In a World Without Congressional Reform: A New (Old) Role for EPA under TSCA Section 6

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Congressional reform of the Toxic Substances Control Act (TSCA)—the nation's chemical management statute—has stalled. Results from last November's midterm elections have revived national reform efforts, but because Republicans still need sufficient support across the aisle to override a presidential veto, significant work remains before TSCA legislative reform is possible. In the meantime, Jim Jones, the assistant administrator for the U.S. Environmental Protection agency's (EPA) Office of Chemical Safety and Pollution Prevention, has indicated the agency intends to use all available tools under TSCA to regulate new and existing chemical substances, including manufacturing and use restrictions under section 6. Many stakeholders may be wary of EPA's intent to rely on section 6 and skeptical in light of the Fifth Circuit's rejection of the agency's attempt to ban asbestos under section 6, as litigated in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th 1991). However, *Corrosion Proof Fittings* should not be read so broadly as to negate section 6, and in fact, there may be reasons to support a narrow reading of what has frequently been couched as the death knell for EPA's authority to regulate existing chemicals under this section.

All interested parties have acknowledged TSCA's limitations, particularly for existing chemicals. Some of these limits were highlighted in *Corrosion Proof Fittings* in which EPA failed to convince the Fifth Circuit that asbestos should be banned under section 6. And, in practice, EPA essentially has conceded defeat under section 6, having regulated only one use of one existing substance in the twenty-plus years since *Corrosion Proof Fittings*. Yet, the current fractured chemical regulatory framework driven by states, retailers, and consumers suggests that there may be benefits to the chemical sector if EPA returns to section 6. Specifically, a reasoned and measured use of section 6, coupled with other measures under TSCA, would put EPA back in the driver's seat for chemical regulation. With a national voice driving chemical regulation, even without preemption, states, retailers, and consumers would have fewer incentives to fill the perceived regulatory gap.

While issues have been identified with both the new and existing chemicals management programs under TSCA, the majority of stakeholders agree the most pressing area for TSCA modernization is the existing chemicals program. When TSCA was passed in 1976, chemicals that were already in commerce were not required to go through any assessment to determine whether their manufacture, processing, use, or disposal would cause an unreasonable risk of injury to health or the environment. Although EPA does have the authority to restrict the use of or otherwise regulate existing chemicals under section 6(a), there are numerous evidentiary hurdles EPA must satisfy before taking such action. As a result, in almost forty years, other than the total ban on polychlorinated biphenyls (PCBs) that was mandated by Congress under TSCA Section 6(e), the agency has banned certain uses of only four existing chemicals (hexavalent chromium, asbestos, dioxin, and fully halogenated chlorofluoroalkanes), has required manufacturers to notify EPA of "significant new uses" prior to the use of an additional 160 existing chemicals, and has compelled the development of toxicity and other data for only 200 substances, in comparison to the more than 84,000 substances in commerce. Many stakeholders have cited the difficult evidentiary hurdle EPA must overcome to regulate existing chemical substances as the main reason for the limited number of existing chemical substances EPA has reviewed.

To regulate a substance under section 6, EPA must find there is a reasonable basis to conclude that a chemical's manufacture, processing, distribution, use, or disposal presents an unreasonable risk to health or the environment. EPA also must demonstrate that it will regulate the substance in the least burdensome way. The various options available to EPA when selecting the least burdensome regulatory action under TSCA Section 6(a) include: (i) banning or restricting the manufacture, processing, or distribution of the chemicals; (ii) limiting the use, amount, or concentration of the chemicals; (iii) adding warnings and instructions; (iv) monitoring/testing and retaining process records; (v) prohibiting or regulating the commercial use of the substance; (vi) prohibiting or regulating the disposal of the substance; and (vii) providing notices of risk of injury and recalling products, if needed. Further, EPA must document its analysis, including (i) the effects on health and the magnitude of the exposure on humans; (ii) the effects on the environment and the magnitude of the exposure of the environment; (iii) the benefits of such substance for various uses and the availability of substitutes for such uses, and (iv) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small businesses, technological innovation, the environment, and public health. EPA's attempt to impose a broad-based

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ban on all commercial uses of asbestos, and the Fifth Circuit's rejection of that attempt, highlight the difficult road EPA must travel to restrict an existing substance under section 6(a).

In 1987, after reviewing more than 100 studies regarding the health and environmental impacts of asbestos and conducting several public meetings, EPA concluded that exposure to asbestos presented an unreasonable risk of injury to human health at any level. EPA then proposed four options for regulating asbestos including: (i) a mixed ban and phase-out of asbestos use; (ii) a two-stage ban depending on usage; (iii) a three-stage ban leading to a total ban; and (iv) the labeling of asbestos products. EPA continued to collect data for two years before promulgating a final rule that banned asbestos in almost all commercial products via a three-stage process. Industry challenged that final rule, and the Fifth Circuit overturned the majority of EPA's ban.

