance *may present* an unreasonable risk because of a *potential hazard and a potential route of exposure* under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA. EPA is required to conduct risk evaluations on all high-priority chemicals.

- Chemicals that do not meet the high-priority standard are designated as low-priority. Low-priority designations are subject to legal challenge.

- EPA must provide at least 90 days for interested persons to submit relevant information on a substance for which EPA has initiated a prioritization process. This period can be extended for no more than three months to allow for receipt or evaluation of prioritization testing conducted under Section 4(a)(2)(B).

- The default decision at the end of the 12-month period, if the available information is insufficient to support a low-priority designation, is to designate a chemical as high-priority.

Risk Evaluations. In addition to requiring that EPA initiate risk evaluations on all high-priority chemicals, Lautenberg also specifies certain timing requirements and goals for risk evaluations. The risk evaluation standard is to determine whether a chemical *presents* an unreasonable risk, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant.

EPA is required to publish the intended scope of the risk evaluation according to aggressive timelines and then to complete the risk evaluation not later than three and a half years after its initiation.

Certain requirements must be met in conducting risk evaluations, including integrating and assessing the available hazard and exposure information, describing the weight of the scientific evidence, and describing whether *aggregate or sentinel exposures* to a chemical were considered and the basis for that consideration.

Chemicals that are determined to meet the risk evaluation standard must be moved into the risk management process.

Subject to certain limitations, a manufacturer of a chemical can request and pay for an EPA risk evaluation. EPA is required to give a preference to such requests if they involve chemicals for which state regulations have been determined by EPA to have a significant impact on interstate commerce. In addition, a provision in Section 26 allows interested persons to develop and submit draft risk evaluations using guidance developed by EPA; the Agency is required to consider such evaluations.

Risk Management. Lautenberg deletes certain procedural requirements from TSCA Section 6(c) that greatly complicated any attempt to regulate existing chemicals. Lautenberg applies a number of requirements to such rulemakings, including that EPA must propose a Section 6(a) rule within one year and publish a final rule within one additional year (extendable in the aggregate for two additional years) for all chemicals determined to meet the risk evaluation standard. Additional requirements apply to certain persistent and bioaccumulative chemicals.

In regulating a chemical, EPA is required to consider and publish a statement concerning various aspects, including:

- The effects and magnitude of exposure;
- The benefits of the chemical;
- The reasonably ascertainable economic consequences of the rule; and
- The costs and benefits of the regulatory action and of one or more primary alternative regulatory actions considered by EPA.

EPA is required to consider these aspects in making its selection among the available risk management options, including whether technically and economically feasible alternatives will be available when the proposed action takes effect.

Lautenberg provides for certain exemptions and limitations from control actions, including:

- An exemption for replacement parts used in complex durable or consumer goods, as defined and as described in the Act.
- A limitation on control measures for chemicals contained in articles where the measure can be applied only as necessary to address the risks from exposure to the chemical in the article.
- A series of exemptions that can be requested and be granted by rule for a specific condition of use if EPA finds, among others, that the use is a critical or essential use for which no technically and economically feasible safer alternative is available, or that compliance would significantly disrupt the national economy.

Final Agency Actions. Lautenberg specifies that risk evaluations concluding that the chemical *does not present* an unreasonable risk and final Section 6(a) rules are, subject to Section 18, considered final agency actions.

Section 8. Reporting and Retention of Information.

Lautenberg substantially amends TSCA Section 8. The changes include provisions concerning an "Inventory reset" process, requiring that EPA continue to use certain Class 2 chemical nomenclatures, treating individual members of TSCA Section 8(b)(2) statutory mixture categories as being included in the Inventory, and requiring that EPA enter into a negotiated rulemaking leading to development of a rule limiting reporting requirements for inorganic byproducts that are recycled, reused, or reprocessed.

The Inventory reset process includes development of a reporting rule to inform EPA's designation of chemicals as *active* or *inactive* in commerce. The status of inactive chemicals can subsequently be changed to active by notifying EPA.

Section 9. Relationship to Other Federal Laws. Lautenberg amends TSCA Section 9 in ways that substantially expand the scope and operation of the section with the result that, whereas actions or referrals under Section 9 were rare over TSCA's history, the situation seems likely to change. For example, Lautenberg includes a new provision that requires EPA, when it obtains information related to chemical *exposures or releases that may be prevented or reduced* under another federal law, to provide such information to the relevant federal agency or EPA office. This requirement is potentially significant in that it does not require an EPA conclusion of *presents an unreasonable risk* to trigger the referral, as is the case for referrals under Section 9(a).

Section 12. Exports. Effective as of **January 1, 2020**, Lautenberg prohibits the export of certain mercury compounds other than to member countries of the Organization of Economic Cooperation and Development (OECD) for environmentally sound disposal. The bill also amends the Mercury Export Ban Act of 2008 concerning temporary generator accumulation of elemental mercury.

Section 14. Confidential Information. Lautenberg revises and completely replaces TSCA Section 14 concerning CBI. It includes several new sections concerning *information not protected from disclosure*. A critical aspect in this regard is information from health and safety studies. While Lautenberg *does not prohibit* the disclosure of such information on chemicals offered for commercial distribution or for which testing or notification is required per Section 4 or 5, the bill makes careful edits to a key passage from TSCA as shown below using redlining:

> This paragraph does not authorize the disclosure ~~release~~ of any information ~~data~~, including formulas (including molecular structures) of a chemical substance or mixture, that ~~which~~ discloses processes used in the manufacturing or processing of a chemical

substance or mixture or, in the case of a mixture, ~~the release of data disclosing~~ the portion of the mixture comprised by any of the chemical substances in the mixture.

Lautenberg makes clear that the release of certain types of *general information* is not prohibited, including, for example, aggregated production volumes.

Lautenberg requires that companies meet certain requirements in asserting CBI claims, including substantiation, and providing additional substantiation in the case of confidential chemical identity. Such claims, when and to the extent approved by EPA, receive protection from disclosure for a period of ten years, which can be renewed if requirements are met. At the same time, Lautenberg also includes a provision stating that certain types of information are essentially presumed to be CBI (for example, marketing and sales information) and are not subject to substantiation requirements. Lautenberg specifies certain *Duties of Administrator* in reviewing and acting on CBI claims, and gives EPA discretion to review claims in certain circumstances, such as when chemicals are designated as high-priority.

In an important shift relative to TSCA, Lautenberg allows certain exceptions to protections from disclosure if various requirements can be met. Under these exceptions, disclosure is allowed, for example, to a state or tribal government for the purpose of administration or enforcement of a law, to a federal, state, or tribal health or environmental professional, or to a treating physician or nurse.

