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Stakeholder perspectives on the REACH revision and the role of the precautionary principle

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Abstract

This article provides a qualitative analysis of stakeholder perspectives on the European Commission's revision of the REACH Regulation, highlighting how these perspectives reveal deeper epistemic and normative tensions in EU risk governance. Beyond summarising stakeholder positions, the paper offers an interpretive reading of how the precautionary principle is invoked to justify competing approaches to scientific uncertainty, risk assessment, and regulatory simplification. The analysis identifies three cross-cutting themes—knowledge and precaution, risk versus hazard, and simplification versus improved protection—and discusses how these reflect divergent legal and epistemological visions of chemical safety in EU. By contextualising stakeholder reasoning within EU regulatory traditions, the study contributes to understanding how precaution continues to shape, and be contested within, contemporary EU chemicals governance.

Keywords REACH regulation, Precautionary principle, Risk versus hazard assessment, Chemical policy, Stakeholder consultation, Chemical strategy for sustainability

Introduction

In the EU, there are several advanced legal acts that regulate chemical pollution. The most comprehensive is the *Regulation on the registration, evaluation, authorisation and restriction of chemicals* (REACH) [1], which aims to ensure a high level of protection of human health and the environment, as well as the free circulation of substances on the internal market, while enhancing competitiveness and innovation. As implied by the name, it establishes a system for the registration, evaluation, authorization and restriction of chemicals.

Since its establishment in 2007, REACH has been instrumental in advancing chemical safety in the EU. However, as highlighted by the European Commission, there is an urgent need to strengthen the management of chemicals and promote a more coherent, predictable, and robust regulatory framework [2]. According to the Commission, REACH does not achieve its objectives, nor does it adequately contribute to the goals outlined in Article 191 of the Treaty on the Functioning of the European Union (TFEU), particularly protecting human health and improving the quality of the environment [3]. REACH needs to significantly contribute to a society where resources are used efficiently in non-toxic circular flows and where the use of substances of concern is minimized.

The current review process, launched in 2021 to address implementation challenges and align REACH with the European Green Deal, has elicited strong and varied opinions in the two consultations conducted. The REACH review has not been completed, despite

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originally being scheduled for completion in 2023, prior to the election and the appointment of new European Commission. Without a revised REACH, key commitments established by the previous Commission under the Chemicals Strategy for Sustainability was not achieved in time. After the establishment of the new commission a revised timeline for the revision was provided by the Directorate-General for Environment at the CARACAL [4] meeting on 3–4 April 2025, and a legislative proposal for the REACH revision is planned for the fourth quarter of 2025 [5]. The meeting documentation indicates institutional discontinuity, whereby post-election changes in the Commission may result in a shift in policy priorities, potentially weakening the political momentum behind more precautionary or sustainability-oriented reforms of REACH found within the previous Commission (2019–2024).

Public consultations aim to inform citizens and stakeholders about the Commission's plans, enable them to provide feedback on the proposed initiatives, and facilitate stakeholders' participation in regulatory developments. Stakeholders are invited to provide views on the Commission's understanding of the problem and possible solutions, and to make available any relevant information that they may have, including about possible impacts of regulatory options. For the REACH revision, the process involved two consultations. First, an opportunity to respond to the Inception Impact Assessment in 2021, followed by a public consultation on the REACH revision in 2022. The key difference between the two consultations is that the first involved submitting responses, while the second included responding to a questionnaire along with the option to provide additional responses. The Commission has synthesized the responses to the questionnaire [6]. Regarding, for example, the question on whether registrants should provide more information on critical hazard properties of substances than is required today, 37% of respondents agreed or strongly agreed (102 and 161, respectively, out of 714 respondents), and 35% disagreed or strongly disagreed (160 and 92, respectively, out of 714 respondents). This leaves the Commission in a challenging position, as the feedback does not offer a clear direction for the regulatory steps to take.

This study aims to analyse the public responses submitted to the Commission during the two public consultations in the REACH revision process to gain insight into stakeholders' perspectives on the proposed regulatory developments. Specifically, we aim to map stakeholders' opinions and arguments regarding the development of EU chemicals legislation by identifying recurring themes and divergences across stakeholder groups in relation to the deficits identified by the Commission and what these interpretations of the purpose of REACH reveal about the epistemic foundations of EU risk regulation. While previous research has focused primarily on the technical and procedural aspects of REACH implementation, this article foregrounds the discursive and normative dimensions of consultation responses, viewing them as arenas in which regulatory principles and knowledge practices are negotiated. By doing so, the paper situates itself at the intersection of legal analysis and social-scientific enquiry, providing a thorough understanding of public responses and their implications, and seeking to elucidate how competing interpretation of REACH's purpose shape the future trajectory of EU chemicals governance.

Revision process of REACH and the CSS

This section contextualises the REACH revision process, providing background information and descriprtions of relevant concepts, and situating the consultations as the empirical foundation for our analysis.

The REACH Regulation was last evaluated in 2018. It concluded that REACH is effective but that there are opportunities for further improvement, simplification and burden reduction to achieve the objectives of REACH [7]. In light of difficulties in achieving the objectives of REACH, the Commission published in 2018 actions to improve REACH [7]. The issues requiring the most urgent action were (1) ensuring the registration of technical dossiers is compliant; (2) simplifying the authorization process for hazardous substances; (3) ensuring a level playing field with non-EU companies through effective restrictions and enforcement; and (4) clarifying the interface between REACH and other EU legislation [8].

In 2020, the Commission developed its Chemicals Strategy for Sustainability, of which an important part is the extension of the so-called "generic approach to risk management". This approach is described as preventive, as some hazardous substances are generally banned from specific uses, e.g. carcinogenic substances in some consumer products [2]. More precisely, the hazard of a substance is the basis for triggering pre-defined measures such as restrictions and bans [9]. According to the Commission, '*[e]xtending the generic approach will ensure that consumers, vulnerable groups and the natural environment are more consistently protected, while still allowing for the use of these most harmful chemicals were proven essential for society*' [2].

Moreover, the Commission has defined guiding criteria and principles for the "essential use concept" in EU legislation for chemicals, to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health [10]. The term

essential use originates from the United Nations' 1987 Montreal Protocol, a global agreement to protect the Earth's ozone layer by phasing out ozone-depleting chemicals. According to the Montreal Protocol, the parties can decide to permit the level of production or consumption of the two most central groups of ozone-depleting substances, CFCs and Halons, that is necessary to satisfy uses agreed to be essential. Certain essential uses are thus considered to justify exceptions to the limitations and prohibitions normally set for hazardous substances.

