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# TSCA Reform, Preemption, and Manufacturer Influence: Does the New Law Hang States Out to Dry?

David R. Sheaffer

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*TSCA Reform, Preemption, and Manufacturer Influence: Does the  
New Law Hang States Out to Dry?*

By: David R. Sheaffer

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Professor Noga Morag-Levine  
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# *TSCA Reform, Preemption, and Manufacturer Influence: Does the New Law Hang States Out to Dry?*

*David R. Sheaffer*

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## INTRODUCTION

Many of the luxuries of modern life would not exist but for explosive growth and innovation in chemical development over the last two centuries.<sup>1</sup> Advances in chemistry modernized medicine, increased crop yields, slowed the spoilage of food, and facilitated low cost manufacturing using new polymer compounds.<sup>2</sup> And according to the American Chemistry Council (ACC), in 2013 American chemical production produced 19% of the world's total output, making it a \$689 billion industry that directly impacts over 96% of manufactured goods across the globe.<sup>3</sup>

However, even beneficial chemical substances and products containing them may pose public health risks. The Toxic Substances Control Act (TSCA), first enacted in 1976, was intended to facilitate the sharing of information about these substances and the promulgation of comprehensive safety regulations.<sup>4</sup> However, regulating existing chemicals under TSCA proved unworkable after 1991,<sup>5</sup> and states stepped in to fill the regulatory void.<sup>6</sup> The patchwork of state regulations that arose and evolving regulations in Europe<sup>7</sup> and Asia<sup>8</sup> mean that manufacturers are

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<sup>1</sup> Lynn L. Bergeson, *Hope Is Restored In Finally Modernizing TSCA*, LAW360, June 19, 2013, <https://www.law360.com/articles/449338/hope-is-restored-in-finally-modernizing-tsca>; *Five Chemistry Inventions That Enabled the Modern World*, THE CONVERSATION, June 1, 2015, <https://theconversation.com/five-chemistry-inventions-that-enabled-the-modern-world-42452>

<sup>2</sup> *Five Chemistry*, *supra* note 1.

<sup>3</sup> Bergeson, *supra* note 1.

<sup>4</sup> Toxic Substances Control Act (TSCA), Pub. L. No. 94-469, 90 Stat 2003 § 2 (codified at 15 U.S.C. § 2601(a)) (2012).

<sup>5</sup> Not a single existing substance has been regulated under § 6 of TSCA since the 1991 *Corrosion Proof Fittings* case, and under the preexisting TSCA, “the EPA ha[d] tested only 200 chemicals and regulated five.” Andy Szal, *EPA Official Takes Issue With Chemical Reform Bill*, MANUFACTURING.NET, April 16, 2015, [https://www.manufacturing.net/news/2015/04/epa-official-takes-issue-chemical-reform-bill?\\_\\_hstc=17104102.197963abef1f120924294a1530410a59d.1493654791648.1493752901913.1493756433621.3&\\_\\_hssc=17104102.9.1493756433621&\\_\\_hsfp=20068296](https://www.manufacturing.net/news/2015/04/epa-official-takes-issue-chemical-reform-bill?__hstc=17104102.197963abef1f120924294a1530410a59d.1493654791648.1493752901913.1493756433621.3&__hssc=17104102.9.1493756433621&__hsfp=20068296) (last visited May 5, 2017).

<sup>6</sup> See NCSL Policy Update: State Statutes on Chemical Safety. <http://www.ncsl.org/research/environment-and-natural-resources/ncsl-policy-update-state-statutes-on-chemical-safety.aspx> (last visited May 5, 2017).

<sup>7</sup> See, e.g., Isabelle Laborde, *Reach: The New European Union Chemicals Regulations*, NAT. RESOURCES & ENV'T, WINTER 2009, at 63-65 (outlining the EU's REACH initiative); European Chemicals Agency, *Understanding REACH*, <https://echa.europa.eu/regulations/reach/understanding-reach> (last visited May 3, 2017).

operating in an increasingly diverse regulatory environment. Additionally, major retailers have begun pulling products containing toxic ingredients, such as endocrine disruptors, in response to consumer advocacy.<sup>9</sup> Changes domestically and abroad led the chemical industry to conclude that it was time to push for modernization of America's chemical laws.<sup>10</sup> This is the background upon which the bipartisan and multi-faceted TSCA reform coalition was conceived.

Reforming TSCA has been a long time coming, and its achievement in 2016 is one of the most significant developments in environmental laws since the Clean Air Act amendments in 1994. The Frank Lautenberg Chemical Safety for the 21st Century Act (FL21) was the product of years of lobbying, research, and painstaking negotiations.<sup>11</sup> There are several overarching

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<sup>8</sup> Regulations and Chemical Lists Continue to Appear in Asia, CHEMICAL WATCH October 2013 <https://chemicalwatch.com/16953/regulations-and-chemical-lists-continue-to-appear-in-asia> [<https://perma.cc/QNU2-P7GL>] (discussing the rise of regulations and banned or restricted chemical lists in Asian countries).

<sup>9</sup> See, e.g. Jan Lee, *CVS Banishes Formaldehyde, Other Toxics From Cosmetics*, TRIPLEPUNDIT, April 24, 2017, <http://www.triplepundit.com/2017/04/cvs-will-ban-formaldehyde-toxic-substances-cosmetics-2019/> (reporting on the decision of CVS to pull cosmetic products containing certain endocrine disruptors); Andy Szal, *Target Aims to Remove 'Unwanted Chemicals' From Its Products*, CHEMINFO, January 4, 2017, <http://www.chem.info/news/2017/01/target-aims-remove-unwanted-chemicals-its-products?cmpid=horizontalcontent> (Discussing Target's decision to identify and eliminate "unwanted chemicals" from its product inventory); Andy Szal, *Report Praises Walmart, But Blasts Home Depot, Walgreens, and Others For Chemical Policies*, CHEMINFO, Nov. 18, 2016, <http://www.chem.info/news/2016/11/report-praises-walmart-blasts-home-depot-walgreens-and-others-chemical-policies?cmpid=verticalcontent> [<https://perma.cc/2YQ2-YBMN>] (discussing a report by "Safer Chemicals Healthy Families" that graded eleven large retail companies on whether they carry products with toxic ingredients and the companies' transparency regarding such information); Wendy Kock, *Ten Retailers Urged to Pull Potentially Toxic Products*, USATODAY, April 9, 2013, <https://www.usatoday.com/story/news/nation/2013/04/09/retailers-products-toxic-chemicals/2067113/> [<https://perma.cc/ED7Q-SR95>] (Discussing campaign to have products containing hazardous ingredients pulled from shelves); Marc Gunther, *Under Pressure: Campaigns That Persuaded Companies to Change the World*, Feb. 9, 2015, <https://www.theguardian.com/sustainable-business/2015/feb/09/corporate-ngo-campaign-environment-climate-change> (discussing how consumer and NGO activism is impacting the business world); Katie Thomas, *The 'No More Tears' Shampoo, Now With No Formaldehyde*, NY TIMES, Jan. 17, 2014, <https://www.nytimes.com/2014/01/18/business/johnson-johnson-takes-first-step-in-removal-of-questionable-chemicals-from-products.html> [<https://perma.cc/U2HG-4DME>]; Dirty Dozen Endocrine Disruptors, ENVIRONMENTAL WORKING GROUP, Oct. 28, 2013, <http://www.ewg.org/research/dirty-dozen-list-endocrine-disruptors> (Listing twelve endocrine disrupters contained in household products and encouraging consumers to avoid purchasing products containing such substances).

<sup>10</sup> Richard A. Denison, *A Primer on The New Toxic Substances Control Act (TSCA) and What Led To It* (hereinafter "Primer"), p 4, April 2017, <https://www.edf.org/sites/default/files/denison-primer-on-lautenberg-act.pdf>

<sup>11</sup> Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub L. No. 114-182, 130 Stat. 448 (June 22, 2016) (codified at 15 U.S.C. 2601 et seq.); Barack Obama, President of the United States, Remarks by the President

goals of the FL21. The first is to make it easier to regulate toxic substances. This involved bringing the pre-market review of § 5 closer to the “No Data, No Market” principle of the European Union’s (“EU”) REACH initiative.<sup>12</sup> Also, for existing chemicals, the “least burdensome” language was removed from § 6 of TSCA and the threshold for risk management is now a pure health-based standard.<sup>13</sup> Second, the public availability access to chemical safety data will be increased.<sup>14</sup> But perhaps the most important goal is to foster the development of a national, uniform system of chemical safety regulation. Such a system will eventually replace much of the patchwork of state laws through the preemption.<sup>15</sup> This Article focuses on the final goal. It analyzes why preemption was so important to reform, explains how preemption functions under the new law, and highlights uncertainties that should be considered moving forward.

Under the new law, upon request from the industry<sup>16</sup> or on its own initiative,<sup>17</sup> the EPA must perform risk evaluations on high-priority substances—those that are thought likely to pose

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at Bill Signing of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (June 22, 2016) [<https://perma.cc/4J57-V8U3>].

<sup>12</sup> See Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1817, 1833-35 (2009). The similarities between the amended TSCA and the EU REACH program are easily seen if one reviews prior scholarly work:

Like [the pre-amended] TSCA, EU chemical legislation prior to REACH focused on testing of “new” chemicals (those introduced after 1981 in Europe), exempted most existing chemicals from testing, and placed the burden of proof on EU Member States to prove that chemicals were unsafe. The older European legislation led to the same informational logjams and data gaps that the United States has experienced under TSCA. Of the 30,000 existing chemicals with annual production volumes in Europe of over one ton, only 140 had been identified as priorities for testing under the prior legislation, and full risk assessments had been prepared for only about seventy of these chemicals. Chemicals introduced since 1981 had been subject to rigorous toxicity testing in Europe, but they represented less than 1 percent of all the chemicals marketed in Europe.

*Id.* at 1833-34.

<sup>13</sup> See 15 U.S.C.A. § 2605(a) (2017).

<sup>14</sup> These changes are encompassed in the loosening of confidential business information (CBI) protections, the granting to the EPA the authority to demand additional testing if believed necessary, and giving local governments, first responders, and health care professionals access to important information. See 15 U.S.C.A. §§ 2603, 2613 (2017).

<sup>15</sup> 15 U.S.C.A § 2617 (2017).

<sup>16</sup> See 15 U.S.C.A. §§ 2605(b)(4)(C)(ii), (4)(E) (2017).

<sup>17</sup> See 15 U.S.C.A. § 2605(b)(4)(C)(i) (2017).

an *unreasonable health and safety risk to the public*.<sup>18</sup> After the evaluation is complete, the regulations promulgated by the Environmental Protection Agency (EPA) will preempt state regulations that fall within the scope of the EPA's pre-regulation review.<sup>19</sup> As such, the federal standard has the potential to set the regulatory floor and the ceiling for many toxic substances. Narrow exceptions do exist if states can convince the EPA to grant a discretionary waiver,<sup>20</sup> and state laws requiring labeling or public disclosure of information will largely remain in place.<sup>21</sup>

Expanding federal preemption was essential to the passage of FL21. While the regulatory schemes of California and Massachusetts were exempted from preemption, other states will be subject to the limitations of federal preemption.<sup>22</sup> This was, however, not an easily won or costless concession from the states. Even among the coalition that supported reform there was much debate about expanding preemption and many states and environmental groups opposed those provisions.<sup>23</sup>

If the EPA implements strong safety regulations, then the sacrifice of state regulatory autonomy may be a fair price to pay for a uniform national scheme. After all, while state level chemical regulations are growing in numbers, they are diverse in their structure, rigor, and protectiveness.<sup>24</sup> As it stands, a citizen's protection from exposure to toxic chemicals depends largely on where they reside.<sup>25</sup> But, there is a concern that federal regulations will not be protective as the state laws they replace, thus "weaker" laws will replace "stronger" ones, or that the EPA

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<sup>18</sup> See 15 U.S.C.A. §§ 2605(b)(1)(A)-(B) (2017).

<sup>19</sup> See 15 U.S.C.A. § 2617(b)(C)(2) (2017).

<sup>20</sup> See 15 U.S.C.A. §§ 2617(d), (e), (f).

<sup>21</sup> 15 U.S.C.A. § 2617(a) (2017).

<sup>22</sup> Accord 15 U.S.C.A. §§ 2617(a), (b), (d)(2) (2017).

<sup>23</sup> See *infra* Part II.

<sup>24</sup> See National Conference of State Legislatures (NCSL), *Toxic Substances Control Act Reform* (May 19, 2014), <http://www.ncsl.org/research/environment-and-natural-resources/state-chemical-statutes.aspx>.

<sup>25</sup> *Id.*

will fail to implement the new law in a timely manner.<sup>26</sup> Additionally, separate legislation making its way through congress would impose a rigorous cost-benefit assessment, *designed to push for regulations with a lower net cost, which could hamper implementation of health based restrictions under the new TSCA.*<sup>27</sup>

There are, however, reasons to believe that the TSCA amendments will result in a net benefit in public health and safety for the American public. The statute itself preserves several alternative legal channels through which states can monitor or limit chemical production and use, short of direct regulation.<sup>28</sup> Also, preemption, while widely applicable, only affects a fairly narrow subset of the most hazardous chemicals.<sup>29</sup> The chemical industry also has invested a great deal of time and money into TSCA reform.<sup>30</sup> In light of the continued ability of consumers to lobby retailers to remove products that are not perceived as adequately regulated, the industry has an economic motive to work with its new found allies to push for strong science-based regulations.<sup>31</sup>

The forthcoming discussion will proceed in four Parts. First, Part I briefly discusses the old law and the rise of regulations among the states and internationally.<sup>32</sup> Part II analyzes the

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<sup>26</sup> Some have pointed out that agencies have notoriously bad track records at meeting deadlines, Scott Atherley, *Federal Agency Compliance With Congressional Regulatory Deadlines*, R STREET POLICY STUDY NO. 39, Aug. 2015, <http://www.rstreet.org/wp-content/uploads/2015/07/RSTREET39.pdf>. [<https://perma.cc/9ZX6-GKAK>]. But the importance of the deadlines in TSCA is that they are explicitly judicially enforceable under the statute, thus if the agencies miss a deadline, a cause of action to compel action automatically ripens. *See, e.g.*, 15 U.S.C.A §§ 2603(a)(2)(B), 2604(a)(4), 2605(b)(2), (4), 2605(c) (2017).

