



WASHINGTON WATCH

TSCA Reform: Key Provisions and Implications

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On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The text of the law is available at: <http://www.congress.gov/bill/114th-congress/house-bill/2576/text>. The law substantially amends the Toxic Substances Control Act (TSCA), and in so doing, fundamentally alters the domestic management of industrial chemicals, the lifeblood of many manufacturing processes. This article summarizes key changes and explains their likely impacts on the manufacturing sector. For the purposes of this article, reference is made to the amended TSCA as “new TSCA.”

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. New TSCA provides additional, more flexible authority, including using orders and consent agreements in addition to test rules, which 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 required to use tiered testing approaches, unless it can justify going directly to advanced testing.

New TSCA 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.

New TSCA 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. New TSCA retains much of TSCA Section 5, but makes important changes. 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. 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 are:

- 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.

Section 6. Prioritization, Risk Evaluation, and Regulation of Chemical Substances and Mixtures. New TSCA 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 including aggressive timelines for completion of the key steps in the process, which include prioritizations, risk evaluations, and risk management actions. The law 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. The new law 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 the Agency. 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 the Agency 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, new TSCA 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 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, and the Agency is required to consider such evaluations.

Risk Management. New TSCA deletes certain procedural requirements from TSCA Section 6(c) that complicated any attempt to regulate existing chemicals. Under the law, EPA is subject to a number of requirements to issue such rulemakings, including that the Agency 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. The Agency 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.

The new law 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. New TSCA 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. The new law 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 the Agency.

Section 9. Relationship to Other Federal Laws. New TSCA amends 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, new TSCA 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, new TSCA 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. New TSCA 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 new TSCA *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 ~~data~~ (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. (United States Congress, 2016, P. 34).

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

New TSCA 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 10 years, which can be renewed if requirements are met. At the same time,

the new law 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.

In an important shift, new TSCA 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, new TSCA 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 the Agency 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. New TSCA 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. New TSCA 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).

Implications for Manufacturers

New TSCA fundamentally changes the United States of America's approach to industrial chemical management, and in so doing, alters the relationship between EPA and chemical manufactures and processors, and the relationship between and among chemical manufacturers and downstream customers. Noted below are key changes.

First, existing chemicals will be reviewed, and in some cases, regulated by EPA. Historically, EPA has been effectively denied the ability to review and regulate existing chemicals that may cause risks to human health or the environment.

New TSCA changes all this. Existing chemicals will be prioritized and reviewed, and those found to pose unreasonable risks will be regulated. If the manufacturers of these chemicals believe the regulatory consequences of EPA's review are too costly or too risky, they may decide to discontinue or limit production. Chemical processors and users should monitor EPA's implementation of TSCA reform and be aware of which chemicals are prioritized and reviewed first. EPA sponsored a public stakeholder meeting in August to outline its thoughts and seek comment, and intends to issue a proposed rule later this year, according to EPA's First Year Implementation Plan issued on June 29, 2016 (EPA, 2016).

Second, EPA must now make an affirmative safety determination on all new chemicals. This is a big change, the results of which remain to be seen. Previously, if the Agency took no action within the statutory 90 day review period following the notification of new chemicals, notifiers were authorized to begin commercial production or import. In other words, no news from the Agency was good news.

Now, notifiers must wait until EPA affirmatively assesses each new chemical and makes a determination as to whether the new chemical may present an

unreasonable risk, including risks to vulnerable subpopulations. Also, the fees associated with new chemical notification will increase, perhaps substantially. This new process is expected to result in the issuance of more SNURs and/or the withdrawal of notifications for chemicals expected to be found to pose an unreasonable risk (or not be amenable to the unreasonable risk determination).

Third, EPA is resetting the TSCA Inventory. This is an important issue to monitor. The 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 the Agency prior to manufacturing or processing. EPA is expected to issue a proposed rule in December 2016 and a final rule in June 2017 implementing this requirement, which will involve reporting on chemicals manufactured, imported, or processed at any time and in any amount during the ten years preceding enactment of the new law.