Another issue mentioned in the Chemicals Strategy for Sustainability is the risk of potential negative effects of exposure to a combination of chemicals. Since thousands of chemicals are used in a large range of products, people and other living organisms are daily exposed to many chemicals at the same time, which risks leading to combination effects [2, 11]. To take these mixtures into account and integrate them into chemical risk assessments, the Commission wants to assess how to best introduce Mixture Assessment Factor(s) (MAF) for the chemical safety assessment of substances [2].

To allow for the introduction of new regulatory measures, the Commission see a need for a revision of REACH, which is also understood as necessary to support the achievement of a toxic-free environment, aligning with the European Green Deal's ambition of zero pollution [12].

The revision of the REACH Regulation has been a source of conflict within the EU administration. The *European Ombudsman* has reviewed the Commission's choice not to share full documents relating to the legislative documents underlying the revision of REACH with an NGO. The Ombudsman noted that the requested documents constitute legislative documents and contain information about the environment. According to the Ombudsman, EU legislation on public access to documents and the EU Aarhus Regulation provides a particularly high standard of transparency to such documents. Based on this, it was recommended by the Ombudsman that the Commission grant full public access to legislative documents concerning the revision of REACH. The Commission has refused, citing a risk that disclosure could lead to undue external pressure affecting the proposal's adoption. The Ombudsman, however, finds no elements that would distinguish this legislative file from any other examined by the EU institutions and concludes that the refusal is based on general and unsubstantiated assertions regarding external pressure. The Ombudsman therefore decided that the Commission's actions constitute maladministration based on Article 17 of the European Code of Good Administrative Behaviour [13].

The Commission's refusal to disclose key legislative documents, justified on the grounds of avoiding external pressure, underscores that the REACH revision is not only a technical process but also a contested space of interpretation in which the very purpose of REACH—balancing precaution, innovation, and transparency—remains open to negotiation among institutional and societal actors.

Method

We analysed 325 stakeholder responses to the Inception Impact Assessment from 2021 and 304 publicly available responses from the 2022 public consultation on the REACH revision (out of 771, 467 were not publicly accessible) [6]. The Inception Impact Assessment responses offered broader perspectives, as they did not allow for non-public submissions [14]. All responses were read in full and analysed qualitatively to identify recurring arguments and positions in relation to the Commission's proposed revisions. Stakeholders were grouped into four categories: (1) NGOs, (2) industry, (3) public authorities and research institutions, and (4) other/EU citizens.

We applied a thematic approach, drawing on both predefined categories from the Commission's proposals, such as information requirements, authorisation and restriction processes, and enforcement, and, in addition to the Commission's categories, emerging themes from the responses, including appeals to the precautionary principle and views on regulatory uncertainty.

This dual approach ensured that both institutional priorities and stakeholder concerns were captured. The relative frequency with which certain arguments appeared across stakeholder groups was noted to indicate the breadth of support or opposition. Select quotations and paraphrased responses were used to illustrate typical positions. When a stakeholder group is described as supporting a particular position, this means that such arguments appeared recurrently within that group.

The analysis employed an inductive–deductive thematic coding process. Each response was read in full and coded to identify recurring argumentative patterns. Initial codes were derived from the Commission's consultation themes, which were refined through repeated close readings. Three dominant themes emerged, selected based on both their frequency across multiple stakeholder groups and their substantive relevance to the core regulatory debates addressed in the review: knowledge and precaution, risk versus hazard, and simplification versus protection. These were subsequently interpreted through the lens of EU environmental law and regulatory theory. This combined legal–qualitative approach enabled a systematic yet interpretive understanding of stakeholder reasoning under conditions of regulatory uncertainty. Analysing consultation responses through this lens, therefore, allows us to capture not only policy

preferences but also the underlying epistemic and normative assumptions that define what REACH is, and what it ought to achieve.

Results

Inception impact assessment

The Inception Impact Assessment consultation on the REACH revision was conducted in 2021 and invited stakeholders to provide early feedback on the Commission's planned policy direction.

Information requirements

NGOs widely acknowledged that the data provided under the current framework is insufficient and believed that collecting more comprehensive information is essential. For example, the European Environmental Bureau stated that there are '*Very high levels of non-compliance under REACH that remained in time over the last decade (on average two thirds of the registration dossiers still not comply since more than a decade ago)*' [15]. Approximately 80% of NGOs advocated for closing data gaps, particularly for low-volume substances, polymers, and chemicals with carcinogenic, neurotoxic, immunotoxic, or endocrine-disrupting properties. NGOs, such as France Nature Environment, stressed the importance of enforcing the "No data, no market" principle and the proper implementation of substitution plans [16]. However, they criticised the weak enforcement of substitution requirements, which leaves significant gaps in hazard assessments. Ethical concerns over expanded animal testing were also prevalent, with groups like PETA and Humane Society International/Europe advocating for advanced non-animal testing methods.

Industry generally supported addressing critical knowledge gaps but emphasised that any additional requirements should be scientifically defined and technologically feasible. A representative from PlasticsEurope argued that '*it is also appropriate that new information requirements are well defined, science based, and do not exceed the limits of current technology, can be fulfilled using reliable, validated and internationally accepted test methods, [or alternatively] can be fulfilled using weight of evidence, which is scientifically sound and based on well-defined protocols which have been agreed upon in advance with stakeholders*' [17]. While about 60% of the responses from industry representatives supported targeted data collection, they caution against overburdening industries with obligations that could hinder innovation. Many industry stakeholders, such as the European Precious Metals Federation, proposed better adherence to current REACH requirements and advocated for standardised data formats to simplify compliance. The American Chemistry Council highlighted that the administrative costs of extended data requirements will impact companies throughout the global supply chain, especially small and medium-sized enterprises.

Public authorities and research institutions broadly supported the enhancement of data quality in REACH technical dossiers. For example, the Spanish Ministry for Ecological Transition and Demographic Challenge emphasised the need for improved data collection on uses and exposures, particularly for substances with variable compositions. They warned against streamlining processes in ways that might compromise the quality and compliance of registration dossiers, noting that maintaining high standards is critical for effective regulation.

