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Chemicals

The New TSCA: Balanced Compromise or Business as Usual?

Lobbied with great energy by the chemical industry and a prominent national environmental group, Congress managed to pass a bipartisan reauthorization of the Toxic Substances Control Act (“new TSCA”) on June 22, 2016, even as the presidential election reached new heights of vituperative energy.

Most of the politicians involved in the deal-making felt entitled to a victory lap, including President Barack Obama. “For the first time in 20 years, we’re updating a national environmental statute. For the first time in our history, we’ll actually be able to regulate chemicals effectively,” the president enthused at the signing ceremony.

This sunny display of consensus dissipated quickly, as expected by any veteran of the decision-making that translates congressional will on environmental issues into action.

Interest groups retreated behind their own lines, assuming that Hillary Clinton, a candidate susceptible to environmentalist pressure but also open to industry concerns, would be the next president of the U.S. With the stunning election victory of President Donald Trump, this premise was turned on its head, as deregulators climbed into the driver’s seat of the executive branch, the House, the Senate, and, soon, the courts.

The unusual alignment left the chemical industry with little incentive to honor the delicate balance of trade-offs that propelled the legislation across the finish line. Now, with compromise a distant memory, the new law teeters on the brink of failure, sabotaged by polarized disputes over the language of the new statute, heavily skewed decision-making, funding gaps, and a brain drain at the EPA. It will be implemented in some fashion, but the effective control of toxic chemicals seems elusive.

Typical Process? Some insist that what is happening now is no more and no less than the typical scenario that occurs whenever Congress passes legislation and the executive branch undertakes the arduous, increasingly fraught process of implementation. When I appeared on a recent American Bar Association panel with Michael Walls, a vice president with the American Chemistry Council, he told me just that in response to my gloomy prediction that a hijack of the compromise was in process. But, as is true in so many other arenas,

the Trump administration’s hostile takeover of the executive branch means anything but business as usual.

What are the implications of failure for public health? In 2009, the EPA’s efforts to assess and control hazardous chemicals was placed on the Government Accountability Office’s (GAO) “High-Risk List” of government programs that are sufficiently dysfunctional and important to require top-level intervention. The list is quite selective, composed of just 34 entries in 2017. The GAO explained that the “EPA had not developed sufficient chemical assessment information under these programs to limit exposure to many chemicals that may pose substantial health risks.”

The vast majority of Americans have no idea that the GAO keeps such a list, and their acute disillusionment with government arises from other priorities. Yet anxiety over toxic exposures erupts periodically with great force, as illustrated by the reaction of activists to emerging science about bisphenol-A (BPA). Its presence in baby bottles and the news that it might be an endocrine disrupter provoked a rapid and successful episode of “regulation by internet,” a phenomenon that chemical manufacturers ignore at their peril.

The bottom line of such incidents is that the popular perception that the EPA is captured by the chemical industry is not good. When government seems inept, and some science indicates a chemical is poisoning people, social media makes boycotts possible, without regard to the elaborate scientific arguments manufacturers make to convince government decision-makers that the public’s reactions are hysterical. Should the EPA’s implementation of the new TSCA be discredited by the appearance of industry capture, its origin as a compromise will be forgotten.

Four aspects of the new law’s implementation bear watching.

Parsing Language One of the biggest victories scored by the Environmental Defense Fund (EDF) in its negotiations with chemical industry leaders was a provision that prohibits the consideration of costs during risk assessments of existing chemicals. Of course, industry got plenty in return, from the continuation of the cost-preoccupied “unreasonable risk” standard for rule-writing to preemption of more aggressive state regulation of substances that the EPA is evaluating.

But insulating scientific evaluation of exposure hazards from mandatory cost-benefit analysis is a big deal, especially because TSCA assessments will become the gold standard for gauging the threat posed by toxics in all the agency’s other programs, from hazardous waste disposal to air pollution. Or, in other words, the implications of TSCA risk assessments extend far beyond the

new law's task of allowing specific chemicals to be made and sold for uses in commerce.

The portent of negative risk assessment findings looms large for industry insiders despite the extraordinarily slow pace at which the agency is supposed to complete evaluations of existing chemicals. (It has begun with just 10 chemicals out of a universe of thousands, with those assessments due in June 2019, and it is only required to address 20 assessments annually in the out-years.) In a recent column, Charles Franklin, a lawyer at Akin Gump, warned against "the potentially catastrophic consequences for the marketability of a chemical product and the reputation of the manufacturer from an unexpected adverse risk determination." No surprise, then, that circumscribing the scope of such assessments became the first battleground, fought first within the agency and now in court.

The chemical industry and its allies inside and outside government were nimble enough to win the naming game regarding the issue when they fought to exclude what they described as "legacy uses" from assessments. This clever *nom de guerre* leaves the impression that assessments have been saved from wasteful tours of ancient historical uses akin to a 24/7 version of the Antiques Roadshow. If a use occurred in the past, goes this argument, how could it possibly have much significance for the future exposure of people who breathe, wash, eat, or work with existing chemicals for which the agency has approved a future use?

