

CHEMICAL SAFETY 2.0

Will the new law improve EPA risk assessment practices?

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Last June 22nd, President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016. The legislation makes significant changes to the 1976 Toxic Substances Control Act (TSCA), which gave the U.S. Environmental Protection Agency authority to regulate chemicals in commerce.

This “modernization” of TSCA—several years in the making—garnered widespread support from industry, led by the American Chemistry Council (ACC); environmental groups, led by the Environmental Defense Fund; and most importantly, the EPA itself, which will now have expanded powers to identify and control chemical products that fail to meet a new, and arguably more stringent, safety standard.

THE OLD TSCA

When it was enacted in 1976, TSCA was focused on new chemicals. It required the EPA to quickly review (within 90 days) each and every new chemical substance before it entered commercial production to determine if it could pose an “unreasonable risk,” a broad term encompassing not only health risks but also economic benefits. As part of that evaluation, the EPA could seek information from the manufacturer, though this power was limited.

This pre-manufacturing notification process was unique to TSCA. It differed significantly from the pre-market approval Congress requires for pharmaceuticals and pesticides, two classes of chemicals that are designed to be biologically active and together represent a far smaller universe of substances than that covered under TSCA. Over four decades, a consensus view emerged that the new chemicals program has worked as intended, ensuring safety while not hindering innovation, a key consideration of Congress.

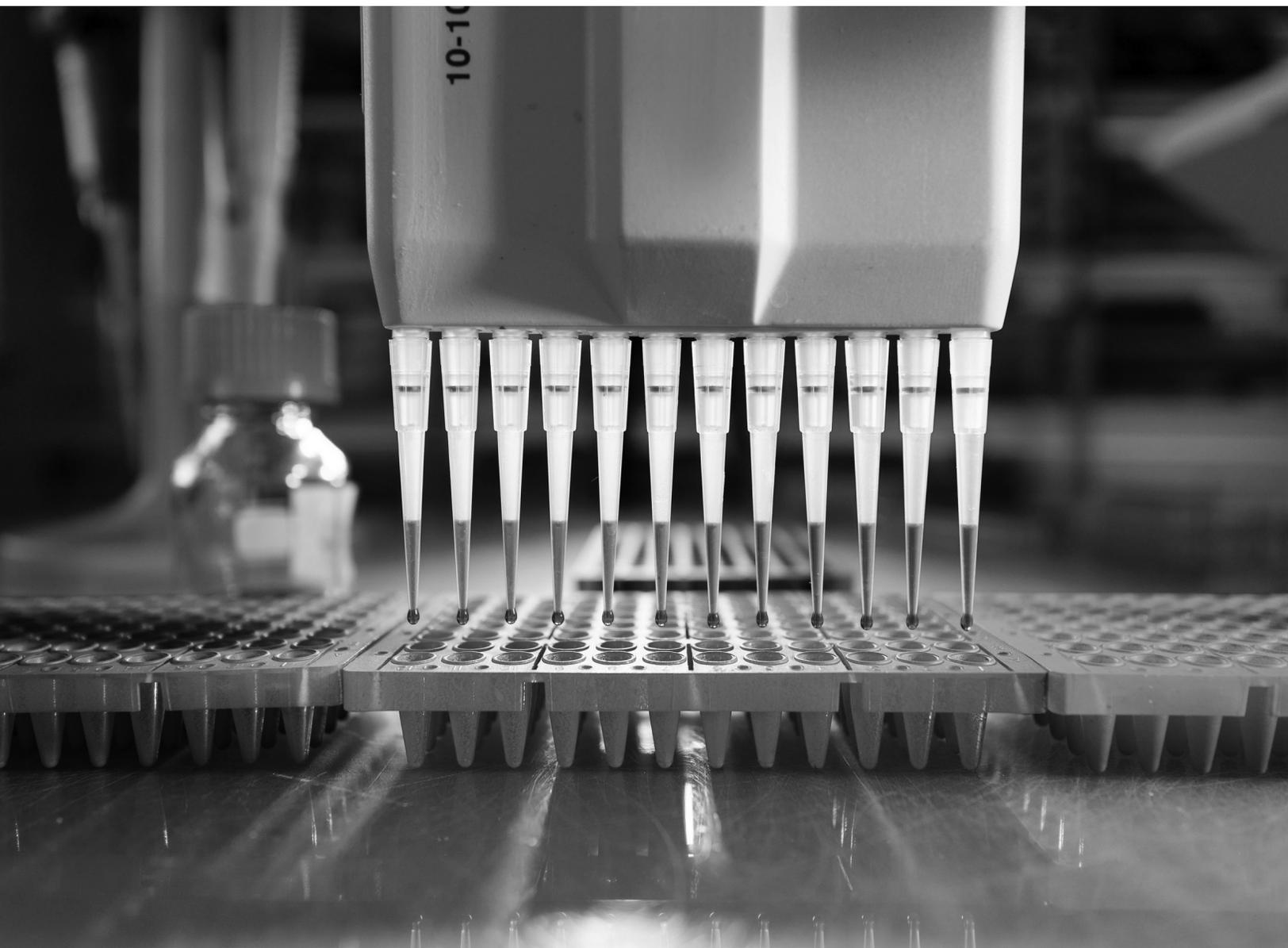
TSCA gave the EPA limited powers to control “existing” chemi-

