# What the "New TSCA" Has Accomplished—and What Comes Next

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This article reviews the successes achieved in the regulation of chemicals under the Toxic Substances Control Act (TSCA), 15 U.S.C. §§ 2601–2697, since Congress amended the Act in 2016. Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016). Despite the fact that further improvements may be necessary—particularly to expedite chemical reviews, encourage timely collection of chemical use and exposure data, and secure more resources—the amended TSCA provides a solid foundation for protecting human health and the environment, and a strong federal program for chemical management across the nation is taking shape. The EPA's implementation of the 2016 amendments has advanced public health protection through nationwide bans on many uses of chemicals—including hazardous solvents, chrysotile asbestos, and a group of persistent, bioaccumulative, and toxic (PBT) chemicals—and through regulations for the majority of new chemicals. Compared to the past, there is far greater public transparency across TSCA's programs today and a rigorous program for inspecting confidential business information (CBI) claims.

## Old TSCA: Key Challenges

Enacted in 1976, TSCA gave the U.S. Environmental Protection Agency (EPA) authority to identify and control potentially hazardous chemicals in U.S. commerce not covered by other environmental laws. While TSCA established an inventory of existing chemical substances in U.S. commerce and required the EPA to review and regulate new chemicals not on this list, it also limited the EPA's ability to collect data on chemicals under Section 4 and to regulate existing chemicals under Section 6. 15 U.S.C. §§ 2603, 2605 (1976).

From 1976 to 2016, the EPA spent most of its TSCA efforts reviewing premanufacture notifications (PMNs) for new chemicals under Section 5 prior to their manufacture or import. *Id.* § 2604. The law permitted commercialization after a 90-day review period if the EPA raised no objections, but it did not require companies to generate new health and safety data before making their submissions. *Id.* § 2604(a)–(b). Nevertheless, the EPA could require data development as a condition of approving the new chemical. Over time, the EPA developed a comprehensive structure-activity relationship (SAR) database of chemical analogs, which allowed it to evaluate the safety of new chemicals despite the absence of data specific to the new chemical. In addition, TSCA did not require the EPA to document and publish determinations of safety for new chemicals or significant new uses, leaving the outcomes a veritable mystery to outsiders.

From the outset, the EPA could require testing of existing chemicals via rulemaking when information gaps impeded risk assessment. *Id.* § 2603(a)–(b). Often, these rulemakings took years. The EPA had to justify testing based on a finding that a chemical substance may present an unreasonable risk to the environment or human health—a determination that frequently required the very information the agency sought to collect. Voluntary negotiated testing consent orders temporarily eased the challenges associated with rulemakings, and the EPA routinely used Section 4 to issue enforceable consent agreements (ECAs) to secure health and safety data. Nevertheless, the EPA increasingly relied on "worst case" modeling and determinations of toxicity based on data about chemicals similar in structure.

The EPA's authority to regulate existing chemicals proved largely ineffective. Over TSCA's first 40 years, the EPA issued only one final, enforceable Section 6 rule to regulate an existing chemical. The 1978 rulemaking for polychlorinated biphenyls (PCBs) established requirements for their manufacture, processing, distribution, use, and disposal, and PCBs were

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ultimately banned in 1979. EPA, Final Rule, Polychlorinated Biphenyls (PCBs): Disposal and Marking, 43 Fed. Reg. 7150 (Feb. 17, 1978); 15 U.S.C. § 2605(e). Efforts to regulate other chemicals like asbestos and acrylamide dragged on with little results. In *Corrosion Proof Fittings v. EPA*, the U.S. Court of Appeals for the Fifth Circuit vacated the EPA's nationwide ban of asbestos under TSCA Section 6, finding that the agency had not adequately considered less restrictive measures such as labeling or partial bans. 947 F.2d 1201, 1230 (5th Cir. 1991). While acknowledging asbestos' hazards, the court concluded that the EPA's record lacked substantial evidence to justify a total ban, sending a strong signal that TSCA's original framework imposed high evidentiary and procedural hurdles to the EPA's imposition of restrictions. The EPA's later attempts to resuscitate existing chemicals regulation were largely unsuccessful, save for the development of the 2014 TSCA Work Plan that identified 90 chemicals for risk evaluation. EPA, Off. of Pollution Prevention & Toxics, *TSCA Work Plan for Chemical Assessments: 2014 Update* (Oct. 2014).

