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How the uneven and sequential production of chemical knowledge shapes chemical regulation

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ABSTRACT

Chemical regulation depends on scientific evidence, yet many widely used chemicals remain poorly studied. The production of this evidence is shaped by institutional incentives governing academic research and industry compliance with regulatory requirements, leading some substances to be repeatedly examined while others receive little attention. We present a conceptual framework showing how academic and industry incentives shape both which chemicals are studied and when evidence emerges. This sequential production of knowledge creates persistent blind spots and allows early producer-generated studies to influence regulatory trajectories before independent scrutiny develops. Regulatory delay, therefore, reflects not only fragmented evidence but also the timing of its emergence. Improving chemical governance requires attention to how evidence is produced and when decision-relevant knowledge becomes available.

1. Introduction

Chemicals are integral to modern life, enabling advancements in agriculture, medicine, and industry. Yet their benefits come with risks. Many chemicals are toxic, persistent, and environmentally damaging, with harmful effects often recognized only after decades of use. Effective regulation is crucial but often delayed, resulting in unnecessary harm.

A key contributor to these delays is the fragmented and biased nature of the scientific information available to regulators (Gold and Wagner, 2020; Henry et al., 2021). Fragmentation refers to the uneven distribution of research across chemicals, whereas bias arises from incentives that shape how and when evidence is produced. Regulators rely on data from industry and independent sources such as academia, but these actors operate under different constraints and objectives that shape the type, timing, and focus of research. Industry studies primarily concern substances expected to have sufficient commercial value to justify the costs of development, testing, and authorization, and often aim to demonstrate product safety to sustain market access or avoid stricter regulation (Volz and Elliott, 2012). In contrast, academic research tends to concentrate on chemicals likely to yield publishable findings (Grandjean et al., 2011). These dynamics generate knowledge gaps and can lead to conflicting conclusions for prominent chemicals.

This paper introduces a conceptual framework that describes how incentives shape both the focus and sequencing of research, thereby creating blind spots in the regulatory process. Of the roughly 350,000 chemicals and chemical mixtures listed in global inventories, fewer than 20,000 have been measured in environmental media in the scientific literature outside mandatory regulatory data requirements (Muir et al., 2023; Wang et al., 2020). This gap between the number of registered chemicals and the subset examined in independent research calls for reconsidering how evidence is produced and when decision-relevant knowledge becomes available. We analyze these dynamics, illustrate them with case studies, and discuss implications for improving regulatory decision-making.

2. Mapping research focus, data gaps, and data biases

Fig. 1 illustrates how the production of chemical knowledge is shaped by two key dimensions: expected economic value and expected damage. These dimensions structure incentives in industry and academia and determine which substances are studied.

Expected economic value captures anticipated commercial returns, combining market size, profitability, and the likelihood of regulatory approval. Expected damage refers to anticipated risks to human health

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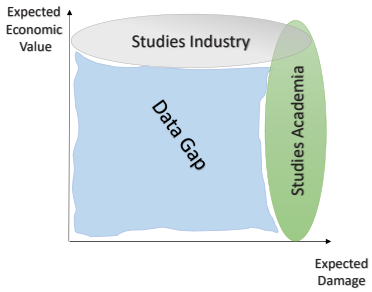

Fig. 1. Conceptual illustration of how scientific information and data gaps emerge across two dimensions: expected economic value and expected damage. High expected economic value tends to attract industry investment, while academia tends to prioritize chemicals associated with high anticipated harm. Chemicals low on both dimensions are therefore less likely to attract attention, creating potential data gaps.

or the environment, including, e.g., toxicity, persistence, and bioaccumulation. Importantly, these anticipated risks reflect current monitoring and toxicological methods, meaning that low expected damage may result from methodological limitations rather than from evidence that a substance is safe.

Academic research tends to focus on chemicals likely to yield measurable, publishable findings, reflecting funding priorities, available methods, and publication biases toward positive results (Fanelli, 2010). Substances that are difficult to measure, lack established analytical or experimental methods, or do not align with current funding calls are less frequently investigated. As evidence accumulates or monitoring capabilities improve, however, perceived risks can increase, shifting some substances from low to high expected damage and thereby attracting greater scientific attention. Industry research, in contrast, focuses on commercially important substances because expected returns shape which substances firms take through costly development and authorization processes, within which safety evidence must be generated to obtain or maintain market access (Kristiansson et al., 2021).