New regulatory approaches

NGOs

Approximately 70% of NGOs advocated for a generic MAF in REACH to address risks from combined chemical exposures. The European Environmental Bureau stated that '*The introduction of one generic MAF will reduce the total toxic pressure from chemicals on human health and the environment and is a practical and a feasible approach*'.[15] There was broad support among NGOs for strengthening the authorisation process through the essential use concept, which they view as a means to improve decision-making and introduce the precautionary principle. The European Consumer Organisation argued that extending the generic approach to risk management should be the default option for the most harmful chemicals: '*This will help ensure that consumers, vulnerable groups, and the natural environment are more consistently protected. Revising Article 68.2 is imperative to support automatic restrictions on such chemicals in consumer goods, e.g. by introducing a strict default concentration limit and derogation criteria for essential use*' [18]. While acknowledging potential regulatory costs for the industry sector, NGOs supported reforms that accelerate the adoption of grouping for structurally related chemicals or chemicals with similar properties and establishing the burden of proof on industry to justify the exclusion of specific chemicals from the group will speed up the substitution of hazardous chemicals [15].

Weak enforcement was frequently cited as a significant barrier to achieving REACH's objectives. Friends of the Earth Germany (BUND) stated that '*all actions from the Chemical Strategy for Sustainability should be addressed, including: zero tolerance to non-compliance and improving the hazard identification*' [19]. Chemsec stated that '*Zero tolerance to non-compliance is crucial, the previously approved, sub-standard registration dossiers and AfA* [Application for Authorisation] *must be re-submitted to save time and resources from MS* [Member States] *and ECHA* [European Chemicals Agency]' [20].

Industry

Industry stakeholders emphasized the importance of a well-functioning internal market and advocated for changes to the authorisation procedure that would make individual applications more attractive, reduce administrative burdens, and promote innovation in sustainable product development. A prevailing concern among these stakeholders was that the proposed regulatory changes adopt a "one-size-fits-all" approach. The Confederation of Swedish Enterprise empathized that '*An effective (regulatory) approach should be as targeted as possible, rather than applying a generic one-size-fits-all approach*' [21]. BioPharmaChem Ireland / Ibec stated that'*The operationalisation of the "Essential Use" concept into the restriction & authorisation processes must take into account the features of the biopharmachem industry in order to secure legal certainty, competitiveness and production of medicines in Europe*' [22]. Additionally, the European steel industry, represented by EUROFER, stated that'*banning of the use of all "most harmful chemicals" should not be linked to hazard properties/classifications, but based on an appropriate assessment of the actual risk including elements of exposure and probability*' [23]. PU Europe stated that '*Although we believe that reforming the restriction process can bring improvements in terms of efficiency, the proposal in the CSS for a hazard-based "generic approach to risk management" is oversimplifying the complexity of the problems at stake*' [24]. A central theme in the industry feedback is thus the transition from a risk-based to a hazard-based regulatory approach (i.e., placing greater emphasis on intrinsic hazard, as opposed to also including exposure data), particularly in the context of a generic approach to risk management, MAF, and essential use. Industry representatives argued that this shift undermines scientific rigor by favouring broad regulatory measures over precise, data-driven evaluations. They strongly advocated for maintaining a risk-based approach that assesses chemicals individually rather than imposing broad, generalised restrictions. Approximately 50% of industry stakeholders favoured a case-by-case approach, warning that an overly broad application could introduce unnecessary regulatory burdens. While there are mixed views on the grouping of chemicals, industry stakeholders advocated for establishing an exhaustive list of substances within group restrictions to ensure regulatory clarity and fairness.

Regarding the MAF, industry stakeholders expressed scepticism about its generic application, citing insufficient scientific and socioeconomic evidence. The European Chemical Industry Council (Cefic) stated that '*An effective (regulatory) approach should be as targeted as possible, rather than applying a generic one-size-fits-all approach to the entire chemical universe. Multiple research projects (incl. EU sponsored projects—such as EU Solutions) indicate that risks of combined exposure in Europe are driven by a very limited number of chemicals and are restricted to specific locations and chemical uses*' [25].

There was strong support for simplifying and streamlining the authorisation process to reduce administrative burdens and encourage innovation in safer chemical alternatives. Industry stressed the need for transparent procedures that uphold legal certainty while ensuring that regulatory measures are based on comprehensive risk assessments of individual substances. Cefic stated that '*We wish to highlight that a new mechanism of revoking non-compliant registration dossiers could be a powerful tool and should be proportional and include clear conditions, legal rights and due process … Cefic welcomes the initiatives to support enforcement and level playing field announced in the Chemical Strategy for Sustainability, including those to revoke deficient registration dossiers when justified*' [27].

Industry stakeholders also highlighted the importance of ensuring that the regulatory framework supports recycling initiatives and aligns with circular economy goals to foster sustainable industrial practices. For example, the European PVC Profiles and related Building Products Association EPPA stated that they '*are deeply concerned that the current REACH framework does not support recycling and the use of recyclate. In the context of the circular economy recycling should be the rule and not the exception which is only assessed on a case by case basis*' [26].

Public authority/research institutes

Public authority and research stakeholders broadly supported enhancing the REACH framework through improved risk assessment, sustainability criteria, and streamlined regulatory processes. They also raised concerns about potential disruptions to the single market, risks of overregulation, and the necessity of evidence-based decision-making. The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) stated that '*Facilitation of a generic approach for restriction is strongly supported*' [27]. However, the German Federal Institute for Risk Assessment (BfR) stated that '*The idea of replacing the established risk-centered approach of regulation in Europe with a purely hazard-based one will have a number of serious consequences, e.g. possible overregulation and stimulation of unwanted substitution, arbitrary removal of safe products from the market, amplifying concern of the public over perfectly safe use of chemicals,* etc*. It also marks a breach of the principle of science-based risk assessment*' [28].

There was a wide-ranging support for incorporating a MAF into chemical safety assessments to account for combination effects. Ministry of Economy of the Slovak republic, Centre for Chemical Substances and Preparations stated that '*We welcome developing a coordinated approach on combination effects of chemicals reflecting the latest scientific understanding, improving and updating registration data and making greater use for acceptance of results from alternative methods*' [29].