As EPA's efforts under TSCA have languished, environmental groups and consumer advocates have sought alternate approaches to restrict chemical substances that they believe harm human health or the environment.

The Fifth Circuit first found that EPA did not consider all evidence, and second, found that EPA did not promulgate the least burdensome regulation to protect health and the environment adequately; to the contrary, EPA selected the most burdensome and harshest option. The court reasoned that "Congress did not enact TSCA as a zero-risk statute . . . EPA, rather, was required to consider both alternatives to a ban and the costs of any proposed actions and to 'carry out [TSCA] in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.'" *Corrosion Proof Fittings*, 947 F.2d at 1215. Therefore, according to the court, TSCA required EPA to determine some level of exposure that would provide adequate protection and then select the least burdensome method of achieving that level of exposure, taking into account both the costs and benefits of the chosen method. EPA's failure to consider alternative options and fully develop the costs and benefits of substitutes for asbestos (or the lack of substitutes) in various industries led the court to reject the majority of EPA's ban. Based on the reasoning that any uses that had either ceased or not yet begun did not have adequate costs to outweigh the benefits of regulation, EPA's regulation of asbestos under TSCA applies only to asbestos-containing products that were no longer in commerce at the time of the final rule—corrugated paper, rollboard, commercial paper, specialty paper, and flooring felt—and new uses of asbestos.

Corrosion Proof Fittings demonstrates the difficulty EPA faces in regulating existing chemicals under TSCA; since the court's decision in 1991, EPA has exercised its authority to ban or limit the production or use of an existing chemical only once (for hexavalent chromium), and only for one, limited use (commercial cooling towers). As a result of this perceived regulatory void, numerous stakeholders have lost faith in TSCA.

As EPA's efforts under TSCA have languished, environmental groups and consumer advocates have sought alternate approaches to restrict chemical substances that they believe harm human health or the environment. These efforts include lobbying state legislatures to restrict or ban chemical substances with perceived impacts to human health or the environment and go so far as exerting pressure on Walmart and other retailers to deselect these chemicals. In turn, the chemical sector has recognized the need for modernization of TSCA to regain consumer confidence in the industry's products and to return to a national, exposure-based program for chemical regulation, rather than a fractionalized approach based on limited data sets or simply misinformation and consumer mistrust. No other chemical substance illustrates these pressures for reform better than bisphenol-A (BPA).

BPA is considered a chemical building block used to form plastics and resins that are turned into a wide range of consumer products such as food and drink containers (including types of baby bottles), medical/dental equipment, sports safety equipment, electronics, and even vehicles. Plastic products built from BPA are lightweight yet tough and clear while being heat and electrical resistant. But certain limited studies have been cited for the proposition that BPA leaching out of plastic products in low levels, particularly in food and drink container linings and dental devices, can cause endocrine-disrupting human health effects.

In 2010, EPA developed a chemical action plan for BPA, which indicated the agency's intent to evaluate studies that had been performed to determine whether it should issue a rule restricting significant new uses of BPA under section 5 and its plan to issue a rule under section 4 to require environmental fate testing of BPA. Despite having developed the chemical action plan more than four years ago, EPA has yet to promulgate any final regulations with regard to BPA. In fact, the only final action the agency has taken is to issue an alternatives assessment for one limited use of BPA—in thermal paper—under its voluntary Design for the Environment program (DfE), which would not satisfy TSCA Section 6's unreasonable risk standard or any other exposure-based risk assessment standard. The agency's regulation of BPA appears to have stalled in part because of the lack of scientific consensus as to whether there are health and environmental risks that justify restricting the use of BPA. EPA's BPA Action Plan Summary www.epa.gov/oppt/existingchemicals/pubs/actionplans/bpa.html. Ironically, however, this regulatory inaction due to a lack of scientific data and consensus has led to a wave of state and local BPA bans and consumer pressure to deselect products manufactured with BPA to fill the presumed regulatory gap left by EPA's inaction.