## Modernized TSCA: New Milestones

Efforts to "reform" TSCA gained momentum as state-level chemical management statutes emerged, simultaneously raising concerns about a fragmented system while highlighting widespread dissatisfaction with TSCA's limited progress in controlling risk from existing chemicals in commerce. By 2012, Senator Frank Lautenberg (D-NJ) had introduced TSCA reform legislation in five consecutive Congresses. When he died in 2013, the torch passed to Senator David Vitter (R-LA) and Senator Tom Udall (D-NM).

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On June 16, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law. Pub. L. No. 114-182, 130 Stat. 448 (2016). Congress' primary aim was to empower the EPA to regulate existing chemicals. The EPA drew the first 10 chemicals for risk evaluation from the 2014 TSCA Work Plan, including asbestos; methylene chloride; NMP; TCE; PCE; carbon tetrachloride; 1,4-dioxane; HBCD; Pigment Violet 29; and 1-bromopropane. The amended statute tasked the EPA thereafter with prioritizing 20 chemicals for designation as low priority for risk evaluation and 20 others for designation as high priority. 15 U.S.C. § 2605(b). Section 6 now requires a three-phase process of prioritization, risk evaluation, and risk management that the EPA must complete within a seven-year period, and the EPA must have at least 20 existing chemicals undergoing risk evaluation at any given time. At least 50% must be chemicals from the 2014 Work Plan. Chemicals that the EPA designates as high priority enter a risk evaluation process that culminates in a risk management rule. *Id*. § 2605(b)–(c).

A defining change in the 2016 amendments was to the Act's safety standard. The EPA must now determine, without consideration of costs or other nonrisk factors, whether a chemical may present an unreasonable risk of injury to health or the environment under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation. *Id*. § 2605(b)(4)(A). The EPA's findings become ripe for judicial review only after a final risk management rule is in place or after the agency issues an order finding no unreasonable risk. *Id*. § 2605(i).

Section 6(a) of TSCA provides the EPA with a number of risk management options and instructs the EPA to deploy them to the extent necessary to ensure that the chemical no longer presents an unreasonable risk. *Id*. § 2605(a). With this language, the 2016 amendments "un-paralyzed" the EPA by removing the mandatory "least burdensome" requirement found in the original version of Section 6(a). Options for regulation now include warning requirements; manufacture, process, distribution, and use limitations; amount and concentration limits; compliance testing; disposal restrictions; customer and public notifications; replacement or repurchase programs; and partial and full bans of the chemical altogether. In deciding whether to prohibit or restrict a condition of use of a chemical substance and setting appropriate transition periods, the EPA must consider, to the extent practicable, whether technically and economically feasible alternatives will be reasonably available. The alternatives should benefit health or the environment compared to the use of the chemical that is being regulated. *Id*. § 2605(c)(2)(C).

The amended TSCA also has allowed the EPA to more comprehensively assess workplace safety, a consideration traditionally left to the Occupational Safety and Health Act (OSH Act). Pub. L. No. 91-596, 84 Stat. 1590 (codified at 29 U.S.C. §§ 651–678); *see* 15 U.S.C. §§ 2605(b)(4)(A), 2602(12). Specifically, the EPA has introduced the concept of Workplace Chemical Protection Plans (WCPPs) to address unreasonable risks without resorting to bans and is issuing occupational exposure limits that are more stringent than the Occupational Safety and Health Administration's (OSHA's) permissible exposure limits (PELs).

The dual role of TSCA's requirement that the EPA protect workers from unreasonable risks associated with chemical substances, 15 U.S.C. §§ 2605(b)(4)(A), 2602(12), and the OSH Act's directive to evaluate and reduce risk to workers, 29 U.S.C § 655(a)–(b), is a reality for regulated industries. Both agencies' rules are intended to reduce workplace exposures, and the control measures they impose can overlap. To foster coordination, in December 2024, the EPA and OSHA signed a memorandum of understanding (MOU) regarding the agencies' working relationship with respect to existing chemicals. U.S. EPA &

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U.S. Dep't of Labor (DOL), Memorandum of Understanding Between the U.S. Env't Prot. Agency Off. of Chem. Safety & Pollution Prevention, Off. of Enf't & Compliance Assurance & the U.S. Dep't of Lab. Occupational Safety & Health Admin. (2024). The objective of this MOU is to facilitate regular information sharing between the agencies. In addition, the agencies will mutually refer to each other potential violations of either set of workplace standards and share information on inspection focus areas, complaints, and enforcement. A 2021 MOU provides for similar information sharing for TSCA Section 5 new chemicals. U.S. EPA & U.S. DOL, Memorandum of Understanding for Implementation of TSCA Section 5 and Sharing of Confidential Business Information (2021). Most recently, a January 2026 House Appropriations Committee report directed the EPA to clarify how the EPA and OSHA will coordinate. H.R. Rep. No. 119-215, at 64 (2025).

