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TSCA

For the first time in 40 years, Congress stands on the brink of reforming the nation's industrial chemicals law with implications up and down the supply chain and for public health. Lawrence Culleen of Arnold & Porter LLP distills the key elements of the new legislation and how it will affect businesses and other organizations.

The TSCA Amendments Simplified: Nine Key Features of the New Law and Three Compromises That Will Affect Business

By Lawrence E. Culleen

Congress is enacting sweeping amendments to the nation's cornerstone chemicals control law, the 40-year-old Toxic Substances Control Act. The amendments are intended to empower and reinvigorate the Environmental Protection Agency's program for controlling risks to human health and the environment from chemical substances that are imported, manufactured, and processed in the United States. President Barack Obama is expected to sign the bill without hesitation. The recently agreed-upon amendments were achieved only after intense behind-the-scenes negotiations necessary to harmonize separate bills passed in the House of Representatives and Senate during 2015. The final bill represents the results of more than a decade of legislative initiatives that in more recent years prompted uncharacteristically collaborative and bipartisan efforts.

Although it may take years for EPA to fully implement the amended law's numerous new requirements, it is important that companies doing business in the U.S.: a) understand the key features of the final legislation; b) gain insight into the three compromises reached on the amended law that are most likely to affect them; and c) take certain simple steps to prepare.

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Background

TSCA provides EPA broad authority to regulate importers, manufacturers, and processors of chemical substances, including authority to regulate commercial and consumer use products into which substances are blended. Since its enactment in 1976, TSCA has required EPA to be notified of, and to review (but not to specifically ''approve''), ''new'' chemical substances be-

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fore they enter U.S. commerce. EPA also must be notified of certain significant new uses of a chemical substance. EPA has been permitted to collect modest fees for processing such notifications. The law enables EPA to require through rulemaking that a chemical substance be tested for health or environmental effects, and has allowed EPA to regulate chemicals in commerce when the agency determines, by rule, that the chemical substance presents unreasonable risks of injury to human health or the environment (using the least burdensome requirements that adequately protect against such risks). Under the current law, EPA requires periodic reporting of certain information including the quantities of chemical substances that are imported and manufactured in the U.S. TSCA has required EPA to maintain confidentiality of information reported to the agency that is considered to be a trade secret. Such information generally could not, under the current law, be disclosed to the states or tribal authorities or to foreign governments. TSCA provides that violations can be punished through civil and criminal penalties. As enacted in 1976, TSCA did little to preempt the authority of the various states to regulate chemical substances except in limited circumstances.

2015 Brought Success

Parallel legislative efforts in the House and Senate finally culminated in both chambers passing amendments to TSCA that were overwhelmingly supported by members. Notwithstanding virtual unanimity with regard to the general problems in TSCA that needed fixing, protracted negotiations were necessary to arrive at a compromise bill. There was no clear path to reaching final agreement on which provisions should be retained from the Senate bill (which contained nearly 200 pages of amendments to virtually every section of Title 1 of TSCA) and the House bill (which reflected a considerably more modest approach and would have amended only those provisions of TSCA that most notoriously constrained EPA's ability to regulate).

Stakeholders from all spectrums who were actively engaged during development of the House and Senate bills advocated strongly for significantly different positions on important provisions of the legislation. Negotiations began in earnest shortly after the new year and, given the distractions of the presidential primaries, competing legislative initiatives, and the president's nomination of Judge Garland to succeed Justice Scalia, it is arguably remarkable that the major legislative players eventually reached agreement on a final bill. This advisory highlights some of the most important provisions of the new law and reviews several significant agreements reached along the way that were instrumental to achieving results.

