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The global diffusion of EU chemical regulation: a review

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Abstract

Background Chemical pollution has emerged as a critical planetary challenge, yet global regulatory responses remain fragmented and insufficient. In this context, the European Union's REACH regulation has been considered a potential global benchmark due to its ambitious provisions, including the principle of "no data, no market," the reversal of the burden of proof onto manufacturers, and the classification and substitution of hazardous substances. This review assesses the extent to which REACH has diffused internationally and influenced domestic chemical regulatory frameworks.

Main text The review systematically analysed 36 peer-reviewed studies comparing REACH with chemical policies in the United States, Canada, Australia, Japan, South Korea, and China. Findings indicate only partial diffusion. South Korea and China have incorporated some REACH-inspired provisions, notably the "no data, no market" rule and the reversal of the burden of proof, though both adapted these principles to domestic priorities and implementation capacities. Other jurisdictions, including the United States and Canada, retained the distinction between existing and new chemicals and maintained regulatory approaches that place greater responsibility on public authorities. Australia relies heavily on industry self-assessment, while Japan continues to prioritize risk assessments by government agencies. Across jurisdictions, approaches to the identification and control of hazardous chemicals also diverge: whereas the EU emphasizes hazard-based criteria and substitution, others combine hazard and exposure considerations and allow broader discretion in prioritization.

Conclusion Nearly two decades after its adoption, REACH has not achieved the global regulatory influence once anticipated. Instead of convergence, national frameworks continue to diverge, reflecting differences in institutional capacity, political priorities, and regulatory philosophies. The EU regime remains distinctive in its precautionary orientation and comprehensive scope, but its global diffusion has been constrained by both practical and ideological barriers. Further comparative and empirical research is needed to assess how national systems function in practice and whether future international initiatives can foster greater harmonization in chemical governance.

Keywords Chemical regulation, REACH, European Union, Policy diffusion

Background

It is worth noting that among the well-known planetary boundaries first proposed by Rockström and colleagues in 2009, the boundary for chemical pollution could not be quantified [1]. It was not until 2023 that authors estimated the impact of synthetic chemicals on the environment [2]. The 15-years delay in compiling data for chemical pollution is indicative of our "toxic ignorance" [3, 4]: we have little and uncertain data on the number of substances in circulation, their properties, their diffusion in the environment and impacts on human health and ecosystems [5, 6]. Yet, the ubiquitous presence of the "chemical avalanche" [7] and the "great acceleration" in their creation and diffusion in the last 70 years is such

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a specific feature of our times that should deserve a sustained attention, at par with climate change and biodiversity loss.

When Persson and his colleagues [8] eventually estimated the boundary for "novel entities", their results were not encouraging: since thousands of substances have been introduced in the environment without any previous tests on their hazardous properties and with little or no regulatory controls the safe boundary is transgressed. The findings provide hard confirmation of what scholars have long suspected and agreed on: both international and national regulatory actions are largely insufficient to address the extent of global chemical contamination and protect the environment and human health [9–11].

The harmonization of chemical regulation at international level is partial. Contrary to climate change and biodiversity conservation that have followed a "convention-cum-protocol" approach, the chemical regime is made of a "series of free-standing treaties that are non-hierarchical" [11] that "cover only a small fraction of the chemicals manufactured and traded across the world" [12] and a series of non-binding commitment, the last being the Global Framework on Chemicals (GFC) signed in 2023. In terms of "toxic ignorance", it is worth noting that at present "no global agreement creates a minimum standard for the amount and type of data to be provided before a chemical is introduced into the market in order to prevent harm to human health and the environment" [13].

So while a comprehensive, ambitious and legally-binding treaty on chemicals remains politically elusive, attention shifts to the regulatory regime of "big players", which are expected to take regulatory action and exert an influential role in other jurisdictions. In this context, the EU chemical regulatory regime, and in particular REACH—was expected to become a benchmark for both developed and developing countries. Despite the adopted regulation being a compromise among competing interests and a significant dilution of the initial proposal [4, 14], REACH still provides regulatory answers to some of the most pressing questions in the chemical sector [15]. Specifically, three features of REACH were innovative: the principle "no data no market" that makes access to EU market conditional to the provision of safety data, the shift of the burden of proof on manufacturers, and the criteria for the regulation hazardous chemicals and their substitution them with safer alternatives [4, 16, 17].

At the time of its development and adoption, the EU explicitly presented REACH as an ambitious and far-reaching reform of chemicals regulation, with the potential to set new international standards. Even prior to its enactment, EU institutions expressed expectations that REACH could exert influence beyond the EU, and contribute to the diffusion of higher levels of chemical protection internationally [18]. In this context, REACH was framed as an example of international leadership in chemicals governance, with possible relevance for a wide range of jurisdictions, mentioning Switzerland, Norway, Canada, Japan, South Korea, New-Zealand, China and United States as areas for diffusion.

Almost twenty years after the adoption of REACH, it is therefore appropriate to assess the extent to which these expectations have materialised. This review addresses this question by synthesising peer-reviewed studies that have examined the cross-national diffusion of EU chemicals regulation and that have compared REACH with regulatory frameworks adopted in other jurisdictions. On the basis of this literature, the review is guided by two analytical questions: do regulatory reforms adopted in different jurisdictions following the introduction of REACH incorporate its core principles and standards for chemical control? If so, to what extent do domestic regulatory provisions converge in line with EU approaches?

Taken together, the reviewed studies suggest that, while REACH has influenced regulatory debates and reforms in several countries, it has not become a global regulatory standard. Its international diffusion appears to be constrained by practical implementation challenges as well as by differences in regulatory traditions and policy priorities, with national systems continuing to develop along distinct trajectories rather than converging fully around the EU model.

The review is structured as follows. The next section describes the criteria and the process of paper selection, which followed a PRISMA methodology. The third section provides an overview of the selected papers in terms of country coverage. From section four to six present the empirical findings, section seven presents a discussion of REACH diffusion and the final section provides concluding remarks.

Criteria for paper selection

This review of existing literature on the diffusion of REACH follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines [19]. PRISMA provides a structured framework to enhance accuracy and reproducibility in literature reviews by requiring transparent documentation and reporting of each step in the study selection process. These steps include identifying sources, developing search strategies, and establishing inclusion and exclusion criteria.