Beyond Section 6 of the Act, the 2016 amendments overhauled the CBI provisions in Section 14 to increase transparency and public access to chemical information that may no longer be considered confidential. 15 U.S.C. § 2613(c)(3), (e). Prior to the amendments, TSCA required substantiation only for limited categories of information such as chemical identity and the EPA did not routinely review CBI claims to determine whether they were still valid. The Lautenberg Amendments identify specific business information that is entitled to protection; requires affirmative, written justifications for other information to maintain confidentiality; and calls for review and renewal of CBI claims every 10 years.

Under TSCA Section 5, the EPA now must affirmatively document its findings and conclusions associated with new chemical reviews. *Id.* § 2604(g). In addition to having the authority to regulate a new chemical or require testing based on hazard or exposure, the absence of information about the chemical is now a sufficient reason for the EPA to regulate its manufacture, processing, distribution, use, and disposal. *Id.* § 2604(e).

Changes in Section 26 direct the EPA to use "best available science" for "a decision based on science," and decisions on chemicals must be based on "the weight of the scientific evidence." 15 U.S.C. § 2625(h), (i). These technical guideposts promote an objective evaluation of the hazards and exposure information on chemicals by the EPA. TSCA reform in 2016 also expanded the services for which the EPA may impose user fees and allow for higher fees and inflationary adjustments, helping to defray EPA's costs. *Id.* § 2625(b).

Congress created new federal preemption provisions in Section 18. *Id.* § 2617. Once EPA takes regulatory action on a specific chemical under TSCA Section 6(c), by issuing either an order or final risk management rule, states are generally precluded from regulating differently. However, TSCA's preemption provisions are subject to pause, various exceptions, and potential waivers, creating a complex balance between TSCA and existing state laws.

Other sections of TSCA that Congress left untouched in 2016 have nonetheless been affected by the new regulatory regime. For instance, the obligation to file export notifications under Section 12(b) has remained substantively the same—exporters must notify the EPA when exporting a chemical that is subject to certain TSCA actions, such as test rules or Section 4 orders, Section 5 consent orders or rules, or Section 6 proposed or final risk management rules. The EPA in turn can notify the importing country of the chemical's U.S. regulatory status to inform their decision-making. The scope of the notification obligation has effectively expanded because there are far more regulatory actions under Sections 5 and 6, each of which triggers this notice requirement.

The 2016 amendments also breathed new life into TSCA's Section 21 citizens petition provision as it relates to existing chemicals. Section 21 enables any person to petition the EPA to initiate a proceeding for the issuance, amendment, or repeal of a Section 6 rule (as well as other types of rules issued under TSCA). 15 U.S.C. § 2620(a). When the EPA denies a Section 21 petition, upon appeal, the district court may make a *de novo* finding of unreasonable risk, supplanting the EPA's authority to conduct its own risk evaluation for the chemical. The district court can then direct the EPA to proceed straight to risk management. Since the 2016 amendments, a range of stakeholders have filed petitions under Section 21 requesting that the EPA initiate Section 6 risk evaluations or promulgate Section 6 risk management rules for existing chemicals such as asbestos, TCE, certain flame retardants, mercury-related activities, the tire additive 6-PPD, and chemicals used in oil refining such as hydrogen fluoride. Most, if not all, of them identify one or a handful of the chemical's uses for EPA to evaluate. Initially, the EPA took the position that these petitions would need to include all conditions of use of a chemical, creating an exceptionally high bar for advancing petitions to restrict chemicals under Section 6 and resulting in rejections on this basis alone. Not all courts have accepted the EPA's position that petitioners must identify all "reasonably known and foreseeable conditions of use" of a chemical substance as a condition for granting these petitions. *Food & Water Watch, Inc. v. U.S. EPA*, 2024 WL 4291497, at *4 (N.D. Cal. Sept. 24, 2024). In addition, the EPA is accepting certain petitions while pointing out the need for additional information. EPA, Final Response to Petition No. 001845: Toxic Substances Control Act Section 21 Petition Regarding N-(1,3-Dimethylbutyl)-N'-phenyl-p-phenylenediamine (CASRN 793-24-8, aka 6PPD) in Tires (Nov. 2, 2023). It is not entirely clear that Congress in 2016 anticipated the extent to which Section 21 would be used to deflect requests for rulemaking by invoking the need for more information or to serve as an end run around comprehensive agency risk determinations.

