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CHEMICALS

The amended toxics law has the potential to move the country away from a set of hamstrung chemical control policies. Continued and active engagement by the public as the Trump Administration implements the updated Toxic Substances Control Act is crucial to ensure that needed protections are established, according to public health professionals from the University of California-San Francisco.

Practitioner Insights: The Peril and Imperative of TSCA Reform

BY TRACEY WOODRUFF AND PATRICE SUTTON

In June, former President Barack Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act—an overhaul of the law responsible for regulating the tens of thousands of industrial chemicals in everyday products such as furniture, building materials, cleaning products and toys. Some sort of overhaul was long overdue, given that the original 1976 legislation, the Toxics Substances Control Act, had not been amended in the 40 years since its passage. Although the original law was intended to protect the public from toxic chemical exposures, it was universally recognized as weak and ineffective—a state of affairs that Carl Cranor, a professor at the University of California, Riverside, characterized as allowing people to be ''legally poisoned.''

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It now falls to the Trump administration to determine how to interpret and implement the new law. From the perspective of the health of Americans, there is much at stake in how TSCA is implemented. Indicators of health and welfare for many Americans are declining. Life expectancy among the U.S. non-Hispanic white population is falling. The burden of non-communicable diseases (NCDs), exemplified by childhood conditions such as obesity, diabetes, autism and attention deficit hyperactivity disorder (ADHD), is rising. The science shows that exposures to the industrial chemicals that permeate our air, water, food, and everyday products impact the health of Americans today.

The volume of chemicals used in U.S. manufacturing grew more than tenfold in the past half-century. If current levels of exposure continue unabated, the consequences will be an even greater toxic legacy for future generations. The economic costs of non-communicable diseases, including health-care expenditures and lost productivity, are increasing. Incoming environmental officials need to take seriously the concerns expressed

by passage—by a Republican-controlled Congress, it should be noted—of the bipartisan TSCA update.

We face formidable hurdles in implementing TSCA to make sure it actually does what it's supposed to—protect public health. In many important respects, the Lautenberg version does not mandate the reforms needed to address our ubiquitous chemical exposures with the most effective and advanced tools and approaches available rather than the flawed methods used in the past. Added to the law's inherent weaknesses, the head of the president-elect's EPA transition team is the head of a group that has a well-documented history of obfuscating the science to promote anti-regulatory policies. Yet the EPA's choices over the next several years will influence the level of toxic chemicals in our homes, communities and bodies for generations to come. Those concerned about the health consequences must push for policies that have real teeth and will require the agency to hold commercial interests to account. That means TSCA implementation is simply too important to be left in the hands of the regulated industry.

Historically—that is, under the original TSCA—a major obstacle to effective regulation was the requirement that the EPA consider the financial costs to industry of complying with agency regulations. This provision created so much opportunity for legal challenges that it became effectively impossible to regulate any chemicals at all, even with clear scientific evidence of danger. Asbestos, a known carcinogen, became the poster child for TSCA's inadequacies after the EPA tried to ban it in 1989—but was overruled by the courts after industry groups sued, arguing that the government's proposed approach was not the ''least burdensome alternative.''

Given the regulatory stalemate, states, cities and other jurisdictions have often stepped into the breach, issuing their own laws and regulations to push environmental protections forward. The chemical industry and other vested interests never liked this development. With the public health, consumer and environmental communities pushing for a revised national law, business groups viewed the effort as an opportunity to preempt states and local communities from enacting their own robust and timely policies.

Now the Lautenberg law—the newly revised TSCA—is in place. Not surprisingly, as the legislation contains strong preemption provisions, the American Chemistry Council is celebrating its passage. And industry does not appear to be wasting time pushing back against the agency's effort to enforce it. According to a recent Environmental Defense Fund blog about the EPA's attempt to regulate the known carcinogen and developmental toxicant trichloroethylene (TCE), ''industry representatives have asked OMB not to even allow EPA to issue its proposal [for TCE] for public comment, despite the fact that the industry and the rest of the public have yet to see it.''

The new law also codifies other principles and ideas proposed by industry, many of which directly conflict with approaches recommended by medical, public health and environmental groups and incorporated into Europe's 2007 revamping of its chemical regulatory framework, called REACH—an acronym for Registration, Evaluation, Authorisation and Restriction of Chemicals.

The new TSCA does have some positive aspects. For the first time, the EPA is required to determine whether or not a chemical is likely ''to ''present an unreasonable risk'' without taking into account economic costs to industry. The agency must also consider the impacts of exposure on vulnerable populations at greatest risk of exposure, such as pregnant women and workers. The new law also mandates the EPA to evaluate the health and environmental risks of the thousands of chemicals already found in industrial and consumer products, most of them with little or no safety data available. And, like REACH, it not only allows for, but actually requires, EPA to evaluate potential harms before a chemical can be introduced into the market, rather than waiting for evidence of negative impacts to appear afterwards.

