TSCA Reform: A Section-by-Section Analysis of Key Provisions

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.

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 the U.S. Environmental Protection Agency (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 EPA with more testing authority, including using orders and consent agreements in addition to test rules, 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; 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 significant new uses (SNU), 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.

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.

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).

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 confidential business information (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 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 that 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.

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).