MANUFACTURING POLICY INITIATIVE AT SPEA
INSIGHT INTO MANUFACTURING POLICY

Is TSCA Impeding Innovation in New Chemicals?

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The U.S. chemical manufacturing sector is globally competitive and thriving. The industry produces 12 percent of global chemical production, second only to China; consistently runs a trade surplus (excluding pharmaceuticals); and the average compensation per worker is much higher than the average for all of US manufacturing. Among the nearly 20 subsectors of domestic manufacturing for which the US government collects data, chemicals provide the highest value-added to the economy.

A major reason for its competitiveness is *innovation*—the development of new products or new processes that achieve market success. The US chemical industry spends $12 billion annually on research and development and has a high level of patent intensity (patents per employee). New chemical products consistently produce between 10 and 20 percent of total revenue for US chemical manufacturers, according to one longitudinal survey.

Despite its status as an engine of innovation, some in the chemical industry are questioning whether a 2016 law is having a negative impact on the industry's productivity. Have federal regulators erected unnecessary barriers to market entry for new chemical substances?

TSCA 2.0

Under the Toxic Substances Control Act of 1976 (TSCA), the US Environmental Protection Agency (EPA) is responsible for ensuring that chemicals in commerce—of which there are tens of thousands—do not pose an "unreasonable risk to health or the environment." In doing so, the EPA must take care not to "impede or create unnecessary economic barriers to technological innovation."

When writing TSCA more than 40 years ago, Congress chose to establish different regulatory programs for existing chemicals already in commerce and new chemical substances. The 62,000 substances on the original chemical inventory were not required to go through EPA review. New chemicals, however, would be subject to a 90-day EPA review before they could be bought or sold, during which the Agency could impose requirements or seek additional information from the manufacturer.

In 2016, Congress significantly amended TSCA with the Frank R. Lautenberg Chemical Safety for the 21st Century Act. This was the first major environmental statute to be enacted in 20 years. It provided the EPA with significant new authority, and it enjoyed overwhelming bipartisan support. The impetus of the new law ("Lautenberg") was an acknowledgment that the existing chemicals program was not working. Tens of thousands of chemicals were allowed to continue in the market without any required review of their safety, and questions arose as to whether the Agency had sufficient authority to effectively regulate them. Under Lautenberg, Congress gave the EPA a mandate and timetable to prioritize, evaluate, and, if appropriate, regulate a minimum number of existing chemicals every year. Congress also gave the Agency more tools to compel testing and impose risk management measures.

Congress made several key changes to the new chemicals program. Specifically, the revised law:

- **Requires the Agency make one of five determinations on every new chemical based on its "reasonably foreseeable" conditions of use.** The substance either (1) presents an unreasonable risk, (2) is not likely to present an unreasonable risk, (3) may present an unreasonable risk, (4) is produced in substantial quantities, or (5) insufficient information exists to make a risk determination;
- **Prohibits the Agency from considering cost or other non-risk factors during its review;** and
- **Allows the EPA to revise the fee that manufacturers are charged when they submit a new chemical application (known as a premanufacture notice, or PMN) for Agency review.** The EPA has since raised the fee from $2,500 to $16,000 for the largest companies and from $200 to $2,800 for small- and medium-sized companies. The new fees went into effect October 1, 2018.

These statutory changes, which were supported by the US chemical industry, are now at the center of the debate over whether the new law is hurting innovation.

TSCA Implementation by the Numbers

The EPA has been implementing the revised law since June 22, 2016. Table 1 shows publicly available statistics for the new chemicals program from October 1, 2012 (the beginning of fiscal year 2013, FY13), to September 30, 2018 (the end of fiscal year 2018, FY18).

Table 1. Statistics on New Chemicals Subject to TSCA, FY13 - FY18.

Category	*FY13*	*FY14*	*FY15*	*FY16*	*FY17*	*FY18*
PMNs	704	704	593	363	437	408
"Drop" or	444 (67%)	500 (71%)	417 (70%)	46 (13%)	36 (8%)	18 (4%)

"Not Likely" Determinations (as % of PMNs)						
Withdrawals (as % of PMNs)	5 (0.7%)	3 (0.4%)	3 (0.5%)	93 (26%)	46 (11%)	12 (3%)
Exemptions (as % of PMNs)	492 (70%)	507 (72%)	455 (77%)	283 (78%)	426 (97%)	382 (94%)
NOCs (adjusted NOCs)	403	395	267	366 (335)	292 (187)	184* (133*)

Note: For PMNs, "drop" or "not likely" determinations, withdrawals, and exemptions, data come from a search of EPA's PMN and SNUN table and exemptions table, accessed on November 23, 2018. For NOCs, data for FY13, FY14, and FY15 come from EPA's website, and data for FY16, FY17, and FY18 come from a search of EPA monthly notices published in the Federal Register as of December 1, 2018. "Adjusted NOCs" eliminates those NOCs that commenced more than 30 days prior to EPA receipt of the NOC. In some cases, these substances commenced years before EPA received the NOC.