Section 16. Penalties. Among other changes, Lautenberg increases penalty amounts for civil and criminal violations.

Section 18. State-Federal Relationship. Preemption is one of the most debated aspects of TSCA reform, and Lautenberg significantly changes when states cannot establish new laws or continue to enforce existing laws. Specifically, while states' actions taken before April 22, 2016, or any action taken pursuant to a state law that was in effect on August 31, 2003, are grandfathered and remain in effect regardless of any EPA action, states are prohibited from establishing or continuing to enforce statutes, administrative actions, or in some cases criminal penalties, that would:

- Require information already required under a TSCA Section 4, 5, or 6 rule, consent agreement, or order;
- Prohibit or restrict a chemical after EPA has made a Section 6(i)(1) determination or issued a final Section 6(a) rule; or
- Subject a chemical to the same notification of use already established in a Section 5 SNUR.

There are additional provisions allowing states to seek from EPA a waiver from preemption restrictions and ensuring that preemption does not affect state or federal common law rights and private remedies (*e.g.*, tort actions).

Section 19. Judicial Review. Lautenberg makes targeted changes to this section, for example, to delete a prescriptive definition of the administrative (rulemaking) record upon which judicial review will be based, while retaining TSCA's unusual "substantial evidence" standard of review for rules and orders under the amended statute, rather than the more common arbitrary and capricious standard for such actions.

Section 26. Administration of the Act. Lautenberg significantly revises and expands this section relative to TSCA, including expanding the fee authority, establishing a fund to hold the fees that are then to be used (subject to appropriations) to defray the costs of certain EPA activities under Sections 4, 5, and 6, requiring the use by EPA of the best available science in making scientific decisions, requiring EPA to develop and periodically review any policies, procedures, and guidance (PP&G) necessary to carry out the amendments to the Act, and requiring EPA to establish a Science Advisory Committee on Chemicals (SACC).

Detailed Review

Lautenberg proposes to amend provisions of TSCA, including those relating to definitions, testing, review and regulation of new and existing chemicals (including for the latter, sequential prioritization, risk evaluation, and risk management steps, as required), information reporting, CBI, preemption, and fees, among others. This summary discusses the changes in Lautenberg relative to TSCA as they relate to these and other provisions. In the review that follows, the Section references refer to those in the amended TSCA rather than as designated in Lautenberg.

Section 3. Definitions.

The approach in Lautenberg has been simplified from that in the earlier Senate and House versions. Lautenberg retains all the definitions in TSCA and proposes three new definitions as follows:

- (4) The term "conditions of use" means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

  - *This key definition more clearly involves an EPA role in determining the circumstances that are involved in a chemical's conditions of use.*

- (7) The term "guidance" means any significant written guidance of general applicability prepared by the Administrator.

- (12) The term "potentially exposed or susceptible subpopulation" means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.

  - *This definition also explicitly includes an EPA role in identifying such subpopulations.*

Section 4. Testing of Chemical Substances and Mixtures

In this section, Lautenberg provides EPA with additional authority whereby it can more effectively require development of new information concerning toxicity or exposure of chemicals. In our view, the approach provided in Lautenberg represents a significant improvement over TSCA and should enable EPA to obtain the understanding needed to prioritize, assess, and regulate chemicals presenting unreasonable risks.

Whereas TSCA had required EPA to satisfy certain findings in developing test rules, Lautenberg retains that authority and expands it by allowing EPA per Section 4(a)(2) also to use rules, orders, and consent agreements to obtain testing that is needed for certain purposes. These include for review of notices under Section 5 or to perform risk evaluations under Section 6(b). EPA can also require development of information needed to establish the priority of an existing chemical under Section 6(b). In such cases, EPA would also be required to meet a 90-day deadline after receipt of the new prioritization testing information for designating the subject chemicals as high- or low-priorities.

Lautenberg Section 4(a)(3) requires that in using the new authority at Section 4(a)(2), EPA must develop a statement identifying the need for the new information and how the information otherwise available to EPA was used to inform the decision to require new information. EPA is also required to explain the basis for requiring the use of vertebrate animal testing and, in the case of an order, explain why that approach was warranted.

Lautenberg Section 4(a)(4) requires use of tiered testing approaches unless available information justifies jumping directly to more advanced testing.

As in TSCA, EPA under Lautenberg can require development of Section 4 information by manufacturers or processors, and also retains the TSCA approach to exemptions and reimbursement at Section 4(c). Lautenberg also retains Section 4(e) concerning the Interagency Testing Committee with a few changes, including expanding the membership to ten agencies by adding a member appointed by the Consumer Product Safety Commission (CPSC) and by the U.S. Food and Drug Administration (FDA).

Whereas TSCA Section 4(f), concerning expedited EPA action when test data or other information indicates that a chemical presents a significant risk or serious or widespread harm from "cancer, gene mutations, or birth defects," Lautenberg has removed the adverse endpoint references and thus applies the requirement for expedited EPA action to *any* such risk or harm.

Section 4(h). Reduction of Testing on Vertebrates. Lautenberg includes this new section which requires EPA to reduce and replace vertebrate animal testing "to the extent practicable, scientifically justified, and consistent with the policies" of the Act. The bill also requires EPA to develop a strategic plan to promote the development and implementation of alternative test methods and strategies and to report on its progress every five years.

Section 5. Manufacturing and Processing Notices.

Lautenberg retains much of TSCA Section 5 with targeted changes, but strengthens the general approach by explicitly requiring that EPA review Section 5 notices, make a determination, and take any required actions.

Section 5(a)(3). Review and Determination. This section allows for any of three determinations and associated actions to be taken on a new chemical or SNU. The focus of the determination concerns whether the new chemical or SNU presents or may present "unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA] under the conditions of use." The determinations, which are not to consider costs or other nonrisk factors, are as follows:

- (A) That the chemical or SNU *presents* an unreasonable risk of injury in which case EPA shall regulate under Section 5(f) and, per Section 5(f)(4), is to consider whether to promulgate a SNUR or, not taking that step, to publish a statement explaining why not. Lautenberg also simplifies the procedural requirements that applied in TSCA Section 5(f) by deleting a provision relating to use of a court injunction in lieu of an order.

- (B) That the information is insufficient to permit a reasoned evaluation of the chemical or SNU; ***or*** that in the absence of sufficient information, the chemical *may present* an unreasonable risk; ***or*** that the chemical will be produced in substantial quantities and it either enters or may be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure. If determination (B) is satisfied, EPA is required to regulate under Section 5(e) and, as described above, to also consider the need for a SNUR/publish reasons for not taking that step.

