

Optimizing the Toxic Substances Control Act to Achieve Greener Chemicals

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The Toxic Substances Control Act (TSCA) offers tremendous unrealized potential to promote the development of more sustainable industrial chemicals. Despite the fact that Congress significantly amended TSCA in 2016 specifically to diminish the human health and environmental footprint of industrial chemicals, the U.S. Environmental Protection Agency (EPA) is interpreting the revised law in ways that ironically discourage the commercialization of new chemicals and reinforce a “new chemical bias” that undermines the commercialization of greener, more sustainable industrial chemicals. This article explores the EPA policies and practices that blunt the commercialization of promising, more sustainable industrial chemicals and offers recommendations to optimize TSCA to achieve greener chemicals.

TSCA: A Focused Overview

TSCA authorizes EPA to regulate industrial “chemical substances,” defined broadly to include “any organic or inorganic substance of a particular molecular identity.” TSCA § 3(2)(A), 15 U.S.C. § 2602(2)(A). “Chemical substance” excludes pesticides, drugs, and food, all regulated under other federal laws. TSCA § 3(2)(B), 15 U.S.C. § 2602(2)(B). Biobased chemicals, often thought to be inherently less “toxic,” are subject to TSCA if used for industrial or commercial purposes. These are a broad class of chemicals derived in whole or in part from biological sources or renewable domestic agricultural materials. That these substances are derivative of renewable feedstocks does not preclude TSCA’s application to them. Even a food product, such as vegetable oil, becomes subject to TSCA if it is put to an industrial or commercial use.

As broadly as “chemical substance” is defined, it is important to remember TSCA’s jurisdiction is limited to industrial chemicals. The term “chemical substance” expressly excludes

pesticides, food, food additives, drugs, cosmetics, or devices, as these items are regulated under other federal laws. Importantly also, the term excludes “articles” defined generally for these purposes as a finished good. Effectively, this means there are many chemicals, including plastics, used in many applications, and included in many finished goods, that are well beyond TSCA’s jurisdictional reach. TSCA is also not particularly effective in controlling the discard of consumer items, including plastic waste, because TSCA cannot be used to impose requirements on consumers.

TSCA is a complicated law, made all the more complex in 2016 with enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg). Pub. L. No. 114-182, 130 Stat. 448 (2016). EPA’s implementation of Lautenberg over the past six years has been uniquely challenging. The Obama administration was in charge when Lautenberg was passed by bipartisan majorities and oversaw the development of three critically important foundational final rules. The Trump administration took over in 2017 and prominent non-governmental organizations claimed it “wreaked havoc” on TSCA’s “potential to improve chemical safety.” The Democrats reclaimed the White House in 2021 and the Biden administration has been driving very different chemical policies than its predecessor. Among the few observations on which industrial chemical stakeholders of all stripes seem to agree is that Lautenberg’s implementation has not been as successful as stakeholders had hoped. A detailed overview of the law is beyond the scope of this article. Some background is essential to understanding how EPA could better optimize TSCA to promote the commercialization of more sustainable industrial chemicals.

TSCA section 2(b) articulates the policy of the United States regarding actions under TSCA. TSCA sections 2(b)(1) and (2), respectively, discuss the need for adequate test data

to be developed on the effects of chemicals (and that industry is responsible for such testing) and that adequate regulatory authority should exist to control chemicals presenting “unreasonable risks” to health and the environment. Section 2(b)(3) urges EPA to discharge its authority “in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this [Act] 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.” 15 U.S.C. § 2601(b)(3).

TSCA section 2(c) expresses Congress’s intent that, in implementing TSCA, EPA “shall consider the environmental, economic, and social impact” of any actions taken. *Id.* § 2601(c). Read in combination, TSCA sections 2(b) and (c) make clear that in taking action to control unreasonable risks from industrial chemicals under TSCA, EPA is to consider and balance the risks, costs, and benefits presented. While not an enforceable mandate, section 2(b)(3) is a clear statement of domestic policy that has remained essentially unchanged since 1976, the year of TSCA enactment.

The classification of industrial chemicals as either “existing” or “new” is binary under TSCA. Chemical substances listed on the TSCA Inventory are “existing” for TSCA purposes, while those not listed are “new” chemical substances and subject to premarket review but may be exempt from notification requirements based on the availability of one or more exemptions.

TSCA section 5 governs the manufacture in and import into the United States of chemical substances considered “new.” Manufacturers (including importers) of new chemical substances must notify EPA of the new chemical substance through the submission of a Premanufacture Notification (PMN), an innocuous-sounding “submission” that is often hundreds of pages. Unless a PMN exemption applies, an entity must submit a completed PMN to EPA at least 90 days before commencing the manufacture or import of a new chemical substance for commercial purposes. EPA is required to review the PMN against the legal standard of safety embedded in the law and to make and publish one of three findings: that the substance is not likely to present unreasonable risk; that a substance “may present” an unreasonable risk either because EPA lacks sufficient information to make a reasoned evaluation or because exposure to the substance could be significant; or that the substance presents an unreasonable risk. The burden of proof for safety is on the chemical producer.