The resulting pattern creates a predictable blind spot, referred to here as the data gap (Fig. 1): at any given point in time, chemicals with both low expected economic value and low anticipated harm attract little attention from either sector. For instance, several assessments indicate that, beyond a relatively small subset of high-volume or well-studied substances, many commercial chemicals lack publicly accessible hazard and risk data. This gap is further amplified by confidentiality claims and incomplete regulatory submissions (Bond and Garny, 2019).

Not every chemical within the data gap necessarily warrants further investigation, and some instances may reflect reasonable prioritization under limited resources. The gap can nevertheless create regulatory risks when low expected damage reflects methodological limitations rather than evidence of safety. In regulatory terms, this creates a risk of false negatives, as substances can appear to pose little risk when relevant hazards remain undetected, particularly when neither firms nor academia has sufficient incentives to investigate them. Because regulatory decisions depend on available evidence, understudied chemicals are less likely to be assessed or restricted even if they pose substantial hazards (Coria et al., 2022). Regulatory agencies often lack the authority or funding to require testing and, in many regimes, have no clear mechanisms to mandate new data even when concerns emerge (Creager, 2021).

Yet the framework also has a temporal dimension. The issue is not only which chemicals are studied, but also when evidence becomes available and when concerns arise that attract broader scientific attention. Firms typically generate information early to satisfy production, liability, and authorization requirements, whereas academic studies tend to emerge once potential harm becomes scientifically and socially salient. This sequencing can shape regulatory trajectories, as illustrated by the cases of asbestos and per- and polyfluoroalkyl substances (PFAS). More fundamentally, this temporal structure reframes the problem of bias: regulatory delay may arise not only from fragmented evidence but from the sequential emergence and diffusion of knowledge.

3. The Timing of Evidence and Regulatory Outcomes: Lessons from Asbestos and PFAS

For both asbestos and PFAS, toxicity evidence generated within industry settings existed decades before broader academic and public-health literature developed, illustrating the sequential production of knowledge described above.

Asbestos became a cornerstone industrial material in the 20th century due to its fire resistance and durability. Evidence of harm appeared early but remained largely confined to occupational settings. By 1930, studies had already shown that workers exposed to asbestos dust developed pulmonary fibrosis (asbestosis), and exposure–disease relationships were documented in manufacturing environments (Barlow et al., 2017). Industrial hygiene programs in the 1940s recognized asbestos as a workplace hazard and recommended exposure controls. Broader epidemiological recognition of cancer risks emerged mainly in the 1950s–1960s, after disease patterns became visible beyond workplaces, and widespread regulation followed decades later (Barlow et al., 2017). Early evidence thus originated in company records and workplace health investigations conducted to address worker illness, insurance requirements, and regulatory compliance, whereas broader scientific attention and policy action followed only after hazards had become widely recognized.

PFAS, widely used in non-stick cookware, waterproof fabrics, and firefighting foams, show a similar temporal pattern. Internal company studies from the 1960s–1970s documented adverse effects in animals and workers, indicating toxicity long before public awareness (Gaber et al., 2023). Yet PFAS hazards remained largely absent from the public scientific literature for decades. Independent environmental-health research expanded only after litigation and regulatory scrutiny in the early 2000s, which triggered a rapid growth in scientific publications (Gaber et al., 2023). Even today, most academic studies focus on well-known long-chain PFAS that have already attracted regulatory and scientific attention. In contrast, the environmental and health effects of short-chain replacements remain understudied in independent research due to the lack of standardized analytical methods for many newer compounds and the limited availability of publicly accessible data (Ateia et al., 2019).

Together, these cases show that regulatory delay results not only from the absence of evidence but from the sequential emergence of knowledge across different actors. Early studies arose from operational and legal pressures rather than proactive investigation of long-term harm. Only after this information became visible beyond the organizations that generated it did wider research and regulation follow.

4. Why Timing of Evidence Matters for Regulation

These dynamics are embedded in regulatory institutions. Across pharmaceuticals, industrial chemicals, and pesticides, regulation commonly requires applicants to assemble and submit toxicological evidence on which decisions are based (Robinson et al., 2020; Siviter et al., 2023). Producers, therefore, generate systematic hazard information prior to market access, and standardized testing is often required for compliance. Such studies are costly and frequently proprietary, so academia rarely produces comparable evidence at this stage. Regulatory assessments, therefore, rely heavily on company dossiers because they provide the earliest readily usable evidence in formats aligned with regulatory procedures (Ågerstrand et al., 2017).