<sup>27</sup> Richard Denison, *Congress Just Fixed TSCA – Yet is Now Gearing Up to Re-Impose the Worst Flaws of the Old Law Across the Entire Federal Government*, ENVIRONMENTAL DEFENSE FUND, March 8, 2017, <http://blogs.edf.org/health/2017/03/08/congress-just-fixed-tsca-yet-is-now-gearing-up-to-re-impose-the-worst-flaws-of-the-old-law-across-the-entire-federal-government/>. (Discussing the proposed Regulatory Accountability Act, H.R. 5, 115<sup>th</sup> Cong. (2017)).

<sup>28</sup> *See infra* Part III and Section IV.A.

<sup>29</sup> *Id.*

<sup>30</sup> *See infra* Section IV.B.

<sup>31</sup> *Id.*

<sup>32</sup> *Infra* Part I

concerns that led preemption to become one of the most important topics in the reform debate.<sup>33</sup> Next, Part III presents some of the most significant changes to TSCA as well as the EPA's proposed rule for the risk evaluation process.<sup>34</sup> Finally, Part IV argues several points.<sup>35</sup> First TSCA leaves states substantial room to continue regulating chemical substances directly and indirectly.<sup>36</sup> Second, while the law gives an avenue for increased control over the regulatory agenda, there are many factors that make it unclear how much this power will be exercised.<sup>37</sup> Additionally, this Part discusses the economic motivations that may encourage the industry be less resistant to strong regulations and some of the uncertainties that remain moving forward.<sup>38</sup>

#### I. THE DRIVE FOR TSCA REFORM THAT MADE PREEMPTION KEY

The push for TSCA's original enactment traces to the Council of Environmental Quality (CEQ)<sup>39</sup> and an early CEQ report.<sup>40</sup> With this report in mind, and with the intention of implementation along-side other environmental legislation, such as the Clean Water Act<sup>41</sup> and the Clean Air Act,<sup>42</sup> the purpose of TSCA was to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances."<sup>43</sup> When enacted, many believed TSCA would be the

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<sup>33</sup> *Infra* Part II

<sup>34</sup> *Infra* Part III.

<sup>35</sup> *Infra* Part IV

<sup>36</sup> *Infra* Section IV.A.

<sup>37</sup> *Infra* Section IV.B

<sup>38</sup> *Infra* Sections IV.C-.D.

<sup>39</sup> David Markell, *New Directions in Environmental Law: An Overview of TSCA, its History and Key Underlying Assumptions, and its Place in Environmental Regulation*, 32 WASH. U. J.L. & POL'Y 333, 338-39 (2010) (discussing the four key conclusions of the CEQ report that formed the foundation for drafting TSCA). *Markell, supra* note 39, at 338-39 (citing U.S. Council on Environmental Quality, Toxic Substances 759-60 (Apr. 1971), reprinted in Environmental and Natural Resources Policy Division, Legislative History of the Toxic Substances Control Act 757 (1976)).

<sup>40</sup> *See* Markell, *supra*, note 39, at 338-39 (discussing the findings of the Toxic Substances report).

<sup>41</sup> Clean Water Act (CWA), 33 U.S.C. §1251 et seq. (1972).

<sup>42</sup> Clean Air Act (CAA), 42 U.S.C. §7401 et seq. (1970).

<sup>43</sup> S. Rep. No. 94-698, at 1 (1976), reprinted in 1976 U.S.C.A.N. 4491, 4491. For a more in-depth review of TSCA prior to its amendment and its place within environmental law *see generally* Markell, *supra* note 39 (reviewing the actions that led to TSCA and the hurdles it has faced since enactment).

mechanism through which the hazards accompanying chemical production and use would be monitored, documented, and controlled. Time and litigation have demonstrated that TSCA did not result in a comprehensive system of national chemical safety laws.<sup>44</sup>

For much of its existence TSCA has been essentially a dead law.<sup>45</sup> “In fact, . . . EPA has issued regulations under the act to ban or limit or restrict the production or use of only five existing chemicals,” since TSCA was enacted.<sup>46</sup> Thousands of existing substances have never being reviewed despite widespread use.<sup>47</sup> And the EPA has only taken twenty-five actions (25) regarding “new chemicals” or “significant new uses” under the old law, only some of which actually restricted toxic substances in any way.<sup>48</sup> Thus, while international chemical regulations have grown, companies in the United States have largely been able to produce and distribute many chemical substances without sharing information with the EPA or the American public.<sup>49</sup>

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<sup>44</sup> A Practitioner's Guide to the Toxic Substances Control Act: Part III, 24 ELR 10357, 10359-60 (hereinafter “Practitioner’s Guide III) (discussing the EPA’s failed attempt to ban asbestos under § 6 of TSCA). For the full text of the *Corrosion Proof* case and further discussion see the following resources: *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1216-17 (5th Cir. 1991) (holding that § 6 of the Toxic Substance Control Act required the EPA to evaluate the costs and benefits of all permissible regulatory regimes for asbestos and choose the *least burdensome* option that would accomplish the desired result). The former rule is contained at Asbestos; Manufacturing, Importation, Processing, and Distribution in Commerce Prohibitions, 54 Fed. Reg. 29460 (1989). See also Chris Hastings, *TSCA Reform and the Need to Preserve State Chemical Safety Laws*, 30 J. LAND USE & ENVTL. LAW 307, 308 (2015).

<sup>45</sup> Mark A. Greenwood, *TSCA Reform: Building a Program That Can Work*, 39 ENVTL. L. REP. 10034, 10034 (2009) (“In the early 1990s, when the courts rejected EPA's comprehensive ban on asbestos, TSCA became widely known as a “broken” statute.”).

<sup>46</sup> Markell, *supra* note 39, at 368-69. Lynn Bergeson, *In-House Counsel Beware: TSCA Reform Impacts Everyone*, LAW360, June 15, 2016, [http://www.actagroup.com/uploads/docs/In-House\\_Counsel\\_Beware\\_TSCA\\_Reform\\_Impacts\\_Everyone.pdf](http://www.actagroup.com/uploads/docs/In-House_Counsel_Beware_TSCA_Reform_Impacts_Everyone.pdf). However, the EPA did restrict four “new chemicals” under § 5(f).

<sup>47</sup> See Sachs, *supra* note 12, at 1831. Sachs notes that despite TSCA’s existence, we still are largely ignorant about the risks that we are exposed to. “Some chemicals that have gone untested for decades may be completely harmless; others may be unidentified agents of endocrine disruption, birth defects, cancer, or neurological damage. The crucial point is that the United States lacks a sophisticated system for obtaining the risk data that would allow regulators, firms, and consumers to distinguish harmful (or potentially harmful) chemicals from harmless ones.” *Id.*

<sup>48</sup> To view these EPA actions I utilized the EPA’s CHEMVIEW database and the following search path. <https://java.epa.gov/chemview#dashboard> (Click advanced search, select text search, enter “section 5” in the text box, click the box for “exact wording of phrase,” under output options select “EPA Actions,” click “Generate Results”). Last visited May 1, 2017.

<sup>49</sup> Sachs, *supra* note 12, at 1831. This is not to say that other laws have not imposed substantial requirements on the industry.

States eventually began efforts to fill this void with the assistance of various NGOs.<sup>50</sup> The failures of TSCA have been well documented and need not be repeated here,<sup>51</sup> rather this Article will focus on what led to reform and the trade-offs made to facilitate passage of the amendments. As a part of this discussion, a few provision of the old law will be summarize, as will the landscape of state and international regulations.

#### A. TSCA's Major Provisions and Flaws

Because preemption became such an important issue in the debate leading to the FL21 amendments, it may come as a surprise that the new law merely expanded on existing preemption provisions.<sup>52</sup> A general understanding of three sections of the old law are key to understanding why preemption was such an important issue. First, are §§ 5 and 6, which provided the EPA authority to regulate new and existing chemicals.<sup>53</sup> Next is § 18, which contained the old preemption standards.<sup>54</sup>

##### *1. Sections 5 and 6: Regulation of New and Existing Chemicals*

Section 5 and 6 of TSCA provided the EPA authority to regulate chemicals. Under § 5 manufacturers had to submit notice and test data to the EPA for all new chemicals or significant new uses of chemicals prior to beginning production.<sup>55</sup> On the basis of that information, the EPA could then regulate or prohibit the production of the new chemical, but only if the agency

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<sup>50</sup> Richard A. Denison, *Policy Options for Generating Information for Sound Chemical Management*, in *OPTIONS OF STATE CHEMICALS POLICY REFORM: A RESOURCE GUIDE*, Univ. of Mass. Lowell Center for Sustainable Prod. 35-69 (2008) available at <http://www.chemicalspolicy.org/downloads/OptionsforStateChemicalsPolicyReform.pdf>.

<sup>51</sup> See, e.g., Markell, *supra*, note 39, at 360-69 (discussing the history and motivation of TSCA); Greenwood, *supra*, note 45 at 10035-41 (discussing various flaws in TSCA and areas that new regulation can help); Hastings, *supra*, note 44 at 307-310 (discussing the history of TSCA, preemption, and the push for reform).

<sup>52</sup> See 15 U.S.C. 2617 (2012).

<sup>53</sup> Subsection II.A.1.

<sup>54</sup> Subsection II.A.2.

<sup>55</sup> Toxic Substance Control Act (TSCA), 15 U.S.C. §§ 2604(a), (b) (2012).

determined that the production or use of the substance presented “an unreasonable risk of injury to health or the environment.”<sup>56</sup>

Additionally, § 6 granted the EPA authority to regulate the over 60,000 existing chemicals at the time of TSCA’s enactment.<sup>57</sup> This section allowed the EPA to regulate, or even ban, the production, use, or distribution of such substance, but only those that the agency determined, “presents or will present an unreasonable risk of injury to health or the environment.”<sup>58</sup> However, because regulations under § 6 were required to be the “least burdensome” necessary to combat the identified risks, which the Fifth Circuit interpreted as requiring a series of independent cost assessments, it became all but impossible to enact comprehensive restrictions.<sup>59</sup>

## 2. Section 18: Preemption and Waiver

It is somewhat surprising that preemption became the key issue surrounding the passage of the FL21 amendments; because, TSCA regulations have always triggered preemption.<sup>60</sup> The

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<sup>56</sup> *Id.* at 2604(e).

<sup>57</sup> Toxic Substance Control Act (TSCA), 15 U.S.C. §§ 2601-2629 (2012); A Practitioner’s Guide to the Toxic Substances Control Act: Part III, 24 ELR 10357, 10358-59 (hereinafter “Practitioner’s Guide III”).

<sup>58</sup> 15 U.S.C § 2605(a) (2012). *See also* Practitioner’s Guide III, *supra* note \_\_\_, at 10358-59.

<sup>59</sup> *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1216-17 (5th Cir. 1991) (holding that § 6 of the Toxic Substance Control Act required the EPA to evaluate the costs and benefits of all permissible regulatory regimes for asbestos and choose the *least burdensome* option that would accomplish the desired result). Prior to FL21, TSCA required that the agency thoroughly address each of the following in a published statement:

- (A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture;
- (B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;
- (C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses; and
- (D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

15 U.S.C. § 2605(c)(1)(A)-(D) (2012).

<sup>60</sup> 15 U.S.C. § 2617 (2012); Hasting, *supra*, note 51 at 311-14; *Toxic Substances Control Act Reform: What’s Happening and What’s Next* (Dialogue, statements of Lawrence Cullen), 46 ELR 10357, 10358 (5-2016).

old preemption provisions were modest and about a page long.<sup>61</sup> Following the *promulgation* of a § 5 or § 6 action, TSCA prohibited the enactment or enforcement of any law regarding a chemical that targets the same risks or uses as the federal rule, unless it is (1) identical to the federal requirement, (2) adopted pursuant to other federal authority, or (3) *completely bans* the use of the substance in the state or political subdivision.<sup>62</sup> The former § 18 also had exemption provisions, which are similar in spirit to the new waiver provisions.<sup>63</sup> A state was permitted to seek a discretionary exemption from the preemptive effect of TSCA if it met the statutory criteria.<sup>64</sup>

Prior to 2016 preemption, while legally possible, remained unused. As an illustration of this point, in a discussion concerning legislative proposals leading to FL21, one commentator noted that he was unaware of “any trace of anybody talking about [preemption] for the preceding 30 years of TSCA’s existence, but it has become a central issue.”<sup>65</sup> This is likely because the

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<sup>61</sup> See Pub. Law 94-469, 90 Stat 2003, 2038-39 (Oct. 11, 1976) (codified at 15 U.S.C. §2617 (2012)). Section 18 also prohibited a state, or political subdivision of the same, from enacting or enforcing a testing requirement for purposes that are similar to those of a rule enacted under § 4. 15 U.S.C. § 2617(a)(2)(A).

<sup>62</sup> 15 U.S.C. § 2617(a)(2)(B) (emphasis added)(“if the Administrator prescribes a rule or order under section 5 or 6 . . . no State or political subdivision of a State may, after the effective date of such requirement, establish or continue in effect, any requirement which is applicable to such substance or mixture, or an article containing such substance or mixture, and which is designed to protect against such risk . . .”).

<sup>63</sup> See 15 U.S.C. § 2617(b) (2012).

<sup>64</sup> *Id.* The exact language is that the state may be granted an exemption from having its regulation preempted if: compliance with the requirement would not cause the manufacturing, processing, distribution in commerce, or use of the substance, mixture, or article to be in violation of the applicable requirement under this Act described in subsection (a) (2), and (2) the State or political subdivision requirement (A) provides a significantly higher degree of protection from such risk than the requirement under this Act described in subsection (a) (2) and (B) does not, through difficulties in marketing, distribution, or other factors, unduly burden interstate commerce. § 2617(b)(1) (2012).

<sup>65</sup> *Toxic Substances Control Act Reform: What’s Happening and What’s Next* (Dialogue, statements of Lawrence Culleen), 46 ELR 10357, 10358 (5-2016). This comment was made by Lawrence E Culleen, a partner at Arnold & Porter, LLP and seasoned practitioner in the realm of chemical compliance, during a discussion about proposed TSCA reform in May 2016.

downstream impacts of the Fifth Circuit's ruling in *Corrosion Proof Fittings v. EPA*<sup>66</sup> prevented courts or states from having to grapple with the concern of § 6 regulations triggering preemption.

