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REACH Regulation revision

Context

REACH Regulation is the most extensive chemicals regulation globally setting reguirements for Registration, Evaluation, Authorisation and Restriction of Chemicals. Since the publication of the 2020 chemical strategy, preparations have been underway for the revision of the REACH regulation. The previous Commission conducted an impact assessment to achieve ambitious goals, but no actual amendment proposal was presented. The new Commission is committed to a targeted revision of the REACH regulation, emphasizing the simplification, modernization, and competitiveness of requirements while maintaining the level of health and environmental protection.

For the EU chemical industry, reducing regulatory burdens is essential to maintaining competitiveness and ensuring progress in the clean transition. Among the many regulations affecting the sector, REACH is one of the most important, although it has also been among the most costly pieces of legislation. Despite the need for changes and some implementation deficiencies, REACH has proven effective, and the chemical industry remains committed to its implementation and goals to protect health and the environment.

The EU Competitiveness Compass states that the REACH revision aims to simplify both existing regulations and upcoming chemical initiatives, accelerate decision-making, and improve sustainability, competitiveness and safety.

Industry Position

The revision of the REACH regulation must simplify requirements for companies, reduce administrative burdens, and make regulations more predictable. Over 18 years, REACH and other chemical regulations have advanced significantly but also become more complex. The revision requires new thinking and cooperation between businesses and authorities to account for the EU's competitiveness and investment environment while enhancing health and environmental protection.

The chemical industry supports Cefic's 10-point proposal for the REACH revision. For Finnish companies, the most critical aspects are:

- Establishing a simpler, more predictable framework for chemical regulation based on scientific evidence.
- Avoiding increased administrative burdens on industry.
- Ensuring that chemical regulations remain feasible and enforceable.

The impact assessment conducted by the previous Commission should be updated to reflect economic changes and the EU's strategic autonomy needs. Special attention should be given to the effects on SMEs and their ability to operate within the EU. If new measures seem to be needed, existing obligations—including those outside the REACH regulation—should be assessed to see if improved enforcement and implementation can achieve the same goals.

Enhancing competitiveness must be considered in the revision. REACH currently leads to situations where the use of a substance may be banned within the EU, but products manufactured with it can still enter the EU market. Given the EU's strict occupational safety and environmental laws, manufacturing products within the EU is done safely, maintaining self-sufficiency and preserving jobs in the region. Competitiveness is also affected by REACH's extensive administrative burden for keeping chemicals on the market and increasing uncertainty regarding classifications and bans on substances in safe uses.

Regulating Priority Substances

The assessment of regulatory needs for priority substances should start with an analysis of existing data and applications in collaboration with companies. This approach allows suitable measures to be selected within REACH or other regulations, targeting only identified risks. Actions should be knowledge-based, making them more predictable while reducing the need for authorization processes. Restrictions under Article 68(1) should only be imposed if the manufacturing, use, or marketing of a substance poses an unacceptable risk to human health or the environment.

Polymer Registration Obligation

Polymer registration has been under discussion in the previous Commission's REACH revision. Implementing requirements for polymers is extremely challenging; polymers form through various processes, come in numerous types, and typically have few hazardous properties—apart from persistence. Any actions related to polymers should be preceded by a thorough assessment, a polymer strategy, to determine which measures are genuinely needed for improved safety.

Mixture Assessment Factor (MAF)

The previous Commission also proposed an assessment factor for substances to take into account the sum effect in mixtures. Industry studies indicate that the environment rarely encounters scenarios where mixture effects outweigh those of individual substances. Half of the rare cases involved already banned substances interacting. The primary goal should be minimizing environmental emissions through measures like the Industrial Emissions Directive rather than recalculating safe concentrations, which would impose a significant workload on companies without notable environmental benefits.

Reducing Animal Testing

The principle of reducing animal testing should be incorporated into REACH, and requirements for animal experiments should be eliminated wherever possible. Authorities should always justify any requirement for animal testing if alternatives or test results from similar substances (read-across methods) exist.

Simplification of Regulations

Regulatory simplification must result in improvements for companies. Automation of procedures or handling large groups of substances in one go is not simplification—it instead weakens scientific risk assessment and investor confidence in the EU if raw materials can be banned without justified reasons.

Feasibility and Enforceability of Regulations

The feasibility and enforceability of regulations should be prerequisites for restrictions and considered during the whole drafting phase of proposals. Enforcement agencies must have the

mandate to influence proposals. Enforceability should also extend to products imported from outside the EU and online marketplaces. If enforcement fails, companies complying with regulations will lose their investments while free riders continue operating under the same market conditions.

Dialogue with Authorities

The revision requires close dialogue between the Commission, national authorities, industry stakeholders, chemical manufacturers, and downstream users. Companies and enforcement authorities bear a significant share of regulatory implementation. Ongoing dialogue should also extend to enforcement, ensuring companies can receive assistance and up-to-date information, such as regarding applications or classification processes from ECHA committees. Chemical safety is a shared goal that should be pursued in constructive cooperation.

Objectives of the Revision

The revision must result in a simpler, predictable, and efficient REACH that enhances competitiveness, strengthens the internal market, and aligns its goals with a broader industrial strategy to secure investments in the EU.

Timeline and Current Status

The European Commission's 2025 work program schedules the targeted REACH revision for the latter half of 2025.

Lisätiedot ja materiaalit:

Cefic 10 point action plan on REACH revision
Arche study on mixture assessment factor