

**American Bar Association
Section of Environment, Energy, and Resources**

**Chemical Management: What All Environmental, Energy,
and Resources Lawyers Need to Know about TSCA Reform and Why**

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ABSTRACT

On June 22, 2016, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg). The new law amended significantly the Toxic Substances Control Act (TSCA) and in so doing, is redefining supply chain relationships, rewriting the rules of engagement for due diligence in mergers and acquisitions, reopening debate on new avenues in product liability and tort law, and raising important questions regarding right-to-know vs. confidential business information (CBI). TSCA, as amended, is no longer an arcane chemical statute that only chemists, consultants, and counsel for chemical manufacturers need to understand. We discuss below the significant changes in commercial transactions, supply chain relationships, and related legal areas of which Section members need to be aware, anticipate, and address. We also briefly consider TSCA and its alignment and differences with the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) program, and speculate on the impact Brexit might have on chemical management.

I. Overview of New TSCA

Lautenberg significantly amended TSCA, resulting in fundamental shifts in the requirements and approach under TSCA that will have significant implications for chemical stakeholders and their lawyers and advisors. The new program faces a variety of hurdles due to the challenge of deadlines, resources, and most recently, a change in the Administration. We highlight below key changes in the law.¹

¹ More information is available on the Section of Environment, Energy, and Resources (SEER) TSCA Reform webpage, at

TSCA applies to “chemical substances” and authorizes the U.S. Environmental Protection Agency (EPA) to regulate the manufacture (including import), distribution in commerce, processing, use, and disposal of chemical substances. As defined, “chemical substance” does not include pesticides, drugs, food additives, and other chemicals that are regulated under other federal laws. TSCA focuses on assessing and regulating “unreasonable risk” presented by chemical substances. TSCA also provides the authority to require testing and reporting of information, and imposes notification requirements on manufacturers and importers of chemicals that are considered new to commerce. In exercising its authority, EPA is instructed by Congress to act so as “not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling” TSCA’s primary purpose “to assure that such innovation and commerce...do not present an unreasonable risk of injury to health or the environment.”²

TSCA’s regulatory authority applies throughout the value chain, from the commercial originators (manufacturers and importers) of a chemical through to those involved in the end stages of commercial life (this can involve final users and those involved in disposal). Along the way, TSCA impacts entities that process, use, and distribute chemicals, mixtures, and manufactured articles.

To address many, if not most, of original TSCA’s³ more well-defined deficiencies, Lautenberg imposes requirements and clear deadlines on EPA to evaluate existing chemical substances, implements a new risk-based safety standard, and requires that EPA make an affirmative finding on the safety of a new chemical or significant new use of an existing chemical before it is allowed into the marketplace. The new law increases public transparency for chemical information by limiting information that can be claimed confidential, requiring upfront substantiation of assertions of CBI as well as certification of such claims, and protecting from disclosure claims that are not presumptively protected under TSCA Section 14(c)(2) pursuant to Section 14(e)(1)(A) for ten years, subject to renewal.

Under Lautenberg, EPA has broader authority to compel chemical testing by order (in addition to rule and consent agreement) when evaluating new chemical notifications and in assessing existing chemicals under TSCA Section 6. TSCA also provides new or expanded authority to EPA and imposes requirements regarding information reporting, preemption, fees, and administrative aspects. For example, Lautenberg requires that EPA undertake a reporting effort to inform determinations whether TSCA chemicals listed on the TSCA Inventory are “active” or “inactive” in commerce. A number of these areas are discussed below.

II. Key Practice Areas Impacted by New TSCA

We make no effort in this paper to address specific issues and controversies pertinent to the new law or EPA’s implementation of it. There are many resources available to assist SEER members in obtaining a better understanding of how the new law works (including the SEER Section’s TSCA Reform webpage,

http://www.americanbar.org/groups/environment_energy_resources/resources/tsc_a_reform.html.

² TSCA Section 2(b)(3), 15 U.S.C. § 2601(b)(3).

³ Pub. L. No. 94-469 (Oct. 11, 1976).

http://www.americanbar.org/groups/environment_energy_resources/resources/tsca_reform.html), and how exactly EPA is implementing it, satisfying its many statutory rulemaking deadlines, and discharging its robust new authority under the law.⁴ Rather, we focus here on TSCA's broader implications for related practice areas to assist Section members and others in anticipating and addressing challenges and optimizing opportunities occasioned by the law's implementation.