  - The language in (B) is carried into Lautenberg Section 5(e) that also makes clear that an order shall be issued. Note that the language in (B) is similar to the provisions in

TSCA Section 5(e)(1)(A) except that in TSCA, the first italicized "or" is an "and" (also nonrisk factors or potentially exposed subpopulations are not discussed). The effect of the change from "and" to "or" is substantially to broaden the effect of the new provision and allow EPA action based merely on insufficient information.

- (C) That the chemical or SNU is "not likely to present an unreasonable risk." In these cases, per Section 5(g), the notifier can commence manufacture or processing for the SNU "notwithstanding any remaining portion of the applicable review period" and, in addition, EPA is required to publish a statement of its finding.

Lautenberg Section 5(a)(4) specifies that if EPA fails to make a determination by the end of the applicable review period (and the notice has not been withdrawn), EPA is required to refund all applicable fees for the notice (subject to certain limitations). In making this change, the provision also makes clear that EPA is still required to meet the requirement that it review and make a determination and the notifier cannot commence manufacture or processing until that happens. The effect of the changes seems to establish a fixed period not to exceed 180 days for EPA to complete its determination, lest the fees be returned.

Section 5(a)(5). Article Consideration. Lautenberg states that EPA may require SNU notifications for import or processing of a chemical as part of an article/category of articles if EPA makes an affirmative finding in the Section 5(a)(2) SNUR that the reasonable potential for exposure through the article/category or articles justifies notification.

Interestingly, Lautenberg retains TSCA Section 5(b)(4) concerning the "chemicals of concern" list. TSCA has been revised to make clear that the unreasonable risk determination does not include consideration of costs or other nonrisk factors and the procedural requirements at Section 5(b)(4)(C) have been streamlined by deleting TSCA's requirement for both oral and written comments.

Section 5(e). Regulation Pending Development of Information. As noted above, Lautenberg revises Section 5(e) to require that EPA issue an order if the Section 5(a)(3)(B) determination has been made by the Agency. This order shall prohibit or limit manufacture, processing, and related activities, "to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant" by EPA. The provision goes on to make clear that the submitter may commence manufacture or processing, "including while any required information is being developed," only in compliance with the order.

Section 5(f). Protection Against Unreasonable Risks. This section contains a new subparagraph (5) requiring consultation with the U.S. Occupational Safety and Health Administration prior to

the imposition of any restrictions under Sections 5(e) or 5(f) addressing workplace exposures, a feature that could invite considerable complications.

Section 5(h). Exemptions. Lautenberg makes conforming changes to this section and removes a procedural reference to Section 6(c) that had appeared in Section 5(h)(4) (which has been used to implement the low volume and polymer exemptions, among others).

Note Regarding Status of New Chemical and SNU Notifications Currently Pending Before EPA and New Section 5 Notifications That Could Be Submitted in the Coming Months

Lautenberg does not include a provision regarding its effective date and the new notification process and regulatory requirements created by the amendments to TSCA Section 5 are in effect now. While Lautenberg does not include detailed provisions governing the disposition of pending or voluntarily suspended Section 5 notices (these would include PMNs and SNUNs, as well as exemption requests under Section 5(h)(4)), it is our view that there are some provisions in amended TSCA Section 26(p) that would appear to afford EPA discretion to take needed actions on such cases using the provisions of existing TSCA Section 5 for some period after enactment. Because these transitional provisions only govern "prior actions," we believe it is doubtful they would allow EPA to utilize the existing TSCA Section 5 provisions for any Section 5 notice that is submitted after enactment.

The second and third subsections in the amended TSCA Section 26(p) arguably afford EPA broad discretion to establish procedures for disposing of any Section 5 cases that are pending before EPA (including those under voluntary suspensions) at the time of enactment. Lautenberg Section 26(p)(2) allows EPA to initiate or to complete a risk evaluation "prior to the effective date of the policies, procedures, and guidance required to be developed by the Administrator pursuant to" Lautenberg. Amended Section 26(*l*) requires EPA to develop these PP&Gs within two years after enactment of Lautenberg. The language in this provision is somewhat ambiguous because the amendments also establish a new process for risk evaluations under TSCA Section 6, but the language can be reasonably construed to include those risk evaluations that EPA currently prepares in response to notices under Section 5.

Amended Lautenberg Section 26(p)(3) allows EPA to complete a risk evaluation, determination, or rule prior to the development of the same PP&Gs required by amended Section 26(*l*). Although this provision does not include any reference to the orders that are one potential outcome of Section 5 notices under the current system, it otherwise appears to afford EPA the discretion to close out pending and suspended cases using the current procedures for up to two years after enactment of Lautenberg.

While Lautenberg appears to afford EPA the discretion needed to fashion an appropriate transitional policy for disposing of currently pending and suspended Section 5 notices, it does not require EPA to do this. Accordingly, in the absence of any further amendments, those parties who currently have Section 5 cases pending before EPA should make reasonable efforts to expedite final EPA action, and those parties who have cases pending before EPA at the time of

signature of the Act should seek prompt clarification on how EPA intends to dispose of such cases.

In addition, now that the law is in effect, parties should plan accordingly with regard to Section 5 notices that would be submitted thereafter.

Section 6. Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures.

Lautenberg significantly revises TSCA Section 6 by adding prioritization and risk evaluation steps to the process, deleting the problematic "least burdensome requirement" language in Section 6(a), and includes aggressive timelines for completion of the key steps in the process, including prioritizations, risk evaluations, and control actions. The bill also revises and to some extent simplifies the procedural requirements for promulgation of Section 6(a) rules, provides for certain exemptions from such rules, and applies timing requirements for effective and mandatory compliance dates.

Section 6(a). Scope of Regulation. Lautenberg revises the chapeau to this section to require an EPA determination (rather than a "finding" as in TSCA) that a chemical "presents an unreasonable risk." If this is met, EPA is required to implement a rule, subject to Section 18 on preemption, to regulate the chemical "to the extent necessary so that the chemical substance or mixture no longer presents such risk" (the corresponding language in TSCA had required EPA to regulate "to the extent necessary to protect adequately against such risk using the least burdensome requirements").

Current TSCA Section 6(b), Quality Control, has been deleted in its entirety and replaced by new Section 6(b). Risk Evaluations, which includes requirements for prioritization and risk evaluation processes as well as specific deadlines and goals. EPA is required to implement procedural rules within one year for each of these processes.