Irish Health and Safety Authority stated that '*We support a reform of the authorisation process to provide for greater flexibility on the risk management options for substances of very high concern while at the same time providing predictability for manufacturers, importers and downstream users*' [30]. The Polish competent authority for REACH and CLP Regulations, Bureau for Chemical Substances, stated that they '*would like to share our concerns and advise against reforming the authorisation process by introducing national authorisation for smaller applications. We believe that such an initiative is likely to negatively impact the functioning of the single market for chemicals in the EU*' [31].

Other/EU citizens

These stakeholders generally acknowledged that the proposed reforms aim to enhance protection and address critical chemical risks. Additionally, stakeholders emphasized the need for better alignment between REACH and other chemical legislation to prevent pollution at the source and protect water quality.

Stakeholders expressed mixed views on key aspects. Starch Europe stated that '*The proposal for a Mixture Assessment Factor (MAF) can have significant unintended consequences. Without any indication of potential risks of combination effects, the introduction of MAF for all substances seems very hard to realize. A generic factor can cause major disruptions of trade of safe, sustainable uses of substances that are indispensable in many end uses*' [32]. While EDC-Free Europe coalition wanted to'*stress the importance of replacing the substance-by-substance approach by a group approach to regulate related chemicals and avoid regrettable substitution. … The proposal for the extension of the Generic Risk Assessment (GRA) approach is key, as this is proven to be a faster and more protective approach*' [33]. The Association of Dutch Water Authorities and the Association of Dutch Water Companies supported '*reforming the restriction process by extending the generic risk approach (GRA) to all chemical substances so that they are regulated according to the intrinsic hazards they pose*' [34].

The REACH revision public consultation

In the public consultation on the REACH revision, industry stakeholders constituted 62% of the responses (479 out of 771), other/EU citizens 13% (104 out of 771), NGOs 8% (60 out of 771), and public authorities/research institutions 9% (67 out of 771).

Information requirements

In response to the question '*Should registrants provide more information on critical hazard properties of substances than currently required under REACH*?', 37% of respondents agreed or strongly agreed (102 and 161 out of 714), while 35% disagreed or strongly disagreed (160 and 92 out of 714) [6].

Stakeholder perspectives varied but converged on the need for greater transparency and precaution. Many industry representatives acknowledged the importance of ensuring safety but expressed concerns about the cost and feasibility of additional data requirements. They argued that existing mechanisms, like the use of read-across and predictive models, should be optimized instead of imposing blanket information obligations. Cefic stated that'*NAMs* [New Approach Methodologies] *can provide benefits for assessing more chemicals against critical hazards (in this case carcinogenicity), and circumvent the critical question of transferability of animal data to humans by replacing it with a more human-relevant approach*' [35].

Conversely, NGOs and research institutes advocated for more robust data requirements. They highlighted gaps in the current system where potentially hazardous properties, such as persistent, bioaccumulative, and toxic (PBT) characteristics, may go undetected. For example, the European Environmental Bureau stated that '*we support additional information requirements for critical hazard endpoints, use and exposure, the registration of polymers and of low tonnage chemicals*' [36].

Public authorities stressed that additional information on critical hazard properties can enhance the scientific basis for decision-making, particularly in identifying substances of very high concern (SVHCs). The Swedish Government stated that '*We strongly agree that registrants should provide more information on critical hazard properties of substances than is required today under the REACH Regulation, including more information on carcinogenicity for all substances registered under REACH.*' [37].

Regarding the potential introduction of additional information requirements for low-tonnage (1–10 tonnes) substances, 35% of respondents agreed or strongly agreed (130 and 121 out of 719), while 40% disagreed or strongly disagreed (167 and 123 out of 719). The remaining

respondents neither agreed nor disagreed, did not know, or had no opinion [6].

The issue of low-tonnage substances has received significantly different responses. Several stakeholders pointed to evidence suggesting that low-tonnage substances can pose significant risks, particularly due to their widespread use in consumer products. Industry representatives cautioned against sweeping reforms, arguing that most low-tonnage substances are used in niche applications with limited exposure. They propose a tiered approach to information requirements based on risk potential rather than tonnage alone. The AeroSpace and Defence Industries Association of Europe stated that '*We strongly disagree that increasing the information requirements for low tonnage substances (1–10 tonnes) under REACH would lead to socio-economic benefits or economic benefits for industry*' [38].

Public authorities appeared divided, some advocating for a precautionary expansion of data requirements and others favouring targeted measures informed by risk assessment tools. However, the Ministry of Environment of Denmark stated that '*Chemical safety assessment (CSA) should be extended to all registered substances, including substances in the 1–10 tonnage/year range*' [39].

Specific chemical concerns

Regarding the registration of certain polymers in REACH, 48% of respondents agreed or strongly agreed (170 and 174 out of 711), and 21% disagreed or strongly disagreed (115 and 36 out of 711). The remaining respondents neither agreed nor disagreed, did not know, or had no opinion [6].

ExxonMobil stated that '*It is essential that a distinction be made between polymers of low concern (PLCs) and PRRs* [polymers requiring registration] via *appropriate and adapted criteria. Once the PRRs are identified, proportionate and relevant data requirements should be defined in relation to the polymers' identified risk*' [40]. PlasticsEurope acknowledged the environmental concerns and '*agrees with the proposal for a practical, proportionate, and cost-efficient way of selecting polymers for registration… We believe that it is crucial that balance is struck between administrative burden and scientific rigor in all regulatory processes leading up to registration*' [41].

NGOs such as the European Environmental Bureau and academic institutions strongly supported the registration of polymers, arguing that polymers can exhibit hazardous properties comparable to other chemicals. They cite examples of microplastics and polymer additives that persist in the environment and accumulate in organisms. Chemsec stated that '*The manufacture, import and use of polymers should follow the same principles as other chemicals. Without registration, it is impossible to ensure safe management of polymers*' [42]. Authorities are inclined to agree with the need for selective registration but highlight the importance of clear criteria to avoid regulatory uncertainty.

Regarding the requirement to facilitate the identification of endocrine disruptors, 29% of respondents strongly agreed (208 out of 719), and 25% agreed (180 out of 719). In contrast, 22% disagreed (160 out of 719), and 6% strongly disagreed (46 out of 719). The remaining respondents neither agreed nor disagreed, did not know, or had no opinion [6].

The need for sufficient information to identify endocrine disruptors was widely acknowledged across stakeholder groups, albeit with differing views on its implementation. ChemSec stated that '*The issue of Endocrine Disrupting Chemicals* [EDC] *has been lagging behind in regulation for much too long time. While since 2012 some EDCs have been identified under SVHC criteria, the slow regulation still causes irreversible damage to people and wildlife as these chemicals are still widespread in consumer products*' [42].