Nine Key Features of the New Law

1. *Revises the threshold for regulating chemical substances and separates consideration of costs and other non-risk factors from the risk assessment process*. When performing risk assessments for chemical substances, EPA will be limited to considering human health and environmental effects, including risks to vulnerable population subgroups that may be uniquely susceptible. If EPA's risk evaluation determines that a substance will, under its intended or reasonably foreseeable conditions of use, present an unreasonable risk, the agency must issue a regulation to manage those risks. Costs, benefits, and other non-risk factors will be considered by EPA only in the context of reaching risk *management* determinations. EPA's decisions will be expected to reflect the ''best available'' science and to be based on the ''weight of the evidence.''
2. *Requires EPA to make a determination for all new chemicals*. New chemical substances will not be able to enter commerce until EPA makes an affirmative determination concerning whether the new chemical substance may present an unreasonable risk to human health or the environment, including risks to vulnerable subpopulations. The same standard which will apply to premanufacture notifications (PMNs) also will apply to EPA's review of notices it receives concerning proposed uses of a substance that EPA has defined to be significant new uses.
3. *Expands EPA's authority to compel chemical testing*. The agency gains authority to issue administrative orders to direct that test data be generated on certain substances, in addition to using its existing rulemaking authority.
4. *Directs EPA to prioritize chemical substances in commerce for review and management and establishes deadlines*. EPA will be required to prioritize chemical substances that are already in commerce for risk assessment and risk management determinations. EPA must establish its risk evaluation process by rule within one year of enactment of the final amendments. However, within six months of enactment, the agency is required to rapidly identify an initial cluster of 10 ''high priority'' chemical substances for risk evaluations and gradually to expand that list.[1] Three years later, EPA must have identified at least 20 substances as high priorities for assessment and 20 as ''low-priority'' substances—half of the prioritized chemicals must be drawn from EPA's roster of Work Plan chemicals issued in 2014. A manufacturer (but not a processor) of a chemical substance may request a risk evaluation provided the manufacturer pays a service fee to offset the agency's cost to perform the assessment. EPA will be expected to give preference in the risk evaluation process to chemicals listed on its Work Plan that are persistent and bioaccumulative as well as known human carcinogens with both acute and chronic toxicity. Persistent and bioaccumulative substances to which the general population is exposed will be subject to expedited regulatory actions for which no risk assessments are required and which are intended to reduce exposures to the ''extent practicable.'' Risk evaluations must be completed within three years of initiation, and if

[1] High priority substances are those which ''may present an unreasonable risk'' because of a ''potential hazard *and* a potential route of exposure under the conditions of use'' including to any ''potentially exposed or susceptible subpopulation'' identified as relevant. In contrast, substances that do not meet this standard will be designated as ''low priority'' for risk evaluation.

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EPA determines that the substance ''presents'' an unreasonable risk, the agency must propose a risk management (Section 6) rule not later than one year from the determination, with the final rule to be issued a year later. If extensions to EPA's deadlines become necessary, they may not exceed two years in the aggregate.

5. *Updates the TSCA Inventory*. Pursuant to TSCA, EPA maintains an inventory of chemical substances that establishes the dividing line between ''existing'' and ''new'' chemicals. The amendments direct EPA to issue a new rule within one year to require reports to update the inventory to get a better understanding of which substances are currently being commercially manufactured, processed or imported into the U.S., and to designate other listed substances as ''inactive.'' EPA is to retain the chemical nomenclature conventions it followed when the initial inventory was created.

6. *Improves transparency*. The amendments require EPA to review existing confidential business information (CBI) claims masking the specific identities of chemical substances in commerce and a sampling of at least 25 percent of other CBI claims. Substantiated claims will be protected for an initial 10-year period, subject to renewals. EPA is granted authority to share CBI with state and tribal governments, health and environmental professionals, and first responders.

7. *Increases fees*. The amended law authorizes EPA to collect considerably higher fees than the current law authorizes. The fees are intended to defray up to 25 percent of EPA's costs of implementing the new chemical notification, risk evaluation, and confidential information review programs. When a manufacturer requests an EPA review of an existing chemical, it must pay as much as 100 percent, depending on the chemical, of EPA's costs for conducting the review.