## B. The Rise of Chemical Regulations Among the States and Abroad

The lack of comprehensive federal regulation for many toxic chemicals should not be taken as a signal that the American public does not care about chemical safety. In fact, many states have been active in passing labeling, disclosure, and use restrictions within their own borders.<sup>67</sup> As of January 1, 2017, thirty-eight states had enacted at least one statute that regulated the manufacture, distribution, labeling, or use of chemicals and the products containing specific substances.<sup>68</sup> Of those states, thirteen regulate the use of flame retardants in consumer products and twelve (plus the District of Columbia) restrictions for the use of bisphenol A (BPA).<sup>69</sup> In a related manner, the market itself became increasingly hostile to chemical manufacturers as companies like Walmart and Home Depot began pulling products containing certain substances in reaction to consumer advocacy.<sup>70</sup>

California, for example, has a comprehensive law commonly known as Proposition 65, which was enacted in 1986. The law requires the state to publish a list of chemicals that are known to cause cancer or reproductive toxicity.<sup>71</sup> Under Prop 65, a business that creates

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<sup>66</sup> See *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1216-17 (5th Cir. 1991) (holding that § 6 of the Toxic Substance Control Act required the EPA to evaluate the costs and benefits of all permissible regulatory regimes for asbestos and choose the least burdensome option that would accomplish the desired result).

<sup>67</sup> See NCSL, *supra*, note 24 (listing states with chemical safety laws); Hasting, *supra*, note 44, at 314-319.

<sup>68</sup> See NCSL, *supra*, note 24 (listing states with chemical safety laws).

<sup>69</sup> See NCSL, *supra*, note 24.. Many flame retardants have been associated with “liver toxicity, thyroid toxicity, and neurodevelopmental toxicity in humans.” *Id.* These substances are commonly used in furniture, building materials, paints, and other consumer products. Bisphenol A (BPA) is a hardening agent in plastics that has been linked to “accelerated puberty and an increased risk for cancer, heart disease and diabetes.” *Id.*

<sup>70</sup> See *supra*, note 9 and the sources cited therein.

<sup>71</sup> CAL. HEALTH & SAFETY §§ 25252, 25252.5, 25253, 25254, 25255, 25257 (2008); Cal. Health & Safety Code §§ 108100-108515 (2008). For history, documents, and controversies see David Roe, *A Quick Reference Guide to California's Proposition 65*, Prop. 65 Kit, at <http://www.prop65kit.org> (last visited June 21, 2002). See also, David Roe, *Ready or Not: The Coming Wave of Toxic Chemicals*, 29 *ECOLOGY L.Q.* 623, 631 (2002) (Mr. Roe was the primary author of the Proposition 65 ballot measure).

exposure to a listed chemical is required to issue warnings to their customers, consumers or buyers of a product, or members of the public so exposed.<sup>72</sup> While not required, the regulatory agencies often produce risk-based calculations, which states what level of exposure will make the product ineligible for an exemption.<sup>73</sup> In practice, the risk-based calculations have become de facto risk-based standards, incentivizing cooperation with the regulators to ensure smooth and unobstructed access to the market.<sup>74</sup> California's Prop 65, as well as the Massachusetts Toxics Use Reduction Act<sup>75</sup> were grandfathered in under the TSCA amendments and are not subject to preemption.<sup>76</sup> Preservation of these two laws was an essential concession in the negotiations leading to TSCA reform, much as preservation of California's emissions standards were essential to the 1994 CAA amendments.<sup>77</sup>

The state of New York, on the other hand, also has a host of chemical regulations that could be subject to preemption. For example, the TRIS-Free Children and Babies Act,<sup>78</sup> which bans the use of the flame retardant tris(2-chloroethyl) phosphate (TRIS) in products intended for use by children under the age of 3 years, could be subject to preemption if those chemicals are evaluated under § 6. New York's attorney general, Eric T. Schneiderman, was a vocal opponent of the expanding TSCA's preemptive powers.<sup>79</sup>

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<sup>72</sup> Roe, *supra*, note 71 at 631.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 632.

<sup>75</sup> Mass. Gen. Laws, ch. 94B, §§ 1-10 (2008).

<sup>76</sup> 15 U.S.C.A. §§ 2617(a), (b), (d)(2) (2017).

<sup>77</sup> See, e.g., Taly L. Jolish, *Negotiating the Smog Away*, 18 VA. ENVTL. L.J. 305, 311-12 (1999) (Discussing the exemption of the California emission standards from preemption). See also, CAA § 209(b), 42 U.S.C. § 7543(b) (2012). When the CAA amendments passed, California was the only state that had adopted emission standards before March 30, 1966. *Motor Vehicle Mfrs. Ass'n v. New York State Dep't of Env'tl. Conservation*, 17 F.3d 521, 525 (2d Cir.1994). California received the exception because one of the state's senators convinced the Senate Committee on Public Works that California's "unique problems and pioneering efforts warranted a waiver from preemption." *Id.*

<sup>78</sup> N.Y. ENVTL. CONSERV. LAW §§ 37-0701-37-0709 (2011).

<sup>79</sup> Pat Rizzuto, *States Can Regulate Chemicals Under TSCA Reform Bill*, BLOOMBERG BNA (June 14, 2016).

States also have been active in restricting the use of lead, BPA, and other substances in children's products,<sup>80</sup> as well as regulating caustic and corrosive chemicals.<sup>81</sup> Many states, through the National Council of State Legislatures (NCSL) opposed earlier proposed TSCA legislation precisely because the preemption language was so strong.<sup>82</sup> Moreover, while NCSL supported TSCA reform as a concept, it submitted a joint letter with the Environmental Council of States (ECOS) to U.S. Senate leadership urging them to avoid having FL21 preempt state chemical laws and to loosen the requirements for obtaining preemption waivers.<sup>83</sup> However, despite the concerns voiced by some states about the preemption language, none are prepared to challenge the TSCA reforms at this time.<sup>84</sup>

## II. PREEMPTION'S MOVEMENT TO THE CENTER OF THE REFORM DEBATE AND THE CONCERNS RAISED BY STAKEHOLDERS

That TSCA needed improvement has long been an accepted reality, but the path to reform was long and difficult. In 2011, the chemical industry joined the push for reform.<sup>85</sup> In 2013, Senator Lautenberg, a longtime advocate for TSCA reform, began to work across the aisle with Senator Vitter, whose home state, Louisiana, includes some of the nation's largest petroleum manufacturers.<sup>86</sup> The fruit of their efforts is a bipartisan piece of legislation supported

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<sup>80</sup> Conn. Gen. Stat. §§ 21a-335 through 21a-376 (2016); Ga. Code Ann. § 31-41-10 et seq.; Me. Rev. Stat. Ann. tit. 38, §§ 1691-1699-B (2008); Mass. Gen. Laws, ch. 94B, §§ 1-10 (2008); Mo. Rev. Stat. § 701.300 (2016) et seq.; N.Y. Public Health Law § 1370 (McKinney 2016) et seq.; Okla. Stat. tit. 63, § 1-114.1; Children's Safe Products Act 70 R.C.W. 280; Relating to the Use of Bisphenol A 70 R.C.W. 240.010-.060.

<sup>81</sup> Ala. Code § 8-17-20 (2016) et seq.; Ariz. Rev. Stat. Ann. § 36-1101 (2016) et seq.; Del. Code. Ann. tit. 16 § 2301 (2016) et seq.

<sup>82</sup> NCSL, *supra* note 6. *See also* NCSL Letter to the House Environment and the Economy Subcommittee regarding the Chemicals in Commerce Act (May 19, 2014) available at [http://www.ncsl.org/documents/standcomm/scnri/NewDraftCICA\\_Letter.pdf](http://www.ncsl.org/documents/standcomm/scnri/NewDraftCICA_Letter.pdf), [<https://perma.cc/5TRG-EB64>];

<sup>83</sup> Joint NCSL & ECOS Letter to U.S. Senate Leadership Regarding FL21 (Sept. 23, 2015) available at [http://www.ncsl.org/documents/standcomm/scnri/NCSL\\_ECOS\\_S697.pdf](http://www.ncsl.org/documents/standcomm/scnri/NCSL_ECOS_S697.pdf), [<https://perma.cc/P4DU-Q2WC>].

<sup>84</sup> *Id.* California, New York, and some southern states will likely be the primary parties of interest.

<sup>85</sup> *See* Bergeson, *supra* note 1; Anthony Adragna, *The Inside Story of Congress' Battle for Chemical Reform*, June 23, 2016, <https://www.bna.com/inside-story-congress-n57982074649/>.

<sup>86</sup> *See* Bergeson, *supra* note 1.

industry and environmental groups alike.<sup>87</sup> However, expanding preemption was hotly contested.<sup>88</sup>

Several earlier efforts at TSCA reform, such as the Chemicals in Commerce Act (CICA) failed to gain traction. These were opposed by organizations like the National Conference of State Legislatures (NCSL) largely because of the broad preemptive language.<sup>89</sup> Testifying on behalf of NCSL, state Senator Michael Moore of Massachusetts argued this earlier bill contained “onerous preemption language that would handcuff states from acting against harmful chemicals to protect their population. It was said, CICA ignored nearly 40 years of state policy in an attempt to provide a one-size-fits-all approach to toxic chemicals regulation.”<sup>90</sup> He also took issue with the fact that CICA did not preserve state regulatory authority concerning air and water quality standards.<sup>91</sup>

Similarly, even the early democratic reform proposals, like the Safe Chemicals Act of 2013, were opposed by representatives from states that already had comprehensive chemical laws, like California and Massachusetts, because the preemption language was viewed as overly broad.<sup>92</sup> Safer Chemicals, Healthy Families (SCHF) went so far as to call the legislation “phony

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<sup>87</sup> Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub L. No. 114-182, 130 Stat. 448 (June 22, 2016) (to be codified at 15 U.S.C. 2601 et seq.). *See also* Denison, *supra*, note 67; 162 Cong Rec S3513, S3514 (daily ed. June 7, 2016) (statement of Sen. Markey) (Noting that FL21 received more votes in the House of Representatives—403 total—than the Clean Air Act, the Clean Water Act, or the Safe Drinking Water Act when they were reauthorized). Unfortunately, Senator Lautenberg did not live to see his crowning achievement become law.

<sup>88</sup> *See, e.g.*, Hasting, *supra* note 44, at 321-25.

<sup>89</sup> NCSL, *supra* note 6. *See also supra* notes 82& 83 and the NCSL letters cited therein.

<sup>90</sup> Testimony of Senator Michael Moore of the Massachusetts State Senate Before the U.S. House Comm. on Energy and Commerce Subcommittee on Env't and the Econ, 114th Cong., p. 2 (April 29, 2014), available at [http://www.ncsl.org/documents/standcomm/scnri/moore\\_cica\\_testimony.pdf](http://www.ncsl.org/documents/standcomm/scnri/moore_cica_testimony.pdf), [<https://perma.cc/VQB9-DPPY>].

<sup>91</sup> *Id.* p 3.

<sup>92</sup> Frederic J. Frommer, *Chemical Bill Faces Uphill Senate Battle*, CHEMINFO, Sept.9, 2015, <http://www.chem.info/news/2014/09/chemical-reform-bill-faces-uphill-senate-battle> (republished from the Associated Press).

reform.”<sup>93</sup> But without support from the industry, the early Democrat sponsored bills failed.<sup>94</sup> Luckily, by 2013, industry advocacy groups were committed to achieving TSCA reform that could be supported by both sides while making safety a top priority.<sup>95</sup> But preemption was still an important issue for industry activists.

The main reasons that the chemical industry wanted strong preemptive language in any TSCA reform bill are fairly straight forward: uniformity, simplicity, and predictability. A survey of chemical manufacturers conducted before FL21 became law presented the following top concerns regarding chemical regulations in the United States:

The top problems included ineffective or duplicative regulations (46.2 percent), reporting and paperwork burdens (46.2 percent) and conflicting state regulations (38.1 percent). In addition, some manufacturers were hopeful that the proposed reforms could meaningfully address misinformation about products (32.0 percent), consumer confusion about chemicals (30.8 percent) and potential supply chain disruptions (17.2 percent).<sup>96</sup>

These justifications are hardly seem surprising as manufacturers are concerned about running a business in a profitable manner, which is made more difficult when each state could potentially have separate safety standards and separate filing requirements.

Many states and advocacy groups were equally concerned about preemption but for different reasons. The bills that were proposed before FL21 were seen as “divesting all authority

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<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> Krystal Gabert, *Groups Clamor for ‘Safer’ Chemicals*, CHEMINFO, April 11, 2013, <http://www.chem.info/blog/2013/04/groups-clamor-%E2%80%98safer%E2%80%99-chemicals> (quoting the American Chemistry Council in stating “The current law needs to be improved to reflect modern scientific developments in the assessment and management of chemicals. A modernized TSCA must put the protection of human and environmental health and safety first, while also enabling America to retain its place as the world’s leading innovator.”).

<sup>96</sup> National Association of Manufacturers (NAM), *Survey Shows Manufacturers’ Commitment to TSCA Reform*, IMPO, March 10, 2016, [https://www.impomag.com/news/2016/03/survey-shows-manufacturers-commitment-tsca-reform?\\_\\_hstc=17104102.197963abe1f120924294a1530410a59d.1493654791648.1493752901913.1493756433621.3&\\_\\_hssc=17104102.2.1493756433621&\\_\\_hsfp=20068296](https://www.impomag.com/news/2016/03/survey-shows-manufacturers-commitment-tsca-reform?__hstc=17104102.197963abe1f120924294a1530410a59d.1493654791648.1493752901913.1493756433621.3&__hssc=17104102.2.1493756433621&__hsfp=20068296). The survey cited by the article is available at <http://www.nam.org/outlook/>.

away from states and localities and placing this authority solely with the . . . EPA.”<sup>97</sup> States and consumer protection groups initially viewed reform efforts as an attempt to strip away regulatory authority in an area where states had been the only active participants for over forty years. Many states were concerned about demographic specific risks, such as risks to children, the elderly, EMS professions, and more.<sup>98</sup> In fact, the attorney generals of twelve states urged Congress to remove any expansion of preemption from FL21.<sup>99</sup> Moreover, a coalition of “thirty-four law professors, legal scholars, and public interest lawyers” argued that an earlier bill aimed at TSCA reform did not alter the cost-benefit approach required under *Corrosion Proof*.<sup>100</sup> Both the state attorney generals and NCSL expressed concern that previous bills did not do enough to protect high-risk or susceptible populations.<sup>101</sup>

After FL21 passed, the California EPA restated its concern about how preemption would be implemented and was quoted as believing “state authorities are excessively and unnecessarily preempted in exchange for the promise of federal protection that is too meagre.”<sup>102</sup> Moreover,

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<sup>97</sup> See *supra* notes 82& 83 and the letters cited therein.