## MORE EXISTING CHEMICALS ARE IN THE PROCESS OF BEING REGULATED TODAY

TSCA observers need look no further than changes to existing chemical regulations for concrete public health "wins." The EPA now has a process that decouples cost considerations from risk. 15 U.S.C. § 2604(b)(1), (4). In 2017, the EPA successfully issued two major procedural rules to prioritize and evaluate chemicals. EPA, Final Rule, Procedures for Prioritization of Chemical Substances for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753, 33,762 (July 20, 2017)

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(codified at 40 C.F.R. pt. 702, subpt. A); EPA, Final Rule, 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, subpt. B). The risk evaluation "framework rule," which explains the procedures the EPA uses to evaluate the risks that existing chemicals pose, was challenged in *Safer Chemicals, Healthy Families v. U.S. Env't Prot. Agency*. 943 F.3d 397 (9th Cir. 2019). The petitioners, including environmental organizations, argued that the rule's preamble statements, which implied that the EPA could exclude some conditions of use from risk evaluations, conflicted with the amended TSCA. The Ninth Circuit found that this language was not a final agency action and thus not reviewable. *Id*. at 416. It directed the EPA to include legacy uses and associated disposal within the scope of "conditions of use," but it upheld the EPA's decision to exclude legacy disposals. *Id*. at 426.

The EPA has undertaken additional rulemakings since 2017 to clarify the procedural underpinnings for conducting risk evaluations, and there are three questions of interpretation that remain in play: First, did Congress intend for the TSCA unreasonable risk determination standard to be applied to the chemical as a whole or to each condition of use? Second, did Congress provide the EPA with discretionary authority to design the scope of a risk evaluation? Third, to what extent should workplace exposure controls be considered during risk evaluation?

The answers to these questions chart the course of TSCA's existing chemicals management program. In the EPA's 2024 revision to the risk evaluation framework rule, the agency concluded in response to these questions that the unreasonable risk determination would be for the chemical itself, the risk evaluation must include all identifiable conditions of use, and workplace exposure controls would not be assumed when assessing risk. EPA, Final Rule, Procedures for Chemical Risk Evaluation Under the Toxic Substance Control Act (TSCA), 89 Fed. Reg. 37,028 (May 3, 2024). In a proposed revision issued one year later, the EPA is reconsidering these questions. EPA, Proposed Rule, Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA), 90 Fed. Reg. 45,690 (Sept. 23, 2025). The agency is now proposing that the best reading of the statute requires that the unreasonable risk determination be made for each condition of use, asserting its authority to exclude certain conditions of use from the scope of a risk evaluation, and has identified workplace controls as risk-based factors to consider in the risk evaluation. *Id*. at 45,699–704. These decisions have separate consequences. For example, the EPA's proposal to make risk determinations for each condition of use and consider workplace controls when doing so begs the question of whether the EPA must incorporate those occupational controls in a risk management rule when it finds that those controls effectively eliminate the unreasonable risk for a condition of use—or whether, instead, it can leave the use out of the risk management rule altogether. When a condition of use receives a "no unreasonable risk" determination, an additional procedural step is required for the finding to be a final agency action with preemptive effect. These determinations will need to be part of either risk management rules or final orders issued no later than concurrent with the rule.