A. Impact on Supply Chain Relationships

One of the defining characteristics of evolving chemical product law and regulation is the growing imperative to share product safety and regulatory information along the value chain. Lawyers, regulatory managers, product stewards, and others increasingly are required by law and regulation, pressured by greater demands for transparency by customers and other stakeholders, and "incentivized" by ever more complex supplier-customer business models to share information believed necessary to evaluate the safety of a chemical product or material, and to assess the product's compliance with applicable laws and regulations. This information generally includes a chemical's physical and chemical characteristics, toxicity data (both human health and environmental), chemical product use and exposure information, and legal and regulatory compliance information.

Increasingly, lawyers and their clients are challenged in satisfying these "requests." They must balance the sometimes competing interests of ensuring the information that is made available in supply chain communications appropriately reflects legitimate claims to CBI, while communicating such information truthfully and meaningfully *and* ensuring the product continues to be commercially viable. Lautenberg revises and completely replaces TSCA Section 14 concerning protecting from disclosure CBI and includes several new sections concerning information not protected from disclosure. Lautenberg requires that companies meet certain requirements in asserting CBI claims, including upfront substantiation, and also requires substantiation for existing claims of confidential chemical identity. Such claims, when and to the extent approved by EPA, receive protection from disclosure for a period of ten years, which can be renewed if certain requirements are met.

At the same time, Lautenberg also includes a provision stating that certain types of information are essentially presumed to be CBI (for example, marketing and sales information), are not subject to substantiation requirements, and that such protection is not time limited. Lautenberg specifies certain duties of the Administrator in reviewing and acting on CBI claims, and gives EPA discretion to review claims in certain circumstances, such as when chemicals are designated as "high-priority," a term new to TSCA but certainly not new to the general public.

The new law will impact greatly the regulated community and EPA alike. On January 19, 2017, EPA issued an interpretation of TSCA Section 14 concerning substantiation of CBI claims for information submitted to EPA.⁵ Under the interpretation, EPA states that new TSCA requires substantiation of all non-exempt CBI claims at the time the information claimed as confidential is submitted to EPA. In the notice, EPA also states that the action "facilitates [its] implementation

⁴ See Bergeson & Campbell, P.C. (B&C[®]), TSCA Reform News Center, available at www.lawbc.com; and B&C TSCA Blog, available at www.tscablog.com.

⁵ 82 Fed. Reg. 6522 (Jan. 19, 2017).

of TSCA section 14(g) to review all CBI claims for chemical identity, with limited exceptions, as well as to review a representative sample of at least 25% of other non-exempt claims.”⁶

Another of the defining characteristics of evolving product law and regulation is the need to undertake and share the responsibilities for chemical safety along the value chain. While sharing such information was evident previously, amended TSCA includes a number of new definitions and concepts, as well as a greater recognition of chemical processors’ responsibilities that underscore and make these downstream responsibilities clearer. While chemical processors have long been subject to TSCA, EPA’s historic emphasis under TSCA has been on chemical producers. “Processors” include any entity that “processes” a chemical substance or mixture. “Processing” includes a broad range of activities, *e.g.*, further chemical mixing, preparing, blending, or otherwise preparing a chemical substance or mixture. These entities may also manufacture a new chemical as a consequence of their chemical processing activities, but processing is legally distinct from manufacturing under TSCA. Lautenberg doubles down on enhanced processor responsibilities. For example, TSCA imposes requirements on processors, in addition to manufacturers and importers, to notify EPA before commercializing an “inactive” chemical and to pay fees to provide a portion of the resources needed to meet certain EPA responsibilities under the new law.

EPA has authority to regulate new and existing chemicals under TSCA Sections 5 and 6, respectively, including with regard to downstream processing, distribution, use, and disposal. Such regulatory action may result in tensions, if not conflicts, along the supply chain as particular commercial activities are targeted for control or other regulatory requirements.

