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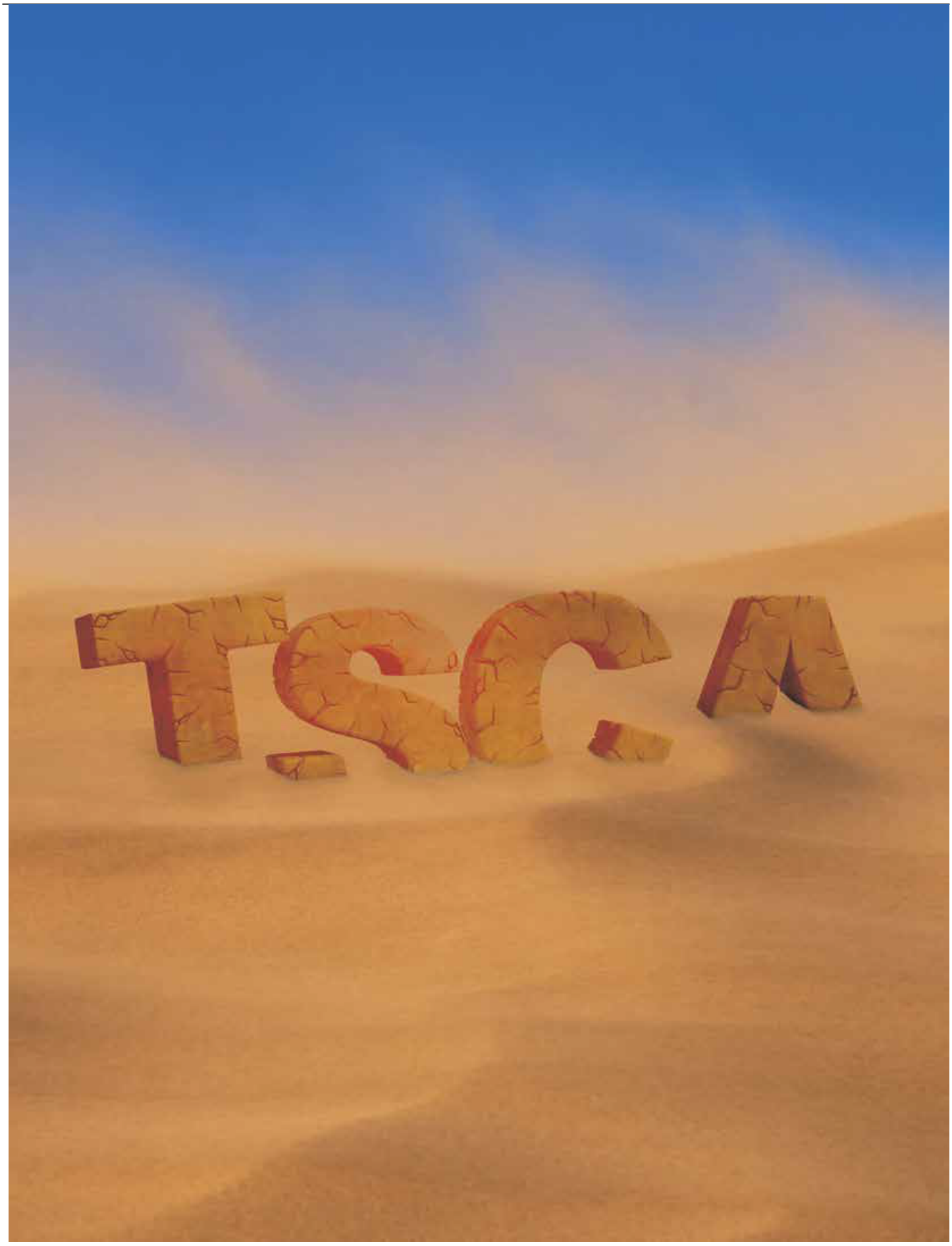
