features

TSCA Chemical Safety
A Sisyphean Journey

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Despite the best efforts and good intentions of a broad community of chemical interests, including industry, nongovernmental organizations (NGO), and government entities, implementation of the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601–2697, has been uneven for as long as memory serves. The many challenges in implementing TSCA after Congress first enacted it in 1976 are well documented. Its aspirational tone and lofty goals were matched only by its unique lack of specificity or a mandate to act. The TSCA do-over almost a decade ago has been held hostage to widely differing scientific and legal interpretations and policy constructs by four different administrations tasked with implementing the 2016 amendments, the result of which has confused the American public; frustrated the regulated community, public health and environmental advocates, and labor unions; undermined consumer confidence in the safety of chemical products; and impeded chemical innovation. There are many reasons for these undeniable realities.

As TSCA approaches its 50th birthday, we must reflect upon our shared failure to implement a durable and effective chemical safety law and to revise TSCA in a focused and smart way. We need targeted amendments to express Congress's goals to ensure that TSCA protects human and environmental health from unreasonable risks from chemicals but does so in a way that does not impede innovation. This article explores the reasons why implementing TSCA has been so challenging and what needs to be done to fix it.

TSCA 1.0 and Its Demise

TSCA's enactment in 1976 reflected congressional concern with high-profile chemical incidents and increased congressional awareness that existing and emerging federal law regulated chemicals only after they become pollutants. Congress intended through TSCA to empower the federal government to control the production, processing, distribution, and export of chemical substances not regulated by other major statutes and to ensure that the new federal mandate worked in tandem with other federal environmental laws to protect human health and the environment. John S. Applegate, *Synthesizing TSCA and REACH: Practical Principles for Chemical Regulation Reform*, 35 Ecology L.Q. 721, 724–25 (2008). These regulatory end-of-pipe measures were necessary but insufficient if, as Congress desired, the federal government were to be successful at assessing chemicals earlier in their life cycles to prevent harm to human health and the environment. Congress intended TSCA to fill this regulatory gap and assess chemicals upstream of their distribution, use, and discharge as pollutants. U.S. Council on Env't Quality, *Toxic Substances* (Apr. 1971).

Despite Congress's good intentions, TSCA's implementation was hampered from the start by its lack of a clear legislative mandate requiring the U.S. Environmental Protection Agency (EPA) to prioritize, evaluate, and regulate the then 62,000-plus existing chemicals in commerce that were "grandfathered" in under TSCA. While the law was clear that Congress intended EPA to regulate new and existing chemicals, have sufficient information about chemicals to inform its judgment in

assessing them, and regulate chemicals found to pose unreasonable risk of injury to human health and the environment, TSCA provided no mandate to achieve these goals. This structural deficit, along with emerging European chemical programs and progressive state chemical initiatives, foreshowed TSCA 1.0's demise.

In 2013, the U.S. Government Accountability Office (GAO) identified TSCA's now well-documented and much publicized shortcomings. U.S. Gov't Accountability Off., GAO-13-696T, *Chemical Regulation: Observations on the Toxic Substances Control Act and EPA Implementation* (2013). Among the most debilitating limitations were EPA's limited ability to compel chemical testing and EPA's truncated authority to regulate existing chemicals because of the "least burdensome" language in TSCA Section 6(a) and its judicial construction in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

Congress intended TSCA to apply to both "existing" chemicals—those actively used and distributed in commerce in the late 1970s—and "new" chemicals, meaning those introduced into commerce after the original TSCA Chemical Substance Inventory (TSCA Inventory) was created in 1978. The 62,000-plus existing chemicals in commerce were grandfathered, meaning only that these chemicals were "covered" under TSCA but were not affirmatively reviewed by EPA as a condition of continued commercialization. Nevertheless, the misperception that grandfathering was the same as approval allowed manufacturing processes to develop and complicated chemical supply chains to evolve over the decades since 1976, limited only by the media-specific statutes protecting air and water and managing waste.