Chemical safety is considered based on known, intended, and reasonably foreseen “conditions of use,” a concept and phrase new to TSCA since Lautenberg and the source of considerable regulatory and policy confusion. If EPA is unable to make this finding, or lacks sufficient information by which to make this finding, commercialization can only proceed with regulatory limitations on the chemical’s production, distribution, use, and/or disposal, typically expressed in a Consent Order and/or Significant New Use Rule (SNUR). To most chemical stakeholders, SNURs are unwelcome red flags that often make a chemical commercially less desirable and thus less competitive than an unrestricted existing chemical regardless

of the relative hazard. EPA’s new chemical review process by statute takes no less than 90 days, but in practice, the process takes considerably longer, spanning typically at least six to nine months, and often considerably longer. The indeterminate nature of the process, as well as the unpredictability of both its duration and outcome, is commercially destabilizing and the source of immense industry frustration.

The New Chemical Bias

There is no dearth of commentary on the industrial chemical community’s concern over the past six years with EPA’s erratic interpretation of Lautenberg, especially as it relates to new chemicals and the counterintuitive impact current policies are having on new chemical commercialization efforts. Much of the concern is rooted in how EPA’s more recent interpretation of TSCA section 5 has ironically amplified, not diminished, the “new chemical bias,” a problem that long predates Lautenberg.

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The new chemical bias is a shorthand phrase used to capture the notion that new chemicals are reviewed against a legal standard that necessarily places them at a competitive disadvantage *vis-à-vis* existing, incumbent chemicals with which they compete in the marketplace when those incumbent chemicals have not yet undergone EPA scrutiny. The bias is an entirely predictable result of the original TSCA’s listing, without review, of all industrial chemicals that were in commerce when EPA created the TSCA Inventory in the late 1970s. EPA conducted no independent risk evaluation of chemicals in commerce at the time; if a chemical was in commerce, EPA listed it on the Inventory, deemed “existing.” EPA had the authority to review a chemical’s potential for risk, but EPA was not required to review existing chemicals and, especially after EPA’s efforts effectively to ban asbestos were overturned in the *Corrosion Proof* case, EPA largely did not undertake review of existing chemicals absent extraordinary circumstances. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991). Indeed, EPA’s functional inability to review and regulate existing chemicals was a driving force in modernizing TSCA in 2016. Under new TSCA section 6, all “high priority” existing chemicals are now subject to a review process intended to identify and address risks determined to be unreasonable. Given the tens of thousands of existing chemicals

in commerce, however, the review process will take many decades, if not longer, to complete.

New chemicals, however, are subject to premarket EPA review, and Congress significantly revised the review process in 2016. The core problem is simple to explain. The vast majority of industrial chemicals are existing and have never been evaluated for risk potential, and a small percentage are subject to regulatory limitations. New chemicals cannot enter commerce absent EPA's premarket review, a review process that Congress made considerably more amenable to EPA discretion in 2016. So, in short, even if an existing chemical possesses the exact same risk profile as does a new chemical, TSCA requires EPA to regulate the new chemical as a predicate to commercialization through the PMN process while precisely the same risk goes unaddressed in commercial applications of the existing chemical unless until EPA reviews it under TSCA section 6. Logically, this makes no sense. Commercially, it puts new chemicals at a distinct competitive disadvantage—hence the “new chemical” bias.

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TSCA section 5 regulatory limitations are in the form of a consent order and/or a SNUR. These limitations take many forms: enhanced worker protective clothing and personal protective equipment requirements, limitations on discharges to water, limitations on workplace exposures, limitations on downstream customers, labeling and mandatory communication requirements, and compelled modifications to safety data sheets, among many other measures. Most importantly, the Consent Order or SNUR imposes recordkeeping and other reporting requirements on all within the supply chain. Industry has had extraordinary difficulty communicating clearly to EPA, other stakeholders, and the public why imposition of a SNUR on a chemical is commercially undesirable and the reasons why the imposition of SNUR restrictions is prejudicial to new chemicals. Think of it this way:

Assume Acme Automotive develops a battery-powered car that performs as well or better than a gasoline-powered car in every way, including driving range. Even when using a U.S. average mix of electricity sources, including coal, the air pollution (including carbon dioxide) from driving the Acme car is reduced by 25 to 50%. In addition, the car is made largely from recycled metals and waste plastic.