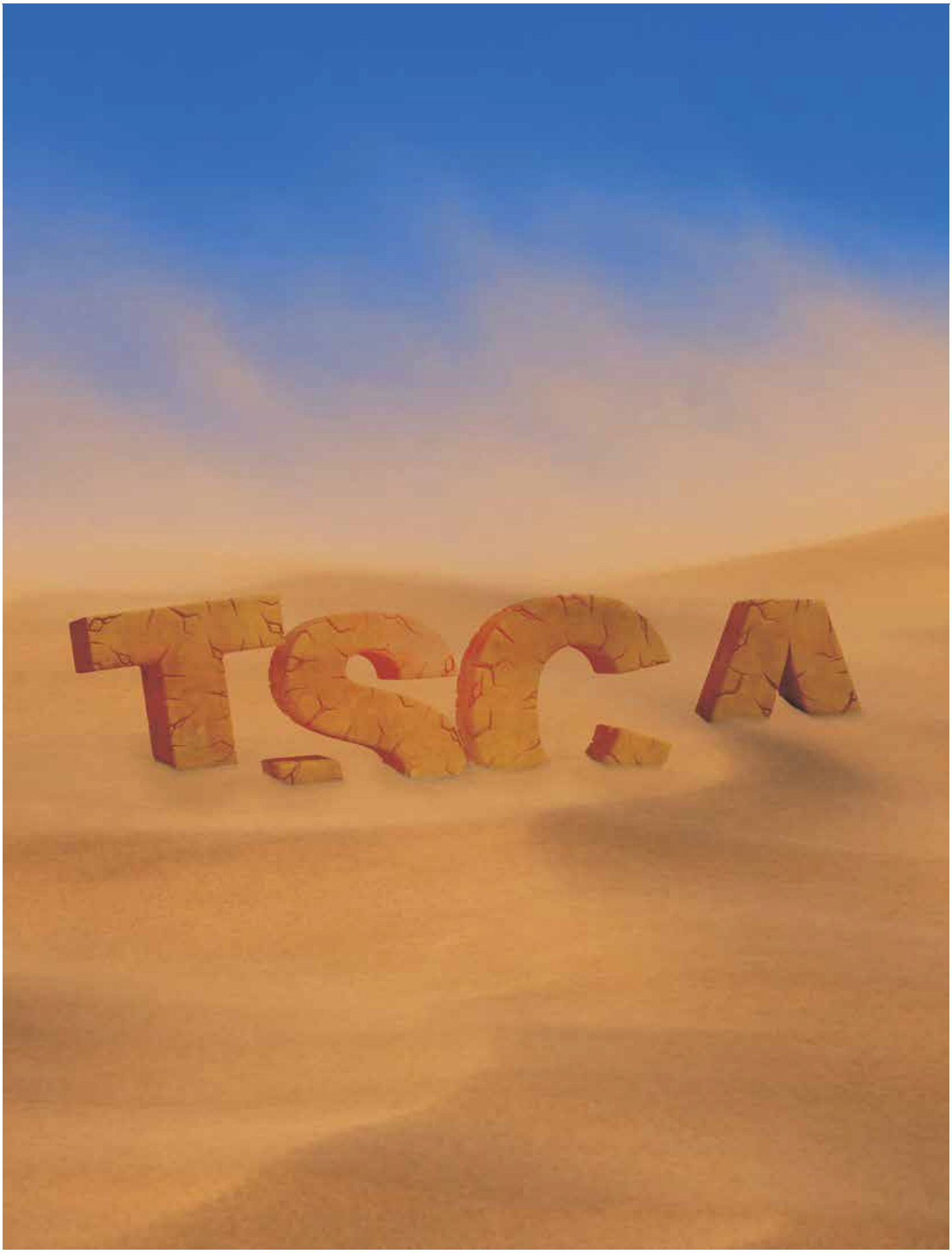
Chemical Regulation Enters the 21st Century: A New Day for the Toxic Substances Control Act