In the early days of TSCA implementation, EPA's focus was on creating the administrative scaffolding of the TSCA regulatory program, not on the risks posed by existing chemicals. During the late 1970s, EPA set up the TSCA Inventory, developed the new chemical review program, implemented TSCA's many recordkeeping and data-reporting provisions under Section 8, developed import and export requirements, and addressed related provisions to implement the then-new law. Unlike existing chemicals, new chemicals were subject to EPA premarket review, and EPA could restrict or ban a substance prior to commercialization. *See* 15 U.S.C. § 2604(a)(3). EPA had plenty on its plate, and regulating existing chemicals was simply not a priority.

EPA's most high-profile foray into reviewing an existing chemical involved asbestos, identified as an extremely toxic chemical long before 1976. In 1989, EPA issued a final rule under TSCA Section 6 (existing chemicals) seeking to ban the manufacture, import, and processing of nearly all asbestos-containing products manufactured in the United States. Asbestos; Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions, 54 Fed. Reg. 29,460 (July 12, 1989). The rule was challenged in the U.S. Court of Appeals for the Fifth Circuit in *Corrosion Proof Fittings* and set aside. The court determined that EPA failed to adequately consider potential regulatory measures less burdensome than a ban to abate the unreasonable risks EPA determined asbestos posed. *Corrosion Proof Fittings*, 947 F.2d at 1229. The Fifth Circuit concluded that EPA must consider substitute products and must support the claimed benefits of the proposed rule by evaluating the toxicity of these substitute products. The court let stand only those narrow portions of the final rule that banned manufacture or importation of asbestos for uses not ongoing at that time.

The Fifth Circuit's determination that EPA must find and evaluate the "least burdensome" alternative to a ban imposed a heavy burden on EPA. Many believed that EPA could never meet this legal standard. The decision effectively ended EPA's administrative efforts to ban existing chemicals, and EPA instead looked for opportunities to restrict certain uses.

The optical impacts of the decision were even more consequential. If EPA could not even ban uses of asbestos—a chemical notorious for causing well-recognized adverse health effects like mesothelioma—what could it ban? After *Corrosion Proof Fittings*, TSCA was widely perceived as being critically flawed and ineffective in controlling unreasonable risks from existing chemicals. The decision diminished the public's confidence in TSCA as an effective tool to ensure chemical safety.

The EU and REACH

While EPA struggled with implementing TSCA, the European Union (EU) was busy updating and strengthening its chemical control programs. Concern with chemical exposures has long been at the forefront of EU regulatory focus. The "precautionary principle" is a foundational concept underlying the EU's approach to policies relating to environmental health and food safety. Core to the precautionary principle is the belief that risk prevention is essential in the face of scientific uncertainty.

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The EU had been considering its approach to chemical management for years before the European Parliament and the Council enacted a groundbreaking new law on December 18, 2006. The law, titled Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), came into force on June 1, 2007. Regulation of the European Parliament and of the Council 1970/2006, 2006 OJ (L 396) 1 (EC). REACH is the functional equivalent of TSCA. Under REACH, the chemical manufacturer and/or importer bears the responsibility of producing data to support the determination that a chemical is safe for its intended uses. Under old TSCA, the reverse was true:

EPA had the burden of proving an existing chemical posed an unreasonable risk before it could act to restrict that substance.

REACH is premised on the precautionary principle and is hazard-based, unlike TSCA, which is risk-based. Under REACH, new and existing chemicals require registration if they are manufactured or imported into the EU in quantities of one metric ton per year or more, unless the substance is exempt. The registration requirements apply to pure chemicals, chemicals in mixtures, and chemicals in articles when the chemicals are intended to be released under normal or reasonably foreseeable conditions of use (COU). Registration requires data, and data requirements increase with the volume of chemicals produced or imported each year. *See* REACH, art. 12. In other words, higher volumes of chemical substances (substances manufactured or imported in quantities of 10 metric tons per year or more) require more data (regardless of exposure) and the preparation of a chemical safety report, among other requirements, as a predicate to registration. An EU member state could initiate proceedings to evaluate and eventually ban a substance if that substance had certain hazard characteristics, regardless of whether that substance could be adequately controlled.