In the past five years, multiple states, the District of Columbia, and even local governments have restricted to some degree the manufacture, sale, and use of BPA. For example, Connecticut banned the manufacture, sale, or distribution of reusable food or beverage containers that contain BPA as well as the manufacture, sale, or distribution of thermal receipt paper or cash register receipt paper containing BPA. Other states such as California, Vermont, and Maryland also require the use of alternatives to BPA in consumer products

and likewise have banned the use of BPA in food or beverage containers to some degree. Maine designated BPA as a priority chemical that requires reporting by manufacturers and allows a sales ban on products. Delaware, Illinois, Massachusetts, Minnesota, New York, Washington, Wisconsin, District of Columbia, in various degrees, prohibit the sale of bottles or cups containing BPA if those containers are designed for use by children or if the container will contain food or beverage. Local governments like Chicago and Suffolk County, New York, banned the sale of baby bottles containing BPA as early as 2009. These BPA-focused efforts highlight the fractionalization of chemical regulation in the absence of EPA action, which puts pressure on the chemical industry to manufacture products that will meet the most stringent requirements. Moreover, as more states jump into the mix, chemical manufacturers must play on an ever-changing field of regulation, which is unworkable. Even more concerning to the chemical sector, however, is the California-led trend toward more broad-based state chemical regulatory frameworks, which are beginning to take the place of EPA as the arbiter of chemical risk assessments.

California's Safer Consumer Products regulations are setting national chemical regulatory policy and will continue to do so unless EPA can regain its primary role to assess and regulate chemical substances.

California enacted its Green Chemistry Law in 2008. www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1851-1900/ab_1879_bill_20080929_chaptered.html. The law requires the Department of Toxic Substances Control (DTSC) to issue regulations to identify, prioritize, and evaluate chemicals of concern in consumer products and then to provide a means for substituting those chemicals with "safer" alternatives. DTSC then issued the Safer Consumer Products regulations to implement the Green Chemistry Law, which took effect on October 1, 2013. By default, California's Safer Consumer Products regulations are setting national chemical regulatory policy and will continue to do so unless EPA can regain its primary role to assess and regulate chemical substances.

Even retail companies are substituting their influence for EPA's judgment. Retailers have an immense amount of influence over product—and therefore chemical—selection and deselection, as the primary interface between product manufacturers and customers. As consumer demand for "safer" chemicals has exponentially increased over the last decade, retailers have similarly increased corresponding incentives to push their suppliers and manufacturers toward these "safer" chemicals. To this end, Wal-Mart issued a Sustainable Chemistry in Consumables policy in March 2014, which seeks to phase out "hazardous" chemicals from consumer products. The policy covers consumer products such as household cleaners and detergents, health and beauty care, baby care, pet supplies, and household paper products. Notably, Walmart relies on a number of lists of "priority chemicals" to develop its list of chemicals that should be phased out, and this list of lists cites to several state regulatory frameworks, including Washington, Maine, Minnesota, and California. Notably absent is any reference to chemicals identified by EPA under TSCA. As the statute under which EPA is assigned the responsibility to evaluate potential health and environmental impacts of chemical substances, the absence of any reference to TSCA on this list is almost laughable.

A New (Old) Role for EPA

In an effort to reassert its authority to drive national chemical regulatory policy, EPA has implemented several programs over the last fifteen years. Three programs in particular have been the focus of EPA's attention, including the High Production Volume (HPV) Challenge Program, the Design for the Environment (DfE) Program, and, most recently, its development and implementation of the TSCA Work Plan. EPA's call to action began in 1998 with the issuance of the results of its Chemical Hazard Data Availability Study for HPV chemicals (those produced or imported annually in quantities of 1 million pounds or more). EPA's study found that hundreds of HPV chemicals had no basic toxicity testing data available and, in collaboration with industry and professional organizations, launched the HPV Challenge Program. The program encouraged companies voluntarily to provide basic hazard information detailing health and environmental effects for certain HPV chemicals. Since the launch of the program, a large amount of data has been collected for more than 2,000 chemicals.

Whereas the HPV program focused on chemicals with a higher likelihood of exposure due to their relative production levels, EPA also has developed a hazard-based voluntary program in partnership with industry, environmental groups, and academia under the DfE Program. The goal of DfE is to reduce risk to people and the environment by identifying alternative chemicals and technologies in specific industries. Some results of the DfE Program include the sharing of best practices, the identification of safer alternative chemicals, and the tagging (with a DfE label) of products that have been determined to be "safer" for human health and the environment. However, the DfE Program has been criticized by industry stakeholders for focusing solely on the hazard of a given substance without any consideration of the potential exposure to humans or the environment.

