SQUIRE PATTON BOGGS

US Congress Passes Landmark TSCA Reform Legislation

On June 7, 2016 the US Senate gave final approval by a voice vote to HR 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the landmark bipartisan, compromise legislation to overhaul the Toxic Substances Control Act (TSCA). The Senate's action followed a 403-12 vote by the US House of Representatives on May 24 approving the Lautenberg Act. The Lautenberg Act is expected to be signed into law by President Obama very soon.

The congressional action came roughly a year after the US House originally passed HR 2576 in June 2015 and six months after the US Senate approved S.697, that body's own TSCA reform bill, in December 2015 as a substitute amendment for HR 2576. Negotiators from the two chambers worked throughout the first several months of 2016 to reconcile the numerous differences between the two bills. The compromise legislation contains key elements of both the House and Senate versions and also reflects other substantive revisions made to accommodate issues raised by legislators raised during the negotiations.

As passed by Congress, the Lautenberg Act makes many significant changes to the current TSCA law, including:

- Requiring the US Environmental Protection Agency (EPA) to evaluate chemicals (both new and existing chemicals) to determine whether they present an "unreasonable risk of injury to health or the environment under the conditions of use."
- Prohibiting consideration of costs or other non-risks factors in chemical evaluations.
- Requiring EPA to consider potentially exposed or susceptible subpopulations in evaluating chemicals.
- Allowing chemical manufacturers to ask EPA to evaluate a chemical.
- Giving EPA the authority to issue administrative orders to require testing of chemicals.
- Requiring EPA to reduce the use of vertebrate animals in testing.
- Eliminating the "least burdensome" requirement for chemical regulations, making it easier for EPA to restrict – or ban – chemicals.
- Preempting state chemical regulations under certain conditions.
- Putting limits on confidential business information (CBI) claims and allowing EPA to share CBI with states.
- Allowing EPA to charge higher fees for chemical reviews.

Review of New Chemicals

Under the Lautenberg Act, EPA would have to make an affirmative determination that a new chemical for which it has received a Pre-Manufacture Notice (PMN) or significant new use of a chemical, for which it has received a Significant New Use Notice (SNUN) is "not likely to present an unreasonable risk of injury to health or the environment ... under the conditions of use" before it can be manufactured, imported or processed in the US. The term "conditions of use" is defined as "the circumstances, as defined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."

In making this determination, EPA must consider the risk to a "potentially exposed or susceptible subpopulation" and is prohibited from considering costs or "other non-risk factors."

If EPA determines that a new chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, the Act states that EPA "shall take the actions required" under TSCA Section 5(f). That section authorizes EPA to (i) issue an immediately effective proposed rule under TSCA Section 6(a) limiting the amount of the chemical that may be manufactured, processed or distributed or imposing other restrictions on the substance, or (ii) issue an order prohibiting the manufacture, processing or distribution of the substance.

If EPA has insufficient information to make a determination about a chemical, it can suspend the review pending receipt of the information, or impose restrictions sufficient for it to make the determination even in the absence of the information. EPA can enter into a consent decree or order to prohibit or restrict the manufacture, processing, use, distribution or disposal of a chemical under TSCA Section 5(e). EPA also can require testing of new chemicals, including by issuing administrative orders.

If EPA determines that a new chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, EPA must publish a statement to that effect in the Federal Register.

The Lautenberg Act provides that EPA may require a company to submit a PMN or SNUN for the importation or processing of a chemical substance as part of an article or category of articles if EPA makes an express finding in a rule that "reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification."

Designation of Existing Chemicals as Active or Inactive

The Lautenberg Act requires that, within one year after enactment, EPA must issue a rule under TSCA Section 8 requiring all manufacturers (and may also require processors) to tell the agency which chemicals on the TSCA Inventory they have manufactured or processed within the 10-year period preceding the date of enactment. Manufacturers and processors will have to provide this information no later than 180 days after the final rule is published. Based on the information provided by these notifications, EPA will develop a list of "active" chemicals and a list of "inactive" chemicals. Chemicals on the "active" list will be prioritized for purposes of risk evaluations. If a chemical is designated as "inactive," a company must notify EPA before it can manufacture or process the chemical (but the chemical will not be subject to a PMN under TSCA Section 5). Once a chemical is moved from the "inactive" list to the "active" list, it is subject to prioritization.

The Lautenberg Act provides that, prior to promulgation of the rule, EPA will designate an "interim" list of active substances that will consist of the chemical substances reported to EPA under the 2016 Chemical Data Reporting (CDR) rule.