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The Transition to TSCA 2.0

Since the European Parliament and Council enacted REACH in 2006, other countries have opted to adopt chemical control laws based on it—and notably not based on TSCA. Versions of REACH are in effect in Turkey, South Korea, China, and the United Kingdom. REACH's enactment in the EU and other countries' adoption of similar constructs were a major impetus for calls for chemical reform in the United States. The EU's REACH program quickly became the default gold standard for chemical control legislation and, in comparison, TSCA was increasingly thought to be substandard.

Confidence in TSCA was tanking. In 2005, the GAO acknowledged in testimony before Congress that EPA had made "little progress in reviewing existing chemicals" and that "TSCA's authority to require testing is difficult to use." Public health professionals, NGOs, and state legislatures were growing increasingly concerned with chemical exposures, their effect on human health, and TSCA's all-too-apparent shortcomings. In his July 2007 report prepared for the Environmental Defense Fund, Dr. Richard A. Denison summarizes well the NGO community's frustration with data deficits and TSCA's inability to address them. Richard A. Denison, Env't Def. Fund, *High Hopes, Low Marks: A Final Report Card on the High Production Volume Chemical Challenge* (2007). The internet facilitated broad distribution of information about chemicals and chemical exposures, and social media fueled the growing interest in knowing more about chemicals in everyday items. These developments amplified the perception that TSCA was ineffective in ensuring chemical safety.

Two states stand out in enacting chemical control measures. Disclosure measures came first. California's Proposition 65 (Prop 65), the Safe Drinking Water and Toxic Enforcement Act of 1986, raised consumer chemical awareness to a whole new level by requiring clear and reasonable warnings on all products known to cause cancer or reproductive toxicity. Cal. Health & Safety Code §§ 25249.5–9.13 (1986). In 2008, California pioneered adoption of "green chemistry" laws, largely patterned after REACH. *Id.* § 25252(a) (2008). Washington state also has been a leader in this area, adopting in 2008 its Children's Safe Products Act, requiring the state to develop a list of chemicals of "high concern for children" and to identify products or product categories that may contain them. Wash. Rev. Code § 70A.430 (2008).

The diversity and scope of these state measures are too numerous to explore further here. Regulations addressing product manufacturing restrictions, product marketing or distribution measures, end-of-pipe restrictions, and product design requirements grew significantly. Industry stakeholders began to appreciate the confounding impact that these state initiatives were having on interstate commerce. Perhaps more than any other, this trend was responsible for growing alarm in the industrial chemical sector and incentivized the business community to consider TSCA "modernization" opportunities as a way of standardizing chemical regulation nationally.

TSCA 2.0: Key Features of Lautenberg and How Each Was Intended to Fix TSCA

In 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg), Pub. L. No. 114-182, 130 Stat. 448 (June 22, 2016), which significantly revised several sections of TSCA, was widely celebrated and rightly seen as a bipartisan triumph. We focus here on the most consequential changes: Section 4 (data development), Section 5 (new chemicals), and Section 6 (existing chemicals). Focus on these sections illustrates the key policy and legal challenges that continue to dominate debate on chemical safety in the United States.