Prioritization. The prioritization process involves a risk-based screening process including criteria for designating high-priority and low-priority chemicals for the risk evaluation step. The screening process is required to consider hazard and exposure potential, including aspects such as persistence and bioaccumulation, exposure to susceptible subpopulations and storage near significant sources of drinking water, conditions of use/changes to such use, and production volume. Lautenberg requires that EPA implement a prioritization process of 9-12 months duration (extendable for up to three months) that includes opportunities for submission of relevant information and a 90-day public comment period on proposed designations. Per Section 6(b)(1)(C)(iii), the deadline for submission of relevant information can be extended for no more than three months to allow for receipt or evaluation of prioritization testing conducted under Section 4(a)(2)(B). Per Subsection 4(a)(2)(B)(i), EPA shall make its designation of high- or low-priority within 90 days of receipt of such prioritization testing.

EPA is required to designate as high-priority chemicals that EPA "concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk…because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant" by EPA.

Chemicals that do not meet this standard are designated as low-priority substances. If, at the end of the three-month extension period, the information available to EPA is insufficient to enable the Agency to designate a chemical as low-priority, it is required to designate the chemical as high-priority.

As we have observed previously in *TSCA Reform Legislation and Its Workability: Thoughts on Steps to Help Ensure Successful Implementation at the Outset and Over Time*, the "potential hazard and a potential route of exposure" phrase in the high-priority designation devolves to a hazard-based standard insofar as every chemical in commerce has a "potential route of exposure." Furthermore, the new requirement that EPA default to high-priority if at the end of the process it is unable to reach the low-priority conclusion, makes clear that it is Congress' intent that the prioritization scheme implemented by EPA be protective and conservative, and that lack of information not provide an out from the process. While low-priority designations are not specified as final agency actions, Section 19(a)(1)(C)(i) states that a civil action can be commenced within 60 days of publication to challenge such designations.

Risk Evaluations. Lautenberg specifies that EPA must initiate risk evaluations on all high-priority chemicals. Furthermore, Lautenberg Section 6(b)(2) requires that, 180 days after enactment, EPA must ensure that risk evaluations are being conducted on ten chemicals from the 2014 update of the TSCA Work Plan for Chemical Assessments (TSCA Work Plan), and that three and a half years after enactment, risk evaluations are to be underway for a least 20 high-priority designations and that at least 20 chemicals have been designated as low-priority substances. In designating high-priority chemicals, EPA is to give preference to highly persistent/highly bioaccumulative chemicals on the 2014 TSCA Work Plan list and chemicals that are "known human carcinogens and have high acute and chronic toxicity."

Per Section 6(b)(4), risk evaluations are required to "determine whether a chemical substance presents an unreasonable risk…without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant" by EPA. EPA is also required to publish the intended scope of the risk evaluation according to aggressive timelines specified in the Act and (per Section 6(b)(4)(G)) to complete a risk evaluation not later than three years after initiation, extendable for six months. In addition, per Section 6(b)(4)(C)(ii), a manufacturer of a chemical can request and pay for a risk evaluation, subject to certain percentage limitations specified at Section 6(b)(4)(E). EPA is also to give a preference to such requests from manufacturers if they involve chemicals, the regulation of which by states has been determined by EPA to have a significant impact on interstate commerce or health or the environment.

Section 6(b)(4)(F) specifies the requirements that must be met in conducting risk evaluations. These include integrating and assessing the available hazard and exposure information, not considering costs or other nonrisk factors, describing "whether *aggregate or sentinel exposures* to a chemical substance under the conditions of use were considered, and the basis for that consideration," and describing the weight of the scientific evidence for the identified hazard and exposure.

Section 6(c). Promulgation of Subsection (a) Rules. This is a key section that describes deadlines, rulemaking requirements, and procedures. Once EPA determines that a chemical satisfies the risk evaluation standard, it is required per Subsection (1) to propose a Section 6(a) rule within one year, and to publish a final rule within one additional year, extendable in the aggregate for not more than two years (additional requirements apply to certain persistent and bioaccumulative chemicals from the 2014 update to the Work Plan list).

Lautenberg deletes TSCA Sections 6(c)(2) through (5) that included certain complex procedural requirements such as informal hearings and cross examination.

Section 6(c)(2). Requirements for Rule. This section specifies that in regulating a chemical, EPA shall consider and publish a statement concerning:

- The effects and magnitude of exposure to humans and the environment;
- The benefits of the chemical for various uses;
- The "reasonably ascertainable economic consequences of the rule," including consideration of the likely effect on the national economy, small business, technological innovation, the environment, and public health;
- The costs and benefits of the regulatory action and "of the 1 or more primary alternative regulatory actions considered by" EPA; and
- The cost effectiveness of the actions and the primary alternative action(s) considered.

EPA is required, in selecting among the prohibitions and other restrictions, to factor in these considerations "to the extent practicable."

Per Section 6(c)(2)(C), EPA is required, in deciding whether to prohibit or restrict "in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action," to consider "to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment…will be reasonably available as a substitute when the proposed" action takes effect.

Replacement Parts. Section 6(c)(2)(D) concerns exemptions for replacement parts for "complex durable goods and complex consumer goods," as defined in the statute, that are designed prior to the date of publication of the rule. The definitions of such goods involve considerations such as a multi-year intended useful life, the presence of 100 or more manufactured components, and others. Such replacement parts are to be exempted from the regulation unless they contribute significantly to the risks identified.

Articles. Section 6(c)(2)(E). This provision specifies that EPA shall apply restrictions to a chemical contained in an article or category of articles "only to the extent necessary to address the identified risks from exposure" to the chemical.

Section 6(c)(3). Procedures. This section specifies that when prescribing a rule under Section 6(a), EPA must proceed in accordance with the Administrative Procedure Act. This is the same as what current TSCA states in Section 6(c)(2). What is significantly different is that Lautenberg has removed the requirement in TSCA Section 6(c)(3) that EPA provide an opportunity for an informal hearing and all related language as to how such informal hearings are conducted.

Effective dates. Lautenberg amends TSCA Section 6(d) concerning the effective date of regulations by adding more specificity to the timing for such actions and allowing for variability in compliance dates for different affected persons. Regarding timing, Section 6(d)(1) requires that EPA specify the effective date, which shall be as soon as practicable; provide for a reasonable transition period; and specify mandatory compliance dates, which shall be as soon as practicable but not later than five years after the date of promulgation (there are various additional provisos concerning timing of ban or phase-out actions or uses exempted per Section 6(g)).

