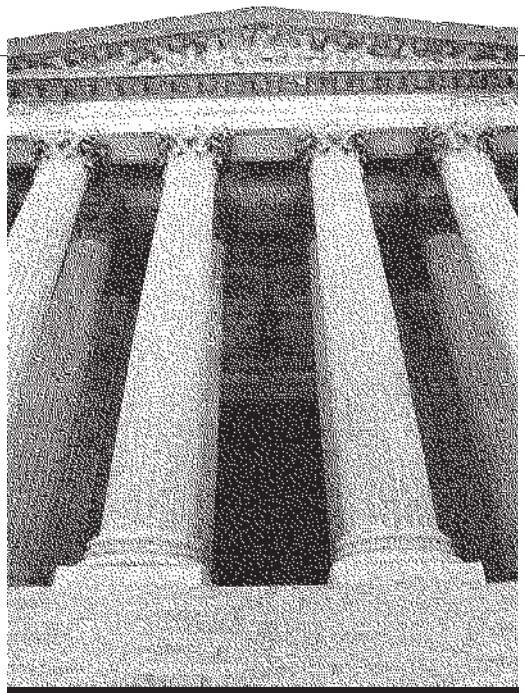

THE DEBATE

The Toxic Substances Control Act Once Again a Center of Controversy

Less than a decade has passed since enactment of the Frank Lautenberg Chemical Safety for the 21st Century Act, the first time the Toxic Substances Control Act was amended since the original law was passed 40 years earlier. Welcomed with broad enthusiasm, the 2016 amendments were intended to correct a number of TSCA's shortcomings. But has the new law worked as expected? Or, as critics have since argued, is it time to consider new amendments because implementation of the 2016 act has revealed significant flaws?

In a January Senate Environment and Public Works Committee hearing on the law's implementation, Ranking Member Shelley Moore Capito (R-WV) complained that chemical reviews are "blowing months" and sometimes years past deadlines, leading her to suggest that the TSCA program "is in a worse state now than before the Lautenberg Act was passed." Committee Chairman Tom Carper (D-DE) acknowledged missed deadlines, but faulted multi-year "insufficient resources." According to a 2022 *Environmental Science & Toxicology* article, the amended law has "failed to protect vulnerable populations." The chemical industry is calling for changes of its own.

But if there are problems, what are practical and durable solutions? Revisions to the Environmental Protection Agency's risk assessment process? More funding? More staff? Would regulatory fixes suffice, or must Congress step in again?

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Assistant Administrator
EPA Office of Chemical Safety and Pollution Prevention

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Doing More With Less Sadly Is Not a Cliche at EPA

By Penelope Fenner-Crisp

The EPA office responsible for implementing the Toxic Substances Control Act has been woefully underfunded for years. Unfortunately, prospects are dim for remedying this situation.

The amended TSCA revised deadlines and added more responsibilities for the new chemicals program. It established an existing chemicals review program with its own set of responsibilities and deadlines. However, missing were adequate resources to implement either program. As we have seen, there has been mixed success in meeting the deadlines, even as significant efforts are being made to make the processes more efficient and thorough without sacrificing the quality and integrity of decisions.

I am a long-time practicing risk assessor. When I analyze legislative mandates as they unfold during implementation, I focus on identifying those aspects of the law that will facilitate or constrain my ability to craft a credible and informative risk assessment in a timely manner, and one that will be of value in the decisionmaking process. As I look at TSCA, I find that the constraints continue to outweigh facilitation.

While amended TSCA has made it easier for EPA to request or require information to fill critical data gaps, the agency has not taken full advantage of this, perhaps in part because the information would not be available in time to meet review and decision deadlines or, more likely, due to the lack of resources to develop all the necessary test orders and information-gathering rules.

The consequences have been significant, as revealed in most of the existing chemical risk evaluations issued to date. It is especially evident in the exposure analyses in both human and environmental risk assessments. Mandated aggregate assessments have been abandoned because of inadequate empirical or modeled exposure information, with the agency concluding that there is too much variability or uncertainty to do them.

This likely has led to an underestimation of risk, perhaps at a level that would meet the unreasonable risk standard. The agency also has been lax in requiring information regarding its human and environmental health concerns, instead depending upon whatever information is available in peer-reviewed and other literature sources. While having scientific merit, these sources do not always fully satisfy the program's regulatory needs.

How might one resolve this situation? While it is a longer-term process requiring amending TSCA, one option would be to mandate the submission of information on hazard and exposure potential earlier, and more systematically, during the life cycle of a chemical, done through a restructuring of the new chemicals program. This would also be useful in the review of existing chemicals already on the TSCA inventory.