ENHANCED CHEMICAL TESTING AUTHORITY (SECTION 4)

Pre-Lautenberg, EPA's authority under TSCA Section 4 to compel chemical testing was limited. Before it could issue a rule to compel chemical manufacturers, importers, and, in some cases, processors to conduct chemical testing, EPA had to find that a chemical's manufacture, distribution, use, or disposal "may present an unreasonable risk" and there are "insufficient data or

experience" to "reasonably determine or predict" health effects so that "testing is necessary to develop" data. 15 U.S.C. § 2603. EPA also could find that "substantial quantities" of the chemical enter the environment and there are insufficient data to determine or predict health effects so that testing is necessary to develop the data. The administrative process to compel chemical data production was lengthy and contentious and elicited few results. In over 30 years, EPA promulgated only 130 testing rules under old TSCA.

The 2016 amendments addressed this problem by providing EPA with significant new, and more flexible, chemical testing authority. Lautenberg authorized EPA to issue unilateral orders compelling the development of new chemical hazard and exposure information, sidestepping the contentious, dysfunctional system under original TSCA. *Id.* § 2603(a)(2).

Despite the expanded authority, EPA was slow to issue unilateral test orders. The Biden administration issued orders for nine chemical substances undergoing Section 6(b) EPA-initiated risk evaluation in 2021, almost five years after Lautenberg's enactment, to address data needs relating to ongoing risk evaluations for priority chemical substances. Press Release, EPA, EPA Issues Test Orders for Nine Chemicals Undergoing Risk Evaluation Under TSCA (Jan. 15, 2021). EPA issued a second round of orders for eight of these chemicals in March 2022 to address remaining data needs. Press Release, EPA, EPA Issues Additional Test Orders to Support Risk Evaluations of Eight Chemicals under TSCA (Mar. 24, 2022). Three of the new orders were challenged on a variety of grounds, including EPA's authority to compel testing by entities not currently manufacturing or processing a substance or intending to do so, challenging the adequacy of existing data, and questioning EPA's demonstration of need for certain data. In connection with EPA's 2021 National PFAS Testing Strategy, EPA issued the first of 24 Section 4 test orders in June 2022. Press Release, EPA, EPA Issues First Test Order Under National Testing Strategy for PFAS in Commercial Fire Fighting Foam and Other Uses (June 6, 2022). Litigation followed. EPA issued two additional per- and polyfluoroalkyl substances (PFAS) test orders in 2023. Press Release, EPA, EPA Issues Next Test Order Under National Testing Strategy for PFAS Used in Plastics, Chemical Manufacturing (Jan. 4, 2023); Press Release, EPA, EPA Issues Next Test Order Under National Testing Strategy for PFAS Used in Chemical Manufacturing (Aug. 15, 2023). Industry largely prevailed in the lawsuits, revealing the haste with which the orders were prepared and an ill-suited regulatory infrastructure unprepared to administer a chemical testing program. *Nat'l Foam v. EPA*, No. 22-1208 (D.C. Cir., Oct. 10, 2025) (according to an August 21, 2025, status report, EPA considers the test order as satisfied and will not order additional testing); *Fluorotelomer Consortium v. EPA*, No. 24-1373 (D.C. Cir.).

The particulars of each test order and the ensuing litigation are not as important as the fact that the EPA testing program was underutilized until 2021 and fraught with implementation problems that remain unresolved. This is not a criticism of EPA. It is a reflection of the inherent challenges posed by implementing any new program as complex as TSCA.

NEW CHEMICAL REVIEW (SECTION 5)

Ironically, Lautenberg was never intended to "fix" TSCA's new chemical program, which was thought at the time to be effective. By most industry accounts, pre-Lautenberg EPA's review of new chemicals under Section 5 was working well and efficiently. Nonetheless, Lautenberg made significant changes to Section 5, the most important of which is the requirement that EPA make certain determinations and take required actions on all new chemicals and significant new uses (SNU) of chemicals. 15 U.S.C. § 2604. Under old TSCA, EPA was not required to, but did, review all new chemicals and SNUs; EPA was not required to publish the basis for its conclusions. Now, EPA must determine whether a chemical substance presents an unreasonable risk; whether insufficient information prevents an assessment of health and environmental effects and, in the absence of sufficient information, the chemical may present an unreasonable risk or will be produced or enter the environment in substantial quantities or have significant or substantial human exposure; or whether the chemical is not likely to present unreasonable health risk. 15 U.S.C. § 2604(a)(3). EPA must publish the basis for its conclusion and, except for the last circumstance, issue restrictions to mitigate the risk identified. *Id.* § 2604(d), (f).