It will be important, however, for manufacturers, importers, and processors to participate in the rulemaking that EPA intends to propose in December, and to ensure all chemicals processed in ongoing manufacturing operations are identified and reported as "active," as the processing of chemicals not on the TSCA Inventory could be considered unlawful. While chemicals can be easily activated as described above, there could be enforcement sensitivities if a company, for example, inadvertently processes a long-standing but infrequently used chemical (perhaps one held in a storage room) that has not been reported as active on the Inventory. Product manufacturers and processors should engage with their suppliers to ensure that all processing aids are reported as active.

Fourth, old TSCA and new TSCA afford chemical manufacturers and processors, their upstream suppliers, and downstream customers, a good deal of privacy in selecting the chemical substances used in their manufacturing operations and to maintain as confidential for many years the precise chemical identities of these selections. Under old TSCA, those entities asserting CBI largely did so without question or the need for upfront substantiation of those CBI claims. EPA was disallowed from sharing such CBI, which often consists of the precise chemical identity of a chemical substance, with state and tribal governments, health and environmental professionals, and first responders. New TSCA will for the most part require substantiation of CBI claims, and claims will be good for 10 years, subject to renewal. First responders will have access to more chemical information. Managing CBI will be important for chemical producers and their downstream users.

Finally, EPA's new, expanded testing authority is expected to result in more demands for chemical testing from manufacturers and, in some cases, processors. Even if your company is not actually conducting the testing or paying for it, your product line will not be immunized from the consequences of testing done on chemicals core to your business. In other words, if an upstream supplier is subject to robust toxicological or environmental fate testing of a chemical critical to your product line, you need to know that this testing is ongoing and anticipate the consequences of it. This could include managing the optics inspired by test results that are unexpected -- and may portray the product in an unfavorable light; or having to consider product reformulation in the event the supplier discontinues production or import of the test chemical or determines your client's use is not sustainable. Under these circumstances, it will be important to assess product liability coverage and related insurance issues, among many other legal and business considerations.

What Stakeholders Should Do Now

First, read and understand the law. While detailed, nothing beats reading the original text of that which Congress has penned. As already given at the beginning of this column, the link to the "enrolled bill" is: <https://www.congress.gov/bill/114th-congress/house-bill/2576/text>. (United States Congress, 2016).

Second, know which chemicals are core to your business. New TSCA mandates that EPA prioritize and evaluate high priority chemicals according to an aggressive and judicially enforceable schedule. The EPA's Work Plan for Chemical Assessments' list of chemicals is a must-read for counsel and, if this program is unfamiliar to you, it would be helpful for you to review EPA's [TSCA Work Plan for Chemical Assessments website](https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals), which is available at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals> (EPA, no date). EPA's review and evaluation of these chemicals, and many others determined to be "high priority," will have significant impacts on the chemicals reviewed, their uses and applications, and even their availability.

Third, focus on the upsides and seize opportunities to innovate new products to fill the inevitable chemical product deselection void. With change comes opportunity, and new products with sustainable profiles will do well under the new law.

Fourth, be mindful of the competitive consequences of the law's implementation. The new law requires many new rules, the implications of which will be vast and consequential for domestic product manufacturers.

Savvy stakeholders appreciate that some rulemakings can be zero sum games with distinct winners and losers. Stakeholders in the rulemaking process need to begin now to think strategically and tactically about the implementation process and influence that process in ways that ensure that your company's products are appropriately considered, or at least not inadvertently victimized because you have been outmaneuvered.

Conclusion

TSCA reform has been a work in progress for more than a decade. As TSCA has now been reformed, it is time to think strategically and prepare to engage in the many initiatives that the new law requires, the collective result of which will fundamentally revolutionize chemical management in the United States. Smart stakeholders will see this for what it is -- a critically important business challenge and opportunity that requires manufacturers to take stock in your manufacturing processes, to assess your product lines' chemical feedstocks, to prepare for the impacts of the new law, and to seize opportunities for change by innovating in ways that improve product safety and your business' bottom line.

References

EPA. (2016). *The Frank R. Lautenberg Chemical Safety for the 21st Century Act: First Year Implementation Plan*, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-lautenberg-chemical-safety-21st-century-act-3>.

EPA. (no date). TSCA Work Plan for Chemical Assessments (website). Available at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-work-plan-chemicals>

United States Congress. (2016). Frank R. Lautenberg Chemical Safety for the 21st Century Act, House bill 2576. January 4, 2016. Available at: <http://www.congress.gov/bill/114th-congress/house-bill/2576/text>.

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