The literature search was conducted in the scientific databases Scopus and Web of Science (WoS). In line with PRISMA's recommendation to cast a wide net, the review was conducted to include studies on chemical regulation

Table 1 List of search terms

Source	Search string
Scopus	(TITLE-ABS (chemical PRE/0 policy)) OR (TITLE-ABS (chemical PRE/0 regulat*)) AND (LIMIT-TO (SUBJAREA, "SOCI"))
Scopus	(TITLE-ABS (chemical AND convergence)) OR (TITLE-ABS (chemical AND policy AND diffusion)) OR (TITLE-ABS (chemical AND harmonisation)) AND (LIMIT-TO (SUBJAREA, "SOCI"))
Scopus	(TITLE-ABS-KEY (precaution AND chemical)) AND (LIMIT-TO (SUBJAREA, "SOCI"))
Web of Science (Social Sciences Citation Index, BKCI-SSH)	TI-AB = (chemical AND (regulat* or policy or convergence or diffusion or harmonisation))
Web of Science (Social Sciences Citation Index, BKCI-SSH)	TI-AB = (precaution* AND chemical)

within the subject area of social sciences. A more specific search strategy was also conducted and included terms derived from existing studies on policy diffusion [20, 21], namely "diffusion", "harmonisation", "convergence", and "policy transfer" in association with "chemical" (see Table 1 below). The search was applied to titles and abstracts, restricted to studies published after the adoption of REACH (2007 onwards) and limited to peer-reviewed journal articles in English.

This process yielded 866 records, of which 275 duplicates were removed. The remaining 591 records underwent a three-stage screening. In the first stage, titles were reviewed to assess their relevance to regulatory issues. Papers that were off-topic—such as ecotoxicology studies captured by broad keywords like "regulation" or "policy"—were excluded. Further, papers focused exclusively on technical risk assessment methodologies or exposure-related issues were excluded. This step eliminated 404 records, leaving 187 for abstract screening.

In the second stage, abstracts were reviewed for geographical scope, with special attention given to the European Union (EU) context. Papers focusing exclusively on domestic issues within single countries—whether EU Member States or non-EU countries—were excluded. The same applied to papers dealing solely with the analysis or evaluation of REACH. This stage led to the removal of an additional 121 records.

The third stage involved a detailed review of introductions and/or conclusions in the remaining 66 papers to determine their central focus. To be included in the final analysis, studies had to meet the following criteria:

1. They examined REACH in a comparative context, rather than focusing solely on EU domestic policy (e.g., REACH evaluations) or the EU's role in global forums (e.g., negotiations on the Global Chemical Framework or the Mercury Convention). This allowed for the inclusion of papers which examine similarities and differences between the EU and other jurisdictions and thereby shed light on the diffusion of EU regulatory principles.
2. They addressed REACH specifically, not other chemical-related legislation (e.g., on cosmetics or pesticides).
3. They included at least one comparison between the EU and another country.

Applying these criteria yielded a final selection of 36 papers, covering comparative perspectives with six countries: the United States, Canada, Australia, Japan, South Korea, and China. The studies were scanned for analysis of the three characteristics that—as mentioned in the section above—reflect the most innovative of the REACH regulation. To ensure the review reflects the most current information, the validity of cited legal provisions was verified using government websites and specialized platforms on chemical regulations, with corrections or updates applied as needed.[1] The following section presents an overview of the selected journal articles (Fig. 1).

General overview of collected papers

A general overview of the selected papers reveals significant gaps in our understanding of diffusion of chemical regulations. An extensive overview is provided by Filipec [22], a 2017 monograph entirely devoted to the diffusion of REACH, and Bradford [23] who analyses the "Brussels effect" in a number of policy areas, including chemicals. Sustained attention has been devoted to Asian countries, in part because some important EU commercial partners have quickly reformed their own chemical legislation in the aftermath of the REACH approval [24, 25]. Available studies on EU influence on specific countries address Japan [26, 27], South Korea [27–29], China [25, 30]. A paper comparing EU and Australian regulations has been published by Gabriela and colleagues [31]. Four papers

[1] China and South Korea have introduced modifications to their regulatory frameworks in 2020 and 2018 respectively. Sources for updated information have been included in footnotes.

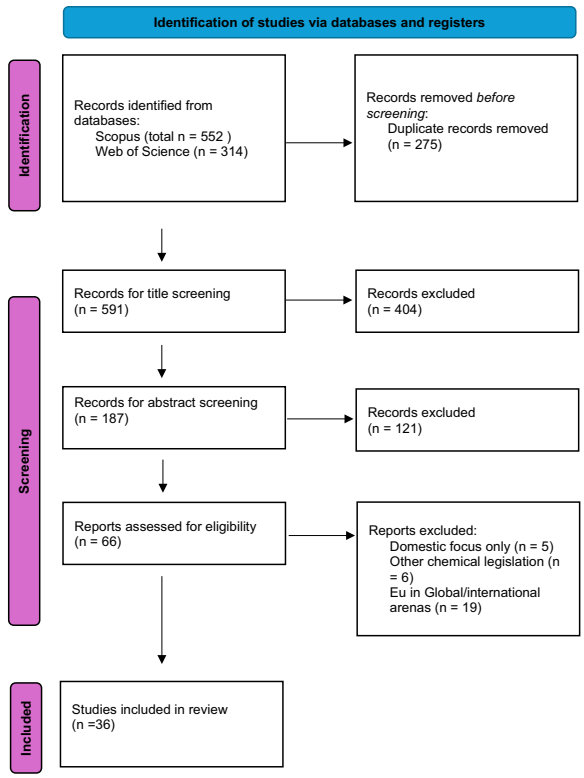


Fig. 1 Application of the PRISMA methodology to the identification of papers. Source: Page MJ, et al. BMJ 2021;372:n71. https://doi.org/10.1136/bmj.n71 [19]. This work is licensed under CC BY 4.0. To view a copy of this license, visit

provide a comparison of EU, Canadian and US provisions [32–35].