Lautenberg provides little guidance on how to make these determinations, and key terms are not defined. The amendments leave terms like "reasonably foreseen" and "not likely to present an unreasonable risk" largely to the purview of individual assessors.

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Since Lautenberg's enactment, the pace of new chemical review has slowed. From 2017 to 2024, EPA has averaged only 185 decisions per year on premanufacture notices (PMN). Prior to 2016, EPA would average over 700 PMN decisions per year. Since 2016, the average review time for a PMN is 512 days, despite the statute requiring EPA to make a determination in no more than 180 days. Bergeson & Campbell, P.C. (B&C®), *Forecast for U.S. Federal and International Chemical Regulatory Policy 2026* (Jan. 2026). New chemical review takes, on average, 502 days, and 85% of all new chemicals have been subject to some restriction. Except for new chemicals deemed

"low hazard" to health and the environment, EPA has imposed restrictions on all new chemicals, regardless of the data available on the new chemical. In contrast, prior to 2016, EPA would evaluate both the chemical hazard and whether there was any reason to suspect there might be an exceedance of the hazard threshold when deciding whether to issue an order or propose a significant new use rule (SNUR). Prior to 2016, about 24% of new chemicals were restricted in some way, largely limited to so-called high-hazard substances. *Id.*

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In addition, PMN submissions are significantly down as companies avoid bringing new products to market in the United States, preferring, paradoxically, to commercialize them in the EU, where REACH is viewed as a significant barrier to innovation, largely because of the upfront chemical testing requirements. Approved registrations in the EU or elsewhere have no effect on Section 5 decisions. Substances with REACH registrations may have robust datasets supporting such registrations, but unless those data document "low hazard," EPA will restrict the chemical.

EXISTING CHEMICAL REVIEW (SECTION 6)

TSCA's most glaring failure, by far, has been its enduring inability to prioritize, evaluate, and manage risk from existing chemicals. While progress has been made under Lautenberg, most would agree it is not enough, and EPA's abrupt policy shifts over the past decade have hampered the pace of chemical reviews, sown broad confusion in the chemical sector, and invited litigation.

Lautenberg directs EPA to establish by rule a process to conduct chemical risk evaluations. 15 U.S.C. § 2605(b)(4)(B). This "framework" would guide EPA's risk evaluations and be used to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under its COU, defined to include how a chemical is made, processed, used, distributed, and disposed. Despite the passage of almost 10 years, EPA has conducted final risk evaluations for only 15 existing chemicals and issued final risk management rules for only five chemicals, all of which are being litigated.

Part of the problem is rooted in the law itself. Lautenberg does not define "risk evaluation" or "unreasonable risk." Over the past decade, four different administrations have issued three different risk evaluation "frameworks," and the relentless flip-flopping of policy constructs has confused all and stalled the process. Under the first risk framework rule issued by the Trump administration in 2017, EPA was to determine if a chemical posed an unreasonable risk of injury to health or the environment under each COU within the scope of the risk evaluation. Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726 (July 20, 2017) (codified at 40 C.F.R. pt. 702). Lautenberg introduced the COU concept. It is defined, as noted, to mean the "circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." 15 U.S.C. § 2602(4). Chemicals are used for many applications, and for some chemicals assessed, EPA has identified dozens of COUs. EPA is required to publish a scope document as part of the risk evaluation in which the COUs it expects to consider are identified. For each such use, EPA makes a determination whether the use presents an unreasonable risk.