Despite the back and forth on crucial programmatic aspects, the number of existing chemicals being evaluated and regulated is at a record high in TSCA's 50-year history. The chemicals currently under evaluation include hazardous solvents, flame retardants, phthalates, fragrance additives, and plastic and rubber feedstocks. Since 2016, the EPA has completed regulations for 10 existing chemicals—five through the Section 6(a) process, plus the EPA has banned five PBTs under the expedited Section 6(h) process. The banned PBTs are decaBDE; PIP (3:1); 2,4,6-TTBP; PCTP; and HCBD. There are now 42 existing chemicals in some stage of review regarding whether they need to be regulated or may qualify for additional scrutiny that could lead to regulation. U.S. EPA, *Ongoing and Completed Chemical Risk Evaluations Under TSCA* (last updated Dec. 31, 2025). When the list of the 22 chemicals the EPA may select in the future ("preprioritization candidates") is also taken into account, the EPA has over 70 existing chemicals under consideration.

The evolution of the EPA's regulatory approach from targeted risk assessments to comprehensive evaluations and risk management that include virtually all of a chemical's conditions of use is itself a significant contribution to public health. The expanded authority to prioritize, assess, and address risk afforded to the EPA under the Lautenberg Amendments is illustrated in the cases of TCE and methylene chloride, both of which are 2014 Work Plan chemicals. In 2014, the EPA published a risk assessment identifying health risks from specific uses of TCE, such as aerosol degreasing and spot cleaning, with the intention of issuing a risk management rule for each of those uses. Following the 2016 amendments, the EPA prioritized TCE as one of the first 10 chemicals to undergo risk evaluation under the new TSCA framework. It proposed to restrict degreasing and spot cleaning uses that same year but withdrew the proposal in January 2021 to align it with the more comprehensive evaluation that the 2016 amendments required. EPA, Proposed Rule, Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91,592, 91,593–54 (Dec. 16, 2016). The final December 2024 rule bans most uses of TCE and imposes strict workplace protections. EPA, Final Rule, Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 102,568 (Dec. 17, 2024).

Similarly, the EPA's regulation of methylene chloride has evolved from targeted restrictions to comprehensive bans. In 2014, the EPA issued a risk assessment identifying risks from paint and coating removers. Notice of Availability of Draft Chemical Risk Assessments; Public Comment Opportunity, 78 Fed. Reg. 1856, 1857 (Jan. 9, 2013); EPA, *TSCA Work Plan Chemical Risk Assessment Methylene Chloride: Paint Stripping Use* (2014). Following the 2016 amendments, the EPA prioritized methylene chloride for risk evaluation. It first acted to manage risk from methylene chloride in 2019 with a Section 6(a) rule banning consumer paint removers. EPA, Final Rule, Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a), 84 Fed. Reg. 11,420 (Mar. 27, 2019). It then finalized a sweeping risk-management rule in May 2024. EPA, Final Rule, Methylene

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Chloride; Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 39,254 (May 8, 2024). The rule includes an alternatives assessment to justify restrictions on certain uses of methylene chloride. As a result of the EPA's identification of available alternatives, the final rule prohibits most consumer, commercial, and industrial uses. *Id.* at 39,255. For the remaining uses found to pose unreasonable risk, the rule mandates a WCPP and time-limited, essential-use exemptions. *Id.* Compliance deadlines have been extended for certain laboratory sectors, *id.* at 39,268–69, marking a decades-long progression from narrow controls to systemic risk elimination.

In addition, the EPA met its mandate under the Lautenberg Amendments to designate 20 chemicals as "low priority" for risk evaluation. These are chemicals that the EPA found met TSCA's safety standard for the chemical's conditions of use. The statute does not require further low-priority designations, and it is unlikely that the EPA will have the time or resources in the future for more of them given the number of high-priority chemicals in the queue.

The EPA has exercised its new authority to issue test orders for many existing chemicals currently under review and now uses the Chemical Data Reporting rule to gather information on chemical substances considered for prioritization. EPA, *List of Chemicals Subject to Section 4 Test Orders* (Oct. 6, 2025). The agency has held webinars and opened a public comment period to gather public input on how it may implement a "pre-prioritization" process to select the next round of chemicals the Agency may prioritize for a risk evaluation. Press Release, EPA, EPA Welcomes Public Input on Next Round of Chemicals to Be Considered for Prioritization Under TSCA (Aug. 28, 2024). In addition, the EPA has advanced the concept of a tiered data collection program to guide and inform the selection of existing chemicals for risk evaluation. EPA, Meeting Notice, Development of Tiered Data Reporting to Inform TSCA Prioritization, Risk Evaluation, and Risk Management; Notice of Public Meeting and Opportunity to Comment, 86 Fed. Reg. 37,152 (July 14, 2021). These processes are mutually beneficial for notice, predictability, and the general readiness of chemicals undergoing risk evaluation. For example, if the EPA were to publish a multiyear schedule for conducting risk evaluations, it would aid data collection by providing time to identify chemicals in supply chains and collect or generate information that would facilitate the EPA's evaluations.