Industry representatives, while supportive of identifying endocrine disruptors, expressed concerns about the cost and complexity of additional testing. They suggested leveraging existing data and international collaboration to develop harmonised testing approaches. Japanese 4EE industrial association [43] stated that '*In the first place, whether endocrine disruptors itself is independent hazard or not has not been concluded and index to categorize the hazard level has not been established*' [44].

Authorities stressed the urgency of addressing this gap, with the German Environment Agency stating that '*even transient exposure to endocrine disruptors during sensitive life stages can have severe consequences in later life stages or even in later generations*' [45].

Risk assessment approaches

On the question of whether a MAF is the most suitable approach to reduce risks from unintentional exposure to chemical mixtures, 27% strongly disagreed (198 out of 726) and 21% disagreed (152 out of 726). In contrast, 13% strongly agreed (91 out of 719 respondents) and 15% agreed (112 out of 719) [6].

The adoption of MAF in REACH garnered widespread support among NGOs and research institutes/public authorities, who argue that the MAF provides a pragmatic approach to addressing cumulative risks, especially in scenarios where individual substance-level assessments fall short. ChemSec stated that they '*see the introduction of a Mixture Assessment Factor as the most realistic and pragmatic approach to, at least to an extent, tackle the cocktail effect and all the unknowns contributing to it*' [42].

Industry stakeholders voiced reservations about the potential for overestimating risks and the lack of consensus on MAF values. They advocated for a phased implementation combined with further research to refine the approach. France Industrie acknowledged the current lack of robust scientific methods for assessing combined effects, stating that MAF should '*Apply only to a limited group of substances based on predefined criteria, differentiate between environmental and human health impacts, use a scientifically robust calculation method, such as the Maximum Cumulative Ratio (MCR)*' (translation by the authors) [46]. Deutsche Bauchemie stated that MAF '*should be limited and specified to relevant cases. … Because the likelihood of potential unintentional co-exposure to chemicals in the environment is greatest for substances that can bioaccumulate and for persistent substances, the focus of a potential MAF approach should be on bioaccumulative and persistent substances that are used in large quantities and in widely dispersed applications*' [47].

The public authorities appeared generally supportive but stressed the need for robust guidance to ensure consistency in application across sectors. The Ministry of Environment of Denmark stated that '*A mixture assessment factor (MAF) addressing co-exposure from unknown unintentional mixtures should be introduced as soon as possible*' [39]. The Government of Sweden shared Denmark's view [37].

The evaluation process

Respondents were asked to assess several options for improving the effectiveness of the evaluation process. The option deemed most effective was to clarify the requirements for registrants if manufacturing ceases or the registered volume changes during the evaluation procedure or any subsequent registration [6].

Stakeholders broadly agree on the need to improve the evaluation process under REACH. NGOs highlighted issues such as delayed evaluations and inconsistent follow-ups as barriers to effective risk management. ClientEarth stated that '*Requiring an annual update of volumes and setting specific triggers for all updates, including an obligation to withdraw registrations when the manufacture/import stops*'. But also that there is need for '*Creating a formal and efficient mechanism for third parties to feed ECHA the studies that have not been taken into account in the evaluation process or which are missing from registration dossiers*' [48]. The European Environmental Bureau stated that it is possible to speed up and simplify the evaluation process by '*Allow ECHA to perform compliance check and substance evaluation in one go, rather than having two parallel processes at the same time. Introduce a legal frame that allows evaluation and testing strategies based on group considerations to maximise the effectiveness of the evaluation procedure while reducing vertebrate testing. Introduce a maximum deadline of 4 years by which dossiers need to be compliant from the start of the compliance check. Revoke registration number if deadlines are not met*' [36]. This is echoed by the Ministry of Environment of Denmark, which stated that'*The REACH legal text should allow ECHA to revoke incompliant and unused registration numbers, and thereby removing the access to the EU market*' [39].

Industry stakeholders advocated for greater clarity in evaluation criteria and the importance of dialogue between registrants and authorities to resolve issues efficiently. Regulators acknowledged these concerns and suggested that digital tools and enhanced guidance could improve the process's efficiency and transparency. The Swedish Forest Industries Federation (*SFIF)* stated that they '*agrees that a dossier should be as complete as possible before submission. However, due to the complexity and how the REACH requirements can be interpreted, there is a need of guiding and feedback even after the submission, where the aim is to reach a fully compliant dossier. Therefore, SFIF emphasizes that there should rather be a gradually step of measures before a dossier is rejected, and where the absolute last resort is the action to prohibit manufacturing and placing the substances on the market*' [49].

The authorization and restriction processes

Concerning the reform of the authorisation and restriction processes in REACH, respondents were asked to assess several options for improving the effectiveness of the evaluation process. Retaining the authorisation process with clarifications and simplifications was the preferred option. It was particularly noted for its potential to enhance legal certainty for companies, improve the allocation of resources for public authorities across the EU, and strengthen protections for the environment, human health, and research and innovation. The option of removing the authorisation from REACH was the least positively rated option [6].

There was an agreement among stakeholders that the current authorization and restriction regime is not working optimally. The Alliance for Sustainable Management of Chemical Risk stated that they '*supports the idea that, if today's Authorisation regime is meant to continue playing a role, it would need to become simpler and more streamlined*' [50]. The European Environmental Bureau suggested that '*to be effective, the revision must speed up the regulation of hazardous chemicals by: Extending the fast-track restriction route (Art 68.2) to additional hazard categories and professional uses as well as clarifying and strengthening the procedure*' [36].

Cefic stated that the proposals to reform REACH authorisation and restriction risk shifting, rather than reducing, the regulatory burden, particularly by transferring administrative workload from authorisation to restriction without resolving underlying inefficiencies [35].

Enforcement of REACH

A total of 36% of the respondents (202 out of 553) stated that creating a new European Audit Capacity would greatly assist Member States to enforce regulations more effectively. Meanwhile, 28% of the respondents (157 out of 553) viewed it as providing a medium contribution, and 16% (86 out of 553) considered its contribution to be minimal [6].