icals, those substances (roughly 60,000) that were in commerce at the time of enactment. Under TSCA Section 6, the EPA could control (i.e., regulate) an existing chemical if the agency first determined that the chemical posed an unreasonable risk. But to make this determination, the agency had to gather significant amounts of data and information. Some argued that this was a Catch 22—the EPA needed information to compel testing of a chemical, but testing was needed to obtain the needed information. Even when the agency had enough data to make an “unreasonable risk” finding, the statute required a “least burdensome” approach to regulation, which required extensive comparison of an array of regulatory alternatives.

With these requirements, the EPA has had limited success under Section 6; only a handful of existing chemicals have been regulated. Unlike the new chemicals program, the reputation of the existing chemicals program has suffered.

A key turning point in TSCA history was the 1991 case, *Corrosion Proof Fittings v. EPA*, in which the EPA’s near-complete ban of existing asbestos-containing products was challenged. The court held that the agency did not have substantial evidence to support its action and remanded the rule back to the agency. The EPA claimed that this court decision, as a practical matter, eviscerated Section 6 of TSCA. If the agency could not even ban asbestos, it argued, then what chemical could it regulate? Industry thought the decision was just; the EPA had not done the requisite analysis to justify such a sweeping ban. Nevertheless, since *Corrosion Proof Fittings*, the agency has not issued a single regulation to control an existing chemical under Section 6.

Despite this relative inactivity at the federal level, other governmental and non-governmental entities have stepped up to meet the demand of a public eager to reduce chemical risk. In recent years, existing chemicals have received a great deal of attention from other countries and regions, from individual states, from major retailers and consumer product companies, and from trial lawyers. In testimony before Congress, ACC president Cal Dooley



summed up industry frustration, “Over the years, public confidence in TSCA has diminished, contributing to misperceptions about the safety of chemicals, ill-conceived state laws, unnecessary product de-selection, and baseless litigation.”

THE NEW TSCA

Given industry frustration with the status quo, Congress has reacted in a predictable manner: it has granted the EPA increased powers (and fewer hurdles) to identify and regulate existing chemicals in return for greater preemption of state action. Once the EPA makes a final decision on a chemical, states are limited in their ability to control it. States are also “paused” from taking action pending EPA evaluation of a chemical.

Specifically, the EPA must utilize a risk-based approach to sift through the tens of thousands of existing chemicals and identify

those that are “high priority” based on hazard and exposure information. Once it designates an existing chemical as high priority, the agency must conduct a risk evaluation.

In the risk evaluation phase, the EPA must determine if the substance “presents an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors, including unreasonable risk to a potentially exposed or susceptible population identified as relevant to the risk evaluation by the Administrator under the conditions of use.”

