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# Simplifying REACH:

# Recommendations to the European Commission

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# Executive summary

The European Commission is expected to deliver a Chemicals Industry Package proposal, which among other objectives, aims to simplify the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) in 2025. As a representative of the entire chemicals value chain from upstream manufacturers to downstream users, the American Chamber of Commerce to the European Union (AmCham EU) offers a unique perspective on EU chemicals legislation.

To be effective and reduce the regulatory burden on companies in an increasingly complex economic and geopolitical context, the Commission should simplify the REACH Regulation by:

- **Regulating based on science and risk assessment**. Policymakers should avoid excessively broad grouping of chemical substances without consideration for their actual properties. They should also review the risk management of substances of very high concern (SVHCs) to allow for a proportionate regulatory approach and ensure predictability across the value chain.
- **Increasing regulatory predictability**. To ensure regulatory stability and consistency, the Commission must strengthen mechanisms for selecting a specific risk management route. In addition, to increase certainty for investments, policymakers should commit to not deviating from this route unless significant new data emerges justifying additional measures.
- **Promoting regulatory coherence with other pieces of legislation.** REACH must remain the main legislative framework for regulating the health and environmental safety of chemicals in the EU. The Commission must enhance legal predictability by not introducing divergent requirements and definitions for chemicals in other pieces of legislation.
- **Strengthening enforcement** to ensure REACH's effective implementation and support competitiveness. Policymakers must elevate the Enforcement Forum to committee status and empower it to deliver opinions on new risk management proposals.
- **Simplifying data requirements** by improving the use and effectiveness of adaptations to the standard information requirements and allowing for more opportunities to use Annex XI adaptations.

# Introduction

President von der Leyen's Political Guidelines for the next European Commission commit to develop 'a new chemicals industry package' aimed at simplifying REACH and providing clarity on per- and polyfluoroalkyl substances (PFAS). Executive Vice-President Stéphane Séjourné and Commissioner Jessika Roswall also committed to address these two topics during their hearings in the European Parliament.

It is critical to reduce unnecessary regulatory burdens and complexities in the current economic and geopolitical climate, as emphasised in the recent Draghi report on *The Future of European Competitiveness*. The report concludes that the chemical regulatory framework in the EU can create barriers and uncertainties for investments. In particular, the report states that 'risk assessment of EU regulation may not always be based on actual exposure, imposing additional constraints on products and processes'.

AmCham EU has a unique, holistic perspective on EU chemicals legislation as it represents the entire chemicals value chain, from upstream manufacturers to downstream users, as well as specialised

consultancies and law firms. With 96% of manufactured goods relying on chemicals,[1] Europe's chemicals industry is at the heart of almost all value chains and provides the key to solutions that will deliver the Green Deal. The industry also makes the economy more resilient and less dependent in areas including renewable energy, batteries, hydrogen, building insulation, pharmaceuticals and electronics.

In its 2018 review of REACH, the Commission concluded that overall, REACH is effective in addressing citizens' concerns about chemical safety. Again in 2020, the Commission rightly recognised that 'the EU already has one of the most comprehensive and protective regulatory frameworks for chemicals, supported by the most advanced knowledge base globally'. Building on this achievement, the Commission should pursue improvements that are targeted and incremental, aimed at truly simplifying REACH to enhance European competitiveness and avoid the regulatory unpredictability and investment uncertainty that would stem from an unjustified overhaul of EU chemicals legislation.

## Regulating based on science and risk assessment

To strengthen competitiveness and reduce regulatory burdens for industry, the EU must keep principles of risk assessment and science-based decision-making at the core of chemicals legislation. This is relevant across numerous areas in the current REACH framework, including grouping of chemical substances and the risk management of SVHCs.

**Rely on actual hazard and risk data and avoid unjustifiably broad grouping**

While grouping in chemicals management legislation can theoretically enhance regulatory efficiency and prevent regrettable substitution, it is crucial that such initiatives have a clear scope, based not just on chemical structure but also actual properties and scientific criteria, including confirmed hazard and risk data. Recent examples, such as the universal PFAS restriction proposal, highlight the difficulty in attempting to regulate overly broad groups of substances and applications without sufficient underlying data. The complexity of such large-scale restrictions can slow down the regulatory process and significantly undermine regulatory certainty and predictability. This lack of clarity on the eventual scope and potential derogations hampers competitiveness and the business case for investments in the European market.