Academic research operates under different incentives. It tends to focus on hazards that are measurable, fundable, and publishable,

leading to persistent underinvestment in emerging risks (Gross and Bergstrom, 2024). Bibliometric analyses show that environmental-health research repeatedly revisits well-known substances while many high-production chemicals receive limited attention—a pattern described as scientific inertia and reinforced by the limited share of funding devoted to anticipatory safety research (Hansen and Gee, 2014).

Regulatory procedures further reinforce this timing gap. Reporting formats, documentation rules, and decision deadlines favor producer-generated studies included in submissions, whereas regulators often have limited capacity to generate or systematically evaluate heterogeneous late-arriving literature. Studies conducted in accordance with OECD test guidelines and Good Laboratory Practice (GLP) often receive greater regulatory weight because their standardized designs, reporting requirements, and quality-assurance procedures facilitate regulatory review and comparison, whereas evaluating heterogeneous non-guideline studies requires additional time and expertise. These standards are commonly applied in studies generated or commissioned by producers for regulatory submission, whereas academic studies often use non-guideline methods and are less commonly conducted under GLP. Compliance with standardized guidelines does not, however, necessarily establish that a method is the most appropriate or sensitive for detecting a particular hazard, since standardized protocols focus on predefined endpoints and study conditions and may not capture effects outside their scope or incorporate newer, more sensitive methods promptly (Elliott, 2016). Reliance on firm data, therefore, reflects its availability, procedural compatibility, and lower assessment costs, rather than necessarily an explicit preference for industry evidence. Over time, these institutional practices can normalize dependence on producer knowledge while leaving some risks insufficiently examined (Jones et al., 2025).

This temporal structure reframes the problem of bias. The issue is not only how evidence is generated but when it becomes available. Because industry-sponsored studies are more likely to report sponsor-favorable conclusions than independently funded work (Woodruff et al., 2023; Bero et al., 2016), effective precaution requires credible independent evidence at the time decisions are made. Yet current institutions often produce most independent knowledge only after harm has already emerged.

5. How Independent Evidence Can Enter Decisions Earlier

If regulatory decisions occur before independent evidence becomes available, improving chemical governance requires reducing the time gap between producer-generated studies and independent research so that regulatory assessments rely on a more balanced evidence base.

First, independent evidence must be introduced earlier in the regulatory process. Regulatory decisions often rely primarily on producer-generated studies because independent research typically emerges only after hazards become scientifically or publicly salient. Mechanisms that enable earlier independent scrutiny, such as requiring registrants to provide complete study data in accessible formats, thereby enabling independent scrutiny and replication of key producer studies, providing targeted public funding for independent replication studies, or having regulators commission independent testing, would allow regulatory assessments to draw on both producer and independent evidence at the time of authorization. Achieving this may require dedicated funding streams or regulatory mechanisms that support independent investigation during the early stages of chemical use. Given limited research resources, public funding for early independent investigation should prioritize chemicals for which delayed recognition of harm could have the greatest consequences. Priorities could be established using a combination of predicted hazards, such as toxicity, persistence and bioaccumulation, anticipated exposure and production volume, and the extent of existing data gaps. Computational toxicology and structure-based hazard prediction could support this initial screening, directing independent research toward chemicals most likely to pose risks.

Second, regulatory assessments currently give greater weight to studies that comply with standardized test guidelines, which favors producer studies submitted in dossiers. Independent studies should not be excluded solely because they use non-guideline methods. However, their regulatory use depends on whether their reliability and relevance can be assessed without disproportionate additional effort. Academic researchers can facilitate this assessment through transparent and sufficiently detailed reporting, clear justification of study designs and deviations from established guidelines, and explicit consideration of regulatory relevance (Ågerstrand et al., 2017). Regulators, in turn, could apply a tiered process that first screens studies for relevance, methodological transparency, robustness, and their potential to identify hazards not captured by guideline tests. This approach would not eliminate the additional administrative burden, but it would concentrate regulatory resources on the non-guideline evidence most likely to affect regulatory decisions and enable independent findings to be considered earlier in the authorization process.