Historically, EPA used TSCA Section 5(e) orders to regulate notifiers by imposing requirements on new chemicals. Such orders frequently included downstream hazard communication requirements. These typically took the form of hazard warnings and information equivalent to that required in the Occupational Safety and Health Administration’s (OSHA) Hazard Communication Standard (HCS).⁷ EPA frequently issued Significant New Use Rules (SNUR) after it issued a Section 5(e) order to extend the order’s requirements to downstream entities. On July 28, 2016, EPA proposed revisions to the regulations governing SNURs under TSCA with revisions to the OSHA HCS,⁸ occasioned by OSHA’s March 2012 final rule modifying the HCS to conform to the United Nations’ (UN) Globally Harmonized System of Classification and Labelling of Chemicals (GHS), changes to OSHA’s Respiratory Protection Standard, and the National Institute for Occupational Safety and Health’s (NIOSH) respirator certification requirements pertaining to respiratory protection of workers from exposure to chemicals. These changes, if promulgated, would modify these requirements as applied in SNURs.

A provision of interest to downstream entities is the requirement that EPA, in promulgating a SNUR imposing notification requirements on chemicals in manufactured articles, must make an affirmative finding in the rulemaking that the reasonable potential for exposure to the chemical

⁶ *Id.* at 6522.

⁷ OSHA HCS, available at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10099.

⁸ 81 Fed. Reg. 49598 (July 28, 2016).

from the article justifies the notification requirement.⁹ Article importers and processors, which include a wide range of industrial and consumer product handlers, will need to monitor such rulemakings closely and provide comment as needed to ensure their commercial and legal interests are protected.

Regarding existing chemicals, TSCA imposes new requirements that EPA undertake sequential efforts to prioritize chemicals for risk evaluation and undertake risk evaluation for so-called “high-priority” chemicals. The prioritization and risk evaluation stages focus on a chemical’s “conditions of use.” This term is defined in TSCA to mean the “circumstances, as determined by [EPA] under which a chemical...is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”¹⁰ Downstream entities will need to ensure that EPA’s understanding of their processing and use activities is accurate and reflects their commercial interests and exposure mitigation practices. Failure to do so could invite significant commercial restrictions and the imposition of risk management measures that may be unduly restrictive.

EPA is also required in the TSCA Section 6 prioritization and risk evaluation stages to consider unreasonable risks to “potentially exposed or susceptible subpopulations” identified by EPA and defined under TSCA to include infants, children, pregnant women, workers, or the elderly.¹¹ Another important takeaway for product manufacturers is to be vigilant in ensuring the record that is developed regarding “unreasonable risk” to such “potentially exposed or susceptible subpopulations” is accurate and avoids assembling misinformation that could be used in ways that could prove legally and commercially challenging for the manufacturer, as discussed more below.

Another aspect of interest to companies in a chemical’s value chain is that EPA, in conducting the risk evaluation required under TSCA Section 6, must describe whether “aggregate or sentinel exposures” to the chemical under the conditions of use were considered.¹² EPA recently proposed procedural rules for its implementation of the prioritization and risk evaluation steps,¹³ including outlining the opportunities for public notice and comment. Given the increased significance of downstream responsibilities under TSCA, such entities will need to understand EPA’s approach, both in the proposed rules and in implementing the prioritization and risk evaluation processes, to ensure that EPA’s approach faithfully elicits and interprets exposure and related record information, and to comment on the risk evaluation proposals that EPA prepares as are relevant to an entity’s particular product line.

⁹ TSCA Section 5(a)(5), 15 U.S.C. § 2604(a)(5).

¹⁰ TSCA Section 3(4), 15 U.S.C. § 2602(4).

¹¹ TSCA Section 3(12), 15 U.S.C. § 2602(12).

¹² TSCA Section 6(b)(4)(F)(ii), 15 U.S.C. § 2605(b)(4)(F)(ii).

¹³ 82 Fed. Reg. 4825 (Jan. 17, 2017) (prioritization); 82 Fed. Reg. 7562 (Jan. 19, 2017) (risk evaluation).

When EPA's risk evaluation determines that a chemical presents an "unreasonable risk," timely risk management is required. In regulating chemicals under TSCA Section 6(a), EPA has authority to prohibit or restrict a chemical's manufacture, processing, or distribution in commerce, both generally and for a particular use, "to the extent necessary so that the chemical no longer presents such risk."¹⁴ EPA can require that the chemical substance or mixture, or any article containing the chemical, be marked with or accompanied by clear and adequate warnings and instructions. EPA can also direct manufacturers and processors to give notice of the Section 6 unreasonable risk regulatory determination to distributors in commerce and to other "reasonably ascertainable" persons in possession of or exposed to the regulated substance.