8. *Partial preemption of state chemical-regulatory actions*. Final EPA regulatory actions on chemical substances will preempt state regulation of such substances, subject to various exceptions and opportunities for state requests for waivers. States will still be permitted to adopt regulations identical to federal standards issued pursuant to TSCA. Both EPA and the states will continue to enforce their respective regulations if the state rule is identical, but penalties will be capped at the federal statutory maximum. Preemption—albeit temporary—also will arise when EPA formally announces the scope of the risk evaluation the agency is undertaking for an existing chemical substance. Following such an announcement, the states may not impose new regulatory requirements that affect activities within the scope of the agency's assessment until EPA completes its review, or 30 months have elapsed (whichever is sooner). When this temporary preemption period concludes, a state may impose a new chemical-regulatory requirement unless EPA has determined that the substance does not present an unreasonable risk to human health or the environment (including to susceptible subpopulations) under the intended and foreseeable conditions of use. Moreover, if EPA issues a final risk management rule which limits or prohibits a chemical substance under certain intended or foreseeable uses, state actions would again be preempted. State statutory and regulatory actions taken prior to April 22, 2016, are not preempted and new actions taken under an existing state law that was in effect on August 31, 2003, are not preempted. States may seek waivers from the preemptive effect of an EPA decision under certain conditions. The compromise bill clarifies that common law rights of action are not affected.

9. *''Hot Spots'' to be identified*. The legislation amends the Public Health Service Act to encourage the identification and investigation of potential cancer clusters.

Three Key Compromises Likely to Affect Business

The following highlights important compromises reached during the negotiations on the final bill that are likely to affect chemical manufacturers, importers and processors.

■ **Compromise #1: Clarify the Regulatory Threshold; No New ''Safety Standard''**

As originally enacted, TSCA enabled EPA to take regulatory actions to limit or prohibit activities associated with a chemical substance when the agency could find that the substance ''may present'' (for a new chemical substance or significant new use) or ''will present'' (for an existing substance) ''an unreasonable risk of injury to [human] health or the environment.'' TSCA neither defines the term ''unreasonable risk'' nor elaborates on application of the ''standard'' for taking regulatory action. The lack of clarity concerning when a risk can be said to be ''reasonable'' proved vexing for nearly 40 years. Thus, a recurring theme in the discussions that informed drafting of the Senate and House bills concerned how to amend the regulatory ''standard'' for taking action. Stakeholders, including agency leaders, have argued that it has been difficult for EPA to demonstrate that the regulatory threshold has been met, especially in light of the requirement that risk management rules should apply the ''least burdensome'' methods.[2] Advocates for strengthening TSCA argued that the ''fix'' should be a new, strict ''safety standard'' that chemical substances entering commerce, and those already in commerce, must meet.

The Senate bill would have inserted the term ''safety standard'' against which chemical substances would have been measured to ensure, ''without taking into consideration cost or other non-risk factors,'' that no ''unreasonable risk'' would occur, including to ''potentially exposed or susceptible subpopulations.''

[2] The unreasonable risk standard as applied in the context of Section 6 regulations for existing chemicals has been interpreted by the Fifth Circuit to require a balancing test. Thus, in its 1991 *Corrosion Proof Fittings v. EPA* decision, the court struck down significant features of EPA's rulemaking that would have effectively banned most uses of asbestos and stated that ''[i]n evaluating what is 'unreasonable,' the EPA is required to consider the costs of any proposed actions and to 'carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.' '' 947 F.2d 1201 (5th Cir. 1991).

The drafters of the House bill elected to retain the basic ''unreasonable risk'' standard. However, in harmony with Senate drafters, the House bill would have required that when strictly assessing the risks of a chemical substance, EPA should not take into consideration ''cost or other non-risk factors'' and should specifically take into consideration risks to ''potentially exposed subpopulations.''

The final bill aligns more closely with the House version in that it retains the existing regulatory standard of TSCA. More importantly, however, it captures the most significant feature of both bills: separating the processes and concepts involved in risk *assessment* and risk *management*. In so doing, the final bill clarifies that risks should be assessed without consideration of costs and other non-risk factors, and that the process should include consideration of exposures to certain populations that can be said to be ''at risk,'' because of their susceptibility (e.g., the young or the aged and infirm). Appropriately, the final bill permits EPA to consider costs and benefits when it is engaged in risk management and selecting from among alternative approaches for regulatory controls.