Section 6(g). Exemptions. This is a new section relative to TSCA that gives EPA authority to grant an exemption, by rule, from a requirement for a "specific condition of use" of a chemical under a Section 6(a) rule. The exemption can be granted if EPA finds that the use is a "critical or essential use for which no technically and economically feasible safer alternative is available," that compliance would significantly disrupt the national economy, national security, or critical infrastructure, or that "the specific condition of use…as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety." EPA is required to make public its analysis of the need for the exemption. The time period for an exemption is required to be determined by EPA as "reasonable on a case-by-case basis" and can be extended, modified, or eliminated as warranted.

Section 6(h). Chemicals that are Persistent, Bioaccumulative, and Toxic. This section concerns certain persistent, bioaccumulative, and toxic (PBT) chemicals and outlines a procedure requiring expedited regulatory action that reduces exposures to the "extent practicable." The section includes provisions that allow chemicals to escape the requirement for expedited action although any action ultimately taken would still need to reduce exposures to the extent practicable.

Section 6(i). Final Agency Action. This section specifies that, subject to Section 18, (1) risk evaluations concluding that the chemical does not present an unreasonable risk (these are issued by order); and (2) final Section 6(a) rules are considered final agency actions beginning on the date of issuance of the order concerning the risk evaluation or promulgation of the rule.

Section 8. Reporting and Retention of Information

Lautenberg largely retains TSCA Section 8(a) while adding new subsections that clarify elements or require specific steps by EPA. Requirements concerning continued use by EPA of certain chemical nomenclatures that had appeared in earlier versions of TSCA reform legislation have been retained. Lautenberg also applies an Inventory reset process to distinguish "active" versus "inactive" chemicals.

Under Lautenberg, TSCA Section 8(a), subsections (1) through (3)(B), are essentially retained without change (this includes the small business exemption at Section 8(a)(3)(A)(ii)), and additional subsections are added, including the following:

- Section 8(a)(3)(C) requires periodic consultations with the Small Business Administration;
- Section 8(a)(4) allows for differing reporting and recordkeeping requirements on manufacturers and processors;
- Section 8(a)(5) states that EPA not require unnecessary or duplicative reporting and that it minimize the cost of compliance for small manufacturers and processors and apply reporting obligations to those persons likely to have relevant information; and
- Section 8(a)(6) requires EPA to enter into a negotiated rulemaking leading to development of a rule for limiting reporting requirements for inorganic byproducts that are recycled, reused, or reprocessed.

Chemical Nomenclature. Provisions that had been proposed in earlier bills are retained at Section 8(b)(3). These include maintaining the use of Class 2 nomenclature and Soap and Detergent Association (SDA) nomenclature, and treating individual members of TSCA Section 8(b)(2) statutory mixture categories as being included in the Inventory.

Inventory Reset. Lautenberg Section 8(b)(4) provides for an Inventory reset process. This includes a reporting rule due one year after enactment that would require manufacturers and may require processors (subject to the limitation that this reporting not be unnecessary or duplicative) to notify EPA within six months that a chemical has been manufactured or processed during the ten year period prior to enactment of Lautenberg. The information is then used by EPA to designate chemicals for which reports are received as "active" and those for which no reports are

received as "inactive." The status of inactive chemicals can subsequently be changed to active by notifying EPA before the chemical is manufactured or processed.

EPA is required to continue to maintain confidential and nonconfidential portions of the Inventory. Any manufacturer or processor seeking to maintain an existing claim of confidential chemical identity must submit a notice that includes this request when reporting active chemicals. EPA is required to establish a plan, by rule and including an opportunity for companies to substantiate such claims made in reset reporting, for EPA to review and approve, approve/deny in part, or deny such claims in accordance with Section 14. The Agency has five years (extendable for two years) to complete this process.

Section 9. Relationship to Other Federal Laws.

Lautenberg amends TSCA Section 9(a), the "hand-off provision" that concerns referrals to other federal agencies, at subsection (2) by giving those agencies a time period specified by EPA in the referral in which to respond. In another change relative to TSCA, if the other agency does not respond and act as required and in a timely manner, EPA is required per Section 9(a)(4) to initiate or take action under TSCA Section 6 or 7.

Section 9(b) concerns laws administered by EPA, and contains, relative to TSCA, a new subsection (2) which states that in determining whether to act under TSCA or another EPA law, the Administrator shall consider all relevant aspects of the risk at issue and compare the estimated costs and efficiencies of the action to be taken under TSCA versus under the other EPA law.

Lautenberg includes a new Section 9(e), Exposure Information, which states that if EPA obtains information related to chemical exposures or releases that "may be prevented or reduced" under another federal law, EPA shall make that information available to the relevant federal agency or to the EPA office. This requirement, which is stated as being "[i]n addition to the requirements" of Section 9(a), does not require an EPA conclusion of "presents an unreasonable risk" as is the case for referrals under Section 9(a).

These changes to Section 9 substantially expand the scope and operation of this section of the Act with the result that, whereas actions or referrals under Section 9 were rare over TSCA's history, the situation seems likely to change.

Section 12. Exports.

Section 12(c). Mercury and Mercury Compounds. This section prohibits the export of certain mercury compounds as of January 1, 2020, other than to member countries of the OECD for environmentally sound disposal.

Lautenberg also amends Section 5 of the Mercury Export Ban Act of 2008 concerning temporary generator accumulation of elemental mercury.

Section 14. Confidential Information.

Lautenberg revises and completely replaces TSCA Section 14 concerning CBI.

Section 14(a) states that except as provided in Section 14, EPA shall not disclose information exempt from disclosure under Section (b)(4) of the Freedom of Information Act (FOIA) that has been reported or otherwise obtained under TSCA, and for which the requirements of Section 14(c) concerning assertion and substantiation of CBI claims have been met.

Section 14(b). Information Not Protected from Disclosure at subsection (1) makes clear that CBI that has been mixed with non-CBI does not lose its protection from disclosure.

Health and Safety Studies. Section 14(b)(2) concerning information from health and safety studies is a key section of the bill and the issues associated with this concept have been handled in a variety of ways in the preceding versions of the House and Senate bills to amend TSCA. The approach taken by Lautenberg generally falls back to that in TSCA Section 14(b) and, consistent with TSCA, "does not prohibit" the disclosure of health and safety data on chemicals that have been offered for commercial distribution or for which testing or notification is required under Section 4 or Section 5, respectively. Lautenberg makes careful changes to the last paragraph in the subsection from that in TSCA as follows (redlining to show changes):

> This paragraph does not authorize the disclosure ~~release~~ of any information ~~data~~, including formulas (including molecular formulas (including molecular structures) of a chemical substance or mixture, that ~~which~~ discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, ~~the release of data disclosing~~ the portion of the mixture comprised by any of the chemical substances in the mixture.

