A 10-POINT ACTION PLAN TO SIMPLIFY REACH

The EU chemicals industry is at a critical juncture as it faces high energy costs, a slow economic recovery, and an increasingly complex regulatory landscape. As Professor Draghi highlighted, reducing regulatory burden is essential for Europe's resilience.

Among the many regulations affecting the sector, REACH remains a cornerstone framework. REACH is the most comprehensive and advanced piece of legislation governing chemicals. Despite gaps in its implementation and enforcement, it has proven to be fit for purpose, ensuring a high level of protection for people's health and the environment.

Any action on REACH must deliver real simplification without compromising the protection of human health and the environment.

Simplification means making regulations more effective: reducing unnecessary burdens while ensuring regulations achieve their intended goals. In line with the EU's commitment to restore competitiveness, the announced REACH simplification must build on a stress test of the EU acquis. It should cut complexity, improve implementation, reduce costs and uncertainty - particularly for SMEs - and strengthen Europe's industrial base and strategic resilience.

The result must be a clear, predictable and effective REACH that boosts competitiveness, avoids regulatory fragmentation across Member States, and aligns with a broader industrial strategy to secure investment in the EU and boost Europe's industrial resilience.

Outlined below are actions that can deliver this, several of which can be implemented immediately by improving the implementation and enforcement of the current framework.

Action 1: Ensure simplified rules that align with Europe's political guidelines and competitiveness objectives

The issue: A simplified REACH must serve a dual purpose: send clear signals to drive investments and innovation in Europe and improve the protection of human health and environment. This can only work if industry needs are mapped out, the initiatives actually bring simplification on the ground, and their impacts are measured against both objectives.

The solution:

- Engage in dialogue with industry to understand its needs.
- Update the previous impact assessment to integrate the changed economic circumstances and regulatory burdens.
- Assess what can be improved under the current system versus introducing new initiatives.
- Explore additional options for simplification within other EU legislations governing chemicals.

The result:

- A simplified regulatory framework that is aligned with the European Commission's political guidelines.
- Identification of quick wins that can be achieved under the current acquis.
- A regulatory system based on reality checks, trust and incentives rather than "detailed control".

Action 2: Increase predictability for regulatory risk management

The issue: The EU regulatory system includes 40+ regulations and directives governing chemicals. The result is a maze of overlapping rules. Once a chemical enters the system, it becomes unclear if, when, or how it will be regulated. This also includes redundant and overlapping rules, which can be a result of fragmentation across Member States. This lack of clarity creates inefficiencies and uncertainty, while also contradicting the objectives of the Single Market.

The solution:

An upfront analysis of available data on chemicals would help to identify priority substances and uses for which regulatory control is needed. The result would be a clear regulatory plan which enables authorities to align actions under REACH or other legal frameworks, maximises resources across the EU and Member States, and facilitates discussions on strategic applications of chemicals.

The result:

- Clear identification of "problematic uses of substances" and appropriate regulatory tools to control identified risks.
- Greater clarity for industry, enabling smarter investment and prioritisation of resources for substitution.
- Enable authorities to prioritise resources where it matters the most.
- Enhance the Single Market by predictable, harmonised and coordinated actions in line with the spirit of One Substance One Assessment (OSOA).

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Action 3: Improve the Authorisation and Restriction Processes

The issue: Since REACH was introduced, the regulatory risk management of chemicals has expanded significantly, covering more substances and uses than authorities can handle. Over the past few years, the restriction route has increasingly used broad scope bans combined with time-limited derogations. This has led to issues like "policy by derogation", enforcement gaps, and inefficiencies e.g. the ongoing PFAS and skin sensitisers restrictions, and the microplastics restriction. The current authorisation system cannot cope with the number of applications, causing a significant backlog of work for the authorities and uncertainty for industry.

The solution:

- Have a strategic discussion at EU level before restriction proposals are submitted to the system (see action 2).
- Limit the use of the authorisation scheme by adjusting the prioritisation criteria and creating more possibilities for granting exemptions when risks are adequately controlled.
- Clarify and tailor the required information submitted in the application for authorisation.
- Go back to the original intent of the restriction process i.e. take action when unacceptable risk is identified and restriction is the most suitable approach (see action 2).
- Exclude chemicals used in the manufacturing processes (intermediates) from the scope of restrictions that are seeking to phase out chemicals. The primary focus of restrictions should be consumer use, final goods and end uses.
- Implement more flexible derogations, with review periods to account for timing of alternative development.
- Have a robust and transparent framework for grouping chemicals that require regulatory action.

The result:

- Greater clarity, predictability and feasibility for restriction proposals.
- Keep critical value chains operating in Europe.
- Adopt a more agile system that accommodates company and sector specific needs.
- Limit excess workload for authorisations.

Action 4: Avoid Overly Simplistic Assessments - Use Targeted Restrictions instead

The issue: Simplified assessment does not always lead to faster decision-making. Overly simplified restrictions, based on generic risk considerations and hazard classifications, risk overregulating substances without adequately assessing exposure and alternatives. This can prolong discussions on derogations and cause disruptions and uncertainties over (un)availability of chemicals for the value chains. Already today, under the current rules, many existing products could be automatically and unnecessarily removed despite safe use, for instance, hand sanitisers, if ethanol were to be classified as “Reprotox 1B”.

The solution:

Do not add more semi-automatic links between hazard classification and regulatory measures. Regular restrictions, including full-fledged risk and socio-economic assessments, ensure a balanced as well as evidence and science-based approach to regulate the most severe hazards (SVHCs). This would provide a more targeted response, while also addressing the regulatory and societal needs without overregulating.