The comparison between EU and US attracted sustained attention, because in the 2010s the US was in the process of reforming the 1976 TSCA. Vogel [36], Smith [37] and Renn and Elliott [38] demonstrated the widening regulatory gap between the two. In this light Uyesato [27] and Heyen [39] anticipated that none of the main features of REACH would be adopted by the US, since the EU regulation was considered too expensive and burdensome. In contrast, a number of scholars analysed the extent to which the US could (and should) follow the EU by adopting some of the main features of REACH as a way to overcome shortcomings in the US legislation, considering it "outdated" and "ineffective" [16, 17, 24, 40–45]. After the adoption of the reformed TSCA in 2016, scholars followed up and published comparisons of EU and the new 2016 US provisions [22, 46, 47].

The following sections detail the extent to which the diffusion of REACH has taken place, distinguishing three issues: the rules for accessing internal markets, the burden of proof, and the criteria for assessment of hazardous chemicals.

Rules for markets access: the "no data no market" principle

The lack of data on chemicals and their properties is recognized as a major problem that prevents the effective protection of human health and environment [40]. A main reason for this gap is identified in the regulatory distinction between old and new chemicals. As Abelkop and Graham [32] explain, "historically, existing substances lacking a significant prior history of major health or environmental risks were simply grandfathered into acceptance under a presumption of safety, without a full set of basic data on uses, exposure pathways, and hazardous properties", while new chemicals were subject to some data provision. As it will be illustrated below, this distinction was in place in EU, US, China and most other countries.

In the EU, the first chemical directive was introduced in 1967 (Directive 67/548/EEC). In 1979 the law was amended to introduce requirements for submitting dossiers on 'new chemicals'—identified as those entering the European single market from September 1981 onwards—while 'existing substances' were exempt.[2] Over time, the regulatory distinction between existing and new substances had significant and negative side effects, in terms of data gaps. Further, it disincentivized innovation, preventing new chemicals to enter the market. According to the European Commission, these new chemicals constituted only 1% of the substances on the market, thus leaving most chemicals on the market untested.

With the adoption of REACH, the EU abandoned this approach to embrace the "no data, no market" principle (Reach Article 5). Since then, access to EU single market for all chemicals—irrespective of their prior history of utilization—is conditional to the provision of data. Specifically, manufacturers or importers must submit data for all chemicals that they utilise above the quantity of one tonne per year. Access to EU single market is therefore granted to companies that register substances and provide data. Dossiers have been incrementally added to the ECHA database and at the time of writing it includes over 109,000 registrations submitted by 18,000 companies covering around 23,000 substances.

There are some exceptions to data provision obligations. First, substances utilised below the threshold of one tonne per year are exempt. Second, polymers do not require data submission.[3] The exclusion of polymers from REACH obligations is a puzzle that scholars explained referring to pressures from business lobbies, some EU states as well as third countries, the United

[2] Later in 1988 the EU introduced the Existing Chemical legislation that set a program of evaluations of old substances which proved largely insufficient.

[3] Information is collected on the monomers used for polymers formulation.

States in particular who lobbied against the adoption of mandatory registration [4]. Finally, some chemicals are not registered under REACH because have dedicated legislations. This is the case of active substances used as pesticides and biocides, which all must be tested and obtain an authorization before entering the EU market [48].

Such changes in REACH amounts to a comprehensive overhaul of chemical policy [49], which provoked what Fisher called "regulatory turbulence" [34]. The new policy was innovative and scholars argue that it was formulated in direct response to pre-existing policy shortcomings that are not unique to the EU [14, 50, 51]. EU decision-makers looked closely at U.S. experiences during the policy formulation stage and "deliberately reverses many of the legislative choices that Congress made in TSCA" [40]. In so doing EU decision-makers delivered a reform that addressed many of the challenges of the extant chemical regimes [16, 17, 37, 40]. Accordingly, because REACH aims at providing a solution to the persistent lack of information on chemicals, data generation is an area of regulatory activity in which scholars expected the EU regime to work as a proxy for a harmonised global system. However, taking stock of the papers that addressed this issue, the diffusion of the "no market no data" principle is very partial, since countries for which there are information sticked to the distinction between existing and new chemicals.

The US legislation—known as Toxic Substances Control Act (TSCA)—has been first introduced in 1974 and eventually amended in 2016, a reform "long overdue" [40]. The shortcomings of the 1976 TSCA were multiple. Indeed, as Sachs [16] wrote, "virtually every expert panel that has examined the U.S. system of chemical regulation has concluded that it inadequately protects public health and the environment". A major criticism of the 1976 TSCA was the poor record on data generation for regulatory purposes that resulted from the original design of the regulation. All chemicals in use in 1975 were grandfathered and included in the TSCA Inventory run by EPA, which in 1979 included around 62,000 chemicals and over time grew to the current 86,000 entries. For these substances no obligations on data or evaluation were in place.

The manufacture of new chemicals—i.e. all substances that are not already registered in the inventory or are not subject to exemptions to registration—should be notified to EPA, a process known as Pre-manufacture notice (PMN), which aims at pre-market scrutiny of chemical risks. Companies however were not required to generate new data to be submitted; rather they were free to submit what they already have. Evidently, companies had very partial data: "the EPA estimates that under TSCA, some 36,000 new chemical pre-manufacture notices (PMNs) were reviewed between 1979 and 2003. By its own records, the EPA notes that 67% of PMNs contained no test data and 85 % contained no human health data" [24]. Renn and Elliott [38] explain that—lacking toxicity and fate data—EPA relied on estimations and simulations for the screening of risky chemicals. The authors affirm that in so doing EPA guaranteed that the PMN process was overall effective in keeping harmful chemicals off the US market, a view that is not generally shared [16, 40].

It is worth noting that TSCA allowed EPA to require companies to generate and provide data, but the agency had to justify its requests based on evidence of unreasonable risks posed by the substance. However, without data, it proved unfeasible to determine whether an unreasonable risk exists. "The result is that for the past 25 years, the agency has asked for very little" [24]. In turn, this prevented the agency from taking regulatory action to control chemicals.[4]

Consequently, many scholars expected and even hoped for the US to take EU principles as example [16, 17, 40], abolishing the distinction between existing and new chemicals and introducing data requirements.

The convergence however did not materialize. In the 2016 TSCA the distinction between existing and new chemicals remains in place, as different requirements apply to chemicals already listed in the TSCA Inventory and those that are not. However, unlike in the past, existing substances are not entirely exempt from evaluation. The EPA must first undergo a prioritization process to determine whether a substance is still in use in the country and if so whether it must be classified as high or low priority for risk evaluation. Risks associated with high-priority existing substances are then assessed and managed.