<sup>98</sup> See Hastings, *supra* note 43, at 322-25; *Strengthening Public Health Protections by addressing Toxic Chemical Threats: hearing on S. 1009 Before the S. Comm. On Env't'l & Pub. Works*, 113th Cong. (2013) (statement of Kenneth A. Cook, President of the Environmental Working Group).

<sup>99</sup> Kamala D. Harris et al, Joint Letter to Comm. On Env't'l and Pub. Works, January 19, 2016 [<https://perma.cc/YE9F-4CKK>] (letter from California, Hawaii, Iowa, Maine, Maryland, Massachusetts, New Hampshire, New York, Oregon, Rhode Island, Vermont and Washington). The letter laid out seven core principles that states wanted to see in the reformed law: (1) States should not be preempted until EPA has taken a final action; (2) Once EPA has taken a final action, the scope of state law preempted should be no broader than the scope of EPA's action; (3) States should not be preempted from continuing to establish requirements on chemicals pursuant to longstanding state laws; (4) States should not be preempted from continuing to enforce existing requirements on chemicals; (5) State laws related to water quality, air quality or waste treatment or disposal should not be preempted; (6) States should be able to obtain a waiver to adopt requirements that are more protective than EPA's if the requirements do not unduly burden interstate commerce and do not make it impossible to comply with both state and federal law; and (7) States should be able to keep “cops on the beat” to co-enforce requirements that have been adopted by EPA. *Id.*

<sup>100</sup> Hastings, *supra* note 44, at 324. The letter cited by Mr. Hastings is available at <http://static.ewg.org/pdf/Combined-CSIA-Letters-2013.pdf> and has been archived at <https://perma.cc/D5AK-U9QF>. These concerns were addressed by FL21 and the removal of the “least burdensome” language from § 6 of TSCA.

<sup>101</sup> *Id.*; Harris, *supra* note 99.

<sup>102</sup> Kelly Franklin, *Reformed TSCA Will Not Constrain Many State-Level Actions*, CHEMICAL WATCH, June 28, 2016, <https://chemicalwatch.com/48287/reformed-tsca-will-not-constrain-many-state-level-actions>.

there was concern that while all states would benefit from strong federal regulations, the “legislation does not provide federal EPA with sufficient funds to fully utilize [sic] its new authorities.”<sup>103</sup>

In the end, FL21 did pass and did manage to garner sixty cosponsors in the Senate, near unanimous supporting votes in both houses,<sup>104</sup> and the backing of dominant industry groups like the ACC, as well as environmental organizations like the EDF.<sup>105</sup> The grandfathering of California’s and Massachusetts’s chemical programs were essential to getting their respective representatives in Congress to support the legislation.<sup>106</sup> The inclusion of preemption waiver language was an additional means of reconciling conflicting bills and placating the concerns of some states,<sup>107</sup> but not all are happy with the final result.<sup>108</sup>

Some groups like NCSL and ECOS continued to believe that states were being stripped of too much authority.<sup>109</sup> But even the most resistant groups, like SCHF, have conceded that while not ideal, FL21 does preserve state authority to regulate chemicals pursuant to other federal laws and allow for the possibility of waivers.<sup>110</sup> The next part of this Article will focus on how preemption functions under the new, and hopefully improved, TSCA.

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<sup>103</sup> *Id.*

<sup>104</sup> Congressional Action Overview for H.R. 2576, the Frank Lautenberg Chemical Safety for the 21st Century Act, <https://www.congress.gov/bill/114th-congress/house-bill/2576/all-info>; June 23, 2015, House Roll Call, <http://clerk.house.gov/evs/2015/roll378.xml>.

<sup>105</sup> *Passing a Strong New Chemical Safety Law*, ENVIRONMENTAL DEFENSE FUND (EDF), <https://www.edf.org/health/policy/chemicals-policy-reform> (last visited May 6, 2017).

<sup>106</sup> *Cf.* Adragna, *supra* note 85.

<sup>107</sup> Juan Carlos Rodriguez, *Quiet Compromises Set Stage For TSCA Reform Bill's Debut*, LAW360, April 25, 2016, [https://www.law360.com/articles/788354/quiet-compromises-set-stage-for-tscareform-bill-s-debut?article\\_related\\_content=1](https://www.law360.com/articles/788354/quiet-compromises-set-stage-for-tscareform-bill-s-debut?article_related_content=1).

<sup>108</sup> Rizzuto, *supra* note 79. Another last minute concession that helped the bill pass was language allowing the prioritization of known carcinogens. Adragna, *supra* note 85.

<sup>109</sup> Joint NCSL & ECOS, *supra* note 83, at 1-2.

<sup>110</sup> An Abbreviated Guide to the Frank R. Lautenberg Chemical Safety for the 21st Century Act, SAFER CHEMICALS, HEALTHY FAMILIES, <http://saferchemicals.org/get-the-facts/an-abbreviated-guide-to-the-frank-r-lautenberg-act-chemical-safety-in-the-21st-century-act/> (last visited May 6, 2017).

### III. THE BREADTH OF PREEMPTION, MANUFACTURE INFLUENCE, AND THE EPA'S PROPOSED RULE

This Part outlines the changes to TSCA and the proposed rule that dictate how risk evaluations and preemption will function. Section 18 preemption, which was rewritten and expanded, largely because strong preemption was necessary to create a uniform system will be presented next. Section 6 will be discussed as necessary to explore how the evaluation process shapes preemption and impacts state regulatory autonomy.<sup>111</sup> Additionally, the EPA's proposed procedural rules for risk evaluations and concerns raised by public comments will be discussed as well.

#### A. Expanding § 18 Preemption of State Law

Preemption come in two forms under the FL21 amendments—Post-Review Preemption and Pause Preemption.<sup>112</sup> Because the latter is defined by reference to the former, it is discussed second. Post-Review Preemption is further divided between informational requirements and substantive restrictions.

Post-Review Preemption targets both informational and substantive state laws. The informational aspects of preemption prevent states from requiring testing and new safety data production beyond what the EPA requires for a § 5 or § 6 risk assessment.<sup>113</sup> This is a more expansive prohibition than in the pre-amendment TSCA,<sup>114</sup> but it still allows states to require the development of additional information that is not encompassed by the federal law.<sup>115</sup> These

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<sup>111</sup> Agency actions on new chemicals only become preemptive if addressed under the risk assessment criteria of § 6, therefore, this Part does not discuss § 5 independently. *Accord Denison Primer, supra* note 10, p 8; TSCA § 18(c). States will also have ample opportunity to participate in the regulatory process for all new substances regulated under TSCA, and if the EPA fails to conduct a review, the state remain free to regulate or file a lawsuit to compel action.

<sup>112</sup> *Denison Primer, supra* note 10, at 8; 15 U.S.C.A. § 2617(a) (2017).

<sup>113</sup> 15 U.S.C.A. §§ 2617(a), (c)(1), (c)(3)-(4) (2017).

<sup>114</sup> *See* Pub. Law 94-469, 90 Stat 2003, 2038-39 § 18(a)(2)(A) (Oct. 11, 1976) (codified at 15 U.S.C. §2617 (2012)).

<sup>115</sup> *Denison Primer, supra* note 10, at 8; 15 U.S.C.A. §§ 2617(a), (c) (2017).

restrictions are also unlikely to affect various state level “right to know” laws, which require public disclosure hazard information or labeling of products containing specific substances.<sup>116</sup>

The next variety of preemption concerns substantive restrictions on chemical substances, categories of chemical substances, or specific uses of chemical substances.<sup>117</sup> The old law only prohibited states and their subdivisions from enacting or enforcing laws that *targeted risks and uses* encompassed in the federal regulation and was not triggered by a finding of no risk.<sup>118</sup> The FL21 amendments are in some ways more expansive. First, the amended law prohibits the enforcement or enactment of civil and criminal penalties, while the old law only concerned administrative and civil laws.<sup>119</sup> Second, and more importantly, preemption now extends to the creation or enforcement of any law that “restrict[s] the manufacture, processing, or distribution in commerce or use of a chemical substance” that has been found “*not to present an unreasonable risk to health or the environment*”<sup>120</sup> under § 6(i)(1) or for which a *final rule is promulgated* under § 6(a),<sup>121</sup> so long as those determinations are consistent with the “*scope of the risk evaluation under section (6)(b)(4)(D)*.”<sup>122</sup> It should be noted, however, that unlike the old

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<sup>116</sup> Accord Denison *Primer*, *supra* note 10, at 8; 15 U.S.C.A. §§ 2617(a), (c) (2017).

<sup>117</sup> 15 U.S.C.A. §§ 2617(b), (c)(2) (2017).

<sup>118</sup> See Pub. Law 94-469, 90 Stat 2003, 2038-39 (Oct. 11, 1976) (codified at 15 U.S.C. §2617 (2012)); see also discussion *infra* Subsection I.A.2.

<sup>119</sup> Compare 15 U.S.C.A. § 2617(b) (2017), with Pub. Law 94-469, 90 Stat 2003, 2038-39 (Oct. 11, 1976) (codified at 15 U.S.C. §2617 (2012)). See also Denison *Primer*, *supra* note 10, at 8

<sup>120</sup> 15 U.S.C.A. § 2605(i)(1) (2017).

<sup>121</sup> 15 U.S.C.A. § 2605(a) (2017).

<sup>122</sup> 15 U.S.C.A. § 2617(a)(1)(B) (2017). As amended, the statute provides, no State or political subdivision of a State may establish or continue to enforce any of the following:

(B) Chemical substances found not to present an unreasonable risk or restricted[:] statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) for which the determination described in section 2605(i)(1) of this title is made, consistent with the scope of the risk evaluation under section 2605(b)(4)(D) of this title; or

(ii) for which a final rule is promulgated under section 2605(a) of this title, after the effective date of the rule issued under section 2605(a) of this title for the chemical substance, consistent with the scope of the risk evaluation under section 2605(b)(4)(D) of this title.

law, this substantive aspect of Post-Review Preemption does not apply to EPA actions on new chemicals in the pre-market review process, unless the EPA also invokes its § 6 risk evaluation authority.<sup>123</sup> Additional subsections further illustrate the potential scope of preemption.

Preemption applies to “the hazards, exposures, risks, and *uses or conditions of use* of such chemical substances included in any final action the [EPA] takes pursuant to § 6(a) (final rule) or § 6(i)(1) (no-risk).”<sup>124</sup> “Conditions of use” is further defined as “the circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.”<sup>125</sup> As will be addressed below, the EPA interpreted this definition to encompassing all foreseeable uses of a chemical or class of chemicals under review.<sup>126</sup> Accordingly, upon the publication of a final risk evaluation, preemption applies to all conditions of use within the scope of the risk evaluation even if the evaluation was triggered by a manufacturer request.<sup>127</sup>

Preemption also applies to conditions of use that the EPA decides not to restrict.<sup>128</sup> The FL21 legislative history makes clear that Congress intended of preemption to apply to all conditions of use within the scope of the risk evaluation, even not regulated.<sup>129</sup> This is because a § 6 determination that a chemical “does not present an unreasonable risk under conditions of use,

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<sup>123</sup> *Accord Denison Primer, supra* note 10, at 8; 15 U.S.C.A § 2617(c) (2017).

<sup>124</sup> 15 U.S.C.A. § 2617(c)(3) (2017) (emphasis added).

<sup>125</sup> 15 U.S.C.A § 2602(4).

<sup>126</sup> *Infra* Section II.D.

<sup>127</sup> *Infra* Section II.D.

<sup>128</sup> *Accord Denison Primer, supra* note 10, at 8; 162 Cong Rec S3513, 3521 (daily ed. June 7, 2016) (statement of Sen. Inhofe).

<sup>129</sup> 162 Cong Rec S3519-20 (daily ed. June 7, 2016) (Dialogue between Sen. Inhofe and Sen. Vitter) Senator Inhofe asked Sen. Vitter, “That response raised an interesting follow up question I would like to ask. If EPA’s final Section 6(a) risk management rule includes a restriction or prohibition on some of the conditions of use identified in EPA’s scope of the risk evaluation, but not all of them, is it final agency action as to those other conditions of use?” *Id.* Senator Vitter responded: “That is a very important question and the clear intent of Congress is the answer is yes. This is because, to be legally sufficient according to EPA’s own technical assistance, EPA’s Section 6(a) rule must ensure that the chemical substance or mixture no longer presents an unreasonable risk.” *Id.* at S3520.

is a . . . final agency action,” which is applicable to all conditions of use identified in the scope.<sup>130</sup>

Before moving on, however, it should be noted that the amended statute provides only limited guidance about defining the scope of a risk evaluation.<sup>131</sup> The EPA is required to publish the scope within six months of initiating the evaluation.<sup>132</sup> The evaluation itself is designed to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors,” and it must specifically address potentially susceptible or exposed populations.<sup>133</sup> The published scope must include “*the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider.*”<sup>134</sup> The Environmental Defense Fund (EDF) has framed preemption as applying only to “direct state restrictions on chemical production or use,”<sup>135</sup> and as permitting states to address “any uses or risks the EPA has not addressed.”<sup>136</sup> As will be discussed *infra* the EPA’s proposed procedural rule for risk evaluations sheds additional light of the question of scope.<sup>137</sup> The proposed rule shows that the EDF’s framing of preemption may be a little optimistic.<sup>138</sup>

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<sup>130</sup> *Id.* at S3520 (Statement of Sen. Vitter).

<sup>131</sup> See 15 U.S.C.A. §§ 2605(b)(4)(D), (G) (2017).

<sup>132</sup> *Id.*

<sup>133</sup> 15 U.S.C.A. § 2605(b)(4)(A) (2017).

<sup>134</sup> 15 U.S.C.A. § 2605(b)(4)(D) (2017) (emphasis added).

<sup>135</sup> Denison *Primer*, *supra* note 10, at 8.