While the Lautenberg Amendments required the EPA to develop procedures to prioritize and review existing chemicals under Section 6, Congress did not specifically instruct the EPA to promulgate a risk management procedural rule. The EPA interprets the authority Congress gave it to "regulat[e] any manner or method of commercial use" under Section 6(a)(5) to reach virtually all aspects of industrial and commercial operations. EPA, Final Rule, Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 102,568, 102,576 (Dec. 17, 2024). In doing so, TSCA risk management rules touch on consumer use of the chemicals as well. TSCA's statutory guardrails require that risk management rules be supported by substantial evidence and the EPA is directed to consider, inter alia, the benefits and economic consequences of its actions when selecting from the potential requirements. 15 U.S.C. § 2605(a), (c)(2)(B). As previously noted, Section 6(c)(2)(C) requires the EPA to consider whether technically and economically feasible alternatives exist in deciding whether to restrict or ban a chemical. When such alternatives are identified, the EPA has aggressively pursued chemical bans. The methylene chloride risk management rule bans all but 13 of over 50 conditions of use, while the TCE rule prohibits 52 of 54 conditions of use and limits the two remaining uses through narrow and time-limited conditions.

While the Lautenberg Amendments required the EPA to develop procedures to prioritize and review existing chemicals under Section 6, Congress did not specifically instruct the EPA to promulgate a risk management procedural rule.

Given the role of alternatives analysis in Section 6 decision-making, it would be helpful for the EPA to specify in a rule what constitutes a technically and economically feasible alternative. The EPA's identification of alternatives that it relied on to support bans of methylene chloride has been challenged on the basis that the alternatives are not functionally equivalent, thus raising the question of congressional intent regarding the meaning of "technically and economically feasible alternatives." Brief for Petitioners at 60–68, East Fork Enterprises, Inc. v. Env't Prot. Agency, No. 24-60256 (5th Cir. Mar. 5, 2025), ECF No. 213. During the passage of the TSCA amendments, Congressman Latta (R-OH) specified in a May 24, 2016, House speech that

> [a] technically feasible alternative substance is intended to mean a chemical for which: the technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after a phase-in period; the product that contains the alternative substance can continue to comply with all applicable legal requirements; the product that contains the alternative substance can continue to comply with all applicable safety standards and regulatory approval or certification requirements applicable to the product; and, the consumer accepts the product as made with the alternative substance.

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162 Cong. Rec. E785 (May 25, 2016). This legislative history suggests the need, at a minimum, to consider several factors that feed into a functional equivalency determination, such as whether the alternative can be developed and implemented, meets performance requirements, and will have customer acceptance.

By the agency's own count, the EPA has regulated (1087), prohibited (23), or caused to be withdrawn (491) a total of 1,576 new chemicals—66% of all PMNs submitted since 2016.

The EPA has exercised TSCA authorities that go beyond Section 6 to regulate high-priority existing chemicals in commerce as well. Prior to 2016, TSCA did little more than authorize reporting on mercury supply and trade, leaving most substantive controls to other statutes or international agreements. The regulation of mercury under TSCA since the 2016 amendments has resulted in a binding national control program and closed long-standing regulatory gaps to further limit mercury's presence in U.S. commerce. In 2021, under Section 6(h), the EPA prohibited or restricted mercury-added products and mercury-using manufacturing processes to lower human and environmental exposure to this persistent neurotoxin, bringing domestic law into closer alignment with the Minamata Convention on Mercury. EPA, Final Rule, 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), 86 Fed. Reg. 879 (Jan. 6, 2021) (codified at 40 C.F.R. pt. 751, subpt. E).