But information does not mean only empirical data. Many predictive tools and models are now available or under development, as are test systems that do generate empirical data, but do so more quickly, less expensively, and without wholesale dependency upon traditional animal studies. Many efforts are underway worldwide to move in this direction, which is consistent with the TSCA mandate on vertebrate animal testing, the agency's New Assessment Methods strategy, and the widely held 3Rs philosophy of replacement, reduction, and refinement.

What might this information-gathering structure look like? It would be driven by what human and environmental health concerns need to be addressed and when, for which (sub)populations/species, over what durations of exposure, at what doses, and by what relevant routes or pathways of exposure. As a new chemical proceeds through the stages of its life cycle from manufacture/import to distribution, processing, incorporation into uses and release/disposal, more information would be needed to characterize risk potential.

Generic minimum information requirements would be established and standardized for each stage. (Quantitative metrics may be warranted in determining when to shift to the next level of information-gathering.) However, even as the body of knowledge accumulates and the hazard and exposure profiles become more clearly defined, there should be flexibility to add to or waive requirements, or modify the study design(s) of a requirement to better tailor the resulting information to more accurately reveal the characteristics of the chemical under evaluation.

If done properly and thoroughly, the agency could keep better track of how a chemical is moving through the chain of commerce. It also could better determine if, when, where, and how the chemical's aggregate presence in the environment may be approaching the threshold of unreasonable risk, and require taking prompt action to prevent this from occurring.

Furthermore, when it comes time to consider whether or not a chemical should be a candidate for the existing chemicals review program, the agency would have accumulated a substantial body of information based upon standardized and validated data collection procedures tailored to their regulatory needs. This would simplify and facilitate the prioritization, risk evaluation, and risk management processes.

Penelope A. Fenner-Crisp is an independent consultant and volunteer with the Environmental Protection Network.

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Inevitably, We Need to Amend the Law Again

By David Fischer

The eighth anniversary of the passage of the Lautenberg amendments to the Toxic Substances Control Act—the most ambitious amendments since its original passage in 1976—has come and gone. Each year seems to bring further confirmation that the optimistic expectations of the 2016 amendments have not been realized. We have all heard the refrain that Congress has failed to adequately fund EPA. And the growing frustrations with TSCA implementation would dissipate if only there were higher funding levels.

But the problem with the new law's implementation has less to do with money and a lot more to do with the amended TSCA itself. And we cannot look to legislative history to help. Regrettably, there is precious little of it, not even a conference report to decipher Congress's intent. What we have instead are insufficient, albeit interesting, House and Senate committee reports and floor statements.

The chemical industry was keenly aware that TSCA needed reform, in part, to stem the growing legislative efforts by states to regulate chemicals, resulting in a proverbial patchwork of chemical regulations. The 1976 version of TSCA did not mandate that EPA evaluate and, if necessary, manage the risks of chemicals in commerce, which prompted states to fill the regulatory void.

If TSCA were amended to mandate evaluations of risks from exposures to chemicals prioritized by EPA, coupled with a strong federal preemption provision, then it was assumed that states would rely on EPA to fill the void. Thus, getting the revisions right was paramount. Missteps in how TSCA was amended could inadvertently hamper the goal of empowering EPA to expeditiously and efficiently implement a chemicals management system, especially for the many thousands of chemicals not previously assessed by the agency.

In the end, after years of negotiations and congressional hearings, and despite the best intentions, the final legislative amendments have fallen far short of what was envisioned, to put it mildly. As a result, states have not curtailed their legislative efforts to manage chemicals.

Numerous critically impactful provisions in amended TSCA were vaguely crafted and key terms left undefined. The predictable result was an invitation for EPA to interpret and then reinterpret the new law. Take, for example, TSCA's 2016 mandate that EPA conduct risk evaluations to determine whether a chemical in commerce presents unreasonable risk of injury to health or the environment based on its hazards, exposures and conditions of use, or COUs.

In issuing the initial bolus of 10 risk evaluations, EPA interpreted this statutory language as granting it discretion to identify those COUs and exposure pathways it would include in a chemical risk evaluation. If the agency had already regulated a chemical under the Safe Drinking Water Act, for instance, then EPA could opt not to include the drinking water exposure pathway in the TSCA risk evaluation. Moreover, for each COU evaluated in a risk evaluation, the agency determined that it either presented unreasonable risk, in which case it would be subject to risk management to eliminate that risk, or did not present unreasonable risk, in which case EPA would issue an order asserting that.