Section 14(b)(3). Other Information Not Protected from Disclosure. This provision does not have a counterpart in TSCA. This provision states that Section 14(a) does not prohibit the disclosure of certain types of "general information," for example, describing aggregated production volumes or a general description of a process used in manufacturing or processing of a chemical or uses of a chemical.

Ban or Phase-outs. Section 14(b)(4) states that CBI protections shall be presumed to no longer apply to information on chemicals that have been banned or phased-out under Section 6(a), although there are limitations, for example, in the case of Section 6(g) exemptions concerning a specific condition of use.

Section 14(c). Requirements for Confidentiality Claims. This states that companies must meet certain requirements in asserting claims for CBI protection, including satisfying specific

additional requirements when claiming chemical identity as confidential, as well as meeting substantiation requirements contained in rules promulgated by EPA.

Section 14(c)(2) states that certain types of information "shall not be subject to substantiation requirements," including specific information describing the processes used in manufacturing or processing a chemical, mixture, or article; marketing and sales information; and specific information regarding the use, function, or application of a chemical in a process, mixture, or article. Subsection (G) reiterates and further clarifies that specific chemical identity information is protected from disclosure prior to the date on which it is first offered for commercial distribution if the identify was claimed as CBI when notice occurred under Section 5.

Exceptions. Section 14(d) provides certain exceptions to protection from disclosure if various requirements can be met. In these cases, disclosure is allowed, for example, to a federal officer or employee, a state or tribal government for the purpose of administration or enforcement of a law, a federal, state, or tribal health or environmental professional, or a treating physician or nurse.

Section 14(e). Duration of Protection from Disclosure. This provision states that information, other than that described in Section 14(c)(2) (information that is not subject to substantiation requirements), shall be protected for a period of ten years unless the claim is withdrawn earlier, and that extensions for additional ten-year periods shall be available if the requirements can be met. Information described in Section 14(c)(2) is protected until the claim on such information is withdrawn.

Review and Resubstantiation. Section 14(f)(1) gives EPA discretion to require any CBI claim to be reasserted/resubstantiated if the chemical is designated as a high-priority substance under Section 6(b) or as an active chemical under Section 8(b)(5)(B)(iii), or if EPA determines that disclosure of certain CBI "would be important to assist" EPA in conducting risk evaluations or promulgating rules under Section 6.

Section 14(g). Duties of Administrator. This provision describes various requirements that must be met by the Agency. These include a general requirement to review and approve/deny CBI claims within 90 days for initial claims and within 30 days for extension requests. EPA is also required to review all CBI claims for the identity of chemicals offered for commercial distribution as well as a representative subset of at least 25 percent of all other CBI claims. The section goes on to describe other requirements on EPA, including company notifications, procedures for appeals by companies, and the need for EPA to develop a system to assign a unique identifier to specific chemicals and to apply that identifier to all information applicable to that chemical.

Section 14(h) describes and imposes criminal penalties, including fines and imprisonment, for wrongful disclosure of CBI, while Section 14(j) states that all information reported to or otherwise obtained under this Act shall be made available upon written request to any duly authorized Congressional committee.

Section 16. Penalties.

Lautenberg increases civil and criminal penalties, respectively from $25,000 to $37,500, and from $25,000 to $50,000, and, as in TSCA applies these penalties as per day violations. Lautenberg also adds a new Section 16(b)(2) concerning criminal penalties for anyone who is convicted of knowingly and willfully violating the law while knowing at the time that the violation places an individual in imminent danger of death or serious bodily injury. Such violations are subject to a fine of not more than $250,000 or imprisonment up to 15 years, or both, for individuals, and a fine of up to $1,000,000 for organizations.

Section 18. State-Federal Relationship.

As with the Senate bill, S. 697 (the Frank R. Lautenberg Chemical Safety for the 21st Century Act that was passed by the Senate on December 17, 2015), Section 18(a) in Lautenberg sets forth the general conditions under which states or political subdivisions of a state cannot establish or continue to enforce certain statutes or administrative actions. Specifically, states or political subdivisions of a state cannot establish or continue to enforce:

- A statute or administrative action that would require the "development of information" that is "reasonably likely to produce the same information required" under a TSCA Section 4, 5, or 6 rule, consent agreement, or order.

- A statute, criminal penalty, or administrative action that would prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance: (1) for which a Section 6(i)(1) determination is made (*i.e.*, that a chemical substance does not present an unreasonable risk of injury to health or the environment), consistent with the scope of the risk evaluation under Section 6(b)(4)(D); or (2) for which a final rule is promulgated under Section 6(a), after the effective date of such rule, consistent with the scope of the risk evaluation under Section 6(b)(4)(D).

- A statute or administrative action requiring notification of a use that is already subject to a Section 5 SNUR.

The specific scope of these preemption conditions is set forth in Lautenberg Section 18(c), and is largely the same as S. 697. For example, Lautenberg states that preemption is applicable with respect to Section 18(a)(1)(B) and 18(b) when "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in" the scope of the risk evaluation pursuant to Section 6(b)(4)(D), or any final action taken pursuant to Section 6(a) or 6(i)(1).

New to Lautenberg in Section 18(a) is the additional preemption of a "criminal penalty" with regard to chemical substances found not to present an unreasonable risk or otherwise restricted.

What is important to note with these provisions is that not only can states not enact new actions but cannot "continue to enforce" existing statutes or other actions when any of these conditions are met. It also means that states could enact such statutes or actions after Lautenberg is passed and continue to enforce them until such time that one of these conditions is met.

Section 18(b) sets forth effective dates after which states cannot establish statutes, criminal penalties, or administrative actions creating prohibitions or other restrictions with regard to high-priority substances. Specifically, the timeframe begins when EPA defines the scope of a risk evaluation under Section 6(b)(4)(D) and ends on the earlier date between: (1) the deadline established under Section 6(b)(4)(G) for completion of the risk evaluation expires; or (2) the date on which EPA publishes the risk evaluation under Section 6(b)(4)(C). This issue of when states could not establish new restrictions was one significantly debated, with some prior versions allowing preemption to commence once EPA makes a final determination that a chemical substance does, or does not, present an unreasonable risk of injury to health or the environment under the intended condition of use, or when a safety assessment was defined. The timeframe set forth in Lautenberg now arguably more clearly states when states are not preempted from regulating chemicals, and modifies those conditions to include after EPA fails to complete certain activities by established deadlines. Section 18(b) further states that this section does not restrict any state to continue to enforce any statute or administrative action enacted prior to the date when EPA defines and publishes the Section 6(b)(4)(D) scope of a risk evaluation. A state cannot, however, enforce any new prohibition or restriction established after the dates set forth in this paragraph.