* Indicates data from October 2017 through May 2018.

Several points can be made from a reading of this table:

First, the number of PMNs—essentially an announcement of intent to introduce a new chemical—initially declined after the new law was enacted. Since then, the numbers have risen, but not to the previous level. There could be several reasons for this decline in PMNs: (A) manufacturers are avoiding submittal of PMNs until greater clarity emerges over the requirements of the new review process (note the decline in PMNs in FY15—as the new law was being re-written), (B) the new law is making PMN review more expensive and manufacturers are therefore not submitting low-value PMNs that are unlikely to be very profitable, (C) manufacturers are not submitting PMNs for chemicals that they believe the EPA will impose restrictions upon or regulate under the new law, or (D) some combination of the above.

Second, the Agency is letting fewer chemicals go through review without some regulatory action. The change here has been remarkable. Before June 22, 2016, the vast majority of PMNs were dropped from review, indicating that the Agency did not believe the risk was significant enough to warrant its attention and that the chemical could enter commerce. Since that date, the Agency no longer has the option to drop a substance from review—it must make a determination as previously described. The EPA is now routinely requiring manufacturers to provide more information to aid its determination, even if the determination is not likely to present an unreasonable risk. This has increased both the review time and the cost to manufacturers, and it has increased the number of restrictions on new chemicals that enter commerce.

Third, the number of withdrawals, after rising initially upon enactment, has almost returned to its pre-Lautenberg level. This makes sense as there were many substances under review at the time of enactment and the EPA concluded that these had to be reevaluated against the new requirements (known as "resets"). A manufacturer

expecting a certain kind of review might withdraw a PMN upon learning that the review process has changed. Now that manufacturers better understand what can be expected under the new law, they are withdrawing fewer PMNs. Indeed, one would expect the EPA to undergo a learning curve as it starts to implement the new law. Such a learning curve also applies to chemical manufacturers as they become more familiar with the new law.

Fourth, there was an initial decline in the number of exemptions granted, but this number has since risen, although not yet reaching pre-Lautenberg levels. A substance may be exempt from PMN review and face a more limited review under certain circumstances; for example, its use in low volumes or its use solely for R&D purposes. As a percentage of total applications (PMNs + exemption requests), exemptions represent a higher share now than before enactment of the new law. This suggests that whatever changes have occurred have affected review of PMNs more than review of exemption requests. This observation could be expected because Congress made few changes to the section of the law that covers exemptions.

Fifth, the rate of new chemicals entering commerce, indicated when a manufacturer sends the Agency a required notice of commencement (NOC) of manufacturing, is lower today than it was pre-Lautenberg. If reviews are taking longer, then one would expect the number of NOCs would experience a decline for some period of time before reaching a steady-state level. This lag represents a delay in innovation. NOCs are a better measure of innovation than PMNs because, historically, only about half of all PMNs are commenced. A change in the number of NOCs (pre- vs. post-Lautenberg) would indicate a change in the level of innovation.

To further investigate this matter, Figure 1 compares the time between the beginning of EPA review (the date of the initial EPA focus group meeting) and the beginning of manufacturing (the date of the NOC) both before and after Lautenberg. The data cover a snapshot in time: a three-month period two years before and two years after the new law was enacted to rule out behavioral changes associated with anticipation of the new law and its initial implementation. Overall, the number of NOCs in May-June 2018 is one-third less than in May-June 2014 (61 versus 92). Interestingly, while the average time is roughly similar, the distribution has shifted. Notably, a relatively speedy review (fewer than 100 days) was commonplace in 2014 but very rare in 2018; only 2 percent of all NOCs logged in at under 100 days in 2018 compared to 20 percent in 2014. This trend continues if we expand the review time to 200 days; 60 percent of new chemicals were commenced in under 200 days in 2014, but this figure drops to 41 percent in 2018.

