Commentary

TSCA Reform: Is It Still in Our Future?

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Introduction

Toxic Substances Control Act (TSCA) reform has been a ''work in progress'' for years. House and Senate passage in 2015 of substantive TSCA reform measures considerably improved the odds that Congress would enact TSCA-reform legislation in 2016. Recent events suggest otherwise, however, and as of this writing in mid-March the fate of TSCA reform remains decidedly uncertain. Momentum has dissipated as a dithering House has been slow to engage with Senate counterparts to reconcile the different approaches contemplated under each bill. The surprisingly harsh Republican response to Associate Supreme Court Justice Scalia's untimely demise has hardened the partisan divide that threatens to tank Congressional action on any important initiative, let alone legislation as significant and potentially divisive as TSCA reform. It is hoped that cooler heads will prevail and leverage the hard work and momentum that has brought us to this momentous place in history. This Commentary provides an update on the current state of TSCA reform efforts.

Background

Before focusing on the more micro aspects of pending TSCA reform efforts, it may be useful to step back and assess TSCA more generally. Enacted almost 40 years ago in October of 1976, Title I of TSCA (the core chemical provisions) was intended to protect human health and the environment from exposure to potentially harmful chemical substances and mixtures. ''Chemical substance'' is defined generously under TSCA, and includes microorganisms and their DNA and DNA molecules. The authority provided under TSCA to the US Environmental Protection Agency (EPA), which is tasked with its implementation, is equally broad. EPA is authorized to require manufacturers, including importers, and processors to test existing chemical substances and mixtures for their effects on human health or the environment in order to assess and potentially regulate chemical substances identified as ''new'' as a condition precedent to commercialization. It also has the authority to require manufacturers and processors to maintain records and submit information to EPA; to regulate imports and exports of chemical substances; and to inspect facilities, impose stiff penalties, and seize non-complaint chemicals.

From the outset, EPA's implementation of TSCA ran into problems. Despite the generous authority given to EPA under TSCA, the law's lack of a specific mandate, clear priorities, and implementation deadlines posed considerable challenges to EPA. Many believe that TSCA's greatest failing, and the deficit that has perhaps most undermined the public's confidence in EPA's ability to assure chemical safety, is EPA's ineffective deployment of TSCA authority to regulate ''existing'' chemical substances believed to pose risks to human health and the environment. The seminal case overturning the TSCA asbestos ban, *Corrosion Proof Fittings v. EPA,* 947 F.2d 1201 (5th Cir. 1991), is famously cited as proof positive that TSCA is hopelessly ineffective. After all, detractors ask, if you can't ban asbestos under TSCA, what can you ban?

While this may be TSCA's greatest failing, it is certainly not TSCA's only failing. For a variety of reasons, EPA has struggled to compel the development of data and information on existing chemicals under TSCA Section 4, and has all but abandoned issuing testing orders mandating data development, settling instead for negotiated Enforceable Consent Agreements (ECA). ECAs give chemical manufacturers considerably more latitude in deciding what will be tested, how, and by when. Similarly, while EPA has done a good job of protecting Confidential Business Information (CBI) from disclosure, many believe the Agency has been too lax in allowing entities to assert and maintain CBI claims over information undeserving of the protection this legend affords.

These and many other perceived TSCA failings were drawn into sharp contrast in 2007 with the enactment of the European Union's TSCA counterpart, the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation. This newer, more robust chemical management program is perceived by many to be considerably tougher than TSCA. It places the burden of demonstrating chemical safety on chemical manufacturers and not on the government to prove the opposite, as is the case under TSCA. REACH regulates all chemicals regardless of their ''new'' or ''existing'' status. According to many, REACH does a lot of things better than TSCA, and its approach to chemical management is thought by some to be a useful template for TSCA reform in the US.