EPA must maintain the confidential and non-confidential portions of the TSCA Inventory, but any company that wishes to maintain an existing confidential business information (CBI) claim must submit a notice to EPA requesting continuation of the claim. EPA must move any active chemical from the confidential portion to the non-confidential portion of the active chemicals list if no such notice is submitted. Any confidentiality claim also must be substantiated in accordance with a CBI review plan that EPA must develop, by rule, within one year after enactment of the Lautenberg Act, under which EPA will review all CBI claims to protect the identities of chemicals on the confidential portion of the Inventory.

When notifying EPA that a chemical is "active," a manufacturer or processor cannot assert a CBI claim for any chemical that is not already on the confidential portion of the TSCA Inventory.

Prioritization of Active Chemicals

The Lautenberg Act requires EPA, within one year after enactment, to establish by rule a "risk-based screening process" for designating existing "active" chemicals as "high priority" for risk evaluations or "low priority," for which risk evaluations "are not warranted at the time." In designating a chemical as high or low priority, EPA must consider a range of factors, including the chemical's hazard and exposure potential (which includes consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and "storage near significant sources of drinking water"), the conditions of use, and the volume or significant changes in the volume of the chemical manufactured or processed.

The Lautenberg Act requires that EPA "shall" designate a chemical as high priority if EPA has determined that it may present an unreasonable risk of injury to health or the environment "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 "shall" designate a chemical as low priority if EPA concludes that it does not meet the criteria for designation as a high priority.

The rule promulgated by EPA establishing the prioritization process also must ensure that the time required for EPA to make a priority designation "be no shorter than nine months and no longer than 1 year." This requirement effectively gives states (and political subdivisions of states) a "heads up," for purposes of preemption, that EPA will be prioritizing the chemical and potentially conducting a risk evaluation and taking regulatory action on it. The rule also must require that, before EPA proposes a priority designation for a chemical, the agency must ask "interested persons" to submit "relevant information" on the chemical and provide 90 days for such information to be provided. EPA can extend this 90-day period for up to three months in order to receive or evaluate information (including by issuing an administrative order for testing), but EPA must designate a chemical as high priority if, at the end of the extension, the information is still insufficient to designate the chemical as low priority.

The Lautenberg Act requires that, within 180 days after enactment, EPA must ensure that risk evaluations are being conducted on 10 chemicals drawn from EPA's TSCA Work Plan and must publish a list of these chemicals during the 180-day period. Within three and one half years, EPA must ensure that risk evaluations are being conducted on at least 20 high-priority chemicals and that 20 chemicals have been designated as low priority. EPA also must ensure that at least 50% of all chemical substances on which risk evaluations are being conducted are drawn from the TSCA Work Plan. Additionally, when designating high-priority substances, EPA must give preference to chemicals on EPA's TSCA Work Plan that have a persistent, bioaccumulative and toxic (PBT) score of 3, as well as chemicals on the TSCA Work Plan that are known human carcinogens and have high acute and chronic toxicity.

Risk Evaluations for Existing Chemicals

Under the Lautenberg Act, EPA must conduct a risk evaluation for each existing chemical on the high-priority list. Not later than one year after enactment, EPA must establish by rule a process to conduct the risk evaluations.

Through the risk evaluation, EPA must determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by EPA. EPA is prohibited from considering costs or other non-risk factors in making this determination.

The Lautenberg Act requires EPA to initiate a risk evaluation "upon designating a chemical substance as a high priority." EPA must publish the scope of the risk evaluation for a chemical not later than six months after the risk evaluation has been initiated. For a chemical that has been designated as high priority, the Lautenberg Act requires that there must be at least 12 months between initiation of the prioritization process and publication of the scope of the risk evaluation. Because EPA's publication of the scoping document will have a preemptive effect (as discussed below), this required gap gives states (and political subdivisions of states) some "lead time" to take action on a chemical. For EPA TSCA Work Plan chemicals undergoing risk evaluations, at least three months must pass before EPA publishes the scope of the risk evaluation. The scope must include the hazards, exposures, conditions of use, and potentially exposed or susceptible populations that EPA expects to consider.

EPA must complete the risk evaluation within three years after the date on which it is initiated. EPA may extend the deadline for a risk evaluation for not more than six months. When performing the risk evaluation, EPA may require additional information to be submitted and require testing to be conducted.