<sup>136</sup> Rizzuto, *supra* note 79. When questioned by Mr. Rizzuto, Richard Denison of the Environmental Defends Fund stated: “The final bill allows states to restrict a chemical until or unless EPA takes up that same chemical and addresses the same uses and concerns, he said. The scope of any preemption is directly tied to the scope of EPA’s review, leaving states free to address any uses or risks EPA has not addressed . . . .” *Id.*

<sup>137</sup> *Infra*, Part III.D.

<sup>138</sup> *Id.*

The final form of preemption is “Pause Preemption,” meaning that it only as long as the risk evaluation is underway.<sup>139</sup> This form of preemption is something completely new and has no parallel in the pre-amendment TSCA.<sup>140</sup> Pause Preemption is triggered when the EPA defines and publishes the scope of a risk evaluation for a high-priority<sup>141</sup> chemical, and it ends on the earlier of the date the full risk evaluation is published in the Federal Register or the expiration of the § 6(b)(4)(G) deadline.<sup>142</sup> This form of preemption applies to all “hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the” § 6 evaluation.<sup>143</sup> Once triggered, a state may not establish any new law that restricts the manufacture, processing, or distribution of a substance subject to review.<sup>144</sup> Pause preemption does not, however, apply to the continued enforcement of laws in effect or an action taken before the scope is published.<sup>145</sup> Nor is it triggered by a manufacturer requested evaluation.<sup>146</sup> Mandatory waivers further protect state enforcement while federal regulations are being promulgated.<sup>147</sup>

Notably absent from the new statute, is an exemption from preemption if a state completely bans the use and distribution of a chemical substance in the state.<sup>148</sup> However there

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<sup>139</sup> 15 U.S.C.A. 2617; Stanford D. Baird, Edward P. Sangster, Cliff L. Rothenstein, Maureen O’Dea Brill, *The “Most Contentious Issue” — Federal Preemption in the Amended Toxic Substances Control Act*, K&L GATES (July 28, 2016), <http://www.klgates.com/the-most-contentious-issue--federal-preemption-in-the-amended-toxic-substances-control-act-07-28-2016/> (under pause preemption “a state is temporarily preempted from imposing any new restrictions on a given chemical from the time that EPA defines the scope of a risk evaluation for a high-priority chemical until EPA publishes its final risk evaluation or when the deadline for completing the evaluation expires, whichever is earlier.”); 15 U.S.C.A. § 2605(E)(vi) (2017).

<sup>140</sup> 15 U.S.C. §§ 2605(a)-(b), 2617(c) (2012).

<sup>141</sup> As defined by 15 U.S.C.A § 2605(b)(1)(B)(i) (2017).

<sup>142</sup> 15 U.S.C.A. § 2617(b)(1) (2017).

<sup>143</sup> 15 U.S.C.A. § 2617(c)(2) (2017).

<sup>144</sup> *Id.*

<sup>145</sup> 15 U.S.C.A. § 2617(b)(2) (2017).

<sup>146</sup> 15 U.S.C.A. § 2605(4)(E)(iv) (2017) (“Chemical substances for which requests have been granted under subparagraph (C)(ii) shall not be subject to section 18(b).”).

<sup>147</sup> See *infra* Section II.C; 15 U.S.C.A. § 2617(f) (2017).

<sup>148</sup> Compare 15 U.S.C. § 2617(a)(2)(B) (2012) with 15 U.S.C.A. § 2617 (2017).

are several exemptions worth mentioning. First, preemption does not apply to any law or rule that was adopted pursuant to another federal law or to satisfy any other federal law.<sup>149</sup> Thus, states remain free to restrict chemical use and production to comply with air and water quality standards, such as those under the CAA and CWA.<sup>150</sup> Preemption also does not preclude states from implementing reporting or monitoring requirements that are not otherwise required by the EPA under TSCA or any other federal law.<sup>151</sup> Nor are states prohibited from enacting local or regional requirements that are identical to federal law.<sup>152</sup> As mentioned above, law that were in effect on or before August 31, 2003 are exempted from preemption, which preserved California's Prop 65 and Massachusetts' Toxics Use Reduction Act.<sup>153</sup>

#### B. Manufacturer Requested Evaluations

As shown by the discussion thus far, preemption is triggered and defined by the published scope of a risk evaluation.<sup>154</sup> Moreover, manufacturer requested evaluations trigger Post-Review Preemption upon promulgation of the final evaluation.<sup>155</sup> The EPA is also required fill 25% to 50% of its evaluation docket with manufacturer requests,<sup>156</sup> which is unique in the

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<sup>149</sup> 15 U.S.C.A. § 2617(d)(1)(A)(i) (2017).

<sup>150</sup> States are permitted to continue enforcing requirements relating to water quality, air quality, and waste treatment laws, so long as they do not (1) impose burdens on commerce, (2) address the same hazards as an action taken pursuant to TSCA, and (3) cause a violation of an action take pursuant to §§ 5 or 6 of TSCA. 15 U.S.C.A. § 2617(d)(1)(A)(iii) (2017).

<sup>151</sup> 15 U.S.C.A. § 2617(d)(1)(A)(ii) (2017); *see also* Denison *Primer*, *supra* note 10.

<sup>152</sup> 15 U.S.C.A. §§ 2617(d)(1)(A)(iv), (d)(1)(B).

<sup>153</sup> *Accord* 15 U.S.C.A. §§ 2617(a), (b), (d)(2) (2017). *See also supra* notes 71& 75 (providing citation to Prop 65 and the Mass. Chem. Safety law). Presently, the dominant view is that even future legal actions taken pursuant to these laws will be immune from preemption.

<sup>154</sup> 15 U.S.C.A. § 2605(b)(4)(D) (2017).

<sup>155</sup> *See* 15 U.S.C.A. §§ 2605(b)(4)(C), (b)(4)(E) (2017).

<sup>156</sup> 15 U.S.C.A. § 2605(b)(4)(E)(i). Substances or classes of substances listed on the 2014 update of the TSCA Work Plan for Chemical Assessments are not subject to the 50% cap. 130 Stat. at 464 § 6 (to be codified at 15 U.S.C § 2605(b)(4)(E)(iv)). Moreover, the statute makes clear that publication of risk evaluations is a mandatory requirement:

- (C) REQUIREMENT. —The [EPA] *shall* conduct and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B) for a chemical substance—
- (i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i), and

realm of health and safety laws.<sup>157</sup> The EPA is required to give preference to requests concerning substances that are currently subject to state restrictions that have “the potential to [for] significant impact on interstate commerce or health or the environment.”<sup>158</sup> The requesting manufacturer is also permitted to submit a proposed risk evaluation with its request, which the EPA may utilize in promulgating its evaluation.<sup>159</sup> While there is certainly a risk of over reliance on or blind deference to such data, there are also practical advantages. The proposed evaluations provides a mechanism by which companies can share risk data that has been compiled for compliance with other regulatory schemes such as the E.U.’s REACH program.<sup>160</sup> This could help the EPA efficiently identify what uses and exposure scenarios warrant the most thorough review.

At first glance, this appears to give industry massive influence over the regulatory agenda. This power is tempered by statutory limitations and the fact that the final regulation could heavily restrictive, or even ban, a substance. First, manufacturer requests do not trigger pause preemption does not apply.<sup>161</sup> Second, the EPA is prohibited from expediting or otherwise

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(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the [EPA] in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

15 U.S.C.A § 2605(b)(4)(C). For a discussion of the proposed procedural rule *see infra*, Section II.D.

<sup>157</sup> The nearest analogy to the manufacture requested risk evaluations that this Author could locate is an application for substance registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§136a-136y (2012), which makes it illegal to sell or market an unregistered substance that is subject to FIFRA. However, the FIFRA registration process is more closely analogous to the new substance review process contained in § 5 of TSCA, 15 U.S.C.A § 2604 et seq (2017), because it is a mandatory review process prior to a product or new use reaching the market, which places the informational burden on the applicant and requires a full risk assessment. *See, e.g.,* Donald B. Myers Jr. & Paul A. Lock, *Modernizing U.S. Chemicals Laws: How the Application of Twenty-First Century Toxicology Can Help Drive Legal Reform*, 20 N.Y.U. ENVTL. L.J. 35, 68-81 (2012) (discussing FIFRA as its provision relate to pesticide residue and providing a general summary of its history and provision); *see also About Pesticide Registration*, EPA, available at <https://www.epa.gov/pesticide-registration/about-pesticide-registration> (last visited May 6, 2017) (describing the pesticide registration process under FIFRA).

<sup>158</sup> 15 U.S.C.A. § 2605(b)(4)(E)(iii) (2017).

<sup>159</sup> 15 U.S.C.A § 2625(1)(5) (2017).

<sup>160</sup> *See e.g.,* Sachs, *supra* note 12 (comparing of U.S. Chemical regulations with the E.U. REACH Initiative).

<sup>161</sup> 15 U.S.C.A. § 2605(b)(4)(E)(iv) (2017).

giving special treatment to manufacturer requested risk evaluations,<sup>162</sup> unless the substance is already subject to state regulation that impacts interstate commerce, as noted above.<sup>163</sup> Moreover, manufacturers must pay 100% of the costs of most requested evaluations.<sup>164</sup> Specifically, fees will be established at a level sufficient to defray the entire cost of manufacturer requested risk evaluations, unless the substance was part of the 2014 Work Plan.<sup>165</sup> If the substance is on the 2014 Work Plan, then fees will be set to defray 50% of the costs.<sup>166</sup> While the general fees has yet to be set, the statute limits the use of manufacturer requested risk evaluation fees to defraying the cost of the same.<sup>167</sup> Thus, it seems likely that the degree to which requests will be utilized hinges depend on the price tag.<sup>168</sup>

### C. Preemption Waivers

In response concerns raised by states and NGO groups about the expansion of preemption, the FL21 amendments also revised the § 18 waiver provisions and preserved common law causes of action.<sup>169</sup> There are two forms of waiver.<sup>170</sup> The first is non-discretionary

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<sup>162</sup> 15 U.S.C § 2605(b)(4)(E)(ii) (2017).

<sup>163</sup> 15 U.S.C § 2605(b)(4)(E)(iii) (2017)

<sup>164</sup> 15 U.S.C § 2605 (2017).

<sup>165</sup> 15 U.S.C § 2625(b)(4)(D) (2017).

<sup>166</sup> *Id.*

<sup>167</sup> *Id.* The public comment period regarding the promulgation of a rule on “Fees for the Administration of the Toxic Substances Control Act” closed on August 24, 2017; however, as of this writing, no proposed rule or fee structure has been published, despite its scheduled December 2016 deadline. The final rule is scheduled for publication in June 2017. See <https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0401>. The statute allows for the lesser 25% of the costs of administering §§ 4, 5, and 6 or up to \$25 million to be defrayed by user fees collected from manufacturers. 15 U.S.C.A. § 2625(b)(4)(B). See also EPA, Consultation to Obtain Input on the New TSCA Provision to Collect Fees (August 11, 2016), available at [https://www.epa.gov/sites/production/files/2016-08/documents/fees\\_consultation\\_meeting\\_rev9.pdf](https://www.epa.gov/sites/production/files/2016-08/documents/fees_consultation_meeting_rev9.pdf).

<sup>168</sup> Individuals from the chemical industry that spoke with this Author suggested that companies will likely be hesitant to submit requests until after observing the EPA conduct several risk evaluations on its own initiative.

<sup>169</sup> 162 Cong Rec S3511 (daily ed. June 7, 2016) (Statements of Sen. Boxer) (“[E]ven after EPA announces its regulation, the States have the ability to get a waiver so they can still regulate the chemical, and we have made improvements to that waiver to make it easier for States to act.”). See also *Id.* at S3521 (Statement of Sen Inhofe) (“These waiver and scope limitations ensure that the piause [sic] has its intended effect—to ensure that there is one, comprehensive, nationally-led risk evaluation occurring at a time, allowing EPA and affected manufacturers to focus on and complete the work on a timely basis, and to ensure a uniform and consistent federal approach to risk evaluation and risk management.”). Congress stressed the need to balance public health with the protection of interstate commerce. *Id.* at S3521.

and exempts a state from Pause Preemption while an agency is conducting a risk evaluation.<sup>171</sup> The second is purely discretionary, but if granted, a waiver exempts a state from Post-Review Preemption for particular substances that are the subject to risk management under § 6.<sup>172</sup> Importantly, and unlike the old law, which provided not legal recourse, if the agency denies a waiver request, the state may appeal the decision in court.<sup>173</sup> The statute also imposes a strict, judicially enforceable time limitation on the Agency’s decision of whether to grant a waiver request.<sup>174</sup> However, it is too early to know how liberal the EPA will be in granting waivers.

#### D. The EPA’s Proposed Rule for Chemical Risk Evaluations Under TSCA and Concerns Raised by Stakeholders

The EPA published the proposed *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* on January 19, 2017,<sup>175</sup> which provides insight into the

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<sup>170</sup> 15 U.S.C.A. § 2617(f)(9)(B) (2017).

<sup>171</sup> 15 U.S.C.A. § 2617(f)(2) (2017). These must be granted if compliance with the local regulation (1) will not unduly burden interstate commerce, (2) will not cause a violation of federal law; and (3) the state can show “a concern about the chemical substance or use . . . based on peer reviewed science.” *Id.* Alternatively, there is 18 month window between the initiation of a risk assessment and its completion (possibly three years later) in which a state can still enact and enforce regulations and receive a waiver. 15 U.S.C.A. §§ 2617(f)(2)(B), 2617(f)(7) (2017).

<sup>172</sup> 15 U.S.C.A. § 2617(f)(1) (2017). However, for the EPA to even consider granting a discretionary waiver the state must meet the following four statutory requirements:

- (A) *compelling conditions* warrant granting the waiver *to protect health or the environment*;
- (B) compliance with the proposed requirement of the State or political subdivision of the State would not *unduly burden* interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;
- (C) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and
- (D) *in the judgment of the Administrator*, the proposed requirement of the State or political subdivision of the State is designed to address a risk of a chemical substance, under the conditions of use, that was identified—
  - (i) *consistent with the best available science*;
  - (ii) using supporting studies conducted in accordance with *sound and objective scientific practices*; and
  - (iii) based on the *weight of the scientific evidence*.

15 U.S.C.A. § 2617(f)(1)(A)-(D) (2017) (emphasis added).

<sup>173</sup> 15 U.S.C.A. § 2617(f)(5), (f)(8) (2017).