Given the passage of time, the enactment and evolution of REACH and REACH-like programs in Europe, Asia, and beyond, and the rapid proliferation of state and municipal chemical-specific and ''green chemistry'' laws that have filled the void created by an ineffective federal law, demand for TSCA reform reached a crescendo in 2014. Building upon Senator Frank R. Lautenberg's (D-NJ) tireless efforts to modernize TSCA, Senator Tom Udall (D-NM) and then ranking member Senator David Vitter (R-LA) endorsed a compromise bill in 2014—in no small part to honor Senator Lautenberg's chemical

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reform legacy after he passed away in 2013. Unlike earlier bills introduced over many years, the draft compromise bill that emerged late in the previous Congressional session showed significant progress in attempting to address the concerns of most of the identified TSCA stakeholders. The most outstanding issue, and the largest hurdle in coming to agreement among the parties, was the issue of state preemption. During TSCA's long lifespan, preemption issues have never loomed large, in part due to TSCA's spotty implementation record. As noted, however, the proliferation of robust state chemical programs, including California's Proposition 65, the California Safer Consumer Product Regulations, and many other similar state legislative initiatives of more recent origins have made preemption a hot-button issue—especially among the California delegation, which includes influential members such as Senator Barbara Boxer (D-CA) and Representative Nancy Pelosi (D-CA).

Even with the change in party control of the Senate, which saw Senator Jim Inhofe (R-OK) take over the Senate Environment and Public Works Committee, work continued towards a successful compromise. The House approved, on June 23, 2015, a compromise bill (H.R. 2576) with a surprisingly large bipartisan vote of 398-1. Very late in the year, on December 17, 2015, a new version of the Senate's compromise bill (S. 697) was unanimously approved by the Senate.

Senate and House Versions of TSCA Reform

The House and Senate versions of TSCA reform legislation are quite different. S. 697, as passed by the Senate, is over 200 pages long and quite detailed. H.R. 2576 is considerably shorter (46 pages), and plainly less detailed. The Senate bill recasts most TSCA provisions, whereas the House version offers targeted solutions to selected issues. The contrast between the versions is best seen in reviewing the solutions that each offers to address some of TSCA's more celebrated deficits.

On chemical testing and prioritization, H.R. 2576 broadens EPA's testing authority, but maintains the current ''findings'' requirement. Except with respect to Persistent, Bioaccumulative, and Toxic (PBT) chemicals, the bill is silent on prioritization. H.R. 2576 allows manufactures to request and pay for EPA assessments. By contrast, the Senate bill significantly increases EPA's testing authority, requires the development and implementation of a risk-based prioritization process, and allows for manufacturers and processors to request and pay for EPA review.

The House bill makes no changes with regard to ''new'' chemicals. The Senate bill requires an EPA decision and, if needed, controls to ensure the safety standard is ''likely to be met.'' It applies additional requirements for the management of PBTs, and requires Significant New Use Rule (SNUR) action on all regulated new chemicals unless EPA ''explains why not.''

Both the House and Senate versions remove the much reviled ''least burdensome'' requirement pertinent to the regulation of existing chemicals. Both bills have schedules for decisions but apply slightly different regulatory standards. Both bills prohibit the inclusion of ''economic'' considerations in risk-based safety assessments, but apply economic considerations to risk management decisions. Both bills apply additional risk management requirements to PBTs.

The House bill proposes no changes regarding information gathering. The Senate bill has several new requirements relative to TSCA; EPA must promptly promulgate reporting rules to obtain ''necessary'' information from both manufacturers and processors; it applies a chemical Inventory ''reset'' process to identify chemicals that are still active in commerce; and it requires EPA to maintain ''active'' and ''inactive'' listings. Shifts to the active list require that EPA be notified. The Senate bill maintains use of several TSCA Inventory chemical nomenclatures; companies must reaffirm and substantiate any existing CBI claims for chemical identity; and EPA must review and deliberate upon all such claims.

The CBI measures are also different. The Senate bill revises the current scheme. The House bill generally retains the TSCA approach. Both make data more public, require substantiation, and impose time limits on CBI claims. The House bill more clearly protects ''molecular structure,'' i.e., chemical identity information.

On the important topic of preemption, the House bill allows preemption once EPA action is final. The Senate bill allows preemption once EPA has issued an assessment plan. The most controversial difference between the two bills is determining when preemption should begin.

Both bills contain deadlines and authorize additional resources for EPA. The House bill allows for relatively less fees, while the Senate bill allows more fees, with a total cap of $25 million. Both bills have numerous new terms and challenging deadlines for rulemaking.