NGOs and some public authorities supported the idea, arguing that it could enhance consistency and effectiveness across Member States. These authorities also stressed the importance of clear mandates and emphasised that cooperation between the European Commission and national authorities is essential to ensure the success of the initiative. The Government Offices of Sweden stated that '*Sweden agrees with the conclusions of the CSS that stepping up implementation and enforcement is necessary in light of current level of compliance, specifically as regards imported articles and online sales. Enforceability is critical to implement a regulatory measure and ensure it delivers on its objectives. We support the establishment of a European Audit Capacity and welcome the idea of increasing the collaboration with customs*' [37].

Industry representatives were more cautious, expressing concerns about potential overlaps with existing national enforcement bodies. However, the AeroSpace and Defence Industries Association of Europe (ASD) stated that '*One challenge for industry is the experienced differences in enforcement and control of REACH provisions between EU Member States. ASD believes that inconsistent policies in controlling REACH provisions could be reduced by a European Audit Capacity that applies common, harmonized EU standards for REACH enforcement*' [51].

Discussion

As this analysis shows, stakeholder consultations are not only administrative procedures but also arenas where the ideas, values, and assumptions underpinning EU regulation are debated and reshaped. The contrasting uses of the precautionary principle across stakeholder groups illuminate the shifting balance between scientific authority, legal accountability, and political legitimacy in the governance of chemical risks. The findings demonstrate that while NGOs and public authorities invoke precaution to advocate for broader regulatory scope and earlier intervention, industry actors deploy scientific rigour and innovation discourses to contest such moves, thereby reframing precaution as excessive caution. This finding deepens existing research on REACH by illustrating how stakeholder debates shape both the meaning of uncertainty and the kinds of regulatory action that are seen as legitimate within the EU system.

These broader dynamics are also reflected in the institutional controversies surrounding the REACH revision itself. The European Ombudsman's finding of maladministration, arising from the Commission's refusal to disclose legislative documents on the grounds of avoiding external pressure, illustrates how struggles over transparency and evidence are intertwined with competing visions of regulatory legitimacy [13]. In this sense, both the stakeholder consultations and the Commission's internal handling of the revision reveal the same underlying contestation: whether REACH should primarily serve as an instrument of precautionary protection or as a framework for predictable, innovation-friendly governance. Viewed together, these processes highlight how the revision of REACH has become a focal point for negotiating not only chemical policy but the very principles that define EU regulatory authority.

Based on the material provided by the Commission for the REACH review, as well as stakeholder responses, many of the problems associated with the regulations that predated REACH are still being discussed today. For example, there is a lack of effectiveness in addressing chemical risks and stimulating innovation. Although the guiding principle of REACH is 'no data, no market,' and the burden of proof has formally shifted away from EU institutions, persistent issues—including inadequate data submission, a regulatory focus on individual substances, and the continued introduction of new chemicals—suggest that structural shortcomings characteristic of pre-REACH legislation remain embedded in the current regulatory framework [52, 53]. At the centre is what to do when there is uncertainty regarding the hazards of a substance. Fleurke and Somsen refer to this as a state of scientific uncertainty in which possible outcomes are clear (such as specific degrees of harm or benefit) but in which it is impossible to quantify the probability of such outcomes materializing [53]. Other literature identifies that the issue often lies in whether it is possible to reach agreement on a substance's hazardousness, and on the type and amount of evidence required before a decision can be made. Thus, uncertainty often arises not only from inherent variability but also from whether there is sufficient and agreed-upon evidence to support a decision. For instance, it is important to explicitly identify and quantify as many sources of uncertainty as scientifically achievable to guide decision-making [54].

Even if stakeholders generally agree that regulatory responses are necessary when there is scientific evidence of risks to human health and the environment, industry stakeholders caution against overburdening industries and authorities with obligations that could hinder innovation, especially when the risk assessment is perceived as containing uncertainties. While some of these knowledge deficits could be addressed through complete dossiers, incomplete dossiers are, according to industry representatives, not necessarily the result of withheld information but may also stem from the complexity of REACH requirements. Simplifying the dossier system and allowing the rejection of dossiers are also seen as necessary by industry stakeholders, although the prohibition of manufacturing and market placement is viewed as a last resort.

Altogether, we have identified three central themes in the stakeholder responses to the REACH review.

Knowledge and precaution

As a general principle of EU law, codified in Article 191(2) TFEU and operationalised in REACH, the precautionary principle serves as a foundational norm guiding action under conditions of scientific uncertainty. The principle prescribes taking protective measures even when all knowledge is not available, but there is reason to believe that damage may occur [55, 56]. There are, however, conflicting perspectives regarding how far the precautionary principle should guide regulatory decisions in chemical governance, which is reflected in the stakeholders' answers. The diverging views between, for example, industry and NGOs reflect broader legal and philosophical questions about what constitutes sufficient knowledge for regulatory intervention. As Fleurke and Somsen note, "toxic uncertainty" characterises situations where potential outcomes are known but their probabilities remain unquantifiable—precisely the kind of situation where precaution becomes a central legal instrument [53].

How regulatory decisions should be made under scientific uncertainty is a central tension in the REACH revision process. Most of the stakeholders share, to a varying degree, the Commission's analysis that the current regulatory approach in REACH is not successful in achieving its objectives. Nevertheless, the industry group places greater demands on scientific evidence before introducing restrictions, while other groups express a greater openness to precaution. NGOs argue that current implementation of REACH fails to capture risks from low-tonnage substances, polymers, and endocrine disruptors, and thus call for a stronger application of the 'no data, no market' principle, especially in light of past regulatory failures concerning PFAS, phthalates, and bisphenols [57]. Incomplete dossiers show persistent data gaps remain inadequately addressed under the current regulatory setting, undermining effective risk management. Industry responses, on the other hand, underscore the importance of scientific rigour and predictability, asserting that new restrictions should only be adopted where quantified data on both hazard and exposure are available [58]. This reflects concerns about overregulation stifling innovation. The industry's position aligns more closely with a risk-based approach, arguing that such regulatory actions are contingent upon robust scientific evidence rather than precautionary assumptions. This sector consistently advocates for a high threshold of scientific evidence prior to the imposition of regulatory restrictions, moving away from precaution. While other stakeholder groups may partly share this position, they tend to show greater receptiveness to precautionary measures in the face of scientific uncertainty. These differences reflect underlying divergences in the preferred standards of proof when deciding whether to prohibit the use of chemical substances, and in the extent to which the precautionary principle should influence such decisions.