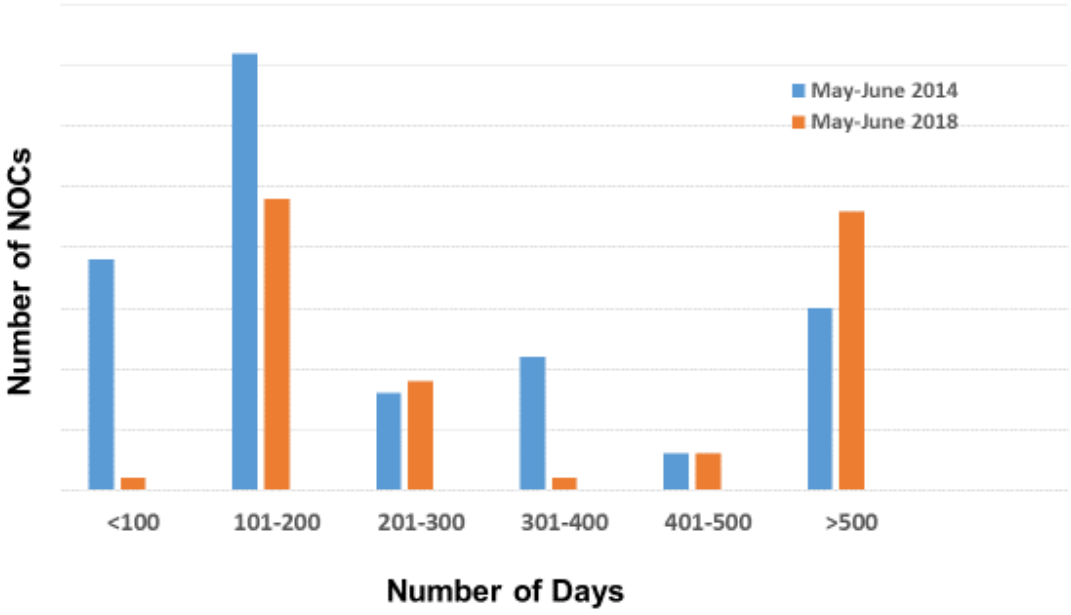

Figure 1. Review times for new chemicals, May-June 2014 (blue) versus May-June 2018 (orange). Source: US EPA.

Although the figure indicates a decline in both the level and timing of new chemicals, it does not show the extent to which a new chemical is restricted or otherwise regulated by the EPA based on its conditions of use. Under TSCA, the EPA can require manufacturers to take risk-reduction actions before a new chemical can enter commerce including, for example, prohibitions on particular uses or requirements to notify customers of particular risks. Such restrictions effectively limit the scope of innovation. Under Lautenberg, such EPA-imposed restrictions have become more frequent (see Table 1).

Other Potential Impacts on Innovation

Other potential impacts of the new law on innovation include: (1) the difference in new chemical review between the US and other countries, and (2) the relative advantage that existing chemicals have over new chemicals.

Are chemical manufacturers shifting innovation from the USA to other countries with less burdensome regulatory programs? This is an important research question. The U.S. was, for decades, considered the best place to introduce a new substance—review was relatively efficient and standards for review well understood. If the U.S. no longer offers the most predictable and efficient review process, firms may choose to first introduce a new substance into a foreign market. If a geographical shift is underway, then TSCA may be impacting the competitiveness of U.S. chemical manufacturers.

Does the new law advantage existing chemicals over new chemicals? One could argue that it does. Whereas every new chemical must go through EPA review before it can enter commerce, existing chemicals are subject to review only after a complex prioritization process that is likely to take centuries before the tens of thousands of existing substances are reviewed. Critics of the new program argue that most existing chemicals would not survive the new PMN review process without additional regulation or EPA-imposed restrictions. Although the original TSCA also heavily favored existing chemicals over new chemicals, the new law may have made the situation worse by taking an overly precautionary approach and increasing the cost and time period for new chemical review and/or increasing the likelihood of restrictions.

Complicating the picture, the EPA has taken the position that, under Lautenberg, it cannot take into account that a new chemical poses less risk than the existing chemical(s) it might replace when reviewing a PMN. For example, pre-Lautenberg, EPA would consider during review whether a new chemical provided pollution prevention benefits. Not so anymore. Thus, the safety benefits of restricting new chemicals may actually be more than offset by the greater safety risks posed by existing chemicals.

Conclusions

The impact of Lautenberg on new chemical innovation will not become completely clear until the initial learning curve is overcome—that is, until the framework rules withstand or adjust to judicial challenge and Agency implementation settles into a routine that provides certainty for would-be manufacturers. At that time, which should be within the next 12-18 months, research should be able to address more clearly issues raised by critics.

Nevertheless, two years after the law was changed, certain trends are emerging that suggest a negative impact on new chemical innovation. Both the time and cost associated with introducing a new chemical into commerce have risen; the number of restrictions on chemicals entering commerce is up; and the number of new chemicals entering commerce is down.

Policy makers responsible for the new law and its implementation should seek answers to the following questions: (1) Is new chemical innovation on the decline in the United States? (2) To what extent are the 2016 changes to TSCA responsible for the observed decline in new chemical innovation? (3) Does a decline in new chemical innovation attributable to the new law equate to “unnecessary economic barriers to technological innovation,” or is some adverse impact on innovation necessary to ensure that new chemicals do not pose an unreasonable risk?

Another way to look at this issue is in terms of the costs and benefits. It might be expected that changes to TSCA would diminish innovation while increasing assurance of safety. If net social benefits are positive, the tradeoff of safety versus innovation can be economically justified.

Peer reviewers: Mark Duvall, Principal, Beveridge & Diamond, PC and Richard E. Engler, Director of Chemistry, Bergeson & Campbell, PC.

For Further Reading

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