New chemicals are subject to notification: manufacturers and importers are required to submit a pre-manufacture notice (PMN) at least 90 days prior to the manufacture of the chemical, and EPA must review it and make a determination. Contrary to EU provisions, there are no exceptions for polymers, with the exception of those considered of low concern (polymers of low concern PLCs) because their molecular weight is too high to pass cell membranes. Additional exemptions to notification are foreseen for substances manufactured only for research, in quantities smaller than 10 tonnes a year, and those that are deemed to have low environmental release and low human exposure.

[4] Most papers addressing this issue cite the EPA's failed 1989 attempt to ban asbestos, a well-known carcinogen. The court rejected the ban due to insufficient evidence of harm for every type and use of asbestos. It wasn't until 2024 that the EPA successfully finalized a rule to prohibit chrysotile asbestos, one of the six asbestos fibres.

So the revised TSCA does not fundamentally alter pre-existing provisions and does not converge with EU ones on this point, since "EPA does not require minimum data-sets from industry" [46]. The reformed TSCA however, makes it easier to EPA to require test data to the U.S. industry on a case-by-case basis, since it "allows EPA to issue orders and sign consent agreements to require testing instead of going through a rule making, which is a far more time-consuming administrative process" [46].

Canada had regulated chemicals in 1988 and reformed the law in 1999 (Canadian Environmental Protection Act 1988/1999). It was based on the existing/new chemical distinction. The 1988 law introduced the Domestic Substances List (DSL), which originally included 23,000 substances that were in commerce in Canada between 1984 and 1986 and now totals around 28,000 chemicals. These do not require any notification, unless there are "significant new activity" to report. A second list—the Non-domestic Substance List (NDSL)—contains substances that are not on the DSL but are used internationally or are listed on TSCA inventory in the United States. There are more than 58,000 entries in NDSL. These require a simplified notification. To regulate such existing chemicals the Canadian government has first gone through a process of categorisation—completed in 2006—and then adopted the Chemical Management Plan that prescribes how to prioritize substances for more refined assessment and how to control for adverse effects.

As for new chemicals, they must be assessed before entering the Canadian market according to the New Substances Notification Regulations (Chemicals and Polymers). Companies have to notify the government before importing or manufacturing a new chemical or polymer for the first time, following a New Substances Notification (NSN). Environment and Climate Change Canada and Health Canada carry out a joint assessment process to determine whether there is a potential for risk to the environment and human health. When potential risks are identified, the Minister of Environment and Climate Change can impose control measures.

The Australian regulation of industrial chemicals has been last reformed in 2020. The new scheme is called Australian Industrial Chemicals Introduction Scheme (AICIS) and has been enacted under the Industrial Chemical Act 2019. According to Gabriela et al. [31], the main principle of AICIS is "Risk Proportionate Regulation, where risk is used as a basis for guiding regulatory effort at the time of introduction of the chemical".[5]

The Australian government keeps the Australian Inventory of Industrial Chemicals which includes around 40,000 chemical substances that are manufactured or imported in the country. What is distinctive of the Australian approach is that the system is largely based on self-regulation. Introducers—the policy jargon for companies—must self-assess their activities and obligation. As a first step, they must categorize their introduction, determining whether the chemical is listed—e.g. already included in the Inventory. If so, the introducer can utilise the substance following the regulatory requirements (if any) described in the inventory. If the chemical can not be categorized as "listed" then the manufacturer or importer has to categorise it, according to the level of health and environmental risks associated with its chemicals. There are 3 possible categories: exempted, reported, assessed. Exempted chemicals are very low risk and can be introduced in Australia without prior information to the Dept of Health. Reported are low risk chemicals or those that are used by a company in less than 10 kg a year, or that are used for research and development. If the chemical meets these criteria, companies must submit a once-off pre-introduction report (PIR) before manufacturing or importing them. Assessed chemicals are the most demanding and must obtain a certification before being introduced.

China first introduced chemical legislation in 2003 and reformed it in 2011. The reformed legislation has been called "China REACH", to stress the adoption of some of the EU principles. However, China mostly adapted the EU provisions to its domestic priorities. When it comes to market access, the distinction between existing and new chemicals that was in force since 2003 has been maintained. Existing chemicals are all those in use in China until 2003 and included in the Inventory of Existing Chemical Substances (IECSC), which was first published in 2013. It originally included 45,612 substances. Since then, 1435 chemicals have been added.[6] There are no requirements for these substances, unless under specific circumstances like changes in uses that require a risk assessment. The"REACH-like" part of the legislation applies to "new" substances, i.e. any substance that is not already listed on IECSC. These require notification in accordance with China MEP Order 7 (China REACH), replaced in 2020 by MEP Order 12.[7] Differently from the EU, the notification for new substances applies irrespective of annual tonnage, but data requirements differ in relation to quantity. Further, the Chinese regulation

[5] It is of note that "introduction" is the Australian jargon for manufacturing and importing chemicals.

[6] See: https://www.cirs-group.com/en/chemicals/the-inventory-of-existing-chemical-substance-in-china-iecsc-2013-and-updates

[7] See: https://www.chemsafetypro.com/Topics/China/China_IECSC_Inventory_Existing_Substances.html

requires the notification of new polymers, even in cases where all monomers are already included in the IECSC.[8]

South Korea legislation was called Toxic Chemicals Control Act (TCCA) and was first introduced in 1991. Discussion on how to reform the TCCA started in 2008, shortly after the adoption of the new EU rules. As Uyesato and colleagues noted [27], the original Korean regulation was largely based on the 1973 Japanese law while the reformed one—called Act on the Registration and Evaluation of Chemicals (AREC)—has been labelled "Korea-REACH", since it is informed by some of the EU principles. Indeed, scholars regard the Korean case very indicative of the potential influence of EU: "The South Korean experience is perhaps the greatest piece of evidence of the potential for REACH to become the global reference model for chemical risk regulation" [52]. The final text of AREC has been adopted in 2013, and presents striking similarities with REACH as well as some differences [28, 53]. As far as market access is concerned, South Korea adopted the "no data, no market" principle pioneered by the EU, though initially with some notable modifications. Similar to the EU, the new Korean legislation abolishes the previous distinction between existing and new chemicals [25]. However, the registration of existing substances—those listed in the Korea Existing Chemical List (KECL)—was delayed and initially required only for a subset of notified chemicals. In 2018, an amendment to AREC made registration mandatory. This amendment also introduced a phased implementation plan, which is set to be fully completed by 2030.