One answer is that many chemicals are persistent inside the body and in the environment. Because they hang around, continuing exposure is a matter of course. A second, related one is that ongoing exposure over a period of several years may have started the process of becoming sick and future exposure will therefore harm a person already made vulnerable by uses the EPA is determined to ignore. In other words, so-called legacy uses have the capacity to make people sick and destroy ecology, no matter when the chemicals were sold and used. Conversely, once an existing chemical clears the hurdle of risk assessment and regulation, the EPA has little control over where and how products are used, whether people already exposed to the chemical might risk further exposure, or how much harm cumulative exposures may do.

Or, to turn the name game around, the new law requires the agency to take members of "susceptible" populations (infants, children, pregnant women, workers, or the elderly) as they find them. Past exposures that increase their risk of harm to future emissions must be taken into account.

Needless to say, the two sides have parsed the statutory language in diametrically opposed ways. The new law authorizes the EPA to define and evaluate "conditions of use" under which "a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." Industry reads the "to be" phrase to mean only future exposure, while environmentalists argue that "known" use means past use and the ongoing exposure caused by such deposits of the chemical into the environment.

The Obama EPA opted for the broader view but the Trump EPA has narrowed its inquiry to nonlegacy uses, defined as the level of production that is occurring today and will occur in the near future. A coalition of environmental groups has challenged the Trump adminis-

tration's definition in court where it will face the traditional government defense that the statutory language is unclear and judges should therefore defer to agency discretion under *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*, a case roundly condemned by conservatives like Justice Neil Gorsuch.

Skewed Decision-Making Nancy Beck, the EPA employee supervising the implementation of the new law, has a high profile among those steeped in the mind-numbing details of toxic chemicals policy making over the last couple of decades. When she was a freshly minted Ph.D., Beck went to work for John Graham, the conservative public policy analyst who served as the regulatory czar under President George W. Bush.

Graham had far-reaching ambitions for the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), including the insertion of its small staff into issues of regulatory science, most particularly the conduct of risk assessment. He assigned Beck to sit down and draft governmentwide standards for risk assessments that, among other things, conflated the distinct activities of assessment and management. The result was that risk was judged through the myopic lens of what management method was affordable. Or, in other words, the government would calculate the levels of exposure to toxic chemicals that regulatory intervention could achieve affordably, but would not address the harmful exposure that remained following such intervention. The guidance was considerably fussier than this core principle, which on its own was a big gift to affected industries, and it was ultimately derailed by objections from within the executive branch and prestigious institutions like the National Academies of Science.

Beck resumed her patrol of day-to-day decision-making at the EPA, compelling career staff to negotiate with her regarding the initiatives, large and small, that were submitted to the OIRA for approval. Eventually, she departed for a job with the American Chemistry Council where she was at the forefront of negotiating the new TSCA. Beck then returned to government service as part of the Trump administration's small cadre of new employees sent to establish a beachhead at the EPA.

Beck was hired in an "administratively determined" position, an unusual category that means she is neither a political appointee nor a competitively hired civil servant. The overriding benefit of this unusual designation is that it exempts such positions from ethical rules that impose a two-year moratorium on political appointees regarding any involvement in matters they had worked on before joining the government. According to Eric Lipton, an investigative reporter for *The New York Times*, no more than a dozen employees are in such positions among the agency's 15,800 employees because the category is usually reserved for especially qualified experts. In a memo justifying Beck's employment obtained by Lipton through an open records request, Kevin Minoli, the agency's acting general counsel, wrote that Beck's extensive background regarding the preferences of the chemical industry in implementing the new law gave her a distinct advantage.

As a practical matter, narrowing conditions of use to overlap exactly with the current and future production of suspect chemicals can have the same result as the conflation of assessment and management during the

risk assessment process. Think of all the ongoing risks that are discarded from consideration by such a process.

Has a chemical leached into groundwater used to irrigate crops and are people ingesting it through food? So long as the current and future production of the chemical does not involve intentional deposition in groundwater, those risks may be ignored, even if the same susceptible people are exposed through the chemical's inclusion in household products or air emissions from nearby factories. Suppose the members of a susceptible population are workers on the line in a factory where the chemical under evaluation is made. If they also live in an airshed where the same chemical once was used in manufacturing processes now discontinued, those same individuals have endured many years of similar exposure. Future exposure resulting from use of a product counts, but exposure resulting from previous use might as well never have happened.

Were she to respond to these concerns, Beck might well say that grave unfairness would result from forcing companies to cease making or using a chemical simply because other companies made or used it in the past. But this kind of balancing is appropriate, if at all, in the risk management phase when the EPA weighs the costs and benefits of potential controls. Under the new law, risk assessments must consider the full range of exposures lest they result in a whitewash of such hazards.