If the EPA judges that the substance does not present an unreasonable risk, the chemical will not be subject to regulation. If, however, the agency determines that it “presents an unreasonable risk,” the EPA must regulate the substance “so that the chemical substance no longer presents such a risk.” When determining how to regulate, the agency must consider costs and benefits and the

ENERGY, ENVIRONMENT & NATURAL RESOURCES

risks posed by chemical substitutes. The agency must consider at least two regulatory alternatives (i.e., its preferred alternative and one other). The new law also provides deadlines by which regulatory action must commence and, in the case of chemical phase-outs or bans, must be “as soon as practicable.”

Aside from these amendments to the existing chemicals provisions, the new law includes many other changes, notably the following:

- **Chemical testing.** The EPA now has greater and more flexible powers to compel chemical testing by manufacturers and gather data for risk-based prioritization and determinations about chemical safety. Most notably, the agency can order testing (as it does under the pesticide program) without having to go through a lengthy rulemaking process. When ordering testing, the EPA must utilize a “tiered approach” to minimize costs.
- **Confidential business information (CBI).** The CBI provisions have been re-written to make clear which information cannot be claimed as CBI and which information can be. Those claiming CBI will have to substantiate their claims periodically.
- **New chemicals.** The agency has additional time to evaluate new chemicals and significant new uses of existing chemicals: essentially 180 days, and the EPA can take even longer if it wishes. However, the agency must now make one of three specific determinations, with specified consequences. Specifically, the agency must determine that a new substance either “presents” an unreasonable risk (which it must then regulate), “is not likely to present” an unreasonable risk (which it cannot regulate), or “may present an unreasonable risk” or it cannot make a determination based on inadequate information (which it may regulate).

The EPA has been quick to point out the improvements in the new law. The following excerpt appeared on the agency’s website on the day of enactment:

Under the old law, the tens of thousands of chemicals already in existence in 1976 were considered in compliance, without any requirement or schedule for EPA to review them for safety. EPA is now required to systematically prioritize and evaluate chemicals on a specific and enforceable schedule. Within a few years, EPA’s chemicals program will have to assess at least 20 chemicals at a time, beginning another chemical review as soon as one is completed.

The old law was so burdensome that it prevented EPA from taking action to protect public health and the environment—even when a chemical posed a known health threat. Now, EPA will have [to] evaluate a chemical’s safety purely based on the health risks it poses—including to vulnerable groups like children and the elderly, and to workers who use chemicals

daily as part of their jobs—and then take steps to eliminate any unreasonable risks we find.

EPA will now be able to collect up to \$25 million a year in user fees from chemical manufacturers and processors, supplemented by Congressional budgeting, to pay for these improvements.

RISK EVALUATION

The new law imposes a few general requirements on the agency during risk evaluation. It must integrate hazard and exposure information on conditions of use. It also must note whether aggregate or sentinel exposures were considered. It cannot consider cost or other non-risk factors. It must account for relevant exposures based on conditions of use. And it must describe the “weight of evidence” on hazard and exposure.

Noticeably absent from the new law are specifics on how the agency is to conduct risk evaluation. Those will be established through future rulemaking and guidance during the implementation phase. Indeed, perhaps the most important provision of the new law is this one:

Not later than two years after the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Implementation will ultimately determine the success or failure of TSCA reform.

Specifics are important here: the outcome of a risk evaluation rests heavily on standardized assumptions used to overcome scientific uncertainty and variability across the human population. For example, how will the agency extrapolate toxicological information from animals (which, in testing, are exposed to high doses of a chemical) to humans (which are typically exposed to much lower doses)? How will it weigh the results from multiple toxicological studies on the same chemical? How will it consider the relative importance of positive studies (showing an adverse effect on health) versus negative studies (showing no adverse effects)? And what is an “adverse” effect? The decision to regulate and the stringency of regulation ultimately will depend on choices made in the risk evaluation process. And while it is true that there is no shortage of internal EPA guidance on how to conduct risk assessment, and much of it has been well accepted (e.g., on risk characterization), it is also true that the agency does not always follow this guidance.