Japan was one of the world pioneers of chemical policy, having adopted the Chemical Substances Control Act—called Kashinho—as soon as 1973. In 2009 the law has been substantially revised to correct some of the difficulties encountered in implementation. The pre-2009 legislation set up the Japanese Existing and New Chemical Substances Inventory (ENCS). It required a pre-market evaluation for every new chemical substance. The law also required safety assessment of around 20,000 chemicals that were considered "existent" at the time. Such assessments however have been delayed and only around 1500 chemicals had been evaluated [26]. After the adoption of REACH the Ministry of started the discussion on options for the reform of Kashinho. The amended law expands the scope for chemical evaluation but does not follow REACH in requiring industries to submit health and environmental safety data on all chemicals in use. Rather, Japanese authorities—as well as Korean ones—require manufacturers and importers to submit data on volume and uses.[9] Based on such information, the government screens and prioritise substances for risk assessment.

This first section has shown that—despite expectations—the influence of EU REACH has been partial. South Korea and China are the only countries where the "no data no market" principle has been enacted, with substantial modifications. Big players like the US and Canada have changed their regulations without taking on board EU-informed principles and rules. Other countries and in particular in Asia—have adapted rules for market access, in general applying them for new chemicals while leaving more favourable regulatory provisions for existing chemicals in place.

The reverse of the burden of proof

A second crucial aspect revolves around the question of who is required to submit data and prove the safety of chemicals. Traditionally, it is public authorities in charge with data gathering and assessments. With the adoption of REACH, the EU reversed the burden of proof and placed it on manufacturers of chemicals.

The shift is described as "clouded" by some limitations [24]. Specifically, while it applies to the registration, evaluation, and authorization of chemicals, it does not extend to restrictions—where the burden remains with authorities [54]. That said, most papers highlight the significance of the reversal of the burden of proof, asserting that "REACH offers a major policy step forward" [24].

The EU decision found its rationale on both normative and practical grounds. From a normative point of view, the reverse of burden of proof is linked to the central role given to the precautionary principle in the EU [4, 36]. Companies must provide evidence of safety because—on the basis of the precautionary principle—a chemical is considered unsafe until proven otherwise. Further, since manufacturers are those profiting from the marketing of chemicals, it is a matter of fairness to ask them to bear the costs—and responsibility—for testing and evaluations. From a more practical side, scholars pointed out that the huge number of existing chemicals that need to be evaluated proves impossible hurdles for governmental agencies who generally lack adequate resources. Indeed, there is strong evidence that public authorities have difficulties in delivering assessments. Prior of REACH, between 1993 and 2003 EU authorities delivered risk assessment for 140 chemicals in total [38, 49]. Likewise, other countries—Canada and Japan for example—experienced similar difficulties [26, 32]. In the US, EPA could review only 10% of the around 35,000 notifications for new chemicals submitted in the period 1979–2004. In

[8] See: https://www.cirs-reach.com/China_Chemical_Regulation/Frequently_Asked_Questions_FAQs_Chinese_Chemical_Legislation.html

[9] See: https://www.env.go.jp/press/files/en/291.pdf

addition, information asymmetries make it difficult for public authorities to collect evidence on properties of chemicals and their use: "manufacturers, processors, and users are in the best position to obtain data on intrinsic properties, uses, releases, exposure scenarios and pathways, and risk management measures" [32]. Consequently, requiring industries to prove safety can speed up data generation and therefore solve the chronic delays in catching up with the evaluation of chemicals already in use.

Putting responsibility on manufacturer and importers has also disadvantages, the main one being identified in the problematic credibility of data generated by industry: "after all, companies may perceive that they have little to gain and much to lose by providing regulators with information about the potential risks of using their chemicals" [32]. EU authorities ensure the quality of dossiers by requesting data generated according to internationally validated testing methodologies, like the standardised guidelines approved by the OECD. However, only a minority of dossiers submitted to EU ECHA are reviewed by authorities, who generally limits control to completeness [34]. In short, despite being well-established in the EU context, the reversal of the burden of proof has at times become controversial.

Also in the US context the respective responsibility of industry and authorities have long been a point of debate. On paper, the US TSCA gives the responsibility for chemical safety to manufacturers. In practice, to trigger obligations on industry EPA must first demonstrate that a substance poses a "unreasonable risk". Scholars noted that the placing of the burden on authorities resulted in "some notable failures", in particular "where a dangerous substance was already on the market and the burden was on a government agency such as EPA to build a factual case that would stand up in court to ban or regulate the substance" [38]. Against expectations, the 2016 reform does not shift the burden of proof on industry but addresses this issue by making it easier for EPA to request data to be supplied by manufacturers.

In the extant literature there are different interpretations on the significance of the shift introduced by the 2016 TSCA reform. According to Filipec [22] "the burden of proof has shifted from the EPA to producers and importers of chemicals which corrects main deficit of the TSCA and shifts the paradigm in line with REACH". In contrast, Botos et al. [46] and Van der Vegt et al. [35] maintain that the burden of proof is still on EPA, which is required "to demonstrate that a chemical poses a risk to human health or the environment before it can be regulated" [35].

In Canada the burden was on authorities to categorize and assess hazards of thousands of existing chemicals included in the DSL, a task made complex by the scarcity of available information. In the case of new substances, manufacturers are obliged to submit basic data. Similarly to what happened in the US, Canadian authorities might request industry to submit additional data, but the Ministry must first have a "reason to suspect that the substance is toxic or capable of becoming toxic". Adjustments to CEPA did not address this aspect of the legislation, and therefore, while the legislation mentions the precautionary principle, it leaves on authorities the burden of proving risks [35]. Briand [33] comments specifically on this point, suggesting that while EU and Canadian regulations are both informed by the principle of precaution, the EU shift of the burden of proof marks a pivotal difference that "achieves a superior balance of effectiveness and efficiency with respect to chemical regulation" [33].