Lautenberg adds reference in Section 18(b) to the preemption of criminal penalties, as is the case with Section 18(a).

Section 18(d) sets forth the exceptions from preemption, and is also similar to the language in S. 697, including but not limited to, allowing states to act under another statutory authority or when such action implements a reporting, monitoring, or other information obligation not otherwise required by EPA under Lautenberg.

Section 18(e), which addresses the Preservation of Certain Laws, is unchanged from S. 697, except for changing the date before which state actions are preserved. Now, Lautenberg preserves any state action taken before April 22, 2016 (previously August 1, 2015) that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance, as well as any action taken pursuant to a state law that was in effect on August 31, 2003. This section seemingly grandfathers in all state actions taken before April 22, 2016, or actions taken pursuant to state law before August 31, 2003, regardless of any subsequent EPA action or conditions set forth in Lautenberg.

The provisions in Section 18(f) establish the criteria that EPA must determine are met for it to approve a state waiver application and exempt a statute or administrative action from preemption, and the process under which EPA will review and either grant or deny a waiver application. There were several important changes made in S. 697, the majority of which were

retained in Lautenberg. One change is to, again, include criminal penalties among the actions for which EPA can grant a discretionary waiver. The other change adds another condition for EPA to determine before granting a "required" exemption, namely, that "no later than the date that is 18 months after the date on which the Administrator has initiated the prioritization process for a chemical substance under the rule promulgated pursuant to section 6(b)(1)(A), or the date on which the Administrator publishes the scope of the risk evaluation for a chemical substance under section 6(b)(4)(D), whichever is sooner, the State or political subdivision of the State has enacted a statue or proposed or finalized an administrative action intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of the chemical substance."

Finally, Section 18(g) regarding the savings provisions remains unchanged from S. 697, meaning that nothing preempts any state or federal common law rights or any state or federal statute creating a remedy for civil relief. Lautenberg likewise is not intended to have any effect on private remedies, meaning actions taken under Lautenberg shall not be interpreted as dispositive in any civil action and do not affect the authority of any court "to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other uses of this Act or rules, regulations, requirements, standards of performance, risk evaluations, scientific assessments, or orders issued pursuant to this Act."

Section 19. Judicial Review.

Lautenberg amends Section 19, as noted earlier, by adding a provision stating that Section 6(i)(1) orders making low-priority determinations are subject to legal challenge within 60 days of the designation. Lautenberg also makes orders under Sections 4, 5(e), and 5(f) subject to legal challenge. In addition, Lautenberg deletes all of TSCA Section 19(a)(3) that had applied a prescriptive definition of the administrative record upon which judicial review will be based, while retaining the same unusual "substantial evidence" standard of review rather than the more common arbitrary and capricious standard for such rules that had been proposed in prior versions of TSCA reform legislation, like S. 697. Under Lautenberg, the substantial evidence standard also applies to orders under Sections 4, 5(e), 5(f), and 6(i)(1). The substantial evidence standard is widely believed to be more demanding than the conventional "arbitrary, capricious, or abuse of discretion" standard of review.

Section 20. Citizens' Civil Actions

The only additional change to this section from S. 697 is to strike the provision allowing a person to petition to initiate a proceeding related to an order under Section 5 to now include Section 4 or 5.

Section 26. Administration of the Act.

Lautenberg significantly revises and expands Section 26 relative to TSCA, including expanding the fee authority, establishing a fund to hold the fees which are then to be used (subject to appropriations) to defray the costs of certain activities, requiring the use by EPA of the best available science in taking scientific decisions, requiring EPA to develop and periodically review any PP&Gs necessary to carry out the amendments to the Act, and establishing a SACC.

TSCA Section 26(b)(1) is revised to allow for payment of fees for review of Section 4 information and Section 5 notices by manufacturers or processors of chemicals subject to risk evaluations under Section 6(b). The fees are to be "sufficient and not more than reasonably necessary to defray" the costs related to administering these sections as well as Section 14 concerning CBI.

Section 26(b)(3) establishes the TSCA Service Fee Fund to hold the fees which will be available for obligation subject to appropriation.

Section 26(b)(4). Amount and Adjustment of Fees. This provision states that in setting fees, EPA shall:

- Prescribe lower fees for small businesses;
- Set the fees at a level that will in aggregate provide a sustainable source of funds to annually defray the lower of:
  - 25 percent of the costs of carry out Sections 4, 5, 6, and 14, other than the costs to conduct risk evaluations under Section 6(b); or
  - $25,000,000.
- Reflect an appropriate balance in the assessment of fees between manufacturers and processors;
- In the case of risk evaluations requested by manufacturers under Section 6(b)(4)(C)(ii), establish the fee at a level sufficient to defray the full costs (or 50 percent of the cost in the case of chemicals in the 2014 update of the TSCA Work Plan) of conducting the risk evaluation;
- Consult with parties potentially subject to fees prior to their establishment and periodically thereafter to increase or decrease fees as necessary to adjust for inflation and to ensure that the fees suffice to defray 25 percent of the costs as noted above; and

- Refund fees (or a potion thereof) if a Section 5 notice is not reviewed or is withdrawn, if no substantial work was performed on the notice.

Section 26(b)(6) states that the fee authority shall terminate ten years after enactment unless reauthorized or modified by Congress.

Lautenberg Section 26(h) requires that EPA, in carrying out Sections 4, 5, and 6, shall use the best available science in taking scientific decisions, while Section 26(i) requires that EPA make such decisions under these sections based on the weight of the scientific evidence.

Section 26(l). Policies, Procedures, and Guidance. This section requires that within two years EPA shall develop any PP&Gs needed to carry out the amendments to TSCA and, every five years thereafter, review the adequacy of and revise such PP&Gs to reflect new scientific developments or understandings. Subsection (4) states that, concerning chemicals listed in the 2014 update to the TSCA Work Plan for which a completed risk has been published prior to enactment of Lautenberg, EPA may propose and promulgate rules under Section 6(a) that are consistent with the scope of the completed risk assessment. Subsection (5) requires that within one year, EPA shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which "shall be considered" by EPA.

Section 26(m) specifies that six months after enactment, EPA shall submit to Congress a report that estimates the capacity of EPA to conduct and publish risk evaluations and the resources needed to conduct the minimum number of risk evaluation required under Section 6(b)(2). EPA is also required to report on its capacity to conduct and publish industry requested risk evaluations under Section 6(b)(4)(C)(ii), and its capacity to promulgate rules under Section 6(a). The report is to be updated every five years.