Compliance and Ethics

Environmental


TSCA


TSCA

CHEAT SHEET

- ***Out with the old.*** Inefficient chemical legislation like the Toxic Substances Control Act are slowly being replaced by new federal reforms like the Lautenberg Act.
- ***In with the new.*** The impact of the Lautenberg Act will be extensive, intensifying regulations for chemical mixtures while thwarting the manufacturing of products deemed unsafe for use.
- ***Assessing the risk.*** Within one year of the enactment of the Lautenberg Act, EPA must establish a risk-based screening process to establish whether a chemical is considered “high” or “low” priority.
- ***State of affairs.*** Provisions in the Lautenberg Act will not affect elements of state law concerning the reporting of chemical risks not otherwise required under federal law.

The modern, well known US environmental protection laws that began in the Nixon era, starting with the National Environmental Policy Act, and followed by the Clean Water Act, Endangered Species Act, and Clean Air Act, have all been imbedded into the national psyche. They have been subject to seminal US Supreme Court cases, integral to the development of certain international treaties, and have served as the basis of any environmental or administrative law class. Left behind, however, was a 1976 law that was supposed to sit on the pantheon with those other laws, but somehow never quite made the grade. The Toxic Substances Control Act (TSCA) was enacted as a measure to evaluate and regulate the tens of thousands of chemicals that were being manufactured or imported into the United States.

However, instead of fulfilling that grand expectation, TSCA has been uniformly viewed as a generally ineffective regulation. In fact, for reasons discussed below, the US Environmental Protection Agency (EPA) has tested only a few hundred of those chemicals over the 40 years that TSCA has been in place. In contrast to TSCA’s ineffectiveness, the European Union, with its 2007 Registration, Evaluation, Authorization, and Restoration of Chemicals regulation, aggressively sought to regulate chemical usage, testing, and alternatives. Significantly, the EU program, commonly referred to as REACH, placed the burden on companies to demonstrate the safety of chemicals that are in the stream of commerce.

Around the same time that REACH was being implemented, and in response to the failure of TSCA to live up to its promise, states became more proactive in regulating chemicals within their borders. Most prominent of these is California’s Green Chemistry Initiative, more formally known as the Safer Consumer Products Regulation (SCPR). Filling the gap created by TSCA’s ineffectiveness, the SCPR requires the review of thousands of chemicals, prioritizing those based on human health and environmental risks, and requires an assessment of the possible use of alternatives in munfactured products. Ultimately, the SCPR provides the state’s overseeing agency with the authority to consider an array of possible regulatory responses to this assessment, one of which being an outright ban of the product for sale in California.

Although implementation of the SCPR is still in its infancy (there were no less than 11 proposed regulations before the final rule was adopted), the California law set off alarms in a multitude of affected industries. Among other concerns was the aspect of having to comply with a patchwork of state standards that, in this time of global commerce, would be an untenable prospect.

As a consequence of that concern, the late US Senator Frank Lautenberg, along with US Senator David Vitter, began efforts in 2013 to craft legislation to overhaul TSCA.The end result would be a consistent national standard for chemical regulation that both modernized TSCA and incorporated “green chemistry” concepts. Senator Lautenberg’s death did not deter those efforts, as US Senator Tom Udall picked up where Senator Lautenberg left off. The result, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), had overwhelming bipartisan support and was signed into law by US President Barack Obama on June 22, 2016.

The impact of the new law will be far reaching. With the Lautenberg Act, new chemical mixtures, or new uses of a chemical, will now be closely regulated. Under new sanctions, a chemical can only be manufactured or used if it is deemed safe by the specifications made under the act. This could be particularly significant as nanotechnology begins to spread its wings, and new nanomaterials will be subject to the same level of review as other new chemicals. State laws will be preempted to some extent, but, as discussed below, not at a level that was initially proposed in the legislation. There is no longer a presumption that the identity of a chemical prior to it entering the marketplace could be prevented from being disclosed, as efforts to claim confidential business information will now face a much higher threshold than was previously the case.

These impacts will be felt throughout the manufacturing and supply chain. It will affect the research and development of new products, potentially changing the way many manufacturers do business. The full impact of the Lautenberg Act will not be clear for a number of years, given the slow ramp up of the number of chemicals that the EPA is required to prioritize and conduct risk evaluations in the short term. Indeed, the true effect of the law might not be known for another decade or so. In addition, many of the mandates placed on the EPA under the new law will require formal rulemaking by the agency, with associated comment periods and administrative, and ultimately judicial, appeal opportunities. That by itself should ensure years of litigation.

However, and notwithstanding the delayed effects of the Lautenberg Act, the prudent course would be for companies to get ahead of the curve now, understand what the potential implications may be as a result of the law, and begin long-term planning to ensure company compliance does not fall short when their competitors run ahead of the field.