The Australia case differs as there is a strong reliance on self-regulation on the part of industry. Manufacturers and importers must self-assess and prove the safety of the chemicals they use. In line with the precautionary principle which prescribe a risk-adverse stance, a substance is considered hazardous if manufacturers can not demonstrate that it is not. Companies go through a procedure to categorise the level of risk associated with each of the chemical they use; data requirements obligations differ in relation to the self-assessed level of risk, with minimal obligations for less risky chemicals and more demanding for those deemed of medium and high risk. As mentioned in the section above, only chemicals of medium and high risk requires action on the part of authorities, who must grant an assessment certificate. Regulatory oversight to check for the quality of assessment submitted by industries is limited, putting into question the ability of AICIS to check and detect misclassifications [31].

The reformed chemical acts in China and in South Korea reversed the burden of proof on manufacturers that are now obliged to generate data, therefore following the EU on this aspect. Available papers do not analyse in detail such provisions. Lee [53] notes that South Korea follows closely the EU, although overall obligations are less burdensome: for the highest volume of hazardous chemicals the total number of test endpoints is 46, against the EU 62.

In Japan, the amended Kashinho does not explicitly state the principle of industry responsibility, and the informational burden placed on industry is significantly lighter than that imposed by REACH [26]. Further, risk assessments are delivered by public authorities who are ultimately responsible for chemical safety.

With the exception of China and South Korea, none of the other jurisdictions here reviewed has shifted the burden of proof in the way the EU did. In part this is because the precautionary principle is enacted in a weaker

version. For example in the US and Canada chemicals are deemed safe until proven unsafe (by authorities) [35], and it is left to authorities to prove risks. Further, the persisting distinction between existing and new chemicals reported above implies that the evaluation of chemicals—and corresponding obligations for industry—are differentiated for the two categories, the former not being included in comprehensive evaluation efforts. To sum up, whereas the EU requires manufacturers to collect data, assess and prove the safety of all chemicals they use above a certain quantity, other countries have required them to submit data on new chemicals only, leaving to authorities to task to determine whether data and safety assessments are necessary for chemicals already on the market.

The assessment of hazardous chemicals

Of the thousands of chemical substances registered in the REACH database over time, around 250 are classified as Substances of Very High Concern (SVHC). This classification means they are subject to further evaluation and potentially to authorization and restriction. These substances have been identified based on a hazard-based approach: they exhibit intrinsic properties deemed unacceptably hazardous. Eight endpoints are of particular relevance in this context: genotoxicity, repeated-dose toxicity, prenatal developmental toxicity, reproductive toxicity, carcinogenicity, long-term aquatic toxicity, biodegradation, and bioaccumulation. Endocrine-disrupting properties are considered to be of an "equivalent level of concern" to carcinogenic, mutagenic, or toxic to reproduction (CMR) substances, as well as persistent, bioaccumulative, and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances. Accordingly, endocrine-disrupting (ED) substances can also be included in the SVHC list [43]. In such cases, applicants are required to submit data on uses and exposure to demonstrate that risks throughout the chemical's life cycle are "adequately controlled." Exposure and economic considerations may be used by applicants to argue that the benefits of using the chemical outweigh the costs. This suggests that the strict hazard-based approach is significantly mitigated, a provision that in the view of Geiser represents a "generous route … left open to the manufacturer or downstream user for presenting their case for authorization" [24]. Further, REACH adopted the principle of substitution, with a view of replacing hazardous chemicals with safer alternatives. Accordingly, applicants are required to demonstrate that no suitable substitute is available. Based on the information provided, the European Commission then decides on the conditions for authorization or restrictions. Notably, certain hazards—specifically CMR, PBT, and vPvB properties—are considered unacceptable, meaning that adequate control is not feasible and substances must be regulated accordingly. To date, the use of 74 substances has been banned or severely restricted.

TSCA inventory is a positive list that includes 82,000 chemicals which—as noted above—were for the most part grandfathered in the mid-1970s. Such existing chemicals were presumed safe and unless EPA could proved they posed an "unreasonable risks", so data requirements were possible. "Since 1976 EPA has been able to require testing on little bit more than 200 existing chemicals and EPA has regulated or banned only five of these chemicals (Jones 2015). This is too few, according to many experts, and was one of the primary motivations for TSCA reform" [46]. Since 2016 EPA can take the initiative to put them on a high priority list, or investigate and assess associated risks for health and safety.

The criteria for prioritization include (1) Persistent, bioaccumulative, and toxic; (2) Used in children's products; (3) Used in consumer products; (4) Detected in human and/or ecological biomonitoring programs; (5) Potentially of concern for children's health, i.e. toxic for reproduction or development; (6) High acute and chronic toxicity; (7) Probable or known carcinogen; (8) Neurotoxicity. In commenting of these criteria, Botos and colleagues concluded that "the current US prioritization process for safety assessment uses a scoring system that is very similar to the scoring system used by ECHA for prioritization of candidate list chemicals in REACH authorization" [46]. In terms of impact, the available studies suggest that the reformed TSCA will not be resolutive of the safety and data gaps [22] since it "will stimulate safety assessments for a maximum of only a few dozen substances over the next several years" [46]. Indeed, an initial list of 10 high-priority chemicals was finalized by the EPA in 2020 and 2021.[10]

In Canada all the chemicals grandfathered in the Domestic Substances List (DSL) underwent a process called categorization, aimed at identifying those with the highest potential for human exposure or those that are persistent, bioaccumulative, and inherently toxic. This categorization process was completed in 2006, resulting in about 4,000 substances being placed on a Priority Substances List (PSL) for further risk assessment by the Canadian government according to the Chemical Management Plan (CMP). In 2023, the Canadian Environmental Protection Act (CEPA) was amended to require the Minister of the Environment and the Minister of Health to update the plan by identifying priority substances that, in their judgment, should be further assessed to determine whether they are toxic or capable

[10] See: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#risk

of becoming toxic. The criteria for the selection of chemicals to be prioritized includes: (1) substances that are hazardous to human health or the environment, including carcinogens, mutagens, reproductive toxicants as well as endocrine disrupting substances, (2) substances that are impacting populations or environments that may be at increased risk due to either greater exposure or greater susceptibility; (3) substances with the potential to contribute to cumulative risks; (4) very hazardous substances that are capable of long-range transport (VH-LRT); (5) substances with known hazardous properties that are used in products available to consumers.[11] Notably, priority is also given to chemicals that are potential substitutes for substances with known toxicity, in order to test their effective suitability as replacements.