Undermining the importance of the precautionary principle within the REACH framework appears problematic given that EU law not only permits, but in some instances mandates, reliance on precaution where potential harm to human health or the environment cannot be conclusively ruled out. Moreover, related principles—such as the polluter pays principle and the principle of preventive action—help strengthen a normative framework that prioritises early regulatory action in response to toxicological risks [56]. A comparison can also be made with waste law, where the EU Court of Justice has clarified how to interpret the classification of waste under mirror codes, where one code may designate the waste as hazardous. If the composition of the waste is not immediately known, it must be assessed, and the presence of hazardous substances reasonably expected in the waste must be identified to determine whether it has hazardous properties [59]. The Court held that where a holder of waste cannot determine, even after carrying out a complete risk assessment, whether the waste contains hazardous substances or has hazardous properties, precautionary principle requires that the waste be classified as hazardous [59]. The Court's reasoning signals an openness to generic assessments based on structural or compositional similarity to known hazardous substances. It affirms the appropriateness of precaution-based, broad-scope assessments in situations of scientific uncertainty. If REACH is to be revised, it would be logical to consider the Court of Justice's case law on the precautionary principle, to ensure that decisions under REACH reflect a coherent and integrated understanding of the principle across related areas of EU law.

Should the REACH revision adopt stricter precautionary measures, industry actors are likely to face higher compliance costs and potential constraints on chemical innovation. However, as has been consistently demonstrated in regulatory theory and practice, the success of co-regulatory approaches is contingent upon numerous factors, not least the presence of mechanisms that incentivise industry to meet, or preferably exceed, regulatory requirements [53]. Conversely, if data requirements remain low, NGOs contend that public health and environmental protection may be compromised due to inadequate risk assessment data. It should also be noted that the industry's insistence on robust scientific justification prior to market removal contrasts with the historical record of delayed regulatory action in cases where chemicals were subsequently found to pose significant risks. This emphasises the importance of adopting a more precautionary regulatory approach, including the use of more generic assessments based on structural similarity to known hazardous substances. While the legal framing of REACH supports the precautionary principle, its practical implementation reveals a shift toward science-led regulatory inertia [60]. In this context, the absence of full scientific certainty increasingly serves to delay regulatory action, even in situations where environmental or health risks are plausibly anticipated. The stronger emphasis among industry stakeholders on grounding regulatory changes in natural scientific knowledge, rather than on ensuring the effective achievement of the broader objectives of REACH, may risk contributing to the under-regulation of hazardous chemicals. Furthermore, it may be questioned whether risk-based approaches always constitute a more rigorous scientific method. Given the many uncertainties inherent in exposure assessment—such as variability in data quality, modelling assumptions, and incomplete information about real-world conditions—it is debatable whether such methods offer such a robust foundation for regulatory decision-making as industry stakeholders presume.

Risk versus hazard

Another core line of conflict in the stakeholder responses is the shift towards a more hazard-based assessment through proposals such as MAF, grouping and the generic approach to risk management. This transition reduces the role of traditional risk assessment procedures favoured by some stakeholder groups and places greater emphasis on intrinsic hazard. This transition means less room for the risk assessment procedures advocated for by several stakeholders in different groups, and instead, gives the question of whether a substance is hazardous greater weight. This is, in some ways, a move towards more precautionary regulatory actions.

In the literature, some argue that assessments without in-depth analysis of exposure would allow for hazard-triggered anxiety to drive regulative actions, which would be unscientific [61]. Similarly, it is argued that hazard assessment alone is inadequate, as it is necessary to assess the probability of adverse effects before management decisions can take place [62], and that risk can only be quantified and managed when both data on effects and exposure are available [63]. However, it has been questioned whether such high demand on standards of proof in risk assessment ensures that no adverse effects on humans and the environment occur over space and time [64]. In addition, it has been argued that the precautionary principle is the major rationale on which regulatory decisions should be based if long-term effects cannot be predicted in the risk assessment [65].

From the stakeholders' responses, it is apparent that NGOs and some public authorities support a shift as a means to accelerate action and reduce cumulative harm [66]. They argue that hazard-based classification offers greater clarity and enforceability, especially in the case of substances with known intrinsic hazards like carcinogens or endocrine disruptors [67]. Industry, however, counters that risk-based assessments are necessary to balance protection with proportionality, as they allow for context-sensitive evaluations based on actual exposure. A major concern among industry representatives is that grouping substances by structural similarity, without adequate exposure data, may lead to overregulation, legal uncertainty and innovation stagnation [68].

The proposed introduction of a MAF highlights these tensions. While NGOs see it as a necessary response to cumulative exposures, industry warns that its scientific basis is underdeveloped [69]. The literature notes that while hazard identification is foundational, regulatory effectiveness also depends on modelling real-world exposure pathways, which may not be feasible under a purely hazard-based model [70]. Although such a shift may entail significant consequences for some stakeholders, it aligns closely with the precautionary principle's function in regulatory decision-making in other areas of EU law, as a necessary tool for addressing cumulative risks.

Historically, there have been several examples of incorrect risk assessments concerning chemicals that were allowed on the market despite existing chemical legislation. PFAS is an example of regulatory failure, where reliance on monitoring data delayed both precautionary and preventive measures despite growing evidence of risk. In 2023, the Swedish Supreme Court (Case T 486-23) acknowledged that elevated PFAS levels in drinking water can cause personal injury, highlighting how legal consequences only followed after serious harm to human health had already occurred [71]. Similar concerns apply

to other substances, such as brominated flame retardants, which are added to some consumer products to protect against rapid fire progression but can be hazardous to health and the environment [72]. Phthalates, used as plasticizers in plastics, are known to have harmful effects on both humans and animals [73]. Bisphenols, including BPA, are used in protective coatings on the inside of food packaging and have been shown to be reprotoxic and endocrine-disrupting [74]. The Commission have also shown incorrect judgement when permitting certain chemicals [75].

The shift within REACH toward greater reliance on hazard-based assessment illustrates the broader regulatory challenge of balancing precaution with the need for regulatory predictability, legal certainty, and continued industrial competitiveness. The disagreement between stakeholders raises fundamental questions about how regulatory bodies should weigh scientific uncertainty against the potential risks of exposure. At the same time, research points out that chemical regulation is less costly than industry representatives assume, and can have positive effects by enhancing the industry's risk management and their reputation as 'green' [76].