<sup>174</sup> 15 U.S.C.A. § 2617(f)(3)-(4) (2017)

<sup>175</sup> EPA, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (hereinafter “Proposed Risk Eval. Rule”), 82 Fed. Reg. 7562 (proposed Jan. 19, 2017) (to be codified at 40 C.F.R. pt. 702).

EPA's present interpretation of the TSCA amendments.<sup>176</sup> Of particular interest regarding this discussion are the procedures for manufacturer requested evaluations, § 6(b)(4)(C), and the scope of risk evaluations, § 6(b)(4)(D). Additionally, a number of industry parties submitted comments taking issue with what they believe is an overly broad scoping of risk evaluations and excessively burdensome procedures for manufacturer requested evaluations.<sup>177</sup>

The first step in any risk evaluation is to define the scope, which in turn will later define the breadth of preemption.<sup>178</sup> In this published scope, the EPA proposes to include methodological information, which will put the public on notice as to how and with what techniques the EPA intends use.<sup>179</sup> More importantly, the agency intends to publish a “draft scope” in the Federal Register prior to the final scope.<sup>180</sup> The EPA expects that comments on the draft scope will “reduce the likelihood of significant comments” when the final scope is published.<sup>181</sup> This is significant for at least two reasons. First, the draft publication will allow for states, citizens, companies, and NGOs to argue, and submit data to show, that the proposed scope is too broad or too narrow prior to Pause-Preemption being triggered. Second, because “all comments that could be raised on information and approaches presented in the scope must be presented during this comment period,” as the EPA intends to foreclose any future challenges

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<sup>176</sup> The public comment period closed on March 20, 2017, and the final rule is scheduled to be published in June 2017.

<sup>177</sup> See, e.g., American Chemistry Council (ACC), Comment Letter on Proposed Risk Eval. Rule (March 20, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0005>; American Petroleum Institute (API), Comment Letter on Proposed Risk Eval. Rule (March 20, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0055>; Biobased and Renewable Products Advocacy Group (BRAG), Comment Letter on Proposed Risk Eval. Rule (March 20, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0015>; Dow Chemical Company (DOW), Comment Letter on Proposed Risk Eval. Rule (March 20, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0019>.

<sup>178</sup> Proposed Rule, 82 Fed. Reg. at 7570.

<sup>179</sup> *Id.*

<sup>180</sup> *Id.*

<sup>181</sup> *Id.*

and objections in future administrative or judicial proceedings concerning comments that could have been, but were not, raised during this initial period.<sup>182</sup>

All evaluations must consider the “uses and conditions of use” of the substance under review. However, as agency interprets the term “conditions of use,” it leaves little discretion in deciding the breadth of uses and exposure scenarios that will be evaluated.<sup>183</sup> Specifically, the EPA interprets a § 6 evaluation to “*encompass all* manufacture, processing, distribution in commerce, use, and disposal activities *that constitute the conditions of use within the meaning of section 3.*”<sup>184</sup> The statute defines “conditions of use” as “the circumstances, as determined by the EPA, under which a chemical substance is *intended, known, reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.*”<sup>185</sup> According an evaluation must consider “*all known, intended, and reasonably foreseen activities*” or uses associated with the chemical substance.<sup>186</sup> While recognizing that a narrower reading may be possible, the EPA argued that the broader reading best effectuates the intent of Congress.<sup>187</sup> The foundation of this belief is that § 6 evaluation should look at a chemical substance as a whole, not a subset of specific uses.<sup>188</sup> Thus, to consider whether a substance presents an unreasonable

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<sup>182</sup> *Id.* The Agency finds its authority for such action in a well-defined body of administrative law, which is described in detail in *Nuclear Energy Institute v. EPA*, 373 F.3d 1251, 1290-91 (D.C. Cir. 2004). *Id.* See also *Nuclear Energy Institute v. EPA*, 373 F.3d 1251, 1290-91 (D.C. Cir. 2004) (“Absent special circumstances, a party must initially present its comments to the agency during the rulemaking in order for the court to consider the issue. As a general rule, claims not presented to the agency may not be made for the first time to a reviewing court. To preserve a legal or factual argument, we require its proponent to have given the agency a ‘fair opportunity’ to entertain it in the administrative forum before raising it in the judicial one.” (internal quotation marks and citations omitted)).

<sup>183</sup> 82 Fed. Reg. at 7570-71.

<sup>184</sup> *Id.*

<sup>185</sup> 15 U.S.C.A § 2602(4) (2017).

<sup>186</sup> 82 Fed. Reg. at 7565; at 7568 (emphasis added).

<sup>187</sup> *Id.* “EPA acknowledges that different readings of the law may be possible. For example [§] 6(b)(4)(D) requires EPA to identify the conditions of use that the Agency expects to consider in a risk evaluation, suggesting that EPA does not need to consider all conditions of use.” *Id.* See also, *id.* at 7568.

<sup>188</sup> 82 Fed. Reg. at 7565-66.

risk of harm under “the conditions of use,” the statute is best effectuated if “the” is interpreted to encompass evaluation of all “conditions of use.”<sup>189</sup>

The agency also argued that if the decision of whether a substance, as a whole, presents an unreasonable risk is based on a mere subset of specific uses, one or more harmful uses could be missed.<sup>190</sup> Such a piecemeal approach, the EPA believes, would also make meeting the judicially enforceable deadlines difficult, if not impossible.<sup>191</sup> Considering the tens of thousands of existing chemicals that must be reprioritized and then potentially evaluated, repeated reevaluation for different subsets of uses could be impracticable.<sup>192</sup>

Turning to manufacturer requests, the EPA was given broad discretion in establishing the criteria for an acceptable evaluation, but very little discretion in whether to grant a request if those conditions are met.<sup>193</sup> The agency proposed to give preference to requests where “there may be relatively high exposure(s) and/or hazard(s) under one or more conditions of use,”<sup>194</sup> and the agency intends to tailor each evaluation to best fit the substance and risks under review.

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<sup>189</sup> *Id.* The EPA also noted its ability to complete risk evaluations in phases according to 15 U.S.C.A. § 2605(a), which will all the expedition of review for specific uses that are known to pose an unreasonable risk if necessary. *Id.* at 7568. However, such an expedited review would merely be the first phase of a more comprehensive risk evaluation. *Id.*

<sup>190</sup> *Id.* at 7565-66.

<sup>191</sup> *Id.*

<sup>192</sup> *Id.* at 7566.<sup>192</sup> However, the agency has also stated that it will not initiate a risk evaluation until it is satisfied that “sufficient reasonably available information exists to complete the evaluation.” *Id.* The proposed rule further defines “reasonably available” “to mean existing information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation.” *Id.* at 7568. Generally, information that has not been, but could be, generated is not reasonably available, “because it will typically not be feasible for EPA to require significant chemical testing and receive and assess those test results during the three to three and a half year window allotted for risk evaluation.” *Id.*

<sup>193</sup> *Id.* 7563. The EPA is promulgating guidance documents that will inform manufacturers who request a risk evaluation how and when to submit draft risk evaluations, as well as the required contents of those drafts, which will then be considered by the Agency. *Id.* at pp 7567. Some commentators suggested that the draft evaluations should be governed by rules nearly identical to that which the EPA follows, which will ensure that the draft evaluations can serve as functional equivalents as EPA created evaluations. *See supra*, note 177 and the letters cited therein. Some others, however, suggested that the EPA should “reserve specific scientific processes regarding hazard and exposure information for Agency guidance and discretion, [and] suggest[ed] the rule should address only the process and procedure.” *Id.*

<sup>194</sup> 82 Fed. Reg. at 7563-65.

However, under the proposal, the EPA will only consider a manufacturer's request if it "demonstrates . . . that there is sufficient, reasonably available information for the Agency to conduct a risk evaluation on the chemical substance under the conditions of use."<sup>195</sup> Manufacturers must also commit to providing any referenced data, even if not publically available and certify as to its accuracy.<sup>196</sup> If any of the data is not possessed by the requestor, the request will be denied.<sup>197</sup>

To more adequately ensure that the EPA has all relevant information before beginning an evaluation, it proposed to publish an announcement of any facially valid risk evaluation request in the Federal Register and take public comment."<sup>198</sup> The public is invited to "to identify and/or submit any reasonably available information regarding hazard, exposure, potentially exposed population(s) and subpopulation(s), and conditions of use that may help inform a risk evaluation, including any information gaps in the proposal."<sup>199</sup> The evaluations will otherwise be conducted in in the same manner as those initiated by the agency.<sup>200</sup>

Several companies and trade associations submitted comments, and a reoccurring theme in these comments was that the EPA was reading its obligations in setting the scope of risk evaluation too broadly. Many manufacturers believe that the EPA's expansive interpretation of "conditions of use" is unnecessary and is likely to impeded timely completion of risk evaluations.<sup>201</sup> The Dow Chemical Company (DOW) specifically recommended a tiered prioritization in the pre-risk evaluation process, during which certain uses of a chemical could be

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<sup>195</sup> 82 Fed. Reg. at 7569. While a manufacturer is not required to submit copies of all relevant data, the EPA proposed that at a minimum, a list identifying the relevant data by citation and affirming that the manufacturer indeed possesses those data. *Id.*

<sup>196</sup> *Id.*

<sup>197</sup> *Id.*

<sup>198</sup> *Id.*

<sup>199</sup> *Id.*

<sup>200</sup> *Id.*

<sup>201</sup> *See supra*, note 177 and the letters cited therein.

ruled out as sufficiently mundane to not requiring further evaluation or inclusion within the final scope.<sup>202</sup> Similarly, the Biobased and Renewable Products Advocacy Group (BRAG) advocated for a flexible approach that allowed the EPA to “employ discretion and judgement using a cost effective and timely approach to focus its assessment on a specific subset of uses.”<sup>203</sup> The concern here may be worry about an inefficient use of a limited resource, which ultimately is not in anyone’s interest. Alternatively, it could be buyer’s remorse as industry groups are realizing just how impactful a thorough EPA evaluation could be on production, distribution, and the bottom line.

Eighteen percent of the total comments addressed the manufacturer requested evaluation procedures in some manner.<sup>204</sup> Two overall themes emerged. On the industry side, commenters opposed requiring a requestor have in its possession *all relevant information concerning all conditions of use* for a substance or group of chemicals. Industry also opposed the requirement that a manufacturer pay for the evaluation of uses outside its intended use for its product.<sup>205</sup> These requirements were viewed as creating an insurmountable burden on industry, which will

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<sup>202</sup> DOW comment letter, *supra* note 177.

<sup>203</sup> BRAG comment letter, *supra* note 177. The American Composites Manufacturers Association (ACMA) and American Fuel & Petrochemical Manufacturers (AFPMP) mirror the sentiment of BRAG in their comments. In addition to the areas discussed above, many commenters were concerned with the lack of stakeholder participation and transparency during the pre-prioritization process. Many commenters also recommended that the EPA exclude non-high-priority uses from the initial scoping phase. *See* American Fuel & Petrochemical Manufacturers (AFPMP), Comment Letter on Proposed Risk Eval. Rule (March 20, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0020>; American Composites Manufacturers Association (ACMA), Comment Letter on Proposed Risk Eval. Rule (March 16, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0009>; Utility Solid Waste Activities Group (USWAG), Comment Letter on Proposed Risk Eval. Rule (March 20, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0070>.

<sup>204</sup> The commenters included the following: National Mining Association, Coalition of Companies and Trade Associations, American Chemistry Council, Environmental Defense Fund, SI Group, Fertilizer Institute, American Petroleum Institute, American Fuel & Petrochemical Manufacturers, AFL-CIO, American Concrete Institute, Natural Resource Defense Council, Styrene Information & Research Center, American Coating Association, and Safer Chemicals Healthy Families. Public Comments on Procedures for Chemical Risk Evaluation under the Toxic Substances Control Act, <https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=EPA-HQ-OPPT-2016-0654> (last visited May 6, 2017).

<sup>205</sup> *See e.g.*, ACA Comment letter, *supra* note 177.

stifle the ability to submit a valid request.<sup>206</sup> On the other side of the argument, a number of public health and environmental groups supported the same requirements. They argued that these are essential to protecting public health and preventing abuse of the system.<sup>207</sup> These groups believe it is in the best interest of the public that the agency be precautionary and that industry, as the creator of the risk, shoulder the cost of proving safety.

#### IV. THE NEW TSCA ADDRESSES MANY STATE AND INDUSTRY CONCERNS, AND WHILE FEDERAL ACTIONS WILL BROADLY PREEMPT STATE LAW, THE STATES WILL CONTINUE DOMINATING CHEMICAL REGULATION FOR YEARS TO COME

Federal actions under TSCA are likely to have broad preemptory effect, thus eventually leading to a more uniformity in chemical regulations. However, only those substances designated as “high-priority” will be subject to risk evaluation, and only a fraction of that group will be evaluated in the near future.<sup>208</sup> Moreover, states retain the ability to develop “right to know laws,” and will have opportunities to influence the rulemaking both officially and unofficially.<sup>209</sup> This Author believes that, on-balance, the new aspects of the law discussed above can and will be implemented in a manner that remains conscious of both state and industry interests, thus resulting in a better system of regulations overall.

There are many open questions about the future of TSCA implementation, but the expansion of federal preemption should not leave Americans as a whole in a worse position than before. The new law addresses many of the concerns that states and NGOs, as well as industry

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<sup>206</sup> *Id.*

<sup>207</sup> *See, e.g.*, Environmental Defense Fund (EDF), Comment Letter on Proposed Risk Eval. Rule (March 20, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0074>; Natural Resource Defense Council (NRDC), Comment Letter on Proposed Risk Eval. Rule (March 20, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0066>; Safer Chemicals, Healthy Families (SCHF), Comment Letter on Proposed Risk Eval. Rule (March 20, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0062>.

<sup>208</sup> 15 U.S.C.A. §§ 2605(b)(1)(B), (b)(2), 2617(a)-(b) (2017)

<sup>209</sup> Denison *Primer*, *supra* note 10.

advocates, raised during the years leading to the FL21 amendments in a balanced manner.<sup>210</sup> All groups received some of the protections they wanted, but none got everything.<sup>211</sup> There will undoubtedly be future debates where members of the old coalition are in conflict, but this does not undermine the integrity of the new law.