Chemicals that are already available in Australia might be evaluated for health and environmental safety if new evidence of harm emerge or if regulatory restrictions are applied in another country, raising doubts on safety. Evaluation Selection Analysis (ESA) proceeds in three steps: first, a risk profile is compiled based on hazard and exposure information; second, a list of additional criteria is considered to weight the priority for evaluation. Among these criteria are evidence of adverse effects, potential for bioaccumulation, persistence in the environment, effects at low exposure, identification of vulnerability in sub-population. Further, regulatory action in other jurisdictions—like the EU—is monitored. Third, considerations of data availability and administrative resources are taken into account to determine the final Rolling Action Plan for evaluations. In other words, the Australian regulation takes into account hazards, exposure as well as administrative feasibility as criteria for safety assessment. At present, the plan comprises around 300 chemicals or families of chemicals, half of which had the evaluation completed and the remaining in progress. Public authorities are in charge of the evaluation, including data collection. They rely on different sources, including: international and national assessments and databases, literature reviews, existing environmental and biomonitoring data, analogue, in vitro, in chemico and in silico data, computational modelling data. In case authorities need information that haven't been able to get by any other means, they can call stakeholders for mandatory data provision.

In China, chemicals that are classified as hazardous fall within the remit of Regulation on the Control over Safety of Hazardous Chemicals, known as "Decree No. 591" and the "SAWS Order 53" containing Measures for the Administration of Registration of Hazardous Chemicals. Adopted in 2011 and 2015 respectively, they cover the life-cycle of chemicals, from manufacture to storage and disposal and regulate the identification and registration of hazardous substances. These are around 2800 substances that are identified as toxic, corrosive, explosive, flammable and capable to do harm to human body, facilities and environment. These chemicals must be registered by the Ministry of Emergency Management (MEM) (until 2018 known as State Administration of Work Safety (SAWS)) and their use might require licences or permit. According to Filipec [22], it mirrors the EU provisions on SVHC, thus suggesting a direct influence of REACH on this point.

In adopting AREC, the government of South Korea designated 510 existing chemicals as Priority Existing Chemicals (PECs). Unlike other existing chemicals listed in the Korea Existing Chemicals List (KECL), PECs were subject to specific regulatory obligations. The original law required their registration by 2018. However, the amended AREC of 2019 extended the registration deadline for all existing substances to 2030, thereby rendering the PEC list redundant.

As previously outlined, Japan's regulatory framework includes a comprehensive list of approximately 20,000 substances referred to as "old" or "existing" chemicals. These are substances that were actively manufactured or imported within the country at the time the original legislation was established in 1973. With the introduction of recent amendments, the Japanese authorities have begun identifying "priority chemicals" from their list of existing substances. These chemicals are selected mainly due to their potential to persist in the environment and their known or suspected harmful effects on human health, wildlife, and plants. The selection process considers factors such as production or import volumes, reported industrial uses, and available toxicity data. Once designated as a priority chemical, the government conducts a detailed risk assessment. If the assessment confirms that the substance is both bioaccumulative and toxic and it is expected to remain over an extensive area, it is classified as a "Class II specified chemical" and subject to labelling and control requirements. During the initial screening, 39 chemicals found to be persistent, bioaccumulative and toxic for humans and the environment were also separated into a distinct category, known as Class I specified chemicals, which require a licence.

This comparative review of legal provisions reveals that the identification, assessment, and regulation of hazardous chemicals vary significantly across the selected countries. The European Union (EU) primarily employs a hazard-based approach, which focuses on the intrinsic properties of chemicals to determine their potential harm. This is subsequently complemented by a

[11] See: https://www.canada.ca/en/health-canada/services/chemical-substances/fact-sheets/identification-risk-assessment-priorities.html

cost–benefit analysis to inform regulatory decisions. In contrast, other countries often adopt a more integrated approach, blending hazard criteria with additional considerations such as the likelihood of exposure, the quantities of chemicals used, and the administrative capacity required for effective regulation. These factors can influence the stringency and scope of regulatory measures, sometimes leading to different outcomes compared to the EU model. Notably, the review highlights a lack of comprehensive information regarding the adoption of the principle of substitution. Again, this suggests that the EU's influence of its key regulatory principles has been limited since EU legal requirements have not been widely adopted in the same manner by other jurisdictions.

Discussion

The review reveals a significant shortfall in the cross-national diffusion of EU chemical regulatory principles and standards. Despite expectations, countries that undertook reforms in their chemical regulations generally refrained from adopting REACH-like provisions, instead maintaining domestic policies largely aligned with pre-existing frameworks. Even in cases where nations—such as South Korea and China—integrated REACH-inspired policies, these provisions were substantially adapted to reflect domestic priorities and regulatory contexts. Based on the analysis of the available literature, it is reasonable to conclude that national regulations are not converging towards an EU-inspired model of chemical regulation. Consequently, the "global ambition" envisioned for REACH has yet to be realized.

Whereas more specific analyses are needed to fully understand the reasons behind the limited diffusion of EU principles, the studies reviewed here provide some useful clues. Explanations generally point to either feasibility or ideological factors.

First, the REACH regulation is often considered too complex. Commenting on the potential diffusion of REACH in China, Park observed that "the REACH system requires a well-structured and functioning chemical regulatory regime, scientific infrastructure (e.g., GLP labs), technical enforcement capacity, scientific data on chemicals, a technical expert pool, and a chemical tracking mechanism locally and nationally. It may be too early for China to introduce REACH-like elements in its existing chemical regulations" [25]. Similarly, in South Korea, limitations in the capacity to implement ambitious chemicals legislation help explain the initial narrower scope of the Act on Registration and Evaluation of Chemical Substances compared to REACH. Biedenkopf [55] noted that whereas the EU created the European Chemicals Agency (ECHA) and relies on twenty-seven Member State authorities for implementation, the institutional and administrative capacity of a single country like South Korea is more constrained.

Studying the Japanese case, Naiki further noted that, for policy diffusion to occur, policy change must be "affordable to a non-EU country, not only in economic terms, but also given the possible disruption caused by introducing a new European regulatory system" [26], thus suggesting that institutional misfit might be another constraining factor. Similarly, China's chemical control system is a complex jurisdictional structure, spread across multiple government ministries. This fragmentation makes integrated workplace chemical control difficult and may hinder the introduction of a holistic regulatory framework like REACH.