Budget Gaps The EPA's preparation of assessments of individual chemicals has proceeded at a snail's pace, whether in the context of the old TSCA, toxicological profiles under the Integrated Risk Information System (IRIS), or pesticide licensing. The stakes for chemical manufacturers in each of these decisions are typically quite high, and most have not stinted on the resources devoted to such battles. An inordinately complex and ossified process is the inevitable result because the EPA does not have the resources to keep up with industry's many objections. The recent history of IRIS is instructive for two, closely related, reasons.

First, formulating a toxicological profile under IRIS does not involve original research, but rather takes the form of a meta-analysis of existing studies. The controversy that has hobbled this apparently straightforward mandate to the point that it has eked out only a small handful of profiles over the last decade is quite likely to pale in comparison to the disputes that will accompany risk assessments under the new TSCA. Indeed, Beck and others argue that severely narrowing the scope of such risk assessments is the only way to move them along in a timely manner, as required by deadlines in the new law.

Some public interest advocates have ignored this concern, urging the agency to either undertake elaborate investigations of whether existing laws are working in the field or to assume that they are not working, expanding the scope of cognizable exposures to an unworkable extent. Even a less hostile administration might have difficulty with such recommendations. To implement the new TSCA effectively, a middle ground must be found. What Beck has decreed so far, though, leans so far right as to lack credibility.

Second, rather than try to fix IRIS by shielding it from delay tactics, Senate appropriators have endorsed killing the program as part of a broader effort to cut the EPA budget. In its initial and preposterous budget, the

Trump administration demanded a reduction of 31 percent, which was estimated to eliminate 4,000 out of 18,500 employees. No one expects such radical reductions to emerge from Congress. But the passage of a tax bill that will reduce available revenues has redoubled the pressure to keep squeezing the discretionary portion of the federal budget.

Stories about the effect of such deep budget cuts often mention the new TSCA as an exception, in part because industry fees could contribute up to \$25 million annually to the program. The industry fees surely will help and it's a shame they are not higher, not least because the EPA also shoulders the daunting responsibility of reviewing applications to approve hundreds of "new" chemicals within tight deadlines. But the conceit that new TSCA implementation will remain immune from chaos in other chemicals programs is wishful thinking, not reality. Already, rumors are circulating that EPA's political leadership plans a reorganization of such programs. The public administration literature warns that this kind of overhaul can set back the productivity of an agency for years.

Brain Drain Last but not least is the acute problem of the brain drain that increasingly afflicts the EPA. As it has done throughout the government, the Trump administration has offered buyouts to senior civil servants while moving very slowly to nominate people to fill top political positions. Even when it has forwarded names, the administration's insistence on ideological purity has complicated the confirmation process. Its nominee to oversee chemicals programs, Michael Dourson, was controversial because of criticism about his work with industry, and ultimately withdrew from consideration. This illustrates why the administration was reluctant to subject Beck to Senate scrutiny. Meanwhile, hundreds of senior and mid-level managers have taken the buyouts offered by the administration and left the agency, including Wendy Cleland-Hannett, the lead EPA negotiator on the new TSCA.

Administrator Scott Pruitt appears unconcerned about such departures. If his goal is to stop the agency from continuing to produce affirmative proposals, and instead to focus on the repeal or revision of Obama-era rules, pushing career staff out the door makes some kind of twisted sense, no matter how harmful it is to the agency as an institution. Satisfying chemical industry demands that favorite aspects of the new TSCA be implemented in a timely manner is a very different challenge. If Beck is left with a cadre of young risk assessors to do work that would have been very challenging for a well-staffed unit including experts at all levels of seniority, the new TSCA is unlikely to be the exception its most fervent supporters demand that it be.

A Law for the 21st Century The full name of the new TSCA is the "Frank R. Lautenberg Chemical Safety for the 21st Century Act." Sen. Lautenberg lived his long career as a progressive on chemicals policy. He came from New Jersey, after all, a small state with an outsized legacy of petrochemical production and Superfund sites where being branded anti-environmental was the true kiss of the pig. The question therefore is not whether Sen. Lautenberg deserved the honor of having a statute carry his name, but rather whether this particular statute will in fact do him honor.

As the first major overhaul of a 20th century law in the 21st century, the new TSCA's fate is quite impor-

tant. The law was written as a compromise. But its destiny will be determined by politicians who simply do not believe that more environmental protection is necessary and that far less is quite desirable. Because these issues have historically been second tier politically, their popularity with healthy margins of the voting public does not appear powerful enough to determine either who is president or who controls the House and Senate. Yet five decades of history suggest the pendulum on en-

vironmental policy swings both back and forth. Those who discount the possibility that today's extremism will be offset by a wider correction in the opposite direction may have more at risk than they realize.

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