Core to this approach is the notion that EPA has discretion to ignore COUs it determines are not in scope and that EPA may evaluate risks of a chemical substance on a COU basis rather than based collectively on a chemical substance "as a whole." EPA has used this process for the initial 10 chemicals that Lautenberg designated as high-priority chemical substances and for those chemical substances for which EPA has initiated a risk evaluation in response to a manufacturer request.

Several NGOs filed petitions for judicial review in 2017 that were consolidated in the U.S. Court of Appeals for the Ninth Circuit. *Safer Chems., Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019). In 2019, the Ninth Circuit ruled that several provisions of the final rule were invalid and vacated and remanded the rule back to EPA. Importantly, however, it declined to rule on certain arguments raised by petitioners, including whether the final rule improperly required EPA to make a final determination for each COU rather than a single determination for the chemical substance as a whole and whether the 2017 final rule improperly granted EPA discretion to exclude certain COUs from the scope of the risk evaluation. The Ninth Circuit determined that the first argument was not ripe and, as for the second argument, stated that it did not "interpret the language in the [2017 final framework rule] to say anything about" EPA being bound to exclude any COUs and thus there was no reviewable final agency action.

Enter the Biden administration. On June 30, 2021, EPA released guidance announcing certain policy changes for TSCA risk evaluations. Press Release, EPA, EPA Announces Path Forward for TSCA Chemical Risk Evaluations (June 30, 2021). Included in the release were three foundational changes to EPA's prior approach to risk evaluation. EPA expanded consideration of exposure pathways (especially chemical exposures subject to other environmental laws), assumed that workers are not protected by the requirements of the Occupational Safety and Health Act, and required a single risk determination to

be made on the "whole chemical" rather than on individual COUs.

Why does this matter? If EPA determines that a COU for a chemical undergoing risk evaluation poses an "unreasonable risk," EPA must mitigate that risk. EPA is authorized to impose, through rulemaking, risk mitigation measures, including banning a chemical, requiring warning and labeling measures, requiring the use of workplace protection measures such as protective clothing and equipment, establishing exposure limits, and/or imposing discharge limitations.

If you are a chemical producer, your employees, customers, and neighbors might well be alarmed by news that the chemical to which they may be exposed poses "unreasonable risk" as a whole chemical. Consumer product companies are especially concerned, as a whole-chemical finding of unreasonable risk can present legal, commercial, and optical challenges, including enhanced tort liability, breach of contract claims, and product sourcing uncertainty, as some chemical producers will exit the market *even if* EPA concludes that the specific COUs in question are not an unreasonable risk.

EPA proposed a new risk framework rule on October 30, 2023, suggesting significant changes to the procedures for chemical risk evaluation under TSCA Section 6. Procedures for Chemical Risk Evaluation Under [TSCA], 88 Fed. Reg. 74,292 (proposed Oct. 30, 2023) (to be codified at 40 C.F.R. pt. 702). The proposed rule included the policy changes identified in the June 30, 2021, press release—changes EPA determined necessary to make the rule consistent with the Ninth Circuit decision in *Safer Chemicals*; and other proposed revisions. EPA issued a final risk framework rule on May 3, 2024. Procedures for Chemical Risk Evaluation Under [TSCA], 89 Fed. Reg. 37,028 (May 3, 2024) (codified at 40 C.F.R. pt. 702). EPA was already re-reviewing all 10 risk evaluations for the first 10 chemical substances evaluated under Lautenberg to align with its policy memorandum issued on June 30, 2021, and was working through additional risk evaluations consistent with the conceptual approach of the framework rule issued in May 2024. Both approaches are the subject of cases pending in different courts of appeal. *See Texas Chem. Council v. EPA*, No. 24-60193 (5th Cir.) (asbestos); *Olin Corp. v. EPA*, No. 25-1014 (8th Cir.) (carbon tetrachloride); *East Fork Enters. v. EPA*, No. 24-60256 (5th Cir.) (methylene chloride); *FabriClean Supply v. EPA*, No. 25-60006 (5th Cir.) (perchloroethylene); *United Steel v. EPA*, No. 25-1055 (3d Cir.) (trichloroethylene).