Ideological and political considerations have also been particularly important. In the United States, according to Botos and colleagues, reluctance in Congress to adopt any policy solution perceived as "European" has been a major source of resistance. In addition, Uyesato points out that U.S. decision-makers considered REACH too costly for the chemical industry [27].

In this light scholars discuss the extent to which REACH can represent an application of the "California effect" elaborated by David Vogel [56]. As explained by Heyen [39] "regulatory reform that is essentially driven by business actors as a result of economic incentives". This means that companies who invest in raising their product standards to be able to export in high-standard markets "lobby their governments for similar standards at home—to remove the cost advantage of competitors who do not export or care about standards elsewhere" [39]. In other words, large U.S. chemical companies—such as Dow, Exxon, and DuPont—have strong business ties in the EU, while small and medium-sized enterprises (SMEs) do not, these larger firms may have an incentive to lobby for EU-style regulations in the US. This would prevent SMEs from gaining a competitive advantage over them [46]. This mechanism—renamed "Brussels effect" by Bradford [23]—was expected to trigger policy change in US as well as in Asian countries that have strong trade relations with the EU. Heyen demonstrates the "California effect" did not occur in the United States: "Contrary to expectations, I show that chemical exporters are currently not lobbying for REACH-like requirements" [39], thus providing an explanation for the missed influence of EU regulatory framework. Similarly, Naiki shows that "there was no emerging action on the part of the Japanese industry to support REACH-type reforms" [26].

The analysis suggests that, contrary to expectations of policy convergence, national chemical legislations continue to diverge in important respects. With the notable exception of South Korea—where a more ambitious overhaul was undertaken—most regulatory reforms

Table 2 Summary of regulatory provisions for chemical control in EU, USA, Canada, Australia, South Korea, China, and Japan

	Legislation	Year of adoption	Authorities in charge	Presence of lists	Condition for market access	Distinction old/new chemicals	Burden of proof	Data supplied by
EU	REACH	2006	EC; ECHA	SVHC	Registration of all chemicals > 1 ton	No	Manufacturers, importers prove safety of substance	Manufacturers, importers
USA	TSCA	1976, reformed 2016	EPA	TSCA Inventory	Pre-manufacture notice for new chemicals[a]	Yes	Public authorities prove unreasonable risks associated to substance	
Canada	CEPA CMP	1999, amended 2023	Environment and Climate Change Canada (ECCC) and Health Canada (HC)	Domestic Substance List; Non Domestic Substance List	Pre-market assessment for new chemicals[b]	Yes, old chem categorised. Priority Substance List assessments	Existing: Public authorities collect info from producers and public sources. Can mandate	Existing: public New: Manufacturers
Australia		1990, reformed in 2020	Department of Health	Australian Inventory of Industrial Chemicals	Pre-introduction certificate for assessed chemicals (= medium to high risk)	Yes	Manufacturers	New: manufacturers Listed: authorities
South Korea	AREC (K-REACH)	1990, reformed in 2013 and 2018	Ministry of Environment	Korean Existing Chemical List (KECL)	Pre-market registration for new and PEC chemicals; Existing chemicals to be registered within grace periods	No	Manufacturers, importers prove safety of substance	Manufacturers, importers
China	Regulation on the Control over Safety of Hazardous Chemicals (Decree 591) Measures for Environmental Administration of New Chemical Substances (MEP Order 7), replaced by MEE Order 12 issued in 2020	2003, reformed 2011, 2020	Ministry of Ecology and Environment (MEE)	IECSC is a positive inventory, all listed substances are considered as existing substances and are exempted from notification	Pre-market notification for new substances	Yes	Manufacturers	Manufacturers, importers
Japan	Chemical Substance Control Act (Kashinho)	1973, amended 2009	Ministry of Economy, Trade and Industry (METI), the Ministry of Labor and Welfare (MHLW), and the Ministry of the Environment (MOE)	Existing and New Chemicals Substance Inventory (ENCS)		Yes Prioritization of existing chemicals	Public authorities	Manufacturers to submit data on volume and uses

[a] All chemicals not listed in the EPA's Toxic Substances Control Act Chemical Substance Inventory (https://www.epa.gov/tsca-inventory). Additional exemptions to notification are for substances manufactured only for research, in quantities smaller than 10,000 kg a year, have low environmental release and low human exposure (Lorex). See https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/basic-information-review-new

[b] https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances.html

introduced over the past 15 years have been incremental in nature, amounting largely to adjustments of pre-existing provisions rather than comprehensive redesigns. As a result, national frameworks remain heterogeneous, particularly with regard to data requirements for industry submissions, and the criteria employed for risk assessment and evaluation (for a summary see Table 2).

Conclusions

This review compiles and synthesizes existing studies on chemical regulation in order to assess the available evidence regarding the diffusion of REACH principles beyond the European Union. The findings of the literature search highlight the limited scope and uneven development of current scholarship on the diffusion, transfer, and adaptation of chemical regulatory frameworks across jurisdictions. Although the selected studies employ diverse theoretical approaches and vary considerably in empirical focus and geographical scope—and while each makes a valuable standalone contribution—the body of work as a whole offers only a fragmented and partial account of the broader dynamics at play. There is, therefore, a pressing need for more systematic and theoretically grounded comparative analyses. Such research should aim to identify not only the key drivers and mechanisms underpinning regulatory change, but also the institutional, political, and economic barriers that impede harmonization and policy convergence across regulatory contexts.

It is also important to note that the present review has concentrated primarily on the legislative provisions as codified "on paper." While this offers insights into the formal architecture of national systems, it is limited since it provides only a partial understanding of how these systems actually function in practice. A more comprehensive perspective would require close attention to implementation processes—such as the allocation of administrative resources, the robustness of enforcement mechanisms, and the degree of transparency and stakeholder engagement. Equally essential would be an evaluation of the outcomes achieved, particularly in terms of measurable improvements in human health and environmental quality. Addressing these gaps will require new empirical research that combines comparative legal analysis with policy evaluation methods, including case studies, cross-national datasets, and outcome indicators. Such work would not only deepen academic understanding of regulatory diversity but could also inform ongoing policy debates, including those concerning global chemicals management frameworks and the feasibility of greater regulatory convergence.

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