Action 3: Improve the Authorisation and Restriction Processes

The Issue?

The REACH regulation requires companies to register their substances with the European Chemicals Agency (ECHA) before they are placed on the market. Information is then evaluated by the authorities; based on their assessment, or should new issues emerge, authorities may decide to take new risk management actions to address any concern identified. Notably they may decide to subject substances to authorisation or to restriction under REACH.

- Authorities can ban the use of a substance that is considered very hazardous; companies that want to continue using the substance need to obtain an authorisation (authorisation process)
- Authorities can limit or ban the manufacture, placing on the market or use of a substance in case unacceptable risk is identified (restriction process). For the most hazardous substances such Carcinogenic, Mutagenic and Reprotoxic (CMR 1A 1B) in consumer uses, authorities can act faster via a special procedure (Article 68(2) process)

The current REACH framework for chemical assessment faces significant challenges in its authorisation and restriction processes, primarily concerning predictability issues and uncertainties in transition periods.

The restriction process currently shows a trend towards grouping multiple chemicals and uses within a single restriction proposal. This broad-scope approach, while efficient in theory, has led to increasingly complex and difficult-to-manage decision-making processes. While it seems easy to include multiple substances in one go, it creates issues later, for instance when certain uses emerge which do not have an alternative or when enforcement becomes an issue due to lack of analytical methods. The authorities then try to fix the issue by inserting derogations, known as “policy by derogation”. This trend is evident from the restriction on synthetic polymer microparticles (the “microplastics” restriction) and ongoing discussions on PFAS restriction proposal.

In the authorisation process, several critical issues have emerged. The complexity of modern supply chains, combined with significant delays in ECHA opinions and European Commission decisions, has created substantial uncertainty for companies. The case of chromium VI has stretched out the current authorisation system – the significant number of applications for authorisation have caused a backlog of work for the authorities and uncertainty for the industry. For instance, the European Commission had to assess and decide on over 90 applications for authorisation in 2024, compared to only 9 back in 2016.

These challenges not only affect business operations but also place considerable strain on Member States’ resources and complicate long-term investment strategies. The current system is overloaded.

The Solution

Improvements to the authorisation and restriction processes need to focus on better prioritisation and focusing regulatory action where it matters the most to keep it manageable.

First, a stepwise risk-based methodology should be implemented, focusing on early identification of relevant chemicals and clear definition of chemical/use combinations. This approach includes targeted

data collection on specific chemical/use combinations throughout the value chain and EU-wide coordination to prevent regulatory overlap. Such process is described in the factsheet on Action 2.

Second, improved communication between stakeholders and authorities is indispensable. This involves early stakeholder engagement, precise scope definition, and enhanced support from authorities, associations, and companies during the whole process. Dedicated communication programs should be established to ensure effective information flow throughout the value chain. Authorities can play a significant role, for instance, by launching communication programs, explaining in layman's terms what is expected and in which format, and coordinating at EU level the most appropriate risk management measure to take.

Third, process optimisation is crucial. This includes adjusting data requirements and granularity based on factors such as volume and SME status, implementing flexible exemption rules which allow authorities to review and expand if e.g. no suitable alternative is available after some time and incorporating additional socio-economic data into decision-making processes. Moreover, creating networking opportunities for alternative solutions would foster innovation and support compliance, while also helping to explore substitution activities, mitigation measures, and related challenges — all of which would help determine the appropriate derogation period.

Looking at alternative solutions to reduce the risk to human health and environment, authorities play a crucial role in overseeing interactions with stakeholders while ensuring transparency, confidentiality and compliance with competition and anti-trust rules. EU and national funding programs for specific projects or policy support can encourage collaboration and industry participation in developing and implementing innovative alternative solutions that meet the regulatory requirements.

The authorisation and restriction systems should be repurposed in a way to address current challenges during decision making and make administrative tasks more manageable, while ensuring thorough scientific evaluation and overall health and environment protection. Additional crucial elements include clear upfront communication, clarification of perceived needs for risk management as well as transparent and thorough preparation of data.

Suggestions to improve the restriction process

- Ensure there is a strategic discussion at EU level before restriction proposals are submitted to the system, as described in the factsheet on Action 2, aligning restrictions with other policy goals.
- Groups of chemicals/uses, when applied, should be based on clear, robust, and transparent criteria, targeting the risks posed by these substances in their particular applications.
- Restrictions should be implemented at the sector level where unacceptable risk is identified using the whole regulatory restrictions toolbox e.g. to impose conditions of use or to phase out specific combination of chemical/use), not only to ban.
- Chemicals used in manufacturing processes (intermediates, solvents, process aids) should be exempt from the scope of restrictions aimed at banning chemicals. These chemicals are used in well-controlled settings where risks can effectively be managed. This is particularly relevant for those chemicals that are building blocks for many strategic value chains in Europe.
- Consider the time it takes to develop alternatives. Since derogations are time-limited and rigid, the system should incorporate more flexibility, allowing industry to request a review of agreed derogations in cases of issues with deadlines, developments of alternatives etc.
- An assessment of alternative should also consider the entire life cycle of the proposed alternative to evaluate its feasibility.

Suggestions to improve the authorisation process

- Limit the use of the authorisation scheme by adjusting the prioritisation criteria in such a way that authorisation would be used only in limited cases and create “breathing space” for authorities to focus their efforts on other tasks.
- Create more possibilities for the European Commission to grant exemptions to the authorisation when risks are adequately controlled.
- Maintain authorisation for single remaining applications for Substances of Very High Concern (SVHC) (which would limit the number of single applications, make them more targeted and less complex to assess). As of today, it is possible to exclude uses from the authorisation scheme for a more targeted process but rarely used, if at all. A flexible exemption system must consider practical feasibility, and regulatory requirements should be balanced to ensure fair competition conditions across the market.

This comprehensive approach aims to create a more efficient, predictable, practical, and manageable regulatory framework while maintaining high standards of chemical safety and environmental protection. The success of these improvements depends on the coordinated efforts of all stakeholders and their commitment to implementing these changes effectively.

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