Potential Effects on Businesses: Although the ''unreasonable risk'' language was retained, submitters of new chemical and new use notifications and proponents of existing substances that will undergo risk evaluations under the clarified regulatory standard (e.g., those on the agency's 2014 Work Plan Chemicals List and those for which a business may request an EPA Risk Assessment be conducted) should be prepared for the expanding contours of what EPA will now be *required* to consider under the new regime. Specifically, proponents of a chemical substance that is undergoing review under the amended TSCA should be prepared to provide to EPA a reasonable and scientifically defensible basis for supporting the conclusion that a substance and its intended uses will not create exposures that present an unreasonable risk to any ''susceptible subpopulation.'' This might require defining and, if possible, quantifying *all* potential exposures that are likely to occur from intended uses of the chemical substance as well as any reasonably foreseeable uses that EPA might imagine could occur. It is worth noting that the new law permits third parties, including non-governmental organizations (NGOs), to submit information for EPA consideration during risk assessment proceedings. Business entities that might be considering paying potentially exorbitant fees to have a valuable commodity voluntarily undergo an EPA risk evaluation (and get a potentially preemptive determination) will need to challenge themselves to consider and anticipate potential exposures to populations that may be at greater risk than the general population, such as infants, pregnant women, and workers, as well as individuals living in disadvantaged communities that might experience exposures due to greater proximity to facilities at which manufacturing, processing and even use of the chemical substance might occur. It will not serve business entities well if they ignore such potential exposures from foreseeable uses only to find themselves ill-prepared to respond to agency assessments that take such exposures into account.

■ **Compromise #2: Require EPA to Make Determinations on All New Chemical Substances/ New Uses**

Under Section 5 of TSCA, EPA is authorized to evaluate new chemical substances and ''significant new uses'' of chemical substances to determine whether regulation may be warranted prior to new substances entering commerce or the new uses commencing. Under the current law, EPA is authorized to issue an administrative order prohibiting or limiting manufacture (or commencement of a new use) if the activity ''may present an unreasonable risk'' to human health or the environment pending the development of additional information necessary to make a more reasoned evaluation. Significantly, if EPA fails to take affirmative action to prohibit or to limit the new chemical or significant new use, the notice submitter may commence the proposed activity without further restriction.

The Senate bill would have materially rewritten Section 5 to require that EPA issue a determination whether the proposed activities are ''likely to meet'' or ''not likely to meet'' the Senate's so-called ''safety standard.'' Alternatively, the Senate bill provided that EPA could require additional information before making a determination.

The House bill did not amend Section 5, viewing that program to be working effectively.

Negotiators took much of the Senate bill's approach on new chemicals and new uses but wisely liberated EPA from having to specifically label a new chemical or significant new use as ''safe.'' Thus, EPA will now be required within 90 days to make an affirmative risk determination on each new chemical or significant use. The final bill specifies three categories of risk determinations. First, EPA may determine that a new chemical substance ''presents'' an unreasonable risk (without considering cost or other non-risk factors) to human health and the environment (including risks to potentially exposed or susceptible subpopulations) under the conditions of use. Second, EPA may determine that insufficient information is available to make the ''unreasonable risk'' determination, that the substance or use ''may present'' an unreasonable risk, or that the substance will be made in substantial quantities. Further, EPA must take regulatory action to limit risks if it makes any of the foregoing determinations, and production may only commence in compliance with the restrictions.

Alternatively, the submitter of a new chemical or a new use notice is free to commence production as soon as EPA has found that the new substance or significant new use is ''not likely'' to present an unreasonable risk (the third category of risk determination).

The Section 5 findings were the subject of considerable discussion up to the very end of the negotiations, perhaps in recognition of the difficulty EPA might face in needing to make a specific risk finding with respect to each new chemical and significant new use, especially in the absence of robust data and in the limited time permitted .