EPA must consider a variety of factors in conducting a risk evaluation, including information on hazards and exposures for the conditions of use of the chemical, potentially exposed or susceptible subpopulations, and the likely duration, intensity, frequency and number of exposures, among others. EPA may not consider costs or other non-risk factors in conducting a risk evaluation.

Also, the Lautenberg Act provides that EPA "shall" consider any draft risk evaluation submitted to it by an "interested" person. The Act requires EPA to develop a guidance document within one year after enactment to assist "interested persons" in developing and submitting draft risk evaluations to the agency.

EPA must provide at least 30 days public notice and comment on a draft risk evaluation before it can publish the final risk evaluation.

The Lautenberg Act requires EPA to designate at least one high-priority substance upon completion of each risk evaluation (except for risk evaluations completed at the request of a manufacturer). EPA also may revise the designation of a low-priority substance based on information it obtains.

A determination by EPA that a chemical does not present an unreasonable risk of injury to health or the environment must be issued by an order and will be considered a final agency action. The determination is subject to judicial review, effective beginning on the date the order is issued.

If EPA determines that an existing chemical presents an unreasonable risk of injury to health or the environment, it must issue a rule under TSCA Section 6 to restrict, ban or phase out the chemical.

Company Requests for Risk Evaluations on Existing Chemicals

The Lautenberg Act provides that a chemical manufacturer can ask EPA to conduct a risk evaluation on a chemical, subject to certain limits on the number of company-requested risk evaluations compared to ones initiated by EPA. In general the number of chemicals undergoing company-requested risk evaluations cannot be less than 25% or more than 50% of the total chemicals undergoing risk evaluations, except that the 50% limit does not apply to company-requested risk evaluations on TSCA Work Plan chemicals. The company must pay the cost of the risk evaluation, and EPA cannot "expedite or otherwise provide special treatment to" company-requested risk evaluations.

In deciding whether to grant a manufacturer's request for a risk evaluation EPA must give preference to requests involving chemical substances "for which EPA determines that restrictions imposed by one or more states have the potential to have a significant impact on interstate commerce or health or the environment." Initiation of a company-requested risk evaluation by EPA would not trigger preemption of state regulation of the chemical.

Authority to Require Testing on Chemicals

The Lautenberg Act gives EPA general authority to require testing on a chemical for certain purposes by issuing an administrative order (instead of having to promulgate a formal rule or enter into a consent agreement) and without having to make the difficult findings required under current TSCA Section 4.

EPA may issue an administrative order requiring the development of "new information" on a chemical substance or mixture by testing if the agency determines that the information is necessary (i) to review a PMN or SNUN or perform a risk evaluation; (ii) implement a requirement imposed in a rule, order or consent agreement under TSCA Sections 5(e) or (f), or a Section 6 rule; (iii) to meet the regulatory testing needs of another federal agency with regard to toxicity and exposure; or (iv) to determine whether a chemical presents an unreasonable risk for purposes of TSCA's Section 12 "export only" exemption. EPA also may issue an administrative order for testing if it is necessary to establish the priority (high or low) of a chemical.

The Lautenberg Act requires EPA to employ "a tiered testing screening and testing process" when deciding what testing will be required for a chemical.

Additionally, the Act requires EPA to "reduce and replace" the use of vertebrate animals in chemical testing. Prior to making a request or adopting a requirement for testing using vertebrate animals, EPA must take into consideration "reasonably available existing information," including toxicity information, computational toxicology and bioinformatics and high-throughput screening methods and models. EPA also must encourage and facilitate the use of "scientifically valid test methods and strategies" that reduce or replace the use of vertebrate animals "while providing information of equivalent or better scientific quality." The Act requires EPA within two years after enactment to develop a strategic plan to "promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing."

When issuing an administrative order for testing, EPA also must issue a "statement" identifying the need for the information to be provided by the testing, describing how EPA decided that the information is needed, explaining the basis for any decision that requires the use of vertebrate animals and why an order is warranted instead of promulgating a rule or entering into a consent agreement.

Regulatory Action on Chemicals

As noted, if EPA determines that an existing chemical presents an unreasonable risk of injury to health or the environment, it must issue a rule under TSCA Section 6 to restrict, ban or phase out the chemical. EPA must propose a Section 6 rule within one year after the final risk evaluation is published and issue a final rule within two years after the final risk evaluation is published. EPA may extend this deadline for up to two years, but the total length of any such extension combined with any extension for conducting the risk evaluation cannot exceed two years.

Significantly, the Lautenberg Act eliminates the current TSCA requirement that EPA must select the "least burdensome" regulatory option when regulating an existing chemical.