Significant elements of the Lautenberg Act

EPA determination of risk. The most significant problem with TSCA had been that a regulatory body had to physically demontrate that a chemical posed an unreasonable risk before the it could be restricted. The burden of establishing the data required to make such a showing was, as a practical matter, almost impossible to overcome. The result was almost unfettered access for chemicals into the marketplace. Indeed, even before a chemical could be tested, there needed to be evidence of a potential risk or exposure. In other words, an unreasonable risk could only be demonstrated if testing of the chemical was available, but the chemical could not be tested unless the potential for risk was established. That catch-22 scenario makes it easy to understand why so few chemicals were regulated under the prior law.

In stark contrast to the prior version of TSCA, and similar to the foundation of the EU REACH regulations, the Lautenberg Act shifts the burden of regulation 180 degrees by requiring the regulation of chemical substances unless there is evidence that “the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment.” Included in that assessment must be the determination of whether the chemical poses an unreasonable risk to “a potentially exposed or susceptible subpopulation,” such as infants,

children, pregnant women, or the elderly. If the chemical is found to pose an unreasonable risk on that susceptible subpopulation, the EPA must impose restrictions sufficient to ensure that the subpopulation is sufficiently protected.

Significantly, under the “old” TSCA, assessment of “unreasonable risk” was required to include a cost-benefit analysis and balancing of non-risk based factors. In contrast, the Lautenberg Act expressly prohibits the EPA from considering cost and other non-risk factors when determining whether a chemical presents a requisite risk. Moreover, the EPA’s consideration of the chemical must be in view of the circumstances under which a chemical is “intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”

Under the Lautenberg Act, a new chemical cannot be manufactured, or processed for significant use, unless, as noted above, the EPA determines that the new chemical substance, or the new use of a chemical, is not likely to present an unreasonable risk. Alternatively, the EPA can determine that the new chemical or the new use of a chemical does present an unreasonable risk, or can determine that it does not have enough information to make a determination one way or another, in which case the EPA will require additional information. Regardless of which determination it ultimately makes, the act mandates that the EPA make a determination within specified time frames.

If the EPA determines that the chemical or new use poses an unreasonable risk (again, without regard to cost or other non-risk factors), it can then propose a rule that imposes either one or a combination of the following measures:

- Limit the amount of the chemical that may be manufactured, processed, or distributed in commerce;
- Prohibit or restrict the manufacturing, processing, or distributing of the chemical for a particular use, or limit the concentration of the chemical for a particular use;
- Require a clear and minimum warning, and instructions on use, distribution, and disposal;
- Require manufacturers and processors of the chemical to make and retain records of the processes used to manufacture the chemical;
- Prohibit or otherwise regulate any manner or method of commercial use of the chemical;
- Prohibit or otherwise regulate any manner or methods of disposal of the chemical; and/or,
- Provide notice of the EPA’s determination to distributors. Those in possession of the chemical or those that have been exposed to the chemical must provide general public notice of the determination, and replace or repurchase the chemical.

Any restriction the EPA applies for a particular chemical or mixture can be limited to a designated geographic area. Moreover, before the EPA adopts any prohibition or restriction relating to workplace exposures, it must consult with the assistant secretary of labor for occupational safety and health. The EPA must also consult with other federal agencies to the extent regulations of those agencies address health or environmental risks already identified by the EPA during its chemical reviews. This serves to ensure that no regulations duplicate or overlap.

Chemical prioritization. A new element of federal chemical regulation, mirroring to some extent California’s SCPR, is the requirement that the EPA designate high priority chemicals and low priority chemicals. The result of such designations, and its subsequent risk evaluation, is, similar to California’s law, an evaluation of alternatives.

Within one year from the date of the law’s enactment, the EPA must establish, by rule, a risk-based screening process to establish whether a chemical is a “high priority” or a “low priority” chemical.

Criteria will include consideration of the hazard and exposure potential of a chemical or category of chemicals, persistence and bioaccumulation, exposure to susceptible subpopulations, and storage near drinking water sources. High priority chemicals will be those that present an unreasonable risk of injury to public health or the environment because of a potential hazard and potential route of exposure under conditions of use. Low priority chemicals are those that do not qualify as high priority chemicals.