Third, institutions must generate decision-relevant signals before widespread exposure occurs. Current regulation primarily responds once harm is observable. Systematic monitoring and screening infrastructures can instead detect potential risks during the early diffusion of substances. Because knowledge about chemical hazards often accumulates only after substances enter widespread use, regulatory systems must include mechanisms for post-market reassessment as new epidemiological, biomonitoring, or clinical evidence emerges. Environmental and human biomonitoring can identify unexpected exposures in air, water, soil, and populations, and surveillance of publications, patents, and production volumes can flag rapidly expanding chemical classes, including persistent, long-lived substances, and trigger targeted assessment while use remains limited. Furthermore, dynamic watchlists—requiring additional reporting, monitoring, or temporary restrictions—would allow agencies to act under uncertainty rather than waiting for definitive evidence.

Finally, although earlier independent evidence is necessary to reduce the imbalance between producer-generated and independent knowledge, it is not sufficient to ensure that regulatory decisions draw on all relevant evidence (Benbrook et al., 2021). Effective precaution also requires oversight at the submission stage to improve the completeness and balance of the evidence entering regulatory assessment (Mie and Rudén, 2022). This includes prospective notification of studies commissioned for regulatory purposes and verification that all notified studies, including those with unfavorable or inconclusive findings, are submitted or that their omission is justified. It also requires systematic procedures for identifying relevant external research and safeguards against the evidence base being shaped solely by studies selected and designed by registrants. Since 2021, EU rules have required companies and testing laboratories to notify EFSA of studies planned for regulatory applications (Chearnaigh, 2021). Applications that include previously unnotified studies, or omit notified studies without a valid justification may be declared inadmissible or delayed by six months. For pesticide assessments, applicants must also submit relevant peer-reviewed literature, while EFSA coordinates the peer review of the Member State assessment and public consultation on the disclosed dossier (Schwingl et al., 2021).

Evidence on the effects of these measures at scale remains limited (Leone, 2020; Mie and Rudén, 2023). Existing assessments document their implementation and administrative consequences but do not establish whether they have made regulatory evidence bases systematically more complete and balanced across applications (Chatzopoulou et al., 2020). Evaluating their effectiveness would require comparing notified and submitted studies across large numbers of dossiers, assessing whether unfavorable or inconclusive findings remain disproportionately absent, and benchmarking applicants' literature searches against independent systematic searches. Systematic evaluation of these reforms should be a priority for future research, both to determine

whether the measures implemented so far are sufficient and to identify whether additional measures are required.

Together, these measures would strengthen the timely production and regulatory use of independent evidence, improve the completeness and balance of the evidence entering assessment, and reduce the delay between early warning signals and regulatory response. They would not eliminate uncertainty or dependence on producer-generated evidence, but they could make regulatory decisions less reliant on an evidence base assembled primarily through studies selected, designed, and submitted by registrants.

6. Conclusion

Chemical regulation is constrained not only by the quality and timing of evidence, but also by how the regulatory evidence base is assembled and evaluated. Producers generate standardized safety information early, and regulators often rely on it because it is available and procedurally compatible with regulatory assessment. Independent research typically emerges later and may receive less regulatory weight as it often uses non-guideline methods. In addition, reliance on studies commissioned and submitted by registrants creates risks that relevant evidence may be omitted or that the resulting evidence base may be incomplete or unbalanced.

The cases of asbestos and PFAS illustrate how the sequential production and disclosure of knowledge can delay recognition and intervention even when relevant information exists. Reducing such delays requires targeted support for early independent research, transparent procedures for considering robust non-guideline evidence, monitoring and reassessment as new signals emerge, and oversight at the submission stage to improve the completeness and balance of the evidence entering regulatory assessment.

Improving chemical governance, therefore, requires more than expanding the volume of available evidence. It requires institutions that ensure that decision-relevant knowledge is generated, disclosed, evaluated, and used when regulatory choices are made. These measures would not eliminate uncertainty or dependence on producer-generated evidence. Still, they could reduce reliance on a narrow evidence base and enable earlier regulatory action when emerging evidence indicates potential harm.

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CRediT authorship contribution statement

Jessica Coria: Writing – review & editing, Writing – original draft, Visualization, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Erik Kristiansson:** Writing – review & editing, Visualization, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Mikael Gustavsson:** Writing – review & editing, Validation, Investigation, Formal analysis, Conceptualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

No data was used for the research described in the article.

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