On September 23, 2025, the Trump EPA proposed significant amendments to the May 2024 final procedural framework rule. Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 90 Fed. Reg. 45,690 (proposed Sept. 23, 2025) (to be codified at 40 C.F.R. pt. 702). With repeated explicit preamble citations to *Loper Bright Enterprises v. Raimando*, 603 U.S. 369 (2024), and EPA's expressed belief that the best reading of TSCA demands a different interpretation than what is expressed in the 2024 risk framework rule, EPA's newly proposed framework rule largely restores the 2017 framework version with consideration of *Safer Chemicals* and thrusts the chemical sector into renewed uncertainty regarding the TSCA rules of engagement for chemicals for which risk evaluations had been conducted and for chemicals for which risk management rules have been issued. (Under *Loper Bright*, the courts decide which approach is the "best" interpretation of TSCA Section 6(b)(4)(B), rather than deferring to reasonable interpretations from EPA under the now overruled *Chevron* doctrine. *See Chevron, U.S.A. v. NRDC*, 467 U.S. 837 (1984)).

EPA's policy pivots have made counseling chemical stakeholders immeasurably more challenging. TSCA disallows judicial review of unreasonable risk determinations as such determinations are not considered final agency action under TSCA. 15 U.S.C. § 2605(i)(2). Interested parties must wait to appeal final risk management standards derivative-of-the-risk determinations that are issued years after the risk findings. That is a long time to straddle the inferences that flow from the almost inevitable finding of "unreasonable risk" of injury under EPA's whole chemical approach.

How to Fix TSCA

Lautenberg addresses the universally acknowledged core deficiencies of TSCA 1.0. Many aspects of Lautenberg work well, but for all the reasons noted above, legislative tweaking is needed in several areas. TSCA fees must be legislatively reauthorized no later than September 30, 2026. This offers a strategic opportunity to engage in some mid-course corrections that are needed in the New Chemicals Program especially, but other provisions as well. Chemical regulation reform is an iterative process, and we have learned a great deal since 2016. In this post-*Chevron*, *Loper Bright* world, legislative definitional clarity is the best way to ensure that chemical testing is more predictable; that new chemicals, especially those with improved risk profiles, have a rational, fair, timely, and predictable shot at commercialization; and that risk assessment rules of engagement are clear and less amenable to episodic reinterpretation.

TSCA fees must be legislatively reauthorized no later than September 30, 2026. This offers a strategic opportunity to engage in some mid-course corrections that are needed in the New Chemicals Program especially.

Lautenberg gave EPA increased authority to compel testing. In addition to rulemaking and negotiated agreements, Lautenberg authorized EPA to unilaterally order testing. The rationale was

that EPA might need to act more expeditiously than it was able under old TSCA to obtain needed information but could only order testing when EPA has a basis to do so, the information is not already reasonably available, and there are test methods available that address EPA's information needs. EPA began to issue Section 4 orders in 2020 in the hope that testing would be completed promptly. Unfortunately, parties disagreed that EPA met the requirements to order some of the testing.

Because the recipient of an order has only 60 days from the date of the order to petition a court for review, 15 U.S.C. § 2618(a), and because the substantive decisions (e.g., whether existing data can be used to address EPA's data need) rarely are resolved within 60 days of the issuance of the order and may not be resolved until many months or even years later, recipients must file a petition for review prophylactically to ensure that if a disagreement arises, the recipients have legal recourse. This is inefficient for recipients, EPA, the U.S. Department of Justice (which represents EPA), and the courts because court-supervised disputes are seldom efficient. Congress could make targeted changes to Section 4 to allow a petition to be filed within 60 days of a substantive decision, not just the date of the order. EPA might also consider using negotiated agreements rather than orders.