In addition, the 90 chemicals that were included in the 2014 update of the TSCA Work Plan for Chemical Assessments (for example, bisphenol (BPA), vinyl chloride, lead, di(2-ethylhexyl) phthalate (DEHP), methylene chloride, to name a few) also require consideration by the EPA. Within 180 days after enactment of the law, the EPA is required to have commenced risk evaluations on at least 10 chemicals that were part of the 2014 update. Within three and one-half years after enactment, risk evaluations must be underway for at least 20 high-priority chemicals, and 20 low priority chemicals, provided that at least half of all chemicals for which risk evaluations are being conducted include chemicals listed in the 2014 update. Thereafter, EPA must continue to designate priority substances "at a pace consistent with the ability of [the EPA] to complete risk evaluations" within three years after an initial evaluation for a particular chemical is initiated.

The EPA will be required to establish, by rule, a process by which to conduct risk evaluations. When conducting a risk evaluation, the EPA must integrate and assess all information on hazards and exposure for conditions of use, describe how those exposures were considered, account for the duration, intensity, and frequency of exposures under the conditions of use for the chemical substance, and describe the weight of scientific evidence for the identified hazard and exposure. Although risk evaluations are vitally important to the process, they are not always required. The process can be expedited for chemicals determined under specified criteria to be persistent, bioaccumulative, and toxic. The the EPA must propose rules for those chemicals within three years after the law was enacted, and promulgate a final rule within 18 months after the proposed rule is published.

In addition to the chemicals that the EPA designates for evaluation, a manufacturer can also request a risk evaluation for a particular chemical. However, risk evaluations requested by manufacturers cannot account for more than half of all evaluations conducted. If there are enough manufacturer requests, those risk evaluations must comprise at least one quarter of all evaluations. If the EPA conducts a risk evaluation that is requested by a manufacturer, the manufacturer must pay the full cost of the risk evaluation.

Finding of unreasonable risk. If, as a result of the risk evaluation, the EPA determines that the chemical poses an unreasonable risk of injury to health or the environment, it must propose a rule in the federal register within one year after the final risk evaluation for that chemical is published, and within two years after the final risk evaluation is conducted to publish a final rule. The rule must provide a "statement of effects" on the chemical. Those considered effects must include:

- Effect on health and the magnitude of exposure of human beings to the chemical or mixture;
- Effect on the environment and the magnitude of exposure of the environment to the chemical or mixture;
- The benefits of the chemical for various uses;
- Likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
- Costs and benefits of the action and of one or more primary alternatives considered; and,
- The cost of effectiveness of the action and one or more of the primary alternatives

considered.

Therefore, even though the EPA may not consider cost or other non-risk factors when evaluating a chemical's risk, it's required to factor in these effects "to the extent practicable" when considering prohibitions and other restrictions. Moreover, in deciding whether to prohibit or restrict the use of a chemical that substantially prevents a specific condition of use for a chemical or mixture, and in deciding an appropriate transition period in which to apply the prohibition or restrictions, the EPA must consider, "to the extent practicable," whether technically and economically feasible alternatives that benefit health or the environment will be reasonably available as a substitute. Under the new law, compliance dates for restrictions, or for a chemical ban or phase out, must be "as soon as practicable" but no longer than five years after the final rule on the chemical is published. However, there are exceptions that may apply in given circumstances that could extend those deadlines. Exemptions may be granted if the EPA finds that:

- The specific conditions of use are critical and there is no technically and economically feasible safer alternative, taking into consideration the hazard and exposure;
- Compliance would significantly disrupt the national economy, national security, or critical infrastructure; or,
- The specific condition of use of the chemical, as compared to the reasonably available alternative, provides a substantial benefit to health, the environment, or public safety.

Preemption of state law. Perhaps the most contentious issue surrounding the various iterations of efforts to reform TSCA concerned preemption of state laws. Earlier versions of the Senate and House bills included broad preemption provisions. Under the final bill that was signed into the law, there remained a number of provisions that act to preempt state chemical regulation and green chemistry laws. The breadth of those preemption provisions, however, pale in comparison to the earlier drafts of the law. Implementation of the Lautenberg Act's preemption provision will not be without contention. The main points of the state preemption provisions are as follows.