EPA reviews the car and concludes that there is a one-in-a-thousand chance of the Acme car causing a vehicle fire, a rate comparable to the rate of vehicle fires in existing gasoline-powered cars. EPA concludes that regular maintenance minimizes the risk of a car fire, which is equally true for a gas-powered car. As a result, EPA imposes a federally enforceable legal requirement that Acme car owners must perform annual regular maintenance. This requirement also triggers a requirement that, prior to entering a state for the first time, the driver must timely submit a form to EPA so EPA can inform the state that the car will be entering the state.

The requirement to perform annual maintenance may not seem like much of a burden. Indeed, car owners may well undertake voluntarily such maintenance regularly anyway. Under the mandated requirement, however, if you are a little late, say 5,100 miles instead of the required 5,000 miles, penalties may apply. Even if the maintenance is performed, the lack of written records may result in penalties. Similarly, failure to file the “new state” form is actionable. Any of these slipups might result in hundreds or thousands of dollars in fines and related reputational damage.

Under these circumstances, there is little doubt that these requirements, albeit not overly “burdensome,” are nonetheless distinctly unwanted. Unsurprisingly, their imposition may cause drivers to deselect the Acme car and opt for a traditional gasoline-powered car. EPA did not identify any risk associated with the new car that is not also present for the existing car, but EPA nevertheless imposes the regulatory requirement only on the new car.

This is exactly the result in the real-world industrial chemical community. SNURed chemicals are subject to reporting obligations, export notification requirements, and related TSCA paperwork requirements, all of which invite significant enforcement opportunities in the event they are not observed and documented. Often these requirements apply to downstream customers, requirements that are difficult commercial provisions to “sell” to customers, particularly if the incumbent product is regulation-free.

Perhaps even more significant is that, increasingly, downstream chemical processors and/or distributors are implementing purchase policies that disallow and deselect SNURed chemicals. Federal, state, and local procurement regulations also tend to exclude SNURed chemicals. These deselection opportunities are rooted in the misperception that SNURed chemicals are more toxic than the existing chemical the downstream chemical user may be purchasing now. All of these factors contribute to a very real commercial perception that SNURed chemicals are damaged goods to be avoided, and after four decades, this perception is deeply baked into the chemical stakeholder community's psyche. EPA is dismissive of this perception, but that does not change the reality in the marketplace.

Core to the problem in EPA's new chemical review process is that it does not in any meaningful way allow for, recognize, or compel the evaluation of comparative risk of a new chemical in relation to an incumbent chemical that it could replace or with which it could compete in the commercial market. This would seem inconsistent with the national policy goals set out under

TSCA section 2. While the PMN form contains an “optional” pollution prevention (P2) information field, EPA does not systematically analyze relative risk information in its review of new chemicals, and PMN submitters may be unaware of the utility of the P2 option. Unfortunately, the experience of many submitters indicates that even if the P2 information is submitted, the P2 attributes of a new chemical, including diminished toxicity, enhanced performance, and lower energy requirements, while perhaps acknowledged, are largely, if not entirely, ignored for purpose of EPA’s risk management of the new chemical. In this context, a greener, faster, better, smarter regulated chemical struggles to compete commercially with an existing more toxic, less efficient existing chemical that is entirely unregulated. This makes no sense.

Greening the Industrial New Chemical Review Process

It remains a mystery why Congress’s focus in revising TSCA section 5 is seemingly indifferent to the competitive concerns occasioned by the new chemical bias. There is no doubt the new chemical review process under Lautenberg imposes commercial restrictions on the majority of new chemicals. And, disappointingly, the reflexive response from critics, including EPA, to industry’s concerns with the commercial implications of unnecessary commercial restrictions is, essentially, “get over it” instead of focusing on the real-world impacts of greener chemicals being denied commercialization.

The numbers do not lie. Since Lautenberg was enacted, 77% of all PMN determinations made by EPA include commercial restriction. More disturbing, there has been a shocking decline in new chemical notifications, reflecting the reality that new chemicals, even chemicals less toxic and more sustainable than those on the market, cannot compete with existing chemicals, causing commercialization efforts to stall or die in the United States. This is the opposite of what a modernized TSCA was intended to achieve. It is also contrary to TSCA’s explicit national policy as stated in TSCA section 2 that TSCA should be exercised in such a manner as not to “impede unduly or create unnecessary economic barriers to technological innovation” while assuring that innovation does not present an unreasonable risk of injury to health or the environment.

A substance that has been specifically designed to eliminate a specific toxic effect in the incumbent product remains effectively unused because EPA imposed restrictions on the new chemical that do not apply to the incumbent product. Biobased substances, including biofuels, that are equivalent to petroleum-based products also face restrictions under TSCA even though the petroleum equivalents are not subject to TSCA restrictions. Furthermore, both the petroleum and biobased products are subject to regulations under the Clean Air Act and Clean Water Act, but EPA still imposes protective measures under TSCA.