Potential Effects on Businesses: The compromise on Section 5 is likely to give stakeholders on both ends of the legislative debate what they wanted: the ability to say EPA is now required to carefully review and make a ''finding'' prior to allowing new chemicals and new uses to enter the market. Unfortunately, it is hard to imagine that this new requirement will *not* significantly slow the ''speed to market'' interval for new chemical substances given how few people EPA has working in the new chemicals program, and how overwhelmed they are already. Whether the additional requirements will unduly inhibit EPA decision making in the new

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chemicals program over time remains to be seen. No matter how one interprets the new Section 5 findings requirement, the changes will require some getting used to for EPA staff and notice submitters alike—and the bill does *not* contain a phase-in period for these particular new features. Manufacturers and importers who have new substances in the research and development lane should be prepared to encounter significant delays and requests for ''voluntary'' suspensions of the 90-day review period since (at least initially) EPA may struggle to get through the new chemical and new use review process for the foreseeable future. An important and very valuable window may exist *now* for getting TSCA premanufacture notifications (PMNs) and significant new use notifications (SNUNs) into EPA *before* the currently-modest PMN fee of $2,500 per substance jumps ups considerably after a new ''user fee'' fee structure is devised.

■ **Compromise #3: Preemption of State Chemical Regulatory Actions**

Conventional wisdom held that commercial interests would only become overtly supportive of amending TSCA when they had reason to believe the *quid pro quo* for providing more regulatory authority to EPA would be federal preemption of the growing patchwork of state legislative efforts to regulate and restrict chemical substances. After years of partisan efforts, a gift from the legislative gods emerged unexpectedly in May of 2013 when Senator Frank Lautenberg (D-N.J.) teamed with Senator David Vitter (R-La.) to introduce bipartisan TSCA reform legislation. The bill embraced a middle ground and would have granted the fulsome state preemption the business community sought. Almost as unexpectedly, and fueled by the advocacy of Senator Barbara Boxer (D-Calif.), opposing preemption became a *cause celeb* for the original proponents of TSCA reform, and delayed a final bill for three full years.

At the end of the day, the amendment's terms on preemption curiously (given Senator Boxer's very vocal support for the House version of the legislation) reflect the most important features of the Senate bill, with modifications reported to have been agreed to only due to personal efforts of Senator (and Environment and Public Works Committee Chair) James Inhofe (R-Okla.) to reach an accord with Senator Boxer.

The compromise language ensures that state actions may continue to be taken pursuant to *existing* state laws enacted before August 31, 2003, (not surprisingly, a date targeted to ensure the continued viability of California's Proposition 65), and that other state actions taken prior to April 22, 2016, (Earth Day) may remain in place. Subject to these exceptions, new state actions will be preempted during the period commencing when EPA announces, pursuant to Section 6, the scope of the risk evaluation for a particular chemical substance and use combinations. This ''pause'' will conclude after 30 months or when EPA has completed its risk evaluation (whichever is sooner). If EPA has determined following its risk evaluation that the substance does not present an unreasonable risk to human health or the environment in the context of certain uses, then new state actions limiting or prohibiting those uses are effectively preempted. Final regulatory actions issued by EPA will preempt new state requirements if the state requirements are intended to address the same risks addressed in EPA's risk determinations and regulatory actions.

Numerous opportunities will continue to exist for activist states to work around the final, very limited preemption language. For example, state requirements for reporting, monitoring, and other ''information obligations'' that are not otherwise required under TSCA are not preempted. Moreover, states may seek complete or partial waivers of federal preemption, and of the temporary preemption phase as well. Of course, a state may simply initiate a new action under a legislative authority not considered to be preempted (e.g., state water or air pollution laws and state waste management authorities). In addition, the TSCA amendments permit states to issue requirements that are identical to an EPA requirement issued under TSCA.