The history of EPA risk evaluation (and a subset of risk evaluation known as risk assessment) is not pretty. The Government Accountability Office currently lists two EPA risk assessment programs on its high-risk list of government programs, noting that it will take the agency 10 years to conduct risk assessments on just 83 substances (which is less than 0.1% of the number of existing chemicals). Since 1983, the National Academy of Sci-

ences has consistently called for improvements in the EPA's risk assessment practices, most recently in 2011 and 2014 with its evaluation of the EPA's Integrated Risk Information System (IRIS) process, and information from IRIS will be used to support risk evaluations under the new law.

Historically, the EPA risk assessments for existing chemicals under TSCA have been few in number, slow in development, and arguable in quality. Will the new law improve this situation? This is the critical question upon which success of the new law will rest. If the EPA cannot dramatically increase the pace and quality of risk evaluation compared to its historical performance, the new law will do little to instill public confidence, and the marketplace will react accordingly, to the dismay of supporters of the new law.

Some believe the solution to this "pace" problem is for Con-

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gress to impose statutory deadlines on the agency. That approach has worked before: under the 1996 Food Quality Protection Act, the agency was required to go back and re-evaluate all pesticide tolerances (a few hundred in total) within six years. The agency managed to complete this exercise in time (although, to be fair, the resources of the pesticide office greatly exceed those of the TSCA office). Public interest groups and environmental advocates pushed hard and successfully for Congress to include deadlines in the new TSCA. The EPA considers these deadlines to be aggressive but achievable.

Yet even if the EPA meets its deadlines under the law (once the program gets up and running, at least 20 chemicals must undergo risk evaluation concurrently), this pace is not likely to stem action by the marketplace in promoting "unnecessary product de-selection" that the chemical industry abhors. The number of existing chemicals is simply too large and risk evaluations take too long. And what about the quality of evaluations? The new bill includes requirements that the agency employ the "best available science" when making decisions on a chemical, but is this language determinative or simply hortatory?

IS COMPETITION THE ANSWER?

If one considers the market for chemical risk assessments, then one must conclude that the government enjoys considerable market power. Regulatory agencies are required by law to assess

risk and regulate based on this assessment. Just as concentrated market power leads to suboptimal outcomes (e.g., low supply, high price), federal risk assessments are also suboptimal (e.g., slow pace, costly, low quality). The good news is that there is a remedy. Seen through the lens of market failure, governmental risk assessment could benefit greatly from competition.

The new law includes a requirement that the EPA "develop guidance to assist interested persons in developing and submitting draft risk evaluations which *shall* be considered by the Administrator." Congress anticipates that third parties will submit their own risk evaluations to the agency, leveraging the considerable expertise on risk evaluation external to the agency.

This isn't exactly new. The EPA's pesticide program considers risk evaluations from industry during the pesticide registration process (even though the underlying statute does not require it explicitly). Such industry-sponsored evaluations have influenced agency decisions (e.g., with respect to the use of mode-of-action information). Leveraging third-party expertise under TSCA seems not only useful but also necessary if the agency is to improve the quantity and quality of evaluations necessary to meet its deadlines, influence markets, and address the GAO and other critics.

The EPA could take steps to leverage third parties to advance implementation of the new law. Foremost, the agency could

make transparent its risk prioritization and evaluation processes such that a third-party could anticipate agency decisions and therefore have more time to plan for a regulatory change. Similarly, the agency could make it easier for third parties to assess and evaluate chemical risk by making publicly available any tools (software, etc.) it plans to use for this purpose, and by reducing user fees for manufacturers that follow EPA protocols (and therefore reduce the EPA's workload). Manufacturers, processors, and others directly affected by the new law will then act on their own in anticipation of EPA action, but only if the agency is willing to be fully transparent in its methods and consistent in their application.

The agency could also employ rigorous external scientific peer review of its risk prioritization and risk evaluation processes in general and specifically for significant chemical decisions.

Although this kind of approach—this "crowdsourcing" mentality—seems optimal (and perhaps necessary to ensure that the EPA is considering "all reasonably available information"), it is not a given. Regulators tend to resist imposing hard-and-fast rules governing their own behavior. Bureaucrats value discretion and elbow room in making regulatory decisions even more than transparency, and even if the result is lower public confidence in a regulatory program. The EPA will have to balance its inherent desire for maximum bureaucratic discretion against the new law's requirements for transparency and leveraging third-party expertise. R