When proposing and promulgating a Section 6 rule, EPA must "consider and publish a statement based on reasonably available information" regarding various factors, including: (i) the effects of the chemical substance or mixture on health and the environment, and the magnitude of the exposure to human beings and the environment; (ii) the benefits of the chemical substance or mixture "for various uses;" (iii) the likely effect of the rule on the national economy, small business, technological innovation, the environment and public health; (iv) the costs and benefits of the proposed and final regulatory action and of the one or more "primary alternative regulatory actions" considered by EPA; and (v) the cost effectiveness of the proposed regulatory action and of the one or more "primary alternative regulatory actions" considered by EPA.

The Lautenberg Act requires that any Section 6 rule specify mandatory compliance dates "which shall be as soon as possible," but not later than five years after the date the final rule is promulgated. Any ban or phase-out of a chemical substance must be initiated as soon as practicable, but not later than five years after the final rule is promulgated, with mandatory compliance dates for full implementation of the ban or phase-out spelled out too.

EPA may grant an exemption from any requirement in a Section 6 rule if EPA finds that: (i) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure; (ii) compliance with the requirement would significantly disrupt the national economy, national security or critical infrastructure; or (iii) the specific condition of use, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment or public safety. Any such exemption must have a time limit, however.

The Lautenberg Act contains certain special requirements relating to restrictions on replacement parts and articles. Replacement parts for "complex durable goods" that are designed prior to the publication date of a Section 6 rule on a chemical are exempt from regulation unless EPA finds that the replacement parts "contribute significantly" to the risk identified in a risk evaluation. Articles (or a category of articles) may be restricted "only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles" to ensure that the chemical substance does not present an unreasonable risk.

The Lautenberg Act also requires that, within three years after enactment, EPA must propose Section 6 rules for any TSCA Work Plan chemical substances (i) that EPA "has a reasonable basis to conclude" are toxic and score high for persistence and bioaccumulation, and score either high or moderate for the other, subject to certain exceptions; and (ii) to which the general population or a potentially exposed or susceptible subpopulation is likely to be exposed. A final rule must be issued within 18 months after the proposed rule is published. EPA is not required to conduct a risk evaluation for any such persistent, bioaccumulation and toxic (PBT) chemical.

As noted, a determination by EPA that a chemical does not present an unreasonable risk of injury must be issued by an order and will be considered a final agency action, subject to judicial review, beginning on the date the order is issued. Likewise, any final Section 6 rule issued for a chemical, along with the determination that the chemical presents an unreasonable risk of injury, will be considered a final agency action subject to judicial review, effective on the date the final rule is promulgated.

Preemption of State Chemical Regulations

Under the Lautenberg Act, a state and any political subdivision of a state (hereinafter collectively "a state") would be preempted from imposing any new regulatory restrictions on a chemical that EPA has found not to present an unreasonable risk of injury or for which EPA has promulgated a rule under TSCA Section 6. A state also would be preempted from requiring notice of any use of a chemical for which EPA has issued an SNUN. Preemption also would apply to any high-priority chemical from the time that EPA defines and publishes the scope of the risk evaluation for the chemical until EPA publishes the risk evaluation (or the deadline for completing the risk evaluation has expired).

However, the preemption would apply only to the specific conditions of use – or the uses – and risks, etc., addressed by EPA. Preemption would apply only to the specific hazards, exposures, risks and uses or conditions of use of the chemical included in the scope of the risk evaluation. For any chemical determined by EPA not to present an unreasonable risk or for which EPA has issued a Section 6 rule, preemption would apply only to the specific hazards, exposures, risks and uses or conditions of use of the chemical covered by EPA's determination or the Section 6 rule.

The Lautenberg Act does not preempt state requirements for reporting, monitoring or disclosure relating to a chemical or any restrictions imposed under a state air quality, water quality, or waste treatment or disposal law. The Act also would not preempt (i) the authority of a state to continue to enforce any action taken or requirement imposed or enacted relating to a specific chemical prior to April 22, 2016 under a state law that prohibits or otherwise restricts manufacturing, processing, distribution, use or disposal of a chemical or (ii) any action taken under a state law that was in effect on August 31, 2003.

The Lautenberg Act provides that states can seek a waiver from preemption under certain conditions.