In taking Section 6(a) action, EPA is required to meet the requirements under Section 6(c) that bring cost and benefits into consideration. Given that such regulations require notice and comment rulemaking, downstream entities along such a chemical's supply chain will need to follow closely and, as appropriate, comment on any such proposed action. The imposition of new warning and labeling requirements in response to a determination of "unreasonable risk" will resonate in other commercial and legal contexts in ways that could prove challenging, if not commercially damaging. Of note to downstream entities also are provisions allowing exemptions for replacement parts for certain complex durable and consumer goods and a requirement that EPA, in selecting control measures for an article containing the chemical, shall take such measures only to the extent necessary to address the identified risks from "exposure to the chemical" from the article.¹⁵

TSCA Section 8 (reporting and recordkeeping) includes several provisions of interest to downstream entities. These include requirements to review periodically the regulatory standard for small manufacturers and processors,¹⁶ to undertake a negotiated rulemaking to limit Section 8(a) reporting requirements for manufacturers of inorganic byproducts¹⁷ (such manufacture can occur during processing activities), to "reset" the TSCA Inventory,¹⁸ and to create an inventory of mercury and mercury compounds supply, use, and trade in the United States.¹⁹ We draw

¹⁴ TSCA Section 6(a), 15 U.S.C. § 2605(a). We note as an aside, a proposed Section 6 action triggers an export notification under TSCA Section 12(b) that applies to manufacturers and processors alike that export. As TSCA Section 6 has been little used in the past, and processors are less likely to be aware of this, this is another consequence of the new law of which practitioners should be aware.

¹⁵ TSCA Section 6(c)(2)(D) and (E), 15 U.S.C. § 2605(c)(2)(D) and (E).

¹⁶ TSCA Section 8(a)(3)(C), 15 U.S.C. § 2607(a)(3)(C). *See* 81 Fed. Reg. 90840 (Dec. 15, 2016) for more information.

¹⁷ TSCA Section 8(a)(6), 15 U.S.C. § 2607(a)(6). *See* 81 Fed. Reg. 90843 (Dec. 15, 2016).

¹⁸ TSCA Section 8(b)(4), 15 U.S.C. § 2607(b)(4). *See* the proposed Inventory reset rule at 82 Fed. Reg. 4255 (Jan. 13, 2017).

¹⁹ TSCA Section 8(b)(10), 15 U.S.C. § 2607(b)(10). Note that this requirement applies to all uses of mercury, including in drugs and pesticides, otherwise excluded from TSCA coverage.

attention to one critical aspect of the Inventory reset effort for downstream entities. As part of this effort, EPA will be determining the set of TSCA chemicals that were reported as manufactured, imported, or processed in the ten years preceding enactment of Lautenberg (these are known as “active chemicals”) versus those for which no such reports are received (“inactive chemicals”). This determination will be based on reporting and other information available to EPA. Downstream entities will need to ensure that any chemicals that they processed during this ten-year lookback period, including in periodic or infrequent batch processes, are accurately captured as active chemicals. While EPA notes that adding chemicals inadvertently overlooked during the reset period will be possible, there could be some, albeit modest, commercial disruption occasioned as a result.

A final point to note regarding new TSCA’s impacts on supply chain relationships is the fees provision at TSCA Section 26(b). EPA is in the process of developing a rulemaking to require payment of fees by manufacturers and processors of chemicals subject to certain requirements under Sections 4, 5, and 6.²⁰ While it is unclear at this time what the fee structure will be, it is widely expected that fees will be higher, and perhaps significantly so, than they are now. Anticipating these fees and preparing for them is critical.

B. Impact on Commercial Transactions

TSCA has long been underutilized or overlooked entirely as a critical component in due diligence investigations routinely conducted as part of a merger, acquisition, and related commercial transaction. For a variety of reasons, TSCA’s application has been associated largely with the chemical producer (including importer) community, and less so to downstream chemical processors, formulators, and/or end users of chemical substances manufacturing finished goods. This narrow interpretation of TSCA’s jurisdictional relevance is likely a product of old TSCA’s reach, which appeared to fall, by operation of law and/or practice and convention, disproportionately on the chemical producer community. As described above, new TSCA expands its reach and reinforces the law’s historic application to a broader range of industry stakeholders, most specifically including chemical processors and downstream article manufacturers and users of chemical substances. Here is a quick overview of changes in the law that will contribute to this new business reality.