However, the agency subsequently reinterpreted TSCA to unequivocally assert that Congress really intended for EPA to consider all COUs and exposure pathways for any existing chemical undergoing risk evaluation. As if meeting the 3-to-3.5-year statutory deadline to complete each risk evaluation was not already a daunting task. And although each evaluation must still account for the risks from individual COUs, the agency makes only a single unreasonable risk determination for the chemical, not individual COUs, dashing the possibility that any COU would be found not to present unreasonable risk.

In amending TSCA, Congress also opted once again not to define the critically important statutory standard of unreasonable risk to health or the environment. Providing at least some guardrails, if not a robust definition, was a missed opportunity, because as previously noted, the 2016 amendments require EPA for the first time to apply this standard in evaluating risks from chemicals in commerce.

Thus, knowing what unreasonable risk is, and equally important, what it isn't, necessarily shapes how the agency identifies those risks it must eliminate. In practice, EPA appears to be defining unreasonable risk as any risk of adverse effects from exposure to a chemical. Is the word "any" synonymous with "unreasonable"? Is that what Congress intended?

I have only scratched the surface of the multitude of TSCA's troubles and tribulations. The eight-year experiment of the amended law has yielded sufficient data for us to know that the expectations of reform have not come to pass. So, what do we do? We will need to change the statute again, but this time with the practical knowledge of eight long years of what worked and did not work in implementing amended TSCA.

David Fischer is counsel with the law firm Keller and Heckman, L.L.P. Previously he served as the deputy assistant administrator within EPA's Office of Chemical Safety and Pollution Prevention.

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TSCA Needs Resources, Not a Re-Write

By Michal Freedhoff

Eight years ago, I was working for Senator Ed Markey (D-MA), negotiating the overhaul of the Toxic Substances Control Act. Now I'm the assistant administrator of EPA's Office of Chemical Safety and Pollution Prevention, implementing the law I helped write. I've seen TSCA up close from both the legislative and executive branches now—and I'm the only one who can make that claim.

We all know why TSCA needed that rewrite: the original 1976 law was not strong enough from the start, and in 1991 a lawsuit so dispositively overturned EPA's ban on asbestos that TSCA was rendered almost powerless to address the risks of the thousands of existing chemicals that had been grandfathered into the law. For new chemicals, the original law allowed the agency to address risks but gave it only 90 days to do so before a chemical was allowed to go into commerce automatically. Between 1976 and 2016, EPA made formal risk findings on only 20 percent of new chemicals, leaving thousands of others, some of which were clearly hazardous like some PFAS and flame retardants, unregulated.

It was clear for decades that the law needed a rewrite. The first meeting I remember on some of the policies that would find their way into the new law was around 2010, when I was still working in the House. It took until May 2013 for the first bipartisan version of what became the Lautenberg Chemical Safety Act for the 21st Century to be introduced, April 2015 for a bipartisan bill to be voted out of Committee, June 2015 until a chamber of Congress voted on a bipartisan TSCA bill, and June 2016 before the law was signed. Congress might seem like it moves quickly—but even though just about everyone agreed we needed a new, strong chemical safety law, it still took years to make it happen.

Like any new project, new TSCA needed new policies, IT, science, and people to make it work. Unfortunately, although Congress expected this would cost money, the previous administration never asked for any additional resources to implement the law. Although President Biden has asked repeatedly, we've never gotten as much as we need, even though EPA's inspector general and the Government Accountability Office have said a lack of resources is a major impediment to meeting our statutory deadlines.

During the last 3.5 years, we've been building the infrastructure of the new law that was sorely lacking. For almost two years we've been finishing 70 percent more risk assessments of new chemicals than we were able to do in FY 2022, and we've cleared out 60 percent of our FY 2022 and older cases.

We've continued to improve new reviews by creating efficient pathways for chemicals in key sectors like semiconductors and batteries. We have worked closely with industry about the data we need up-front, transparently tracked and addressed the steps in the review process where things get stuck, and created tiger teams to modernize our science policies and standard operating procedures. I'm confident that with more time, and ideally with more money, we'll continue to improve.

We've finalized rules for asbestos and methylene chloride and proposed rules for most of the rest of the first 10 chemicals to be reviewed under amended TSCA—rules that will protect people while also ensuring that industry has time to transition to alternatives and that allow important uses of these chemicals to continue safely wherever possible. For methylene chloride, we met the statutory requirement to finalize the rule a year after proposing it. We won't meet that one-year deadline for all our upcoming rules, but we're getting close to doing it with some regularity.