Recommendations to Promote Green Chemicals

To address these issues, EPA could consider implementing several policy changes. First, EPA could redefine unreasonable risk

to include whether the new chemical’s commercialization has the potential to prevent pollution, reduce exposures, or otherwise diminish the hazard or risk profile of chemicals now in use. This approach is recommended by noted TSCA experts and, if implemented, would go a long way in addressing the new chemical bias. Jeffery T. Morris & Richard E. Engler, *Why the US EPA Can, and Should, Evaluate the Risk-Reducing Role a New Chemical May Play if Allowed on the Market*, Chem. Watch (Feb. 22, 2021).

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Second, EPA could make better use of its new TSCA section 4 testing authority by requiring chemical testing of all chemicals, new and existing, once EPA has identified a particular hazard associated with a chemical type. Currently, new chemicals bear the brunt of chemical testing even though existing chemicals, in the marketplace and generating a revenue stream, have largely escaped chemical testing initiatives unless they are undergoing risk evaluation or EPA is prioritizing high-priority existing chemicals for risk evaluation.

For example, EPA has expressed concern for lung effects from new surfactants (e.g., detergent molecules) and requires that new chemicals not be utilized for any spray uses unless and until inhalation testing is completed on the new substance. EPA has dozens of surfactants listed on its Safer Chemical Ingredient List (SCIL), and, yet, it has no inhalation data on the SCIL-listed surfactants. EPA’s explanation is that its criteria for SCIL listing and PMN review are different. While true, it is unclear how EPA can justify representing that a substance is a “safer chemical ingredient” when EPA also concludes that a nearly identical substance notified in a PMN may present “unreasonable risk” if used in a consumer spray cleaner and must be prohibited from such use.

Third, EPA could take the information submitted in the optional P2 portion of the PMN form into account in a more meaningful way. There is little indication how this information is currently being reviewed, let alone relied upon. As part of a national stakeholder dialogue, EPA could solicit and consider the range of factors that might be considered in a P2 assessment and make the “optional” P2 information fields more muscular and a more influential factor in the new chemicals risk analysis. This would be a wasted effort if the

information is not then incorporated into the risk management decision.

Fourth, for new chemicals meeting certain defined sustainability criteria, EPA could more affirmatively and more publicly reward submitters. Developing a Reduced Risk program similar to the Federal Insecticide, Fungicide, and Rodenticide Act program would elevate EPA's acknowledgment of the essential role chemical innovation plays in a circular economy. EPA could consider incentivizing SNURed chemicals with an EPA "safer" brand or logo in an effort to lessen the stigma of a SNUR.

Our nation's industrial product control law offers powerful opportunities to promote and achieve a circular economy.

Fifth, EPA should broaden its TSCA New Chemicals Collaborative Research Program. On March 10, 2022, EPA posted a draft document entitled "Modernizing the Process and Bringing Innovative Science to Evaluate New Chemicals Under TSCA." EPA has proposed to develop and implement a multiyear collaborative research program focused on approaches for performing risk assessments on TSCA new chemical substances. The Office of Pollution Prevention and Toxics is collaborating closely with the EPA Office of Research and Development to develop and implement the research plan.

The research program will greatly enhance the new chemical review process in a number of ways. EPA intends to tackle

five areas: update and refine chemical categories; develop and expand databases containing TSCA chemical information; develop and refine quantitative structure-activity relationships and predictive models for physical-chemical properties, environmental fate/transport, hazard, exposure, and toxicokinetics; explore ways to integrate and apply new approach methodologies in new chemical assessments; and develop a TSCA new chemicals decision support tool to modernize the process. Optimizing resources in other EPA program offices is an efficient way to modernize the new chemical review process. As EPA's own commentary notes, each of the five areas is in need of modernizing, and chemical innovation under TSCA will be advanced as a result as the desired outcomes are achieved. If, however, EPA neglects to take steps to eliminate the new chemical bias, the core problems slowing the commercializing of sustainable new chemicals will persist.

Sixth, EPA's program office should be better resourced, in terms of both financial support and ensuring the technological literacy of those tasked with reviewing new industrial technologies. EPA scientists are challenged to keep pace with the speed of innovation, but a more focused effort to eliminate the imbalance could resolve the problem.

Our nation's industrial product control law offers powerful opportunities to promote and achieve a circular economy. Implementing TSCA differently, and with a sharper focus on incentivizing and rewarding greener, less toxic, and more sustainable chemical products, will optimize TSCA's utility in fulfilling its potential to achieve circularity. 🌱

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