New TSCA draws chemical processors much further into TSCA in at least two consequential ways. First, as noted above, EPA is now authorized to determine in several key regulatory contexts how a chemical is made, processed, used, and disposed of as a “condition of use.” This is a term new to TSCA and promises to have a profound impact on how EPA assesses new chemical notifications under TSCA Section 5, and how it prepares risk evaluations of existing chemicals under TSCA Section 6. As defined under TSCA, the term “conditions of use” means the circumstances, as determined by EPA, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. The term is used in TSCA Sections 5, 6, 9, 14, 18, 21, and 26, and noticeably not found in Sections 4 and 8.²¹

²⁰ EPA, Lautenberg: First Year Implementation Plan, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-2>.

²¹ Charles M. Auer and Lynn L. Bergeson, “Role of ‘Conditions of Use’ under Sections 5 and 6 of Amended Toxics Law,” *Bloomberg BNA Daily Env’t Rep.*

While EPA is just now beginning to interpret and apply this new concept to its regulatory decision-making activities, it is clear that the concept's application may yield differences of opinion. For example, in TSCA Section 5 new chemical notification contexts, EPA may be of the view that the term "reasonably foreseen" enables EPA to consider conditions of use not intended by the PMN submitter nor reasonably anticipated from the conditions of use that are described in the PMN. This expansive interpretation of "reasonably foreseen" within the concept of "conditions of use" could trigger the application of use restrictions and other commercial limitations that otherwise would not apply to the new chemical -- conditions that could materially limit the commercial use and application of the new chemical substance and in products that contain it.

Second, new TSCA requires that EPA review the TSCA Inventory and sort chemicals according to whether they are active or inactive in commerce. Chemicals listed on the TSCA Inventory (either the public portion or the confidential portion) are considered existing and may be manufactured and processed commercially without prior EPA notification, unless a specific listing dictates otherwise. Chemicals not listed on the TSCA Inventory and not otherwise exempt from notification are subject to prior EPA chemical notification requirements. New TSCA mandates that EPA reset the Inventory to obtain a clear line of sight on which chemicals are actually used in commerce.

EPA proposed Inventory reset requirements in January 2017²² and is required to issue final regulations in June 2017. The proposed rule applies specifically to chemical manufacturers, including importers, but invites chemical processors to participate in the reset activities on a voluntary basis. The proposed rule would allow processors to report chemicals to EPA no later than 360 days after EPA publishes the final rule in the *Federal Register*. According to EPA, the 360-day time period for the retrospective reporting for processors would allow processors to search EPA's publication of a first draft of the TSCA Inventory with active designations and draft inactive designations, based on retrospective reporting by manufacturers, and to report only those chemical substances not already reported. EPA notes that the first draft with active designations and draft inactive designations would not have the legal effect of designating any chemical substance as inactive. Under the proposed rule, processors would have the option not to report under TSCA Section 8(b)(4) and to continue processing until such time as when EPA actually designates a chemical substance as inactive. At that time, any further processing of the chemical substance, without prior notification to EPA, would be prohibited by TSCA Section 8(b)(5). Prior notification would allow EPA to add the chemical substance to the TSCA Inventory listing of an active substance. The operation of the Inventory reset will have important commercial consequences for processors whose chemicals are not properly captured by the reset process. Chemical stakeholders will need to be cautious in protecting their interest in navigating the reset period. In any due diligence investigation, care will need to be taken to ensure chemical products of interest in any transaction are properly aligned under TSCA Section 8 and related provisions.

Another area to note is the greatly enhanced opportunity for non-compliance generally with TSCA occasioned by EPA's more muscular implementation of old TSCA in new and creative

(Oct. 14, 2016), available at <http://www.lawbc.com/news/conditions-of-use-section-5-review-period-flexibility-and-other-resources>.