We're also making changes to ensure that the next round of risk evaluations is more efficient than our current crop. We've adopted a more sustainable pace of prioritizing five chemicals a year. We're moving faster in getting the data we need for prioritization while also prepping the data we'll need later to make risk evaluations faster. And we'll be making a considerable amount of data on the chemicals we're proposing to prioritize available a year earlier than we've done in the past—which means we'll get public input sooner and have more time to find anything we're missing.

By any objective metric, EPA is building the foundation of a functioning new law that achieves the strong, credible federal chemical safety statute that Congress envisioned, after the unfortunate first few years when that effort was not what it should have been.

And by any objective metric, the primary barrier to speeding up that work is the sustained failure to provide EPA with the resources it needs. It took decades for Congress to overhaul TSCA. It's simply too soon to say we need to start that years-long effort all over again. Instead, let's continue to work together to better realize the promise so many of us celebrated when President Obama signed the law eight years ago.

Michal Freedhoff is assistant administrator for EPA's Office of Chemical Safety and Pollution Prevention.

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What This Law Needs Is Honest Implementation

By Daniel Rosenberg

Should Congress revisit its 2016 revisions of TSCA? No. The law significantly changed the way EPA is required to evaluate the risks of both new and existing chemicals. The bulk of the changes were to make the law more health protective by requiring that the evaluations of chemicals be more searching (and informed by data) and prioritizing greater protection for human health and the environment. Particularly important was the mandate for EPA to consider and protect "potentially exposed or susceptible subpopulations," which is critical to ensure that everyone who faces harm from chemical exposure is protected under the law.

While implementation of the revised law has encountered challenges, the legislative revisions to weaken the law sought by the chemical industry are not the answer. After an initial six months of implementation at the end of the Obama administration, the first four years of implementation were, unfortunately, led by EPA Administrators Scott Pruitt and Andrew Wheeler, with former (and future) industry lobbyists and scientists in key positions of power.

Those years were marred by numerous decisions that were unwise, unsound, and illegal. The Greatest Hits include excluding consideration of exposure to any existing chemical being evaluated—including methylene chloride, TCE, and 1,4 dioxane—from drinking water or air pollution; adopting an assumption that all workers exposed to chemicals wear effective personal protective equipment 100 percent of the time; excluding "legacy" exposures to chemicals like asbestos from consideration in risk evaluations; and outrageously lowballing the fee that industry was required to pay to support implementation. These decisions, and many others, led, predictably, to failing peer reviews of all 10 of the initial risk evaluations by the Science Advisory Committee on Chemicals—and a loss for EPA in the federal court of appeals (on the "legacy" issue).

Meanwhile, on the new chemicals side of the ledger, the agency found creative ways to avoid the law's new requirements, including failing to fill data gaps when approving new chemicals; neglecting to consider most "foreseeable" uses of new chemicals in their evaluations; and weakening the standard provisions of consent orders for new chemicals. As a result, the effort to stand up a functioning and effective chemical review and regulation program under TSCA was stalled.

The second four years of implementation under the current administration has seen improvement, although many problems remain, including an ongoing failure to account for and ensure protection of potentially exposed or susceptible subpopulations, especially fenceline communities; continued approval of new chemicals that pose an unreasonable risk to human health and the environment (PFAS and chemicals derived from plastic waste, to name two glaring examples); and the recent curtailment of full panel and public peer review of risk evaluations.

None of these problems require action by Congress to fix, other than increasing appropriations for implementation of the program. Rather, they require the agency to implement the law as written, and to use the increased authorities provided by Congress—including expanded testing authority to ensure the public is protected from unreasonable risk from both new and existing chemicals.

While these failures and shortcomings have delayed and denied protection for the public, the chemical industry—which vocally and enthusiastically endorsed the 2016 amendments—is experiencing buyer's remorse over the legislation and is now campaigning for a do-over, calling (including in the *Environmental Forum*)—for Congress to revisit their revisions from only eight years ago.

To put the absurdity of that notion in perspective, the Clean Water Act was last significantly amended in 1977 (47 years); the Clean Air Act was last amended in 1990 (34 years), the Safe Drinking Water Act in 1996 (28 years). Serious implementation of TSCA is barely underway, and court challenges from both industry and public interest advocates that will shape the program lie ahead. Major federal laws take shape through a combination of agency efforts and court rulings. It is premature, in the extreme, to decide that TSCA should again be revised.