Finally, the EPA has kept TSCA in its sights as a tool for regulating PFAS. The EPA has issued significant new use rules (SNURs) to prevent the reintroduction of long-chain PFAS in commerce without agency approval. *See, e.g.*, EPA, Final Rule, Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, 85 Fed. Reg. 45,109 (July 27, 2020). In 2026, entities that manufactured or imported PFAS since January 1, 2011, will report on their uses, volumes, byproducts, disposal, exposures, and hazards. EPA, Final Rule, Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 88 Fed. Reg. 70,516 (Oct. 11, 2023); EPA, Proposed Rule, Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) Data Reporting and Recordkeeping Under the Toxic Substances Control Act (TSCA); Revision to Regulation, 90 Fed. Reg. 50,923 (Nov. 13, 2025).

## NEW CHEMICALS ARE NOW HIGHLY REGULATED

The number of new chemicals subject to regulation under TSCA is also at a record high. By the agency's own count, the EPA has regulated (1087), prohibited (23), or caused to be withdrawn (491) a total of 1,576 new chemicals—66% of all PMNs submitted since 2016. EPA, *Statistics for the New Chemicals Program Under TSCA* (last updated Feb. 3, 2026). In 2024, EPA aligned its regulatory text with the amendments to TSCA's new chemicals review provisions in the Lautenberg Amendments, with the laudable goal of strengthening the quality of information initially submitted in new chemicals notices. EPA, Final Rule, Updates to New Chemicals Regulations Under the Toxic Substances Control Act (TSCA), 89 Fed. Reg. 102,773 (Dec. 18, 2024). That rule significantly raises the bar for the introduction of new PBT and new PFAS chemicals. In 2025, the EPA also was able to secure much-needed funding from Congress to update its outdated electronic reporting platform for PMN submissions, known as the Central Data Exchange (CDX).

From TSCA's inception, Section 5 has directed the EPA to review new chemicals before market entry under tight 90-day deadlines. 15 U.S.C. § 2604(a)(1)(B), (i)(3). A high degree of transparency that the Lautenberg Amendments demands from the process makes this timeline challenging. The EPA prepares numerous technical reports to document the outcomes for each new chemical. As noted, the review process frequently results in regulating new chemicals through lengthy and complex consent orders generated on an individual chemical-by-chemical basis. Subsequently, the EPA will prepare and issue SNURs that hold other market participants to the same conditions that PMN submitters are bound to through consent orders. As a result, the EPA frequently exceeds the 90-day timeframe by months and even years. Overall, the annual number of new chemical approvals has declined, with an average of 142 PMNs completed per year since 2021. While gains in the form of greater regulation and improved transparency have been made, the new chemicals program remains challenging for those both experienced with and new to TSCA alike.

## TSCA DECISIONS ARE MORE TRANSPARENT

In June 2023, the EPA finalized a comprehensive CBI procedural rule under Section 14, standardizing the assertion and substantiation of confidentiality claims, narrowing the scope for health and safety study claims, expanding electronic reporting, and accelerating the public release of nonconfidential information. EPA, Final Rule, Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 37,155 (June 7, 2023). In 2026, the EPA will launch a new program to review extension requests for CBI claims that have reached the 10-year limit. EPA, Expiration and Extension of Confidential Business Information (CBI) Claims Under the Toxic Substances Control Act (TSCA), 91 Fed. Reg. 371 (Jan. 6, 2026).

The changes to TSCA have led to greater regulatory transparency in the new chemicals program in particular. As a result of the EPA's Inventory Reset program, we now have a better understanding of the number of active chemicals in commerce. Only about half of the chemicals listed on the pre-Lautenberg TSCA Inventory are actually in commercial use. The inactive

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substances remain listed as existing substances under TSCA, but companies must notify EPA to change their status from inactive to active if and when commercialization resumes. Through the public disclosure requirements in the Act, there is significantly more information available on new chemicals through the publication of PMN applications, EPA consent orders, and health and safety information. 15 U.S.C. §§ 2603(d), 2604(d)(2)–(4), 2613(b)(2).

Before 2016, companies could assert CBI claims largely as a matter of course to shield chemical identities and uses from public view without significant EPA oversight. The 2016 amendments strengthened agency oversight to improve confidence in EPA's chemical safety decisions without eliminating protections for legitimate proprietary information. Now, the EPA must review each CBI claim seeking to place a chemical identity on the confidential portion of the TSCA Inventory, and companies need to explain the reasons for these requests. This greater oversight authority has allowed the EPA to move 1,109 chemicals from the confidential to the public portion of the Inventory. EPA, *Frequent Questions About TSCA CBI* (last updated Sept. 16, 2025). The EPA must review at least 25% of other types of CBI claims that are submitted in TSCA filings. It has created public dashboards like Chemview to promote communication and ready access to information regarding TSCA submissions for the public.