Regulatory initiatives aimed at restricting the use of substances must be grounded in harmonised hazard classes under the Regulation on the classification, labelling and packaging of substances and mixtures (CLP Regulation), as well as adequate risk information. Unfortunately, measures under REACH are increasingly based on broad assumptions and generalisations. For example, the proposed PFAS restriction's inclusion of over 10,000 PFAS substances is based on persistence alone, without data indicating whether the vast majority of these substances meet criteria for relevant hazard classes under the CLP Regulation (eg persistence, bioaccumulation and toxic substances/very persistent and very bioaccumulative substances) or information indicating a major risk that must be addressed at the EU level.

Similarly broad assumptions have been made to support other recent REACH restrictions, such as that on intentionally added microplastics, as well as several recent European Chemicals Agency (ECHA) assessments on regulatory needs (ARNs). Although ARNs are not legally binding, they significantly impact the marketplace and generate regulatory uncertainty for large groups of substances.

[1] Cefic's position on chemicals strategy for sustainability.

**Recommendation:**

- Base grouping approaches under REACH on clearly identified substances where appropriate, including recognised substance identifiers. Authorities preparing new regulatory proposals based on grouping must use actual hazard and risk assessment information available for the substances covered that demonstrate the need for action at the EU level. Existing guidance on grouping and read-across should apply to regulatory proposals as much as they apply to industry registrations.

**Allow a more proportionate regulatory approach for the risk management of SVHCs**

One of REACH's key mechanisms is the identification and regulation of SVHCs. Under REACH, when a substance is identified as an SVHC based on hazard and included on the Candidate List, ECHA eventually prioritises it for inclusion on the Authorisation List (Annex XIV). However, case history under REACH has shown that not all SVHCs warrant automatic prioritisation for eventual inclusion in the Authorisation List.

SVHCs are wide ranging and have varying properties and uses. Given this diversity, a one-size-fits-all approach to authorisation is impractical and may not effectively address the specific risks associated with individual SVHCs. Automatically subjecting all SVHCs to authorisation could impose significant economic burdens on industry. For substances placed in Annex XIV, applications for authorisation for uses where no alternatives exist is resource intensive, requiring extensive data collection, risk assessments and the development of substitution plans. For many small and medium-sized enterprises, these requirements can be prohibitively expensive and time consuming. This leads to reduced competitiveness within the EU market.

The principle of proportionality is fundamental to effective regulation. Not all SVHCs pose the same level of risk, and their uses vary widely in terms of exposure and potential harm. For example, an SVHC used primarily in industrial processes with minimal exposure to workers and the environment does not warrant the same level of regulatory scrutiny as one used primarily in consumer products. A flexible approach that considers the specific context and use of each SVHC would allow for more proportionate and effective risk management. By selectively applying authorisation to the most critical cases, regulators can strike a balance between promoting safety and fostering competitiveness.

The authorisation process is equally highly resource intensive for regulatory bodies. It requires significant time and effort to evaluate each application, conduct thorough risk assessments and review substitution plans. A large number of SVHCs could overwhelm regulatory bodies, leading to delays and potential backlogs, which in turn would cause significant, lasting uncertainty for industry and disrupt business. Also, when resources are spread thin across many substances, regulators may not be able to focus adequately on the highest-risk substances and uses. This could result in less effective risk management and potentially allow more harmful substances to remain in use longer than necessary.

While authorisation may still have a role to play in a simplified REACH, a more targeted approach would allow regulators to allocate their resources more effectively, ensuring better protection for human health and the environment. Regulators should use a more open assessment of the most appropriate risk management route for a given SVHC or group of SVHCs. Formalising the use of Regulatory Management Options Analysis (RMOAs) as a mandatory step for each new SVHC, for example, could lead to more informed and transparent decision-making processes. By systematically evaluating different risk management options, regulators and stakeholders can better assess the

potential impacts and benefits of various regulatory options, leading to more effective and balanced regulatory decisions. A more structured RMOA process would also facilitate greater stakeholder engagement by providing a clear framework for input and feedback. By documenting the rationale behind regulatory decisions, stakeholders can better understand the basis for actions taken and the expected outcomes.

**Recommendations:**

- Remove the Candidate List from the Authorisation Title in REACH. Identification as SVHCs should not put substances on an automatic path to prioritisation for inclusion in Annex XIV.
- Create a requirement to conduct formal RMOAs for newly listed SVHCs to help identify the most suitable risk management route based on clear criteria and with input from stakeholders, enhancing proportionality and predictability of regulatory decisions.