EPA's efforts to maintain a central role in protecting health and the environment from the risks of and exposure to chemical substances through the HPV and DfE Programs can only go so far, however. Both of these programs are voluntary, and each relies primarily on only one aspect of a robust risk assessment: exposure or hazard. Without evaluating the hazard of and potential for exposure to a given chemical, EPA's DfE program in particular unnecessarily disincentivizes innovation and relies too heavily on overly conservative, hazard-based assessments without taking into account the likelihood of exposure. As a result of the limitations of these voluntary programs, increasing discontent by consumers, state-level political

measures, and continuous delays in congressional TSCA reform efforts, EPA has recognized a need to return to TSCA's roots.

Beginning in 2012, EPA kicked off a new initiative, which the agency deemed its "TSCA Work Plan." Under this plan, EPA has identified eighty-three chemicals for which the agency intends to prioritize further assessment to support exercising its existing authority under various sections of TSCA, including section 6. EPA developed the list of eighty-three substances by reviewing existing data that indicated these substances pose possible risks to human health or the environment. These assessments focus on those uses of the chemical with significant potential for exposure to humans and the environment, and assess both the potential hazards associated with the chemical and the likelihood of exposure to the chemical.

The TCE risk assessment provides a comprehensive assessment of the scientific data regarding potential health and environmental impacts of TCE in its most likely routes of exposure for its most common uses.

The agency recently released its first round of final risk assessments under its Work Plan, for methylene chloride, antimony trioxide, tricholorethylene (TCE), and 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[γ]-2-benzopyran (HHCB). These final risk assessments demonstrate a promising first step toward regaining consumers' confidence in the agency's capacity to assess and respond adequately to potential human health or environmental risks. They also demonstrate the potential benefits and drawbacks of such an approach for the chemical industry.

On June 25, 2014, EPA released a final risk assessment for TCE that identifies health risks to consumers using spray aerosol degreasers and spray fixatives and to workers when TCE is used as a degreaser in small commercial shops and as a stain removing agent in dry cleaning. The report concludes that long-term exposure to TCE can cause cancer and other health issues, and recommends that workers take serious precautions if they must use TCE. EPA has acknowledged that it chose TCE for its first risk assessment in nearly three decades because the agency has a significant amount of data on the substance, thereby eliminating the need for EPA to obtain that data either under section 4 or convince parties to submit it voluntarily. Yet, despite the amount of existing data, it still required a two-year effort for EPA to issue the TCE risk assessment. Notably, by focusing on limited uses, exposures, and risks of TCE, EPA appears to be testing the waters for a more measured, narrow use of section 6 to avoid the pitfalls of *Corrosion Proof Fittings*.

While the final risk assessment does not directly restrict TCE, it will serve as the backbone of any subsequent actions EPA may take under TSCA to regulate TCE, including establishing best practices and phasing out certain uses under section 6. Just as significantly, however, the TCE risk assessment provides a comprehensive assessment of the scientific data regarding potential health and environmental impacts of TCE in its most likely routes of exposure for its most common uses. This type of assessment is exactly what has been missing under TSCA for existing chemical substances for more than two decades. As a result, it should be considered a weighty resource for states and non-governmental entities who are interested in assessing the risk of and regulating TCE. And, while stakeholders in the chemical sector may not agree with the conclusions of the TCE risk assessment, this approach provides a central, one-stop opportunity for interested industry stakeholders to participate in the process and provide input to the agency, which can then be touted by industry as the basis for a de facto nationwide standard for regulation of TCE.

An even more direct illustration of the potential benefits of EPA's return to section 6 are the risk assessments that EPA recently released for antimony trioxide and HHCB. On August 28, 2014, EPA issued final risk assessments for these substances that concluded, based on available exposure and hazard data, antimony trioxide does not present a risk to human health or the environment as a synergist in halogenated flame retardants and HHCB does not present a risk to human health or the environment as a fragrance ingredient in commercial and consumer products. Put another way, these risk assessments demonstrate that these substances should not be regulated under TSCA Section 6, or even under section 4, which would require additional testing. Even if EPA's issuance of these risk assessments does not preempt state regulation of these substances—which is far beyond the scope of this article—they provide a level of certainty to the chemical sector that these substances, when used in the manner described in the risk assessments, should be a low priority for any state or nongovernmental entity attention. In today's world, this level of regulatory certainty may be as much as the chemical industry can hope to attain.

There is no doubt that there are drawbacks to EPA's use of section 6 to restrict chemical substances, through development of and reliance on risk assessments that the agency needs to support its conclusions. It is cumbersome, time consuming, and costly, and moreover, may not provide the result that interested stakeholders hope for or expect. However, in the current regulatory climate, unless and until congressional reform occurs and with ever-increasing fractionalization of chemical regulation and consumer pressures, section 6 of TSCA may be the U.S. chemical sector's best bet for survival in the twenty-first century.