## Judicial Review and Congressional Oversight Are Part of the TSCA Life Cycle

Judicial review has become prevalent as questions of interpretation have emerged from the EPA's implementation of the Lautenberg Amendments. The EPA's risk evaluation procedural rule is once again under court scrutiny, as are all five final risk management rules and the Deca-BDE PBT ban. *USW v. EPA*, No. 24-1151 (D.C. Cir.) (in abeyance); *Texas Chem. Council v. EPA*, No. 24-60193 (5th Cir.); *Olin Corp. v. EPA*, Case No. 25-1014 (8th Cir.) (in abeyance); *East Fork Enter. v. EPA*, Case No. 24-60227 (5th Cir.); *FabriClean Supply & Tech. Chem. Co., Inc. v. EPA*, Case No. 25-60006 (5th Cir.); *United Steel, Paper & Forestry, Rubber, Mfg. v. EPA*, Case No. 25-1055 (3d Cir.); *Yurok Tribe v. EPA*, Case No. 24-7497 (9th Cir.). In these pending cases, the EPA's expertise on the three "core questions" for how risk evaluations should be conducted will be persuasive rather than controlling. Prior to *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), courts typically deferred to agency interpretations of statutes under the *Chevron* doctrine, relying on agency expertise if the statute was unclear. The *Loper Bright* decision overturned *Chevron* and affirmed the independent duty of the courts to interpret statutes.

The unresolved areas of TSCA implementation are leading to calls for new legislative fixes, and legislative proposals are beginning to emerge. In January 2026, the House of Representatives released "discussion draft" legislation. U.S. House of Representatives, Discussion Draft, To Amend the Toxic Substances Control Act and for Other Purposes, 119th Cong. (2026). It would require the EPA to document when and why new chemical reviews take longer than 90 days. To add greater certainty to risk determinations, the legislation proposes to require that the EPA find that the unreasonable risk is "more likely than not" to occur. Additionally, it directs the EPA to prioritize reviews for substances like those on EPA's Safer Choice list and that improve the security and resiliency of critical supply chains. In other areas of the discussion draft, the EPA is directed to conduct reviews by grouping similar chemistries, improve outdated models, standardize risk management outcomes, streamline consent orders, issue SNURs without consent orders when a submitter's use meets the safety standard, and issue consent orders and SNURs together when the use does not meet the safety standard.

The Senate followed with a discussion draft in February. U.S. Senate, Discussion Draft, Toxic Substances Control Act Fee Reauthorization and Improvement Act of 2026, 119th Cong. (2026). It would revise TSCA's definition of "conditions of use" to exclude hypothetical circumstances and uses that violate other federal laws or constitute misuse. The EPA would be required to have a "cognizable basis" for determining that a use is reasonably foreseen and broadly applied exposure controls would create a rebuttable presumption against foreseeability. The draft proposes a new four-tier review framework for TSCA Section 5 and would create a stewardship pathway for the EPA to authorize manufacture and distribution of new chemicals subject to enforceable stewardship implementation plans. The Senate discussion draft has provisions governing review timelines, extensions, failure-to-act consequences, enforcement, revocation standards, contractual obligations for downstream recipients, and limits on liability for manufacturers and importers that comply with the approved plans. It also would require the EPA to establish a program to accredit third-party assessors to conduct completeness and risk assessment reviews. Finally, the discussion draft includes changes to the current low-volume exemption, low-release and exposure exemption, additional restrictions for PBTs and PFAS, and a de minimis quantity authorization for certain new substances produced below 500 kg/year.

## Conclusion

Almost 10 years after Congress enacted the Lautenberg Amendments, it is an opportune time to acknowledge the mark that those amendments have made on federal chemical management. The achievements discussed in this article represent a substantial advancement in safeguarding human health and the environment. The EPA is regulating more existing and new chemicals than ever before, providing increased transparency regarding its risk decisions by documenting review outcomes and transferring many confidential chemical names to the public inventory. Although the promise of preemption has yet to materialize, the existing chemicals that the EPA is regulating under TSCA lay that groundwork. The primary objectives that originally inspired the 2016 amendments are largely being realized—even if not everyone agrees with the approach that the EPA is taking, the results are consequential.

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