Potential Effects on Businesses: Ironically, state enthusiasm for taking legislative action on certain chemicals might be further encouraged by provisions in the final bill. First, the temporary preemption provisions might cause especially eager state legislatures to seek to issue new actions in advance of EPA's initial prioritization announcements to be issued not later than 180 days following enactment. Second, the final bill provides that a state's chemical-regulatory requirement is not preempted if the state enacts a requirement that is identical to an EPA requirement. This has enabled the concept of state and federal ''co-enforcement'' of TSCA to emerge in the context of the debate and find its way into the final terms on preemption. Under the amendments, states are able to independently assess penalties for violations of state requirements if the requirement is identical to one issued by EPA under TSCA (provided EPA has not already issued an ''adequate'' penalty). EPA would not be permitted to issue a separate penalty for the same violation in addition to a state penalty if the aggregate fine would exceed the statutory limit under TSCA. Regulated entities could also face penalties under TSCA's provision that authorizes third parties to bring civil actions in federal court alleging violations of certain provisions of TSCA (after providing notice to EPA).

The amended law should serve as a reminder to entities having even recordkeeping obligations under TSCA to be mindful that a state could enact legislation adopting existing TSCA recordkeeping and reporting rules (e.g., Sections 8(c) and 8(e)) hoping that state inspectors (having little if any TSCA experience) might visit facilities and corporate headquarters located in the state to search for lucrative penalty opportunities. Perhaps an even greater concern emerges because the amended law permits EPA to share with state regulatory agencies, for purposes of implementing and enforcing environmental programs, confidential business information provided to EPA by entities subject to TSCA. If they are not doing so already, businesses in the U.S. will need to keep an eye on new and developing state chemical control legislation and regulations.

Near-Term Prognosis: Simple Steps to Prepare

It is difficult to predict how readily EPA will be able to implement the amended law. EPA's TSCA program continues to struggle with resource issues. Moreover, the impending presidential election, coupled with a possible change in leadership (and potentially a change in temperament) at the agency, could present further chal-

lenges and delays. EPA likely will have a difficult time simply meeting the largely procedural and administrative obligations that must be met within the first two years of enactment, including: a) identifying initial lists of high (and low) priority substances; b) promulgating various policies, procedures, and guidance to implement the prioritization and risk evaluation processes, and new CBI review procedures; c) establishing a revised and expanded fee structure before new and increased user fees can be selected.

Nevertheless, there are certain steps businesses that are subject to EPA requirements can take now to prepare for changes to come under a revamped TSCA.

- **Review your product lines now.** Identify product lines that are of greatest value, and determine which ones are likely to become ''high priority'' targets for EPA risk evaluations. Ascertain whether the product lines have or depend upon component chemicals that are among the ''Work Plan'' chemicals. Flag those which have characteristics of persistence and bioaccumulation and those which are carcinogens, and commit to collating and reviewing all health, safety and environmental fate and effects data you can gather. Begin to identify all ongoing and foreseeable uses for the substance(s)—whether or not they are engaged in by your business. Fully assess whether any of those uses can lead to exposures to consumers, the general population and susceptible subpopulations. Do some business planning now, because customers and users of your products may begin de-selecting them if they learn of an EPA decision to commence a risk evaluation that includes your chemical.
- **Confirm the chemical nomenclature for all substances in your product lines.** When EPA begins to re-establish the inventory and to classify the active and inactive substances, the process for confirming an ''active'' inventory listing for your chemical substances will result in new scrutiny being given to your use of chemical names and CAS numbers. The TSCA Inventory is the dividing line between ''existing'' and ''new'' chemicals. Being on the wrong side of a nomenclature debate with EPA can result in an important product being erroneously treated as ''new'' or not listed.
- **Continue to keep ahead of state chemical-regulatory actions.** As discussed above, preemption under the amended TSCA will be limited, and the desire among certain states to be involved in the regulatory arena is unlikely to diminish soon.
- **Review existing claims of confidentiality for information in EPA's possession.** New CBI claims will be subject to scrutiny and existing claims will undergo another review eventually. Be prepared to re-substantiate confidentiality claims previously asserted and to carefully substantiate initial claims.
- **Submit new chemical and new use notifications now before higher user fees kick in and new findings must be made**.

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