²² 82 Fed. Reg. 4255.

ways,²³ and of course EPA's greatly expanded authority under new TSCA. All the typical checklist items are important: are all chemicals listed on the TSCA Inventory or otherwise exempt; are Section 8 recordkeeping and reporting requirements current; have all import and export certifications been made properly and timely; and so forth. Commercial transactions, however, now require a much more disciplined and nuanced review to ensure many more TSCA provisions are addressed, including: are all SNUR limitations being properly communicated; are chemicals of commercial interest either already targeted for review as high-priority chemicals (and the legal and commercial implications of that review), or likely to be reviewed as part of the first tranche of chemicals targeted for risk evaluation; for new product development, will key new technologies pass the gauntlet of Section 5 notification requirements, and if so, at what commercial cost in terms of data development and/or capital retrofits on the production line; and so forth. A keen understanding of TSCA and how EPA's new authorities impact the commercialization of chemicals and the commercial products in which they are included is a must in commercial due diligence.

C. Impact on Product, Tort, and Business Liability

Opportunities for enhanced product, tort, and business liability are very much a part of the new chemical product landscape. There are several provisions in Lautenberg that could enhance a product's potential for product and/or tort liability and thus impact a business' ability to insure against that risk.

First, as discussed above, EPA has expanded authority to compel chemical testing under TSCA Section 4(a)(2) in reviewing chemical notifications under Section 5 or to perform risk evaluations under Section 6(b). EPA can also require the development of information needed to establish the priority of an existing chemical under Section 6(b). Lautenberg requires that, in using its new order authority under Section 4(a)(2), EPA must develop a statement identifying the need for the new information and how the information otherwise available to EPA was used to inform the decision to require new information. EPA must also explain the basis for requiring the use of vertebrate animal testing and, in the case of an order, explain why that approach was warranted.

EPA's new authority to compel chemical testing poses both opportunities and risks for the chemical community. On the opportunity side, chemical producers, processors, and others may wish to consider developing data on their own terms voluntarily if, upon review, the development of data may be inevitable in any given setting. This would provide for a more flexible testing approach and timetable, and avoid the optics of compelled testing to rejoin a regulatory assertion of data inadequacy to rebut a perceived risk. On the risk side, the development of toxicological and/or environmental effects data is by its very nature an open-ended proposition that may invite uncertain, equivocal, and/or unpredicted results that need to be managed in regulatory risk evaluation contexts and in more public settings that could invite adverse optics when viewed by stakeholders across the board. Any new adverse "positive" health or environmental result must be reported to EPA under TSCA Section 8(e) and will quickly become part of a narrative that could be the basis of product and/or tort liability. Even if no litigation results in a determination as to injury or loss, the transaction costs and potential for reputational damage can be consequential.

²³ See Lynn L. Bergeson, *Old Dogs and New Tricks: US EPA Gets Creative with TSCA*, *Environmental Quality Management*, Autumn (Fall) 2012, available at <http://www.lawbc.com/published-articles/tsca/L25/P50>.

Lautenberg plainly offers opportunities for new chemical innovators whose products are greener and/or bring performance benefits, and may also avoid some of the baggage associated with more conventional fossil fuel-based chemicals. These innovators, as noted above, will be challenged by EPA's current interpretation of the new TSCA Section 5 requirement that EPA make an affirmative finding as to the new chemical's likelihood of posing unreasonable risk. This interpretation is raising renewed "new chemical bias" and anti-innovation concerns, meaning that new chemicals are subject to commercialization challenges that prolong the commercial life of older, less environmentally friendly or lower performing existing chemicals, a development that over time will produce a less innovative domestic chemicals sector.

Second, other provisions in Lautenberg raise the stakes for inviting product liability. As noted, EPA is now required in the prioritization and risk evaluation stages to consider unreasonable risks to "potentially exposed or susceptible subpopulations" identified by EPA and defined in TSCA to include infants, children, pregnant women, workers, or the elderly.²⁴ Product manufacturers must be vigilant in ensuring the record that is developed in risk evaluations regarding "unreasonable risks" to "potentially exposed or susceptible subpopulations" is accurate to avoid creating a factual predicate for product and/or tort liability. Any government finding that a susceptible subpopulation is uniquely or disproportionately adversely impacted by exposure to a particular chemical substance under certain circumstances could easily be seized upon by commercial competitors, product detractors, citizen activists, the plaintiffs' bar, and jostled about in social media, print media, and other venues in ways that could be commercially and legally damaging.