To sum up, this brings up a vital issue: does the shift toward hazard-based assessment primarily aim to accelerate precautionary action, or does it also reshape the balance between regulatory stringency and proportionality? Stakeholder responses suggest that the emphasis on hazard can serve different purposes depending on perspective: NGOs view it as a tool for faster, more protective interventions, while industry frames it as a potential source of overregulation and uncertainty. Importantly, prioritising intrinsic hazard does not inherently preclude context-sensitive risk management. When carefully applied, hazard-based approaches, such as grouping chemicals or adopting generic risk management measures, can both streamline decision-making and prevent regrettable substitution, ensuring that regulatory outcomes remain protective, coherent, and timely. The challenge lies in designing these approaches so that precaution, scientific robustness, and regulatory efficiency reinforce rather than undermine each other.

Simplication versus improved protection

A recurring theme in debates surrounding REACH is the apparent tension between simplifying regulatory procedures and strengthening the protection of human health and the environment. Industry stakeholders often emphasize the need for simplification, citing administrative burden, compliance costs, and regulatory uncertainty as barriers to innovation and competitiveness. At face value, such calls appear reasonable: streamlined procedures and clearer rules could, in principle, benefit all actors by improving predictability and efficiency.

However, a closer look reveals a more complex dynamic. Several recent regulatory proposals, such as the introduction of a Mixture Assessment Factor (MAF), the grouping of structurally similar chemicals, and the Generic Approach to Risk Management (GRA), arguably represent forms of simplification. These measures aim to make chemical regulation more efficient, proactive, and protective by addressing systemic issues such as mixture effects, regulatory delays, and chemical-by-chemical decision-making. Yet, these same measures have been met with strong opposition from industry actors, who argue that they oversimplify hazard and risk assessments and threaten to undermine scientific rigor. Instead, industry proposals often advocate for more specific, case-by-case evidence to justify regulatory action, an approach that risks slowing down restrictions and undermining the precautionary intent of REACH [77–79].

This raises an important question: is the call for simplification primarily directed at improving regulatory efficiency, or can it also influence the stringency and timing of regulatory outcomes? The varying responses to simplification initiatives indicate that the term may at times be used flexibly, serving different purposes depending on context. It is also worth noting that simplification and stronger protection are not necessarily mutually exclusive. Carefully designed simplification can contribute to more coherent and timely regulatory action while maintaining high levels of protection for human health and the environment. For example, grouping chemicals can help prevent regrettable substitution, where restricted substances are replaced by structurally similar analogues, and the GRA can facilitate the management of known high-concern chemicals in a more streamlined manner. The challenge, therefore, lies in ensuring that simplification measures are implemented in ways that support both regulatory efficiency and protective outcomes.

Representation of stakeholders

Consistent with previous empirical evidence, we find that industry actors dominate the public consultation responses, while NGOs form the main counter-vailing group [80]. Academia and public authorities are more absent, a pattern observed in past regulatory reviews [81].

This pattern is consistent with the strategic motivations of these groups. For industry stakeholders, regulatory decisions often carry direct economic consequences, creating a strong incentive to influence policy outcomes in ways that protect or promote their commercial interests. NGOs, on the other hand, frequently participate to advance specific social or environmental goals,

leveraging consultations as an opportunity to advocate for public interest concerns and to hold regulatory bodies accountable. In contrast, academic institutions are notably underrepresented. This may be attributed to the limited institutional incentives for academics to engage in time-consuming policy processes that are not typically recognized or rewarded in academic career advancement. Public authorities, while they might have a vested interest in the outcomes of such consultations, often have alternative, more formalized channels through which to exert influence—such as intergovernmental negotiations or advisory roles. Additionally, some public bodies may lack the necessary resources or internal capacity to submit detailed consultation responses. These disparities in participation raise important questions about the representativeness and inclusiveness of consultation processes, and highlight the need for mechanisms that encourage broader stakeholder engagement.

Limitations

While the analysis provides systematic insight into stakeholder reasoning, it is limited by its reliance on publicly available consultation documents, which may not fully capture the dynamics of informal lobbying or interinstitutional negotiation. Moreover, because the analysis precedes the Commission's legislative proposal, subsequent developments may reshape stakeholder alignments. Finally, as with all qualitative interpretive analyses, findings should be viewed as indicative of argumentative trends rather than statistically representative outcomes.

Conclusion

The REACH revision debate reveals how the precautionary principle functions not only as a legal norm but also as a contested political symbol within EU environmental governance. By analysing stakeholder discourse, this study has shown how competing appeals to science, innovation, and precaution structure the negotiation of regulatory reform. These rhetorical patterns expose deeper tensions in EU risk governance—between harmonisation and flexibility, evidence and precaution, and protection and competitiveness—that continue to shape the meaning and practical implementation of precaution in the EU context.

The ongoing REACH revision process brings these tensions into sharp relief. Stakeholders remain divided over core regulatory principles, particularly regarding data requirements, precautionary measures, and the balance between risk- and hazard-based approaches. While there is broad agreement on the need to strengthen health and environmental protection, consensus on specific measures remains elusive. NGOs call for harmonised, transparent, and enforceable rules, whereas industry seeks flexibility, regulatory certainty, and safeguards for innovation. Without reconciliation, the revision risks perpetuating fragmented interpretations and undermining key principles such as "no data, no market," with potential consequences for both environmental protection and the pursuit of a non-toxic circular economy.

At stake in this process is the broader legitimacy of EU chemicals policy. The European Commission's refusal to publish the REACH revision proposal—criticised by the European Ombudsman as maladministration—highlights how transparency and accountability are themselves contested within EU regulatory governance. Such opacity threatens to erode public trust and weaken the democratic legitimacy of environmental policymaking.

Ultimately, the REACH revision illustrates the persistent dilemma of how to legislate under conditions of uncertainty while maintaining both regulatory integrity and democratic legitimacy. The analysis suggests that future regulatory models could adopt more tiered or hybrid approaches, using hazard-based triggers for the most hazardous substances, to ensure that precaution and proportionality remain systematically embedded in EU decision-making. Maintaining this balance is essential not only for achieving the EU's ambition of a non-toxic environment but also for securing public confidence in the institutions that govern it.

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HJ wrote the main manuscript text. CG and MÅ revised it critically for important intellectual content and made substantial contributions to the analysis. All authors reviewed the manuscript.

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