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Chemicals

How TSCA Modernization May Harm Innovation, And What Companies Can Do In Response

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TSCA

Upcoming chemical management rules from the Environmental Protection Agency could constrain innovation in chemistry, two attorneys say. What companies can do to continue to break new ground is explored in the light of the amended Toxic Substances Control Act.

BY WARREN LEHRENBAUM AND PREETHA CHAKRABARTI

On June 22, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the Lautenberg Act). This legislation, which capped several years of difficult negotiations on Capitol Hill, is intended to modernize the 40-year old Toxic Substances Control Act (TSCA) and completely overhaul how chemical products are regulated in the U.S.

One of the justifications for industry support of TSCA modernization legislation was the promise that a more modern TSCA would spur innovation. Indeed, “promoting innovation” was one of the core principles of TSCA reform that the American Chemistry Council adopted to guide the chemical industry’s participation. Distressingly, with the enactment of the Lautenberg Act, it appears that some of the changes that have been made to TSCA will actually have the opposite effect—impeding innovation in the chemicals industry and, therefore, industry in general.

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Root of the Problem.

In the run-up to enactment of TSCA modernization legislation, much of the debate among stakeholders focused on the appropriate safety standard that the EPA should apply in conducting risk assessments on chemical substances. To be acceptable, the safety standard would have to adequately protect health and the environment; but from industry’s perspective it also was essential that the standard not be overly-restrictive. Ultimately, Congress adopted a standard of no “unreasonable risk of injury to health or the environment.”

In addition to including this new safety standard in TSCA, the Lautenberg Act also shifted the burden to the EPA when applying that safety standard to a new chemical substance. Under the new TSCA, before a new substance can be placed on the market, the EPA must make an affirmative determination that the substance satisfies the safety standard.

Previously, the agency was not required to make such an affirmative determination; instead, manufacture (and import) of a new chemical substance could commence following completion of a 90-day review period, *unless* the EPA concluded that the substance *did* present an unreasonable risk. In such circumstances the agency was empowered to impose restrictions on the new substance or require the submission of additional data as a condition of allowing commercialization of the substance.

These changes to TSCA—specifically, the fact that the EPA is now required to apply a new safety standard and to make an affirmative determination that the safety standard will be met before commercialization of a new substance is allowed—will likely slow the agency’s pace of new chemical reviews. Despite all the attention these changes received, however, during the legis-

lative process, the real threat that new TSCA poses to innovation in the chemical industry is not the new safety standard, nor the requirement that the EPA make an affirmative safety determination. Instead, the greater challenge lies with the requirement that the agency makes this positive safety determination with respect to the “**conditions of use**” of the new chemical and how that term is defined under new TSCA.

Specifically, the new law defines conditions of use to include all **foreseeable** uses of a chemical substance. Previously, under “old” TSCA, when the EPA would review a pre-manufacture notice (PMN) for a new chemical substance, the agency would focus its risk assessment on the *intended* uses for the substance, as identified by the PMN submitter. This allowed the EPA to conduct a relatively focused risk assessment, which in turn helped to facilitate its completion of the review.

Now under the new law, the EPA will have to conduct a risk assessment that addresses all foreseeable uses of a new chemical—which could exponentially expand the scope of its review, as well as the time needed to complete it. In particular, the EPA will first have to identify the foreseeable uses of the new substance and then assess the potential exposures associated with each of those foreseeable uses in order to evaluate the risks.

The net effect of this expanded review will likely be delay, particularly for chemicals with any degree of toxicity and especially for highly functional substances with multiple foreseeable uses. Thus, it can be expected that, overall, it will take the EPA longer to complete pre-market review of new chemical substances, and therefore, will take longer to reach the market under new TSCA. Accordingly, for new substances it appears likely that implementation of the new TSCA will have a negative effect on innovation in the chemicals sector, at least in the near term.

How Can Companies Respond?

A company that wants to bring a new chemical to market without undue delay may be able to limit the scope of the EPA’s pre-market risk review—and thereby reduce the time required for that review—by crafting a PMN that expressly limits the potential uses of the new chemical to only those specific uses that are identified in the PMN.

A company can accomplish this by designating the uses identified in its PMN as a “binding option.” This would effectively establish what the conditions of use are for the new substance (by defining the universe of allowed uses of the substance), which would permit the EPA to focus its risk assessment only on the specific uses identified in the PMN, rather than having to evaluate “all foreseeable uses” of the substance and the potential exposures associated with those foreseeable uses.

While this binding option could prove helpful in expediting the EPA’s review of new substances, the approach has important limitations as well. If a company submits a PMN for a new substance to the EPA and designates its intended uses of that substance as a binding option, then the EPA would enforce that limitation on potential uses of the substance by issuing an adminis-

trative order under TSCA Section 5(e) that would limit the allowed uses for the substance to those identified in the PMN.

Indeed, EPA officials have indicated that PMN submitters could be asked to agree to such orders more frequently, regardless of whether they choose the binding option in their PMNs, so that the agency can narrow the focus of its risk assessments rather than examining all **foreseeable** uses of the new substance.

In addition, once a Section 5(e) order is finalized, the EPA would be expected to promulgate a Significant New Use Rule (SNUR) for the new substance, under which *any* person who wants to manufacture, import or process the substance for a use *other than* the specific use(s) identified in the PMN first would have to submit a pre-manufacture notice (referred to as a significant new use notice or SNUN) to the EPA for review. Of course, the preparation of a Section 5(e) order and the promulgation of a SNUR are time-consuming and resource-intensive activities that will likely add to the overall amount of time the agency needs to complete its review of a PMN substance.

Thus, while the binding option approach could facilitate the EPA’s review of a new chemical substance by defining a narrow set of conditions of use, the added steps of preparing a Section 5(e) order and promulgating a SNUR will still contribute to delay in the completion of its review.

Another weakness of the binding option in pre-manufacture notice submissions followed by issuance of a Section 5(e) order is the EPA’s “approval” of the new PMN substance will extend only to the specific uses of the substance that are identified in the PMN.

Thus, if a promising new use for the substance were to be identified in the future, a new notification (a SNUN) would have to be submitted to the EPA for review before that new use could be commercialized. This places an inherent burden on innovation that did not exist under the “old” TSCA. Accordingly, although the binding option and Section 5(e) order provide an avenue for chemical manufacturers to reduce the time to market for a new chemical substance as applied to specific uses, it is not a panacea and it could still result in some dampening of innovation.

As the EPA continues the long process of implementing the new TSCA, it remains to be seen how exactly innovation will be affected. It is important, however, to remember that the underlying policy of TSCA is unchanged under the new law. Specifically, Congress directed that:

- authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

Accordingly, it will be important for industry to keep an eye on the EPA’s implementation of the new TSCA and to be as engaged as possible to help ensure that the underlying purpose and policy of the act are fulfilled.