President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg) (P.L. 114-182) on June 22, 2016. It makes important changes to the Toxic Substances Control Act (TSCA) that result in fundamental shifts in the requirements and approach under the law, while introducing important new concepts and approaches. This summary presents an initial overview of the changes in Lautenberg relative to TSCA as they relate to these and other provisions.

Section Summary

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 U.S. Environmental Protection Agency (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. 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 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 requiring that EPA review all new chemicals and significant new uses (SNU) 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, EPA 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.

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.

Risk Evaluations. In addition to requiring that EPA initiate risk evaluations on all high-priority chemicals, the new law 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.

Risk Management. Lautenberg deletes certain procedural requirements from TSCA section 6(c) that 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.
Final Agency Actions. 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. The substantial changes to section 8 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 by-products 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. EPA, for example, is required 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.

Section 12. Exports. Effective as of January 1, 2020, the new law prohibits the export of certain mercury compounds other than to member countries of the Organization for 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 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 the new law 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.

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 the new law 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.

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 necessary to carry out the amendments to the act; and requiring EPA to establish a Science Advisory Committee on Chemicals.

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