Section 26(n) requires that EPA release an annual plan for risk evaluations that identifies the chemical assessments expected to be initiated or completed that year and the resources needed, describes the status of each ongoing risk evaluation, and updates the schedule for their completion.

Section 26(o) requires that EPA establish SACC within one year. The purpose of SACC is to provide independent advice and expert consultation with respect to scientific and technical aspects of issues under the Act.

Other Provisions

Lautenberg amends Part P of title III of the Public Health Service Act by adding a provision concerning designation and investigation of potential cancer clusters. The purposes of the provision are to provide federal agencies with authority to help conduct investigations into and to help address potential cancer clusters and factors that may contribute to the creation of such potential clusters.

Lautenberg includes the Rural Healthcare Connectivity Act of 2016 that amends the Communications Act related to Universal Service by adding the term "skilled nursing facilities" to the definition of Health Provider in Section 254 of the Act.

It is of note that Lautenberg does not include a green chemistry provision. S. 697, at Section 27(c), had proposed to establish a Sustainable Chemistry Program, while H.R. 2576 (the TSCA Modernization Act of 2015 passed by the House on June 23, 2015) was silent.

Timing and Dates

Lautenberg includes a number of specific deadlines for various decisions, rules, and reports. We have attempted to pull together a listing of the key dates and timing aspects that the bill imposes.

Dates Tied to Enactment

Ten years prior to enactment: Period covered by the Inventory reset reporting rule at Section 8(b)(4).

Six months after enactment: EPA is to complete its initial report to Congress under Section 26(m) on EPA's capacity to handle risk evaluations and to promulgate Section 6(a) rules, and to update the report every five years.

One year after enactment:

- Finalize procedural rule establishing the prioritization and risk evaluation processes (Section 6(b));
- Issue Inventory reset reporting rule (Section 8(b)(4)) followed by six-month reporting period for active chemicals that were manufactured or processed;
- Issue guidance document for interested persons to use in preparing draft risk evaluations that "shall be considered" by EPA (Section 26(l)(5)); and
- Establish SACC (Section 26(o)).

180 days after enactment: Risk evaluations are to be underway for ten chemicals from the 2014 update to the TSCA Work Plan (Section 6(b)(2)).

Two years after enactment:

- Develop strategic plan to promote the development and implementation of alternative test methods and strategies and update the plan every five years (Section 4(h)(2)); and

- Develop PP&Gs needed to carry out amendments to TSCA and review/update every five years thereafter to reflect new scientific developments or understandings (Section 26(*l*)).

In the fiscal year three years after enactment and every three years thereafter: consult with parties and increase or decrease fees as necessary to adjust for inflation and to ensure that the fees collected are sufficient to meet certain requirements (Section 26(b)(4)).

Three and a half years after enactment: Risk evaluations underway for at least 20 high-priority designations and that at least 20 chemicals have been designated as low-priority (Section 6(b)(2)).

Every five years after enactment: Report to Congress on progress made on the strategic plan for alternative test methods (Section 4(h)(2)).

At the conclusion of the fiscal year that is ten years after enactment: fee authority terminates if not reauthorized by Congress (Section 26(b)(6)).

Other Timing Requirements and Dates

Section 4 receipt and review of prioritization testing conducted under Section 4(a)(2)(B): Per Subsection (i), EPA is required to meet a 90-day deadline after receipt of the new information for designating subject chemicals as high- or low-priorities under Section 6(b).

Section 5 reviews: EPA reviews and determinations on new chemicals and SNUs must be completed during the applicable review period (generally 90 days, extendable to 180 days), or fees must be returned to the notifier (Section 5(a)(4)).

Section 6 prioritizations, risk evaluations, and control measures:

- Prioritizations:
  - The duration of the prioritization process for a chemical is set at 9-12 months. If at the end of this period EPA is unable to support a low-priority determination for a chemical, it shall be designated a high-priority (Section 6(b)(1)(C)); and
  - Low-priority determinations can be challenged within 60 days of publication (Section 19(a)(1)).
- Risk evaluations (Section 6(b)(3) and (4)):

- Shall be initiated upon the designation of a high-priority chemical;

- The scope of a risk evaluation is to be published six months after initiation; and

- Risk evaluations are to be completed as soon as practicable but not later than three years after initiation, extendable for six months. Includes determination whether risk evaluation standard has been met.

- At the start of every calendar year, EPA is required to publish an annual plan and report concerning risk evaluations (Section 26 (n)).

■ Risk management rules for chemicals determined to meet the risk evaluation standard (Sections 6(a),(c), and (g)):

- Rule shall be proposed one year after publication of the final risk evaluation and be finalized in one additional year, extendable for two years in the aggregate; and

- Mandatory compliance date shall be as soon as practicable but not later than five years after date of promulgation, except in case of an exemption under Section 6(g).

  - Full implementation date for ban or phase-out requirements shall be as soon as practicable.

  - The duration of exemptions granted under Section 6(g) shall be determined by EPA as reasonable on a case-by-case basis.

Confidentiality claims under Section 14:

■ One year after compiling the list of active chemicals, EPA is required to promulgate a rule that establishes a five-year plan (extendable for two years) to complete its review of CBI chemical identity claims made on active chemicals (Section 8(b)(4)(E)).

■ General requirement for EPA to review and make determinations on initial CBI claims within 90 days (Section 14(g)).

- CBI claims approved by EPA have a duration of ten years and can be extended if requirements are met (Section 14(e)).

Preemption (Section 18):

- Lautenberg preserves any state action taken before April 22, 2016, that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance (Section 18(e)(1)(A)).
- Lautenberg preserves any action taken pursuant to a state law that was in effect on August 31, 2003 (Section 18(e)(1)(B)).

Fees under Section 26:

- Prior to establishing fees, consult and meet with potentially subject parties (Section 26(b)(4)).

Bergeson & Campbell, P.C. (B&C®) is a Washington, D.C. law firm offering clients an unparalleled level of experience and excellence in matters relating to TSCA. Our TSCA practice group includes five former senior EPA scientific and executive staff, seven Ph.D.s, and a robust and highly experienced team of lawyers and non-lawyer professionals extremely well versed in all aspects of TSCA law, regulation, and litigation. More information on TSCA Reform is available on our TSCA Reform News and Information page. Visit our website for Regulatory Memoranda regarding TSCA, Articles on TSCA and TSCA Reform, and TSCA FAQs.