As of this writing in mid-March, it remains unclear how, or even whether, the bills will be reconciled. Representative John Shimkus (R-IL), Chair of the Subcommittee on Environment and the Economy in the House, noted in early February that he expected lawmakers would establish a formal Conference Committee to address bill differences. Neither a formal Conference Committee has been established, nor has a less formal reconciliation process been identified to date.

More recently, concern has been expressed by the Senate over the House's failure to engage more expeditiously on TSCA issues generally. All of this predated Associate Supreme Court Justice Scalia's unexpected death on February 13, 2016, and the bitter partisan rancor that quickly developed since then. While it remains unclear how much of an impact the Supreme Court nomination process might have on Congress, it is reasonable to assume that this new wrinkle is more hurtful than helpful, and that whatever bipartisan goodwill existed late last year has all but dissipated.

So What Is Next?

Stakeholders may understandably be puzzled as to what happens if TSCA reform does not happen in 2016. The short answer is life as we know it will continue and TSCA reform legislation may well be introduced in the next legislative session. The election results will determine whether stakeholders will pick up where they left off in 2016 or instead hope for more, one way or the other, depending upon whether the balance of power shifts in the Senate and the Democrats prevail in keeping the White House.

Regardless of TSCA reform, another initiative is ongoing in 2016 that could influence TSCA reform measures next year

should election year politics stymie current efforts and improve government oversight of products of biotechnology. On July 2, 2015, the White House Office of Science and Technology Policy (OSTP), the Office of Management and Budget (OMB), the US Trade Representative, and the Council on Environmental Quality issued a memorandum directing EPA, the US Food and Drug Administration (FDA), and the US Department of Agriculture (USDA) to update and modernize the Coordinated Framework for the Regulation of Biotechnology.

Ensuring public confidence in the federal oversight of products of biotechnology is a key goal of these efforts and a ''must have'' if biotechnology is to succeed. The effort has three key components. First, the Administration will update the Coordinated Framework, after accepting public comment, to clarify the roles and responsibilities of the federal agencies that now regulate the products of biotechnology: EPA, FDA, and USDA. It is hoped that this process will clarify which biotechnology product areas are within the authority and responsibility of each Agency and better outline how the Agencies can work together to regulate products that fall within the respective jurisdictional scope of each Agency. On October 30, 2015, under the auspices of the National Science and Technology Council, FDA, EPA, USDA, and OSTP convened the first of three public meetings to discuss the OSTP memorandum. The second public engagement session was held in Dallas, Texas in early March, and the third took place at the University of California, Davis in late March. The Administration hopes to issue a draft of the updated Coordinated Framework this spring and seek public comment on it.

Second, the Administration will commission an external, independent analysis of the future landscape of biotechnology products. The Administration has asked that the National Academies of Sciences, Engineering, and Medicine (The Academies) conduct such an analysis. Candidates for inclusion on The Academies' panel were solicited in January 2016.

Third, the Administration will formulate a long-term strategy to ensure that the federal regulatory system is equipped to efficiently assess the risks, if any, associated with future products of biotechnology. This component is essential and holds considerable promise in developing a game plan for achieving success.

The Obama Administration's efforts to update the Coordinated Framework, to develop a long-term strategy, and to commission an independent analysis of the future landscape of the products of biotechnology are important, laudable, and essential. While the first component of the initiative will be completed by the end of the current Administration, the other two efforts will not. It will be essential for stakeholders to ensure that the new Administration continues and builds upon this initiative to ensure that the federal oversight of the products of biotechnology is efficiently executed and sufficiently transparent to invite broad public support.

In a perfect world, Congress will pass TSCA reform legislation this year, President Obama will sign it into law, and the next Administration will faithfully carry on the efforts now underway to modernize the Coordinated Framework. These efforts will help ensure that the federal oversight of products of biotechnology works efficiently and transparently to facilitate the commercialization of innovative new technologies that make the world a better place.

While time is running out on TSCA reform, industry can do its part and urge Congress to stay the course and get the job done during this Congress. Even if it does not happen in this Congress, biotechnology stakeholders should work hard to ensure efforts now underway to modernize the Coordinated Framework continue in the next Administration. These efforts should build upon the excellent work that will jump-start a new Administration's contributions to improve federal oversight of products of biotechnology and, thus, ensure the public's confidence in the federal oversight system.

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