The remainder of this Article expands on the following observations. First, despite the preemptive potential of TSCA, states will remain dominant in chemical regulations as a whole.<sup>212</sup> Second, industry parties have an economic motivation to support strong, science-based regulations.<sup>213</sup> Lastly, in addition to uncertainties discussed in earlier Parts, commentators and practitioners should closely follow the EPA's funding, manufacturer requested risk evaluations, and the utilization of preemption waivers as TSCA reform is implemented and enforced.<sup>214</sup>

#### A. The FL21 Amendments Addressed Many State Concerns About Preemption and Allow States Continued Dominance in Chemical Regulation for the Near Future

While it is unlikely that any stakeholder views the new TSCA as perfect, Congress included provisions that attempt to address the interests of all sides. The primary concerns that states and NGOs raised about preemption included (1) protecting high-exposure or particularly susceptible populations, (2) preserve state regulatory autonomy, and (3) maintaining air and water quality standards pursuant to state and federal programs.<sup>215</sup> Some concerns were also raised about whether the EPA is provided with enough funding and whether early drafts would

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<sup>210</sup> *Infra* Section IV.A.

<sup>211</sup> See, e.g., Melanie Benesh, *New TSCA Falls Short of Protecting Americans From Toxic Chemicals*, ENVIRONMENTAL WORKING GROUP, May 24, 2016, <http://www.ewg.org/enviroblog/2016/05/new-tsca-bill-falls-short-protecting-americans-toxic-chemicals> (discussing the benefits and shortcoming of the legislation).

<sup>212</sup> *Infra* Section IV.A.

<sup>213</sup> *Infra* Section IV.B

<sup>214</sup> *Infra* Section IV.C.

<sup>215</sup> See discussion *supra* Part II.

actually eliminated the burdens imposed by the *Corrosion Proof* case.<sup>216</sup> Industry, on the other hand, was and remains concerned with (1) eliminating duplicative or conflicting regulations through uniform federal regulations, (2) lessening compliance and reporting paperwork, and (3) eliminated perceived misconceptions about certain substances/product.<sup>217</sup> The amendments gave chemical manufacturers more influence in the regulatory process, but states received protections as well.

### *1. States Retain Substantial Regulatory Power Despite the Expansion of Preemption*

The FL21 amendments go quite far to protect state interests, despite the fact that § 6 actions by the EPA will be broadly preemptive with regard to a specific substance. First, the TSCA specifically preserves the ability of states to regulate chemicals for the purpose of meeting state or federal air and water quality standards.<sup>218</sup> And, state “right to know” public disclosure laws are largely unaffected.<sup>219</sup> This means there will remain indirect avenues to regulate and monitor chemicals even if preemption is triggered. Second, if the EPA pursues § 6 risk management, it is statutorily required to consider the impacts of a substance on “potentially exposed or susceptible subpopulation[s],”<sup>220</sup> which means that federal restrictions can and should be tailored specifically protect those most at risk. This allows for special considerations to be made with regard to groups like the elderly, children, EMS workers, and company employees. Additionally, only high-priority substances, which are those substances the EPA determines present the possibility of *unreasonable risk*, are subject to § 6 evaluations and preemption.<sup>221</sup>

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<sup>216</sup> Hastings, *supra* note 44, at 324; Harris, *supra* note 99.

<sup>217</sup> NAM, *supra* note 85 (discussing a survey of chemical manufactures and their hopes for TSCA reform). The survey is available at <http://www.nam.org/outlook/>.

<sup>218</sup> 15 U.S.C.A. § 2617(d)(1)(A)(i)-(iv) (2017).

<sup>219</sup> 15 U.S.C.A. § 2617(d)(1)(A)(i)-(iv) (2017).

<sup>220</sup> 15 U.S.C.A. §§ 2602(12) (defining potentially exposed or susceptible subpopulation), 2605(b)(1)(A)-(B), (b)(4)(F).

<sup>221</sup> 15 U.S.C.A. §§ 2605(b)(1)(B), (b)(2), 2617(a)-(b) (2017).

Thus, if the EPA does not identify a substances as high-priority states remain free to regulate that substance without fear of preemption. The practical impact of this is that most chemicals will not be subject to federal regulation even under the amended law, and the expansion of preemption will be slow moving and substance specific.

Another practical factor weighing in favor of state regulatory power, although likely not the only one, that it will likely be many years before the EPA is able complete a substantial number of risk evaluations on existing chemicals.<sup>222</sup> Ninety chemicals have already been identified by the EPA as high-priority, but the statute only requires twenty substances to be under evaluation by 2022, each review can take 3.5 years once initiated.<sup>223</sup> Once the evaluations are completed, the EPA will still need to draft and promulgate any regulations that it views as necessary. The Environmental Working Group (EWG), a staunch opponent of the FL21 amendments, has been cited stating the EPA will need “28 years to complete risk evaluations on the 90 chemicals in its work plan, 30 years to finalize related regulations on those chemicals, and 35 years to implement the resulting rules.”<sup>224</sup> This timeline also assumes that Congress adequately funds the EPA, which raises another important concern that states were right to raise: Does TSCA provide adequate funding? This is a question that remains unanswered and will be expanded on below.<sup>225</sup>

It is clear that states will still be in the business of regulating chemicals for a long time to come and they know it. As the § 6 review process takes some time, and the EPA has a backlog of

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<sup>222</sup> Catherine Traywick and Jack Kaskey, EPA Wins Clout to Fight Toxic Chemicals, But it May Take a While, BLOOMBERG POLITICS, June 8, 2016, <https://www.bloomberg.com/politics/articles/2016-06-08/with-chemical-safety-law-congress-hands-epa-herculean-task>.

<sup>223</sup> *Id.*; 15 U.S.C.A. § 2605(b)(G) (2017).

<sup>224</sup> Traywick, *supra* note 222.

<sup>225</sup> *Infra* Section IV.C.

chemicals to reprioritize,<sup>226</sup> states will likely find it worthwhile to continue restricting substances of concern, even with preemption possible. Moreover, non-discretionary waivers will allow states to continue enforcing and developing science-based restrictions while federal rules are developed.<sup>227</sup> Also, states can continue activities in areas where TSCA does not have jurisdiction, namely “food contact materials, cosmetics, and increasing disclosure of substances in product.”<sup>228</sup>

No one really expects the EPA to completely replace states as the only regulator of chemicals. Moreover, states can enact and implement regulations more quickly than the EPA as they are not constrained by the federal APA and TSCA’s “unreasonable risk” standard.<sup>229</sup> States seem to be well aware of this fact as the 2016-2017 legislative term has been busy around the country. For example, twenty-one states are expected to introduce bills, during the 2017 legislative cycle, to reduce exposures to chemicals of concern in consumer products, at least fifteen are expected to address flame retardants, and fourteen are expected to push for identification and disclosure laws.<sup>230</sup> While one class of flame retardants—the Cyclic Aliphatic Bromide Cluster—is included in the EPA’s first ten substances for review, there remain three other widely used categories that states are free to regulate.<sup>231</sup> However, if the EPA evaluates a high-priority substance pursuant to § 6 its decisions regarding regulation will set the floor and ceiling for the country.

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<sup>226</sup> 15 U.S.C.A. § 2605(b)(1) (2017).

<sup>227</sup> U.S.C.A. § 2617(f)(2) (2017); *see also* discussion *supra* Section III.C.

<sup>228</sup> Franklin, *supra* note 102.

<sup>229</sup> *Id.*

<sup>230</sup> David Stegon, *US State Legislatures Look to Fill TSCA Gaps*, CHEMICAL WATCH, Feb. 9, 2017, <https://chemicalwatch.com/53470/us-state-legislatures-look-to-fill-tsca-gaps>; Kelly Franklin, *US State Legislative Activity Unrestrained By TSCA Reform*, CHEMICAL WATCH, March 1, 2017, <https://chemicalwatch.com/53943/us-state-legislative-activity-unrestrained-by-tsca-reform>.

<sup>231</sup> ENVIRONMENTAL PROTECTION AGENCY, *EPA Names First Chemicals for Review Under New TSCA Legislation*, Nov. 29, 2016, <https://www.epa.gov/newsreleases/epa-names-first-chemicals-review-under-new-tsca-legislation>.

## 2. TSCA Gives the Chemical Industry More Influence in Setting the EPA's Agenda

Chemical manufacturers, and downstream entities using hazardous substance in their products, benefit from the FL21 amendments principally in two ways, at least as is relevant to this paper. First is the ability to request a § 6 risk evaluation for a specific substance. Second, once the EPA finishes a § 6 evaluation, preemption is triggered, meaning that industry will generally be subject to one set of regulations.

If utilized, manufacturer requested evaluations give chemical companies an unprecedented ability to shape the federal regulatory agenda.<sup>232</sup> Recall that the statute mandates that 25% to 50% of the risk evaluation docket be manufacturer requests.<sup>233</sup> This allows companies to focus the federal government's regulatory attention, and thus its power of preemption, on specific chemicals of the industries' choosing.<sup>234</sup> This power is limited by the fact that manufacturers must pay for the costs of such evaluations,<sup>235</sup> and the procedural burdens imposed by the EPA.<sup>236</sup>

As put forth in the EPA's proposed rule, only the largest of chemical manufacturers will likely have the resources to utilize the request provisions.<sup>237</sup> This is because of the EPA's interpretation requires it to assess *all* "conditions of use" for a substance in a risk evaluation,<sup>238</sup> not just those that pose the highest possibility of risk as advocated for by the ACA and DOW.<sup>239</sup> As chemical manufacturers have much to gain by federal preemption, there are at least two

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<sup>232</sup> See discussion *supra* Section III.B.

<sup>233</sup> 15 U.S.C.A. § 2605(b)(4)(E)(i).

<sup>234</sup> AMERICAN CHEMISTRY COUNCIL, *Lautenberg Chemical Safety Act (LSCA)*, <https://www.americanchemistry.com/Policy/Chemical-Management/LCSA.html> (last visited May 10, 2017).

<sup>235</sup> 15 U.S.C § 2625(b)(4)(D) (2017).

<sup>236</sup> See 82 Fed. Reg. at 7569-71.

<sup>237</sup> *Id.*

<sup>238</sup> *Id.*

<sup>239</sup> DOW comment letter, *supra* note 177; AMERICAN CHEMISTRY COUNCIL, *Implementing the Lautenberg Chemical Safety Act*, <https://www.americanchemistry.com/Implementing-the-Lautenberg-Chemical-Safety-Act.html> (last visited May 10, 2017).

possible explanations for this position. The first, perhaps the industry's perspective, is that the EPA interpretation is economically and practically wasteful as there is no need to fully assess exposure paths that are not likely to pose a risk. The second, a more cynical take, is that the industry hopes to influence the "scoping" process to ensure that only those uses that it wants reviewed receive federal scrutiny.

Moreover, both the statute and the proposed rule require the company to pay for the entire evaluation, unless the substance was on a preexisting worklist from 2014, in which case 50% of the costs must still be paid.<sup>240</sup> The proposed rule creates a very burdensome fiscal and informational obstacle for any company wishing to request that a specific substance be evaluated.<sup>241</sup> While the exact costs are not known, it is not unreasonable to assume that risk evaluations will cost hundreds of thousands to millions of dollars.<sup>242</sup> Such a financial obstacle is cost prohibitive for smaller companies that likely produce only a handful of substances. However, these costs may also give larger companies pause. If there is a fair likelihood that the scientific evidence will warrant restrictive regulations, or even a ban, it may not be economically wise to take a gamble by requesting an evaluation. In these scenarios it may be more financially sound to wait for the EPA to take action on its own, in which case a company can submit the data that it already possess, such as that created pursuant to REACH,<sup>243</sup> or wait for the EPA to demand data pursuant to § 4.<sup>244</sup>

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<sup>240</sup> See 82 Fed. Reg. at 7569-71; 15 U.S.C § 2625(b)(4)(D) (2017).

<sup>241</sup> See discussion *supra* Sections III.B, III.D.

<sup>242</sup> Risk evaluation costs for 2017 alone are projected to be \$12.3 million dollars. ENVIRONMENTAL PROTECTION AGENCY, *Initial Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act* 4 (January 2017), [https://www.epa.gov/sites/production/files/2017-01/documents/tsca\\_report\\_to\\_congress.pdf](https://www.epa.gov/sites/production/files/2017-01/documents/tsca_report_to_congress.pdf). These costs increase to just under \$25 million in subsequent years once the EPA begins its future docket of 20 ongoing evaluations each year. *Id.*

<sup>243</sup> See *e.g.*, Sachs, *supra* note 12 (comparing U.S. Chemical regulations with the E.U. REACH Initiative).

<sup>244</sup> 15 U.S.C.A. § 2603(a) (2017).

For the substances that EPA does evaluate, preemption will give the industry the benefit, or burden, of a nationwide regulation. While the EPA could come down heavy handed or even ban some uses, there are reasons to believe that federal regulation will often be less burdensome than existing state rules. There are at least two reasons to doubt that the current EPA will regulate in a manner materially adverse to industry interests, unless urged by the industry itself.

First, the EPA can only initiate risk evaluations on substances that present an “unreasonable risk,” and the evaluation is only meant to address those “unreasonable risks.”<sup>245</sup> This is a high standards that must be support by “substantial evidence” on the record<sup>246</sup> and the “weight of the science” regarding the substance.<sup>247</sup> States are free to regulate so long as they rationally believe a public interest would be served by such regulation, but the federal government must support its conclusions with better evidence. Moreover, the EPA will probably only restrict the most dangerous uses because of the procedural burdens imposed on the risk evaluation process.<sup>248</sup> Thus, whether a substance as a whole may pose an “unreasonable risk” under the statute is key, and once that is determined the EPA’s interpretation will dictate what uses of that substance do or do not create that risk. Whatever the result, the EPA’s interpretation likely receive substantial deference if challenged in court.<sup>249</sup>

The second explanation is illustrated by way of example. The EPA recently reversed its position with regard to a controversial insecticide, chlorpyrifos, which as of 2015 the agency was

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<sup>245</sup> 15 U.S.C.A. §§ 2605(a), (b) (2017).

<sup>246</sup> 5 U.S.C. § 706 (2012).

<sup>247</sup> 15 U.S.C.A. § 2605(b)(4)(F)(v) (2017).