A clue to the direction industry wants to take TSCA can be found in the bill introduced last year that would give the Department of Energy the ability to short-circuit EPA review of new chemicals deemed by DOE to be "critical energy resources," coded language for, *inter alia*, PFAS and highly toxic chemicals derived from plastic waste. And the industry-supported (and written?) 2018 Accurate Labels Act, which would preempt the state right-to-know laws that were explicitly preserved in the 2016 amendments.

The public needs an effective TSCA program. The answer is not for Congress to weaken what they finished only eight years ago, it is for EPA to recommit to implementing the law as written, and for the complaints and preferences of the chemical industry to finally take a back seat to the interests of the public and the environment.

Daniel Rosenberg is a senior attorney and the director of federal toxics policy at the Natural Resources Defense Council.

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Congress Can Fix the Handful of Statutory Flaws

By Kimberly Wise White

In the years leading up to the 2016 amendments to the Toxic Substances Control Act, the American Chemistry Council worked with elected officials and NGOs to help make TSCA reform a reality.

The Lautenberg Chemical Safety Act—as the amendments were named to honor the late New Jersey Senator Frank Lautenberg, who made TSCA reform his life's work—also marked the first time Congress passed major environmental legislation in more than 25 years.

Although no law is perfect, the challenges that have come with implementing the TSCA amendments are both well-known and persistent, prompting some to ask if it's time for a do-over.

My answer is no, it would be not only impractical in these times, but also unnecessary when you look at some of the surgical fixes that have already been identified that would help our chemical regulatory system hum-along again in the way Senator Lautenberg and Congress originally intended.

Below I unpack just two of the biggest challenges plaguing TSCA, along with practical solutions.

First, let's support innovation and increase new chemicals program throughput. This challenge reflects the fact that there is a huge backlog of new chemical reviews hung up at EPA. As of July, the agency's 90-day backlog is at 88 percent—a 7 percent increase since May. A staggering 68 percent of the backlogged chemicals have been under review for a year or more.

The impact is that EPA's lack of timeliness in TSCA new chemical reviews throws the supply chain out of whack, delays American innovation, and can incentivize companies to move their chemicals research, development, and manufacturing offshore—along with the jobs and economic growth that come with them.

In an ACC member survey, 80 percent of respondents reported that it took EPA more than 365 days to complete their new chemical review. And 70 percent of respondents say they have decided to introduce new chemicals outside the United States because of uncertainties and challenges with the new chemicals program.

EPA should accept that raising fees won't solve its root, systematic problems. The agency must apply clearer, more consistent, and more concise data submission requirements as part of its pre-notice and interim communication processes with new chemical submitters. The Lautenberg Chemical Safety Act did not change TSCA's 90-day statutory review requirement. EPA should complete new chemical reviews within that period. This must be true for all chemicals, in order to support stewardship and innovation. Finally, the agency and industry must continue to grow and strengthen our working relationship. Like many EPA staff, ACC and its members are scientists, engineers, and environmental stewards—and we should treat each other respectfully and as the scientific and technical career professionals and subject matter experts that we all are.

The second of the two big challenges facing the agency is to strengthen existing chemical risk evaluations. This challenge arises from the fact that TSCA risk evaluations for existing chemicals don't consistently rely on the best available science, and they don't adequately consider real-world workplace protections like personal protective equipment when establishing worker safety limits.

Forgoing the best available science, and not considering the use of PPE in the workplace when evaluating risk, leads to overly restrictive regulations that can scare workers, paint an inaccurate picture of the workplace, and push American jobs, innovation, and manufacturing overseas.

EPA has already established several Existing Chemical Exposure Limits, or ECELs, that are consistently lower than worker exposure limits recognized by other global regulatory and scientific bodies. The agency also recently finalized a new framework rule for existing chemical risk evaluations that removes definitions for best available science and weight of the evidence in chemical safety reviews. Both of these terms are critical requirements that Congress included in the 2016 TSCA reforms.

To resolve this problem, Congress should continue to exercise its oversight authority, engage industrial hygiene, toxicology, engineering, and process-safety experts, and consider establishing a council to ensure risk evaluations and resulting ECELs are science based and in line with best practices for assessing workplace exposures. EPA should work more consistently and transparently with the other federal agencies charged with worker protection to establish ECELs and ensure workplace exposure levels are consistent with other comparable jurisdictions in the world.

While TSCA implementation can be frustrating at times, ACC's commitment to protecting human health and the environment, championing the science, and empowering American manufacturers to lead through innovation hasn't wavered in the last eight years. Neither has our dedication to working with EPA to make TSCA implementation function as Congress intended.

Kimberly Wise White is the vice president, regulatory & scientific affairs, at the American Chemistry Council.