## Increasing predictability by avoiding inconsistent and overlapping regulations

A major focus of simplifying REACH should be avoiding inconsistent and overlapping regulatory measures. Once the relevant authority (European Commission, ECHA or Member State) identifies a risk management route as the most suitable one to address a given substance or group of substances, it must adhere to it unless significant new data emerges indicating additional concerns that are unaddressed under the selected route. This would ensure regulatory stability and predictability, which are critical for both industry and regulatory authorities. Recent examples where multiple, inconsistent regulatory initiatives have been proposed in a short period of time include siloxanes, ethanol and PFAS.

Under current REACH rules, industry often faces multiple, overlapping regulatory proposals for the same substances. These include several sequential restrictions, prioritisation for authorisation in addition to comprehensive REACH restrictions and assessments of regulatory needs, among others. Overlapping regulations can lead to confusion and inefficiencies, as companies need to comply with redundant or contradictory requirements.

When regulatory approaches are consistent, industries can better plan and allocate resources to comply with regulations and invest in products and technologies. This predictability reduces the administrative burden and costs associated with constantly adapting to new and potentially conflicting regulatory requirements. Maintaining a clear and consistent regulatory path – whether a REACH restriction, authorisation or measures outside of REACH such as the Occupational Safety and Health framework – would streamline compliance and reduce unnecessary complexity. It would also enhance regulatory credibility, helping to foster trust with stakeholders. Industry is more likely to invest in compliance and innovation when it has confidence that the regulatory environment is stable and predictable.

Efficient and effective chemicals risk management relies on selecting the most relevant and optimal risk management option. These decisions are influenced by specific uses and potential exposure points, such as in the workplace, article releases or the environment. A thorough assessment helps identify which uses may be exempt from additional risk management due to their significant societal value (eg supporting vaccination strategies or advancing the green and digital transitions) and avoids implementing ineffective management measures or substitutions that fail to control risks adequately.

This underscores the essential role of a well-executed RMOA before initiating regulatory action. RMOAs, if properly implemented, have proven to be efficient, cost effective and time saving, especially when compared to the repercussions of selecting inadequate or conflicting risk management measures.

Implementing the Green Deal requires balancing crucial factors, such as climate impact and circularity, while ensuring the safe use of chemicals throughout manufacturing, imports and applications. Holistically integrating these considerations is essential for defining the optimal risk management strategy.

**Recommendations:**

- Include a more formalised, transparent and mandatory RMOA step following identification of SVHCs to help relevant authorities select the most appropriate risk management route.
- Include in RMOA conclusions a commitment not to deviate from the selected risk management route unless significant new data emerges justifying the need for additional measures.
- Include in the RMOA a mapping of the uses within the relevant industrial ecosystems and critical value chains, as well as initial socio-economic data, including climate and circularity considerations, based on stakeholder consultation.

## Promoting regulatory coherence with other legislation

In recent years, policymakers have included references to new substance categories in new pieces of legislation, contributing to regulatory complexity and uncertainty. For example, a broad reference and dynamic definition of 'substance of concern' has been introduced under the Ecodesign for Sustainable Products Regulation (ESPR). The legal text states that 'the setting of performance requirements shall also, where appropriate, reduce significant risks to human health or the environment.' Concerningly, this suggests that ESPR may start regulating substances for chemical safety outside of REACH.

The same term has also appeared in other existing and emerging EU laws and policy initiatives, namely those under the European Green Deal, where it already triggers reporting actions for certain large companies (corporate sustainability reporting) and the European Commission (for batteries), while other regulations still to be adopted (packaging and packaging waste and vehicles) also make use of it.

**Recommendations:**

- Ensure that the REACH regulation remains the main legislative framework to regulate chemicals in the EU and the main reference for substance categories and definitions.
- Avoid the introduction of further requirements and definitions for chemicals that relate to chemical safety under other legislation.

## Strengthening enforcement

To effectively implement REACH, policymakers must strengthen enforcement mechanisms. The European Commission already identified enhancing enforcement as a key area for action in its 2018

REACH review. Lagging enforcement, particularly for imported articles, contributes to an uneven playing field for businesses operating in the EU, undermining competitiveness.