First, the preemption provisions do not affect elements of a state's law concerning reporting, monitoring, or disclosure requirements not otherwise required under the federal law. Rather, it is only restrictions that a state law places on a chemical or its use that may be subject to preemption by the federal act. Moreover, those restrictions are subject to federal preemption only with respect to the hazards, exposures, risks, and conditions of use that are included within the scope of the EPA's risk evaluation. If the state is considering health or environmental risks that are not within the scope of the EPA's review, state restrictions based on those other risks would not be preempted. Further, a chemical with a low priority designation would not be subject to preemption, nor would a state law be affected if it is adopted or authorized under authority of another federal law, or adopted under a state's law relating to water quality, air quality, or waste treatment and disposal except to the extent it imposes a restriction on the manufacture or use of the chemical, or address the hazards or exposures for the use considered in the EPA's risk evaluation.

Second, certain state laws can be grandfathered in to avoid preemption. Specifically, if the state took action on a chemical prior to April 22, 2016, or took action pursuant to a state law that was in effect on August 31, 2003, those actions would not be preempted. This would not necessarily help California's Green Chemistry Initiative, because with few exceptions it has not yet taken actions on specific chemicals under its SCPR. However, California's Proposition 65, which has been in effect since 1986, and Massachusetts's Toxic Use Reduction Act, will not be subject to preemption under the Lautenberg Act.

Third, absent a waiver from the EPA, a state cannot apply a restriction on a chemical during the period beginning on the date the EPA defines as the scope of a risk evaluation for the chemical. Similary, a state cannot end earlier than the date the EPA either publishes the risk evaluation or the date by which the EPA was to have published the risk evaluation. This restriction does not apply to low priority chemicals.

Fourth, if the EPA makes a determination that a chemical does not present an unreasonable risk, any state law restriction on that chemical will be preempted, unless a waiver is granted by EPA.

In practice, it may be difficult to determine whether the specific hazards, exposure, risks, and conditions of use that serve as the basis of a state restriction specifically match the scope of the EPA's consideration when its conducts its own risk evaluation for the same chemical. Assessing the extent to which a state restriction is preempted will likely involve both detailed legal and technical analysis, and will not be a straightforward exercise. However, perhaps the EPA's implementation of the act will be such that states will not be compelled to implement their own restrictions. Not necessarily a likely scenario, but time will tell.

Confidential business information. As noted above, the threshold by which to succeed in keeping information from being disclosed is significantly higher than under the prior law.