The result:

- Avoid retroactively fixing issues caused by an overly simplified approach.
- A balanced, evidence and science-based framework for managing harmful substances.
- Improved regulatory coherence and credibility through targeted, well-designed restrictions.
- Prevent banning of critical applications through the hazard classification route.

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Action 5: Avoid Additional Requirements for Polymers - Develop a Holistic Strategy First

The issue: Polymers are different from traditional substances because of their unique properties. Estimates count between 200,000–400,000 on the EU market. The current REACH system indirectly addresses polymers by managing their monomers (the smaller building blocks) used in their production and additives used in their application. While the existing registration system under REACH is tailored for individual substances, it does not work for polymers. Introducing new notifications and/or registration requirements for polymers under REACH would create unnecessary complexity, redundancy and inefficiencies in the chemicals management. It would require significant additional resources both for the industry and the European Chemicals Agency (ECHA). The industries' administrative workload would increase, particularly putting SMEs under pressure. ECHA would need to add new expertise and resources to process the vast amount of notifications and registrations. Current fragmented attempts to address polymers across multiple frameworks risk creating redundancies and inefficiencies, i.e. Packaging and Packaging Waste Regulation (PPWR), End-of-Life Vehicles Regulation (ELVR) and product regulations.

The solution:
Before taking any action on polymers, a clear problem definition for polymers resulting in a coherent, holistic strategy is needed to streamline the regulatory approach for polymers, ensuring alignment with simplification and burden-reduction goals, while also tackling the identified problems.

The result:
- A unified, efficient policy for polymers.
- Eliminate unnecessary notifications, testing for polymers and administrative complexity.

Action 6: Avoid integrating MAF in REACH

The issue: Industry studies e.g. the Ricardo case study and examples from downstream users, reveal that a generic Mixture Allocation Factor (MAF) would impose significant administrative burdens without effectively addressing combined exposures. Evidence suggests that a blanket MAF applied to all chemicals is not the right solution since the majority of unintentional mixtures of chemicals present no concern.

The solution:
Existing measures seeking to reduce emissions to the environment i.e. Industrial Emissions Directive, Urban Waste Water Treatment Directive, or assess real-life combined exposures i.e. Water Framework Directive and Chemicals Agents Directive, offer more targeted and impactful ways to address harmful combined exposures.

The result:
- A more focused, meaningful and effective approach to managing combined exposure.
- Greater alignment with existing legislation, improving efficiency and environmental outcomes.

Action 7: Ensure a continuous dialogue between industry and ECHA during dossier evaluation process

The issue: Generating necessary safety data and filling REACH registration dossiers can be a difficult and time-consuming process (some safety studies take 3-4 years to complete) and information requirements may vary from case to case.

The solution:
An open dialogue and agreeing with ECHA in advance are key for the smooth updating or development of new registration dossiers.

The result:
- Safety data is generated faster.
- Clearer expectations on what is required from the industry.
- Dossiers fulfill the expectations of authorities.

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Action 8: Introduce a new safety assessment scheme that supports an increased uptake of reliable animal-free safety assessment methods (New Approach Methodologies or 'NAMs')

The issue: Current data requirements under REACH still heavily rely on animal testing. The European Commission has ambition to phase out animal testing in chemical safety assessments.

The solution:

- Reduce the hazard focus of REACH, allowing more flexibility in achieving a high degree of safety.
- Remove default requirements for animal testing wherever possible.
- Regulators should justify why concerns cannot be addressed using exposure-based approaches or NAMs, such as when rejecting proposals for read-across, grouping, or NAMs to avoid animal tests.
- Adapt data requirements to utilise NAMs together with exposure considerations: a chemical can only cause harm if it can reach a target and interact with it.

The result:

- More targeted data requirements leading to reduced use of animal testing.

Action 9: Smoothen the registration process

The issue: Currently, data requirements are too often applied as a tick-box exercise. Waiving tests based on Annex XI is almost impossible. The added value of certain tests for assessing safety of chemicals is questionable. Each time a dossier is updated with new data, the full dossier must be revised in line with the latest ECHA IT software (IUCLID) in order to pass a technical completeness check. This creates significant workload and delays in keeping dossiers up to date.

The solution:

- Simplify data requirements by improving the use and effectiveness of adaptations to the standard information requirements and allowing data waiving under Annex XI.
- Allow targeted updates of registration dossiers.
- Put a freeze on updating IT formats for registration dossiers.

The result:

- Reduces redundant administrative workload for companies.
- Facilitates uptake of latest science and data in dossiers.
- Reduces the use of animals in chemical safety assessment.

Action 10: Ensure rules are enforced and enforceable

The issue: Evidence of enforcement of EU chemical laws shows a high rate of non-compliance, particularly in imported goods/products and online sales. The advice on enforceability developed by the ECHA Enforcement Forum is not fully considered in the final decision-making. The growing complexity of legislation and simplistic assessments mentioned in Action 4, make it difficult for enforcement authorities to target inspections where needed the most especially when faced with significant number of imports. Weak enforcement risks jeopardising human health and environment protection, as well as competitiveness of EU companies that are investing in compliance but are facing unfair competition.

The solution:

Enforcement and enforceability must be considered at the very beginning and throughout all stages of the decision-making process. The ECHA Enforcement Forum should have a stronger role and voice when it comes to enforceability assessment; if enforceability gaps are identified, the European Commission should find a solution how to solve it e.g. launching a CEN request for harmonised test method development, ensuring there is laboratory capacity to check imports. Online platforms should become legally responsible and be considered as a responsible economic operator.

The result:

- New rules can be properly enforced including for online sales.
- Enhanced protection of human health, environment and EU competitiveness.
- Strengthen the effectiveness of the EU Single Market.

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