Chemical testing results could also invite commercial and business challenges arising from downstream purchasers and users and their ability to qualify for certain uses, applications, and markets and, thus, trigger contractual provisions embedded in supply agreements and other commercial documents. If, for example, a test result is inconsistent with previous product profiles and disqualifies a product for a particular application or market segment, a supplier's ability to perform or a product's fitness for a particular use could be called into question, inviting collateral contractual and related business litigation risks.

D. Global Context to the TSCA Reforms and Comparisons to EU REACH

One of the drivers of the reform of TSCA was a perception that the previous system in the United States was not keeping pace with emerging global chemical management regimes, such as the EU's REACH and The Act on the Registration and Evaluation of Chemicals (K-REACH) in Korea. There has been pressure from some sectors to promulgate a regime that will compare favorably, and potentially increase alignment with those other regimes. It is interesting that Lautenberg, while adopting a number of features that are akin to the EU's REACH, continues to take a markedly different approach. On the one hand it has introduced a number of "REACH-like" features: increased emphasis and obligations on downstream users; a risk evaluation and restriction process for "high-priority" substances that have some definite parallels to REACH's "Substances of Very High Concern" (and distinct differences); and the fact that the initial screening and risk evaluation must be based solely on risk without regard to costs. The distinctions from EU REACH are also clear. Lautenberg does not require effectively a registration obligation for all chemicals in commerce. It also continues to take a more "risk" based approach, rather than the "hazard" focused approach of EU REACH. Lautenberg also

²⁴ TSCA Section 3(12), 15 U.S.C § 2602(12).

treats the transition of existing chemicals differently and does not look down the supply chain as aggressively as does EU REACH.

As practical experience under the new TSCA regime, including in particular the impacts discussed above, develops, there will inevitably be extended comparisons of its successes or failures with the approach taken in the EU. This will be the case not only in the United States, but also in the EU, where REACH remains a subject of ongoing scrutiny given its intense administrative burden and complexity. This is all the more so given Brexit, with the United Kingdom (UK), a major chemicals market having strong sectoral trading links with the United States, now having to determine the future shape of its own domestic regulatory regime. The prevailing assumption is that the UK will model its regime as closely as possible to the EU REACH regime to minimize trade barriers and maximize access to the EU market. In that case, the UK would be well advised to seek a harmonized regime with “grandfathering” of existing EU REACH registrations and “pass porting” of chemicals registered in the UK so that they are recognized in the EU, and vice versa, creating a *de facto* chemical regulation trading bloc. If the UK were able to agree to such a model (even if only on a transitional basis), it would go further than the existing harmonization approaches seen elsewhere in world, and be an important step forward in avoiding yet more regulatory burdens and uncertainty for industry. While this would not have direct implications for TSCA, because the TSCA regulatory and policy approach, as discussed above, is distinct from that in REACH, a full mutual recognition between the two regimes is difficult to conceive of at this point. Given the similarities, however, the presence of new TSCA alongside REACH may contribute to a trend of enhanced global cooperation and data sharing, both bilaterally and globally.

Such a post-Brexit outcome would require agreement between the UK and the EU, which in turn will be dependent upon various practical issues and political factors. There are accordingly some in the UK who believe that, if full mutual recognition is not achievable, the UK should take the opportunity to adopt a more flexible, open national model, for example, moving towards a more “risk” based approach (more akin to TSCA) rather than the “hazard” based focus of EU REACH. Furthermore, the realities of resource constraints within the UK may mean that, should it not be able to negotiate some form of (at least transitional) access to the existing EU systems and mutual recognition of standards, it may be forced to adopt a less administratively intense approach. Such a development may favor adoption by the UK of some TSCA-like features.

In short, TSCA reforms are key to not only those based in the United States, but are also being avidly scrutinized by our colleagues elsewhere in the world, particularly in the EU and the UK.

Conclusion

This paper introduces and briefly discusses a handful of the many potential commercial, regulatory, and litigation consequences of Lautenberg’s enactment. Our goal is to help practitioners appreciate that new TSCA is one of the most consequential legislative acts affecting the chemical community and the domestic manufacturing sector at large. For all the reasons noted above, and the many more that space constraints do not allow, Section members and other practitioners should follow closely the UK’s Brexit odyssey, as well as EPA’s implementation of TSCA and engage robustly to ensure TSCA achieves the laudable goals Congress and other stakeholders worked hard to realize when drafting the law.