EPA has discretionary authority to grant a waiver if the agency determines that (i) "compelling conditions" warrant granting the waiver to protect health or the environment; (ii) compliance with the proposed state requirement would not unduly burden interstate commerce; (iii) compliance with the proposed state requirement would not cause a violation of any applicable federal law, rule or order; and (iv) the proposed state requirement is designed to address a risk of a chemical under the conditions of use that was identified consistent with best available science, using supporting studies conducted in accordance with sound and objective scientific practices and based on the weight of the scientific evidence. If EPA grants such a discretionary waiver, it must do so by issuing a formal rule.

The Lautenberg Act requires that EPA must grant a waiver if EPA determines that (i) compliance with a proposed state requirement would not unduly burden interstate commerce in the manufacturing, processing, distribution or use of a chemical; (ii) compliance with the proposed state requirement would not cause a violation of any applicable federal law, rule or order; and (iii) the state has a concern about the chemical substance or use "based in peer-reviewed science." EPA also must grant a waiver for any statute that a state has enacted – or administrative action that a state has proposed or finalized – no later than (i) 18 months after the date on which EPA has initiated the prioritization process for a chemical or (ii) the date on which EPA publishes the scope of the risk evaluation for a chemical, whichever date is sooner. A "required" waiver will remain in effect until EPA publishes the risk evaluation.

EPA must make a decision on an application for a discretionary waiver within 180 days, and within 110 days for a required waiver. If EPA fails to make a decision on a required waiver within the 110-day period, the waiver will be automatically granted on the date that is 10 days after the deadline.

A state's application for a waiver is subject to public notice and comment. EPA's decision on a waiver would be a final agency action subject to judicial review.

The Lautenberg Act also allows states to "co-enforce" regulations on chemicals, including seeking penalties, but the combined total penalty obtained by EPA and a state cannot exceed the TSCA statutory amount.

Confidential Business Information Claims

The Lautenberg Act identifies categories of information that generally may not be protected from disclosure (such as health and safety studies, general aggregate production volume information, and general descriptions of manufacturing and processing processes), while stating that information such as formulas (including molecular structures) that disclose processes used in the manufacturing or processing of a chemical substance or mixture generally are protected from disclosure.

The Lautenberg Act requires that new confidential business information (CBI) claims must be substantiated and reviewed and approved by EPA, although claims regarding certain detailed types of information need not be substantiated – e.g., claims relating to the specific processes used in manufacturing or processing a substance or mixture, specific marketing and sales data, supplier and customer lists, specific production or import volumes and the percentage composition of a mixture. The Act also imposes certain requirements for CBI claims for chemical identity (for substances not already on the confidential portion of the TSCA Inventory). The Act further provides that all CBI claims will expire after 10 years unless they are renewed and re-substantiated.

The Lautenberg Act also requires that, within one year after the date on which the initial list of active chemicals is compiled, EPA must promulgate a rule that establishes a plan to review all active chemicals on the confidential portion of the TSCA Inventory within five years after compiling the initial active chemicals list.

Manufacturers and processors will be required to re-substantiate their CBI claims for the chemical identities of these chemicals. If EPA determines that the CBI claims are valid and the identities of these chemicals should remain confidential, the CBI claims would be subject to the 10-year time limit and would expire at the end of that period unless renewed and re-substantiated. A request for renewal, including re-substantiation, must be submitted to EPA at least 30 days before the 10-year period expires.

If a company notifies EPA that it intends to manufacture or process a confidential chemical on the inactive list and move it to the active list, it must assert the CBI claim in the notice and then substantiate the claim within 30 days of the notice. EPA then will decide whether to approve or deny the claim.

Under the Lautenberg Act, EPA may review and require re-substantiation of any CBI claim for any chemical that has been designated as high priority or as an active chemical substance at any time. CBI claims made before enactment that are reviewed by EPA would be subject to the 10-year time limit, unless renewed and re-substantiated by the end of that period.

Finally, the Lautenberg Act permits EPA to share CBI with state and local governments, health professionals, emergency responders and other specified individuals under certain conditions. The Act also provides that otherwise-confidential information can be disclosed "as required pursuant to discovery, subpoena, other court order, or any other judicial process otherwise allowed" under federal or state law.

Fees

The Lautenberg Act removes the specific fee set in the current TSCA law (which has stayed the same since 1976) and gives EPA the authority to establish fees that are "sufficient and not more than reasonably necessary," subject to an initial total limit of US$25 million or 25% of the costs for the activities covered by the fees, whichever is lower. EPA would be permitted to adjust fees in the future, however, to account for inflation and ensure that they are sufficient to defray 25% of the relevant costs, even if they exceed US$25 million.