Legislative relief is especially needed in the Section 5 new chemicals area. The GAO released a report on the New Chemicals Program in January 2025 that echoes a 2023 report by the EPA Office of Inspector General. Off. of Inspector Gen., EPA, *23-P-0026, The EPA Lacks Complete Guidance for the New Chemicals Program to Ensure Consistency and Transparency in Decisions* (Aug. 2, 2023). The GAO found that EPA's New Chemicals Division "does not follow most key practices for managing and assessing the results of the New Chemicals Program." U.S. Gov't Accountability Off., *GAO-25-106839, New Chemicals Program: EPA Needs a Systematic Process to Better Manage and Assess Performance* (Jan. 2025).

At the root of the regulatory dysfunction is the lack of definitional clarity around key legislative terms, including "reasonably foreseen," "not likely," and the EPA's stubborn conflation of "hazard" and "risk." "Reasonably foreseen" requires clarification to avoid interpretations that include every conceivable chemical use condition, however improbable. "Not likely" is amenable to as many diverse interpretations as there are individuals asked to opine on the term, especially when the alternative is "may"—a term that can be interpreted as anything other than "certainly not." None of the three past administrations implementing TSCA has provided a rationale for its interpretation of any of these terms or developed a process to ensure consistent decision-making between and among reviewers, and there is no reason to believe that Trump 2.0 will be different. Congress would be wise to clarify its intent, especially in a post–*Loper Bright* world, so EPA, submitters, and the public at large understand how TSCA should be implemented and can be confident that EPA is implementing TSCA as intended.

New chemicals are needed to replace older, less sustainable chemistries. Implementation of Lautenberg is impeding new chemical innovation and driving new chemical commercialization offshore. Most new chemicals that make it through the years-long new chemical gauntlet enter the market hobbled by often poorly scientifically supported regulatory limitations that make them commercially uncompetitive and contribute little to protect human health and safety. The current regulatory incoherence perversely favors the continuation of older chemistries and chemical products rather than promote market substitutes with preferable risk profiles.

EPA's risk evaluation and risk management activities under Section 6 have been hampered by pendulum swings of heroic proportion between administrations, with lawsuits filed over several major actions, including the risk evaluation framework rule and several of EPA's conclusions of no unreasonable risks under certain COUs. Two major issues on which the Trump and Biden administrations disagreed are the whole chemical/single determination approach to risk determinations and whether and how EPA can and should take workplace protections into account. EPA's recent proposal to revise, yet again, the risk evaluation framework rule will likely draw further litigation, but the updated rule and likely litigation may finally resolve these issues.

One issue that will likely require Congress to resolve is the lack of an efficient mechanism to correct flawed risk evaluations. As the law is currently written, if EPA determines that a substance or a COU is not an unreasonable risk, EPA issues an order to that effect. Such an order is considered final agency action that can be challenged under TSCA Section 19. 15 U.S.C. § 2618(a)(1)(A). In contrast, risk evaluations and determinations that a substance or a COU is an unreasonable risk are not final agency action. *Id.* § 2605(a)(2). In this case, EPA's determination cannot be challenged until the risk management rule is final. If a court finds EPA's risk evaluation or determination was flawed, EPA must correct the risk evaluation and determination and then re-propose the risk management rule. Congress could step in and revise TSCA Section 6 or 19 to allow parties to challenge immediately final risk evaluations and EPA determinations that a substance is an unreasonable risk.

TSCA stakeholders are mindful of EPA's heroic efforts over the past decade to implement Lautenberg but disappointed with the result. The Supreme Court's dicta in *Loper Bright* that Congress give agencies clear authority and requirements is an invitation and an opportunity for all stakeholders to find common ground to make TSCA more efficient and to achieve stakeholders' shared goals of protecting health and the environment, fostering a more sustainable economy, and keeping innovation vibrant in the United States.

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