The European Commission could address this issue by elevating the ECHA Enforcement Forum to the status of a true committee in risk management processes (eg for REACH restrictions or in the authorisation process), on the same level as the Risk Assessment Committee (RAC) and the Socio-Economic Analysis Committee (SEAC). Formalising the Forum's Committee status would enhance its credibility and authority. It would gain greater recognition and influence within the regulatory framework and facilitate better resource allocation by ECHA. It would also promote greater transparency and accountability, as the Forum would be required to operate with the same level of transparency as RAC and SEAC, providing opportunities for stakeholder engagement through consultations on draft opinions and participation in deliberations on specific substances.

Most importantly, elevating the Enforcement Forum to committee status would align enforcement efforts with risk assessment and socio-economic analysis. By integrating enforcement more closely with the work of RAC and SEAC, the regulatory framework would become more cohesive and coordinated. This would ensure that consolidated ECHA opinions delivered to the Commission to inform regulatory decision-making formally include information on enforceability.

**Recommendations:**

- Amend REACH articles 76 and 77, as well as the relevant titles covering restriction and authorisation processes, to elevate the Enforcement Forum to full committee status, on par with RAC and SEAC.
- Empower the new Enforcement Committee to deliver opinions on new risk management proposals under REACH (eg restriction and authorisation decisions), following similar rules as RAC and SEAC.

## Simplifying data requirements and enhancing digital tools

**Improve the use and effectiveness of adaptations to the standard information requirements**

REACH data requirements should better account for exposure potential and consequently allow greater opportunities to adapt requirements on an exposure basis. To some degree, the data requirements currently factor in exposure. Each annex is linked to a volume band that is a proxy for exposure potential. This approach also gives some degree of regulatory certainty in what a registrant must provide to satisfy their registration requirements.

However, the current approach does not adequately address situations where a high-volume substance (>1000t) is used in a way where exposure potential may be low, for example as an intermediate or monomer in polymer production. In this case, unless it can be demonstrated that intermediate or monomer use is 'under strictly controlled conditions', the standard data requirements in Annexes IX and X apply.

In principle, the exposure-based adaptations provided in Annex XI should allow a registrant to waive higher tier (Annex IX and X) data requirements, but in practice, the requirements for this approach are unattainable in most cases. As a result, this adaptation is seldomly used successfully. For many substances, data is generated (using a substantial number of animals) that ultimately does not impact whether the substance can be used safely, even if it identifies potential hazards relevant for classification. Given the significant use of experimental animals to meet the information requirements

in Annexes IX and X, the current application of REACH's information requirements is inconsistent with the objective to use animal testing as a last resort and with the European Commission roadmap to phase out animal testing for chemical safety assessments.

To provide registrants with regulatory certainty, allow for more realistic use of exposure information to inform data requirements and reduce the need for animal studies to only the most impactful cases, the information requirements listed in Annexes IX and X should become 'triggered' versus mandatory, taking into account hazard potential, total volume on the market and exposure potential. Exposure potential should consider both end uses and bioavailability. Annexes VII and VIII should be combined and make use of all available new approach methodologies to address the information requirements.

**Efficiently communicate with digital tools**

The European Commission should optimise the use of digital tools to communicate hazard and safety information as well as use instructions to users. Communicating digitally allows companies to provide additional information, in multiple languages, in a more user-friendly format and for information to be updated more quickly than is currently the case. The simplification of supply chain communication and the improvement of extended safety data sheets (SDS), including in harmonised electronic formats like QR codes, would be positive.

**Recommendations:**

- Simplify REACH's information requirements by improving the use and effectiveness of adaptations to the standard information requirements. Column 2 of Annexes VII-X and Annex XI of the current legal text provide several potential adaptations to the standard information requirements listed in Annexes VII-X. However, in practice, many are impossible to use due to either unjustifiably high requirements (eg exposure-based adaptations) or overly complex requirements (weight of evidence/non-animal approaches). Consequently, industry must perform substantial testing (often using significant numbers of animals), which does not always have a meaningful impact on the substance's classification or risk assessment. This is particularly true for non-strictly controlled intermediates and monomers in imported polymers.
- Identify more opportunities to use the existing Annex XI adaptations by, for example, simplifying the requirements to justify the adaptation, providing greater allowances for using exposure-based adaptations and low toxicity adaptations, providing more suitable guidance on how to prepare adaptations and justify them, and increasing regulatory acceptance of exposure-based adaptations.
- Simplify and digitise supply chain communication tools to make information transmission more efficient and up to date.

# Conclusion

By simplifying REACH, the European Commission can increase consistency and predictability for the public and private sectors alike. These revisions would help the regulation strike the right balance between ensuring a high degree of safety and decreasing the regulatory burden on companies.