Rulemaking

As noted, the Lautenberg Act requires EPA to develop formal rules to implement a number of processes and requirements established by the Act, such as rulemakings:

- To establish a process for conducting risk evaluations (including criteria for manufacturers to propose chemicals for risk evaluation)
- To establish a risk-based prioritization screening process
- To require reporting for "active" substances by manufacturers and processors
- To establish a plan for reviewing CBI claims for active substances (including on the confidential Inventory)
- For payment of fees by industry
- For reporting by manufacturers and users of mercury and mercury-added products

The Lautenberg Act sets various deadlines for the rulemakings, often within one year of enactment. These rulemakings are in addition to any rules that EPA is required to issue when taking regulatory actions under TSCA Section 6 and Section 5, and otherwise under the law.

Policies, Procedures and Guidance Documents

The Lautenberg Act requires EPA to develop a variety of policies, procedures and guidance documents necessary to carry out the Act, including:

- Policies, procedures and guidance for testing of chemical substances and mixtures (including how the level or exposure potential of a chemical will factor into decisions to require new testing)
- Guidance regarding "the manner in which EPA will determine that additional information is necessary to carry out" TSCA (including information relating to potentially exposed or susceptible populations)
- Guidance to assist interested persons in developing and submitting their own draft risk evaluations to the EPA
- Guidance on development of generic names for CBI substances
- Guidance on the content and form of the statement of need and agreements for sharing CBI with states and other parties
- Guidance regarding animal, non-animal and epidemiological test methods and procedures for assessing and determining risk
- Plan to reduce testing on vertebrate animals
- Guidance that establishes procedures and standards for the management and short-term storage of elemental mercury by generators

The Lautenberg Act requires that EPA must develop all such policies, procedures and guidance within two years of enactment.

Penalties

The Lautenberg Act formally increases the maximum TSCA penalty to US$37,500 per violation per day. EPA has been authorized to seek (and has been imposing) this penalty amount for several years through congressional adjustments, but the Act now officially codifies it in the TSCA statue itself (in place of the US$25,000 figure now on the books). The Act also imposes a penalty of up to US$250,000 – and possible imprisonment up to 15 years – on any person who "knowingly violates" TSCA and "who knows at the time of the violation that the violation places an individual in imminent danger of death or serious bodily injury." An organization that commits such a knowing violation will be subject to a fine of up to US$1 million for each violation.

Other Provisions

The Lautenberg Act adds language to TSCA Section 9 requiring EPA to compare the "estimated costs and efficiencies" of addressing a chemical risk under TSCA versus another federal law. The Act also imposes various requirements that EPA must meet with regard to the use of science and scientific data and information in carrying out TSCA Sections 4, 5 and 6.

Additionally, the Lautenberg Act amends TSCA Sections 8 and 12 to add language requiring EPA to develop an inventory of mercury "supply, use and trade" in the US, prohibiting the export of certain mercury compounds and establishing new restrictions on the accumulation, storage and disposal of elemental mercury. The Act also amends the Public Health Services Act to direct the Department of Health and Human Services to establish criteria and guidance for the identification and investigation of cancer clusters in the US.

What's Next

Because the Lautenberg Act makes so many significant changes to the current TSCA statute, EPA's actions to interpret and implement the numerous new provisions and requirements in the Act will be critically important – especially during the first one to two years. As noted, EPA must develop and issue a number of policies, procedures, guidance documents and formal rulemakings during this time, as well as begin to develop early lists of existing chemicals for prioritization and risk evaluation, collect data on chemicals and initiate the risk evaluations. Moreover, EPA must begin to give greater scrutiny to PMNs for all new chemicals (and SNUNs for new uses of existing chemicals) and evaluate them for safety under their conditions of use, require more testing of chemicals, and take stronger action on chemicals that EPA determines present an unreasonable risk of injury to health or the environment. The impacts of EPA's actions under the Act on the manufacture, import, processing, distribution and use of chemicals – and products containing chemicals – in the US will be significant and far-reaching. Our lawyers will monitor EPA's actions closely.

Contacts

Stephen A. Owens
Principal
T +1 602 528 4170
T +1 202 626 4170
E steve.owens@squirepb.com

Karen A. Winters
Environmental, Safety & Health Practice Group Leader
T +1 614 365 2750
E karen.winters@squirepb.com

Allen A. Kacenjar
Partner
T +1 216 479 8296
E allen.kacenjar@squirepb.com

W. Caffey Norman
Partner
T +1 202 457 5270
E caffey.norman@squirepb.com