<sup>248</sup> 15 U.S.C.A. §§ 2604, 2605 (2017)

<sup>249</sup> *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 104 S. Ct. 2778 (1984). However, Congress is considering legislation that would effectively do away with *Chevron* deference. See Michael Macagnone, *House Passes Bill Ending Chevron Deference*, LAW360, Jan. 11, 2017, <https://www.law360.com/articles/879235/house-passes-bill-ending-chevron-deference>; The Regulatory Accountability Act of 2017, H.R. 5, 115th Cong. (1st Sess. 2017).

poised to ban completely.<sup>250</sup> The EPA's own risk evaluation pursuant to the Food Quality Protection Act<sup>251</sup> found numerous scientifically proven links between exposure and a range of health problems in children.<sup>252</sup> The new administration's EPA now seeks to perform more studies, a decision that is being challenged in court.<sup>253</sup> This suggests that the EPA may be hesitant to harshly regulate in a manner that is contrary to commercial interests, even when there is a wealth of scientific data supporting such regulations. Despite this, some experts in the area of chemical regulation have expressed optimism that the "scientific standards" required under § 26 of TSCA will prevent political and economic motives from undermining the integrity of the law.<sup>254</sup>

#### B. Industry Has an Interest in Effective Implementation of TSCA Reform in Light of its Economic Investment in Reform and Continued Consumer Advocacy Against Weak Regulations

The diverse coalition that supported the amendment of TSCA, may also be key to facilitating the implementation of effective and rigorous chemical safety laws. The new TSCA is supported by a number of environmental groups, most importantly the EDF, which will likely seek legal recourse if the EPA fails to meet its statutory deadlines. But more importantly, the chemical industry itself is heavily invested in TSCA reform.<sup>255</sup>

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<sup>250</sup> Sharon Lerner, *Environmental Groups Sue EPA to Force Ban of Pesticide Linked to Autism*, THE INTERCEPT, April 5, 2017, <https://theintercept.com/2017/04/05/environmental-groups-sue-epa-to-force-ban-of-pesticide-linked-to-autism/>; David Trilling, *A Controversial Insecticide and Its Effect on Brain Development: Research and Resources*, April 7, 2017, <https://journalistsresource.org/studies/society/public-health/chlorpyrifos-insecticide-brain-development-children-epa>.

<sup>251</sup> 7 U.S.C. § 136 et seq. (2012).

<sup>252</sup> Lerner, *supra* note 250; Trilling, *supra* note 250.

<sup>253</sup> Petitioner's Motion for Mandamus Relief, In re Pesticide Action Network North America & NRDC v EPA, Case No. 14-72794, Filed with the Ninth Circuit Court of Appeals, April 5, 2017, available at <http://earthjustice.org/sites/default/files/files/Motion%20for%20Further%20Relief%204-5-17.pdf>.

<sup>254</sup> Pat Rizzuto, *Trade Groups Split on Chemicals, Trump's Pick for EPA*, BLOOMBERG BNA, Dec. 14, 2016, <https://www.bna.com/trade-groups-split-n73014448569/>.

<sup>255</sup> Robert Coleman, *Chemical Giants Spend \$55 Million to Weaken Toxic Chemical Laws*, ENVIRONMENTAL WORKING GROUP, March 4, 2016, <http://www.ewg.org/enviroblog/2016/03/chemical-giants-spend-55-million-weaken-toxic-chemicals-law>. For the data EWG relied on see OPENSECRETS.ORG, Chemical and Manufacturing - Industry Profile: Summary, 2017, <https://www.opensecrets.org/lobby/indusclient.php?id=N13&year=2017>.

There are several economic reasons that the chemical industry will want to see the new TSCA implemented a thoughtful manner. For example, in the four years leading to the passage of FL21, the chemical industry spent over \$245 million in lobbying efforts relating to TSCA.<sup>256</sup> Some of these funds were spent by entities that opposed much of the reform efforts, but others like the ACC, which was key to getting reform through Congress, also were large spenders behind or against the reform effort.<sup>257</sup> The ACC has further been quoted stating that “its top priority is to reform the TSCA in a way that reflects advances in science, today’s global marketplace and improve consumer confidence in the chemicals in their everyday goods.”<sup>258</sup> While the TSCA coalition may disagree about what regulation the science supports, neither the public or industry benefit from arbitrary decisions.

These factors are significant for several reasons. First, the rise of consumer activism targeting potential or known toxic substances suggests that the public has lost confidence in safety regulators and the industry.<sup>259</sup> Second, the ACC and other groups spent significant funds to shape the final TSCA amendments, and it would be financially foolish to let that money go to waste. Third, environmental groups are often viewed as more trustworthy than industry groups in

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<sup>256</sup> Coleman, *supra* note 255.

<sup>257</sup> OPENSECRETS.ORG, *supra* note 255; Graph Depicting Lobbying Expense by Year that Mentioned TSCA, ENVIRONMENTAL WORKING GROUP, <https://public.tableau.com/profile/environmental.working.group#!/vizhome/MajorCompaniesYear-by-Year/4YearBreakdown>. Rebecca Trager, US Chemical Industry Lobby Group in the Hot Seat Again, CHEMISTRY WORLD, July 20, 2015, <https://www.chemistryworld.com/news/us-chemical-industry-lobby-group-in-the-hot-seat-again/8759.article> (ACC has spent more than \$11 million (£7 million) annually on lobbying, and has also made generous political contributions to key members of Congress in charge of chemical reform. In all, the organisation has spent \$1.8 million on more than 6000 ads in the 2014 election cycle. Further, the UCS says that lobbying by the chemical industry as a whole has more than doubled since 2005 to \$64.9 million in 2014.”).

<sup>258</sup> Trager, *supra* note 257.

<sup>259</sup> See discussion *supra* Part II.

the public eye.<sup>260</sup> These three factors give industry a unique opportunity when it comes to TSCA reform

The chemical industry can, and should, work with environmental groups and federal regulators to ensure that strong science based federal regulations are enacted. This would economically benefit the chemical industry because it could help to serve as a rebranding tool in an era where these companies are increasingly being cast as not caring about public safety. A cooperative campaign of this nature allows the industry to influence public opinion and regulation in a manner that it has not previously been able to do. Pointing to the EDF as an ally in reform efforts is valuable for an industry that has often been on the opposite side of safety and environmental issues. Thus, while there will be disagreement about how rigorous regulations should be, this is a unique opportunity for the chemical industry to rebuild public confidence.

However, if chemical industry does not join the push for strong regulations, there is nothing to stop consumer advocacy from continuing as a market-based counterbalance. The FL21 amendments do nothing to prevent consumers and NGOs from continuing to pressure retailers to remove “unwanted chemicals” from their products. These efforts are largely undertaken based on public perception backed by the reports and data presented by NGO groups.<sup>261</sup> Whether these activism efforts actually lead to the utilization of safer alternatives or not, which is an open question, they have proven very effective when organized and targeted at major retail giants.<sup>262</sup> Weak federal laws will not inspire public confidence and TSCA can do nothing to impact these market based forms of public retaliation. Industry trade groups have expressed a desire to see the Trump administration implement TSCA reform in a thoughtful

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<sup>260</sup> Cf. Robert F. Hurley, *The Decision to Trust*, HARV. BUS. REV. Sept. 2006, <https://hbr.org/2006/09/the-decision-to-trust> (discussing the growing issue of distrust within companies and the distrust of companies by consumers).

<sup>261</sup> *Supra* Section I.B and Part III.

<sup>262</sup> *See supra*, note 9 and the sources cited therein.

manner,<sup>263</sup> it would also be in their interests to push for implementation that the public will view as protective. Without public confidence, more lenient federal laws will do little to alleviate consumer pressures on the market and the commercial benefits of preemption could be lost.

### C. Unknowns and a Look at the Impact of Waivers and Budgets

TSCA reform is still in its infancy and many things remain unknown. As already discussed, the interaction between states, industry, and NGOs will be important to implementation efforts, but other constraints should be followed as this law is put into effect. Some of these uncertainties, such as the use of manufacturer requests and changes to the EPA's proposed rule have already been discussed. Two other important unknowns are the impacts of state preemption waivers and the EPA's budget.

Little can be said about waivers at this time. Both the non-discretionary and discretionary waivers must be justified by science-based evidence.<sup>264</sup> However, to receive a discretionary waiver, an applying state must meet a rigorous legal standard.<sup>265</sup> The statute imposes a requirement of seemingly high level of scientific support and health-based justification, while still giving the Agency ultimate discretion in whether such evidence warrants a waiver.<sup>266</sup> If dealing with a less regulatory prone EPA, there is a chance that these waiver provisions could end up being no more than an empty promise with no real teeth. However, denial or inaction on a waiver is legally actionable and must be rational, so this could be a fruitful area of litigation.<sup>267</sup> The evaluation of waivers should be closely studied as the first round of risk evaluations are published and some states inevitably seek waivers to facilitate for more stringent regulations.

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<sup>263</sup> Megan Parrish, *How Chemical Industry Trade Groups Are Reacting to Trump's Win*, ChemInfo, Nov. 10, 2016, <http://www.chem.info/news/2016/11/how-chemical-industry-trade-groups-are-reacting-trumps-win>.

<sup>264</sup> *Supra* Section III.C. This makes good sense as a matter of policy, because even state regulations that are not based on science should not be enforced as there is no way to objectively justify the restriction.

<sup>265</sup> 15 U.S.C.A. § 2617(f)(1)(A)-(D) (2017) (emphasis added).

<sup>266</sup> *Id.*

<sup>267</sup> 15 U.S.C.A. § 2617(f)(3)-(4) (2017)

Another area of uncertainty that has received the attention of both industry advocates and NGOs is that of the EPA's budget. Congress committed to provide \$56 million to the EPA in the first year to facilitate the evaluation of the first ten chemicals.<sup>268</sup> There is, however, nothing guaranteeing Congress' continued financial support, and the EPA has not published its rules regarding industry fees, which are supposed to provide \$25 million annually.<sup>269</sup> Once the fees are set, it will be some time before the EPA begins seeing that revenue.<sup>270</sup>

Both the ACC and the EWG have expressed concern that TSCA does not provide the EPA with sufficient funding or staff to carry out its new obligations.<sup>271</sup> Without adequate funding the EPA will be hard pressed in its effort to evaluate chemical substances in a timely manner or enact science-based, protective chemical regulations. In light of this, the ACC has already committed to further lobbying to increase the EPA's funding with regard to TSCA.<sup>272</sup>

However, the White House's 2018 budget, if adopted, would cut the EPA's budget by between 25% and 32% eliminate up to one-fifth of the staff.<sup>273</sup> Moreover, as a cost saving measure President Trump signed an executive order that requires federal agencies to repeal two regulations for every new regulation promulgated and second calling for zero net spending increases by the government.<sup>274</sup> If these orders can be lawfully executed, they raise serious

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<sup>268</sup>Traywick, *supra* note 222.

<sup>269</sup> Brian Dabbs, *TSCA Reform Faces Uncertain Funding Future*, BLOOMBERG BNA, June 9, 2016, <https://www.bna.com/tsca-reform-faces-n57982073848/>.

<sup>270</sup>*Id.*

<sup>271</sup> Andy Szal, *Will the EPA be up to the Task of Enforcing TSCA Reform*, CHEMINFO, June 8, 2016, <http://www.chem.info/news/2016/06/will-epa-be-task-enforcing-tsca-reform-rules?cmpid=horizontalcontent>.

<sup>272</sup> Traywick, *supra* note 222.

<sup>273</sup> Devin Henry, *House Passes Interior, EPA Spending Bill*, THE HILL, July 14, 2016, <http://thehill.com/policy/energy-environment/287725-house-passes-interior-epa-spending-bill>, Warren Cornwall, *Trump Plan for 40% Cut Could Cause EPA Science Office 'To Implode,' Official Warns*, SCIENCE, March 3, 2017, <http://www.sciencemag.org/news/2017/03/trump-plan-40-cut-could-cause-epa-science-office-implode-official-warns>.

<sup>274</sup> Henry, *supra* note 273.

questions about how the new TSCA program would function.<sup>275</sup> The temporary funding resolution passed by Congress on April 30, 2017 did not slash the EPA's budget as requested by the administration and left TSCA funding "largely intact."<sup>276</sup> But it is safe to say that the EPA's future under this administration is itself full of uncertainties.

## CONCLUSION

Without a question TSCA reform is a milestone in environmental law and one of the most significant developments in the realm of chemical regulations to ever occur in America. The law provides the federal government with expanded regulatory authority that will allow for the preemption of many existing state programs. Such an expansion of power was important to the passage of the law as it was a key factor bringing the chemical industry to the negotiating table. However, despite this, the law provides a number of important protections for states as well and the EPA is unlikely to replace the states completely.

The new TSCA may eventually lead to a more uniform system of chemical regulations, but this system will only include the most hazardous substances. The creation of federal rules will also be relatively slow. This means that despite the expansion of preemption, states are likely to continue playing an important role chemical regulation across this country. States will continue to be the primary regulatory entity for most chemicals in this country, and retain the ability to regulate even those substances subject to TSCA through other federal laws.

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<sup>275</sup> Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs (Jan. 30, 2017), available at <https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling>. This order had already been challenged in court at the time this Article was being drafted. See Gloria Gonzales, *Trump Administration Sued Over Regulations Order*, BUSINESS INSURANCE, Feb. 9, 2017, <http://www.businessinsurance.com/article/20170209/NEWS06/912311840/Trump-administration-sued-over-regulations-executive-over>.

<sup>276</sup> Christopher R. Bryant, Lynn L. Bergeson, and Margaret R. Graham, *FY 2017 Budget Agreement Leaves EPA Budget Largely Intact*, TSCA BLOG, May 3, 2017, <http://www.tscablog.com/entry/fy-2017-budget-agreement-leaves-epa-budget-largely-intact>.

With luck, the industry, states, and NGOs will work together to ensure that the EPA implements TSCA in a manner that achieves the goal of consistent, protective, and science based federal regulations. All interested parties have a financial and political stake in ensuring that TSCA reform is a success. And, even if the industry pushes for less rigorous regulations in some areas, the ability of consumers to directly lobby the market for change remains unaffected.

There are still many uncertainties in the future of TSCA reform, and this law should be closely followed. Ongoing debates about funding TSCA reform are likely to continue. Moreover, the reform process is likely to provide a bountiful source of litigation and other policy issues to be studied by scholars and practitioners alike. Depending on the course the future takes, Senator Lautenberg's crowning achievement will likely be remembered as smashing success or a crushing failure.