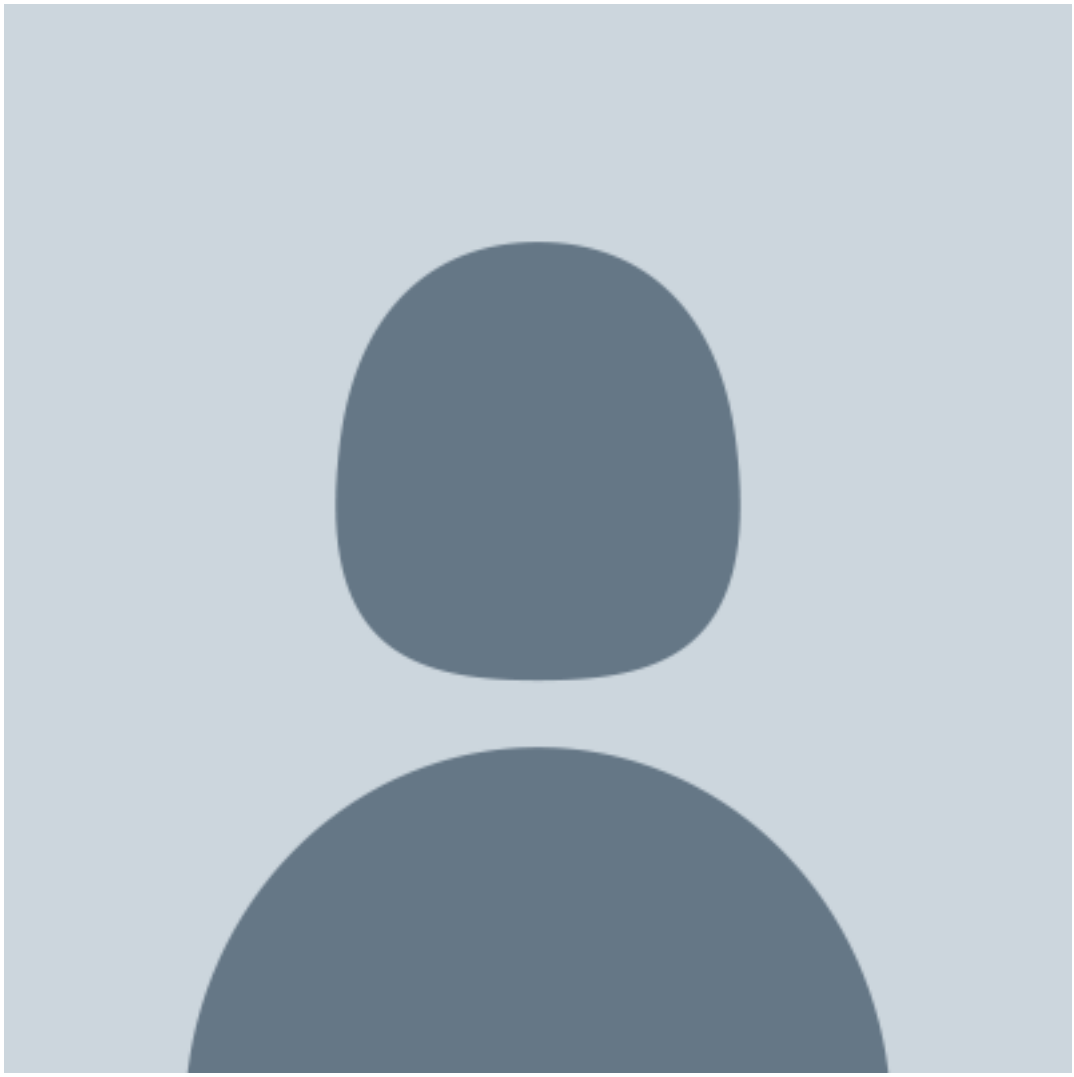
- Disclosure of chemical identities prior to being placed in the marketplace — there is no presumption that such information should be confidential. Claims must be asserted to the EPA, and the claim must be substantiated.
- Information from health and safety studies — generally, such information, including the identity of the chemical being reviewed, cannot be claimed as confidential business information. However, the prohibition on disclosure will be applied to formulas (including molecular structures) of a chemical substance or mixture, processes used in the manufacturing or processing of a chemical substance or mixture, or, in the case of a mixture, data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.
- Claims of confidentiality must generally be substantiated when the claim is asserted. A claimant must show that reasonable measures have been taken to protect confidentiality, that the information is not required to be disclosed or made available to the public under any other federal law, that there is a reasonable basis to conclude that disclosure is likely to cause substantial harm to the competitive position of the claimant, and that there is a reasonable basis to conclude that the information is not readily discoverable through reverse engineering.
- Typically, a claimant will not need to substantiate claims that seek to protect information describing processes, marketing and sales information, information identifying a supplier or customer, for mixtures, details of the full composition of the mixture and respective percentages of its constituents, specific information regarding use, function, or application of a chemical substance or mixture in a process, mixture, or article, specific production, or import volumes, or, prior to the date on which the chemical is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, CAS number, and the like.
- Within one year, EPA must promulgate a rule by which manufacturers, and in some cases, processors must notify EPA of chemicals that have been manufactured or processed within the 10 years immediately preceding the enactment of the Lautenberg Act. That notification must be provided within 180 days after EPA promulgates the rule. The list of chemicals to be gathered by EPA must segregate confidential from non-confidential information. For those chemicals that had been previously deemed confidential, the new act requires that the claim be substantiated. Where no request is made to maintain the existing claim of confidentiality,

the chemical will be re-designated as non-confidential.

Citizen suits. The citizen suit provisions in the Lautenberg Act are generally similar to those in the prior version of TSCA. A citizen can file a civil action after providing 60-days' notice against any person it alleges is violating the act, or against EPA to compel the agency to perform any non-discretionary duty of the agency under the act.

Ultimately, although a number of provisions remain of the "old" TSCA, the Lautenberg Act in many ways turns it on its head. As discussed above, it will be many years before the full impact of the law will be felt. There are many regulations that need to be developed, and many moving parts to the law. The one thing that is certain, however, is that the prior course of business is no longer in effect, but understanding what the new order will look like is still to come.

Simone Schiller



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