But how will the agency get there? And what will be the rules of the game? While the mandate that health impacts should be the key decision-making factor is a welcome shift in approach and philosophy, there are some important, and concerning, obstacles to the goal of truly protecting the public's health.

First, lack of available data will hamper the agency's task. For the vast majority of high-use chemicals in commerce, there is insufficient toxicity data to assess their effects on health. Unlike other U.S. and European environmental laws, the new legislation does not require that industry provide a basic or minimum set of data for every chemical in use—data that would help establish whether the substance poses a risk in the first place. Instead, for chemicals currently registered for use, the EPA is supposed to create what the law calls a ''prioritization'' process. Chemicals for which there is little information available for making the determination could get assessed as having a low chance of generating risk and would therefore receive a low priority—essentially a ''get-out-of-jail-free'' card.

On top of that, the new law will make it more difficult to obtain the necessary data from studies using vertebrate animals—data that has formed the basis of most of EPA decision-making about chemical risks. While relying on in vitro screening and testing is a laudable goal, at the present time this approach is simply not up to the task of predicting health outcomes in humans, particularly for the wide range of susceptibilities in the population due to age, disease status and genetic variability. Recent EPA decisions on the screening of endocrine-disrupting chemicals, for which the Agency requires both in vitro and whole animal testing before making a final assessment, demonstrate that environmental officials recognize the shortcomings of relying solely on the former.

Once EPA actually receives the data, more complications arise, with the law's mandate that the agency ''describe the weight of the scientific evidence.'' The National Academy of Sciences, in a 2014 review of EPA's risk assessment process, declared the standard embodied in the phrase ''weight of the scientific evidence'' to be ''too vague and. . .of little scientific use.'' The NAS instead recommends systematic review methods, such as those that have been adopted by the National Toxicology Program. Case studies developed through use of our program's Navigation Guide, a comprehensive framework for conducting systematic reviews, have demonstrated the feasibility and improved scientific rigor of such methods for hazard and risk assessment. (The report accompanying the legislation, fortunately, supports the use of systematic review methods, but the inclusion of the ''weight of scientific evidence'' standard in the law itself remains troubling.)

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Moreover, both the 1996 federal pesticide law and the European REACH framework require aggregate risk assessments—an evaluation of the impact of multiple exposures to the same chemical from different sources. Yet the new version of TSCA does not require assessment of aggregate risk. It only requires that the agency describe whether aggregate risk was considered and, if not, why not. The law also does not mention what is called cumulative risk, or simultaneous exposures to multiple chemicals that can have a greater impact on the same health outcome, such as brain development, than if a chemical is considered by itself. Evaluating both aggregate and cumulative risk is important to characterize—and not underestimate—the full potential risk of exposure to an individual chemical. Further, assessment of cumulative exposures and aggregate risk were codified in the Food Quality Protection Act of 1996 and recommended by the NAS.

Finally, the time frame for undertaking evaluations of existing chemicals is exceedingly slow. The EPA is required to initiate reviews of 30 chemicals within the next three to five years, and will be required thereafter to be reviewing 20 at a time. The agency is unlikely to have the resources or political will to move faster. Even with specified deadlines, the process of evaluating a single chemical is likely to take years. With thousands of high-use chemicals needing to undergo evaluation, we will all continue to be ''legally poisoned'' well into the future.

Many of these flaws might be less worrisome if not for the dangerous new provisions that preempt the authority of states, cities and other jurisdictions to continue their own unilateral efforts to regulate toxic chemicals—a situation that will put more of a burden on the EPA to make the difficult decisions. The environmental and health communities have long recognized that such preemption is not in the best interest of the public, and the National Academy of Medicine has recommended against it.

The new law grandfathers in existing state and local regulations. However, after the EPA has declared a chemical to be a ''high priority'' for investigation, any new state or local action on the chemical is suspended during the agency's review, a period of up to three years. And once the EPA regulates a chemical, its decision is considered the final word; other jurisdictions are barred from issuing stronger standards or further protections. The law includes some wiggle room for states and local communities to regulate these chemicals under other federal and state legislation. But the chemical industry fought hard to retain the broadest exemptions possible, and the bill leaves huge gaps in the ability of states, cities and other jurisdictions to protect their residents.

In light of these strengths and weaknesses, public engagement in EPA's decision-making process as it develops regulations for the new version of TSCA will be critical. Leading clinical and scientific reports have already laid out a clear path for EPA to pursue in improving health risk assessments and the implementation of greater protections against industrial chemicals. But it is up to all of us to make sure the agency does not underestimate health risks and adopts the most health protective strategy using the best available science.

As EPA moves forward, individuals as well as professional and scientific organizations must make their voices heard through public comments and other means. That's the only way to ensure that science and the public's health are incorporated into the process. Regulating environmental chemical exposures at the state and local level will also remain critical to protecting public health and maintaining pressure on the EPA to act when needed. Given the current shift of our country's politics and priorities, ensuring a strong TSCA may seem like a luxury item for public action. But only strong action will start to reverse our legacy of being ''legally poisoned'' and help us protect the health of our families, communities, and country.