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REVISION OF THE REACH REGULATION

INTRODUCTION

- Chemicals are key components of materials used in every-day life, from the food we eat to the medicines we take, from the cosmetics we apply to the devices we use or the clothes we wear. As the EU aims for climate neutrality by 2050, chemicals are integral to low-carbon, zero-pollution, and resource-efficient technologies like wind turbines, solar panels, and chips. Achieving EU Green Deal objectives depends on a wide range of chemicals.
- To develop and use innovative solutions and socially relevant technologies in the future that might be essential for the functioning of the society, it must remain possible to produce and use hazardous chemicals if there are safe use conditions.
- While the intention to revise REACH is framed as part of the drive towards simplification, many of the current proposals risk introducing new layers of complexity and administrative burden. The revision of the REACH Regulation must be in line with the Commission's general objective of making Europe more competitive, more resilient and more independent. In the spirit of "Making Europe simpler and faster", the revision of the REACH Regulation should be carried out with a sense of proportionality and must avoid introducing further and unnecessary complexity. Changes to the existing regulations that would further reduce both effectiveness and efficiency (e.g., GRA, MAF) should be prevented. Also, new measures must not lead to the creation of additional bureaucratic hurdles for companies.
- The envisaged approaches presented by the European Commission at the CARACAL-Meeting in April 2025 for the revision of REACH represents a paradigm shift, away from a proven risk-based approach towards an unproven hazard-based approach. A thorough impact assessment is necessary to evaluate cost-benefit trade-offs, as manufacturers and users of chemicals along the entire value chain would be significantly affected. The EU already has one of the world's most advanced set of chemical regulations, and any revision must balance safety, innovation, and competitiveness.

REGISTRATION REQUIREMENTS

- Chemical Safety Assessment (CSA) requirements for substances above 10 tonnes per year must remain proportionate to avoid disproportionate costs, particularly for SMEs. Exposure-led approaches should be considered, with derogations for substances with minimal risk profiles. Increased information requirements for Annex VII substances must be carefully assessed, and New Approach Methodologies (NAMs) should be applied only when valuable for risk management, incorporating exposure considerations to ensure efficient use of testing resources.
- The existing registration system in REACH is tailored for substances, not polymers. Due to this and the immense number of polymers on the market (200,000 - 400,000), introducing new registration duties for polymers would require substantial resources from both industry and regulatory authorities. Polymers are sufficiently addressed by the REACH regulation, the management of monomers and the mandatory classification of polymer-containing products under the CLP. It is suggested to identify if there are still any gaps as a first step (e.g., data collection and handling of polymers), define the problem, if any, and then see if there is a need to come forward with any polymer-targeted requirements under REACH.
- The introduction of a limited validity period is primarily aimed at those dossiers that are not systematically kept up to date and that have not been updated over long periods of time. However, this is a question of implementation and enforcement. The existing legal framework provides ECHA with sufficient tools to identify and address non-compliant dossiers through compliance checks, evaluations and enforcement tools.
- The generic introduction of a Mixture Allocation Factor (MAF) would massively curtail substances and their uses even without relevant combination effects. The introduction of a generic MAF would lead to significant administrative burdens. Existing regulations (OHS-Legislation, etc.) offer more effective ways to address harmful combined exposures.

GENERIC APPROACH TO RISK MANAGEMENT (GRA)

- Regulatory decisions must continue to be based on scientific risk assessments. The current restriction process under REACH allows for appropriate risk management, targeting those substances and uses that pose a risk that cannot be adequately controlled. The existing procedure (including Art. 68(1) restrictions) should therefore not be replaced by a generic approach, whereby substances and uses can be banned and restricted solely based on their intrinsic hazardous properties (GRA-based restrictions, Art. 68(2)), irrespective of whether there is an actual risk to health or the environment. Alternatively, a strengthened Risk-Management Option Analysis (RMOA) should be developed (see the respective section below) to avoid choosing the GRA-based approach as default for all consumer and professional uses of hazardous substances, including industrial uses of SVHCs.
- Neither the extension to additional hazard classes nor the extension to professional and industrial applications would be appropriate and effective. Risks in the workplace should continue to be addressed via occupational health and safety measures. The existing EU directives already ensure a high level of protection.

AUTHORISATION & RESTRICTION REFORM

- When revising the authorisation and restriction system under REACH, a well-balanced approach is needed. In principle, the positive aspects of the authorisation procedure should be retained and not replaced completely by a generic restriction process. Advantages of the two procedures must be maintained, particularly in relation with the use of GRA, which would lead to restrictions based primarily on hazard profiles rather than specific risk assessments, and the use of the 'Essential Use Concept' (EUC).
- However, experience clearly shows that the authorisation process would benefit considerably from simplification and clarification. The procedure has proven to be too lengthy and too resource-intensive for all parties involved. The authorisation process should therefore be simplified (especially for small quantities) and deadlines for review periods must be adjusted based on existence of alternatives. The principle of "repair as produced" should be introduced for spare parts.
- The difficulties in handling applications for authorisation have led to avoidance of the authorisation process. Rather, a move towards broader restrictions with time-limited exceptions are being proposed, resulting in a policy of "regulation by exception". This approach is reaching its limits and leads to planning uncertainty for companies due to the lengthy procedures. Thus, restrictions should continue to be targeted at uses that pose unacceptable risks, as far-reaching bans contradict the risk-based principles of REACH and have significant socio-economic impacts.
- Regarding the Proposed reform of Candidate List, whereas only substances identified Substances of Very High Concern (SVHC) should be added to the future Candidate List, there is a need to improve supply chain transparency and give downstream users early notice to prepare for potential regulatory action. Therefore, an information mechanism within the supply chain should be considered prior to new restriction. It should also be considered what triggers can lead to remove substances from the Candidate List, upon receipt of new data which allowed to refine, hazard, exposure and risk prioritisation.

RISK MANAGEMENT OPTION ANALYSIS (RMOA)

- A targeted Risk Management Option Analysis (RMOA) approach can meaningfully contribute to the simplification of REACH while ensuring that risk management remains both proportionate and flexible. This approach should include an upfront screening procedure that incorporates information provided by industry at an early stage, i.e., before a regulatory pathway is selected.
- Such early engagement would facilitate a more balanced distribution of work between authorities and industry. It would also allow for the early identification of uses that are either demonstrably safe and lack acceptable alternatives. These uses could be excluded from further regulatory action, enabling authorities to focus resources on those cases where risk management is truly required.
- Depending on the specific risk identified, the most appropriate measures could include REACH authorisation or restriction, but also alternative instruments such as Occupational Safety and Health (OSH) legislation for workplace risks, the Industrial Emissions Directive (IED) for

air emissions, or the Water Framework Directive for aquatic pollutants. This targeted and flexible approach would improve regulatory efficiency and ensure that the most suitable risk management tools are applied.

THE EXTENDED SAFETY DATA SHEETS (ESDS)

- We support the simplification of supply chain communication to improve the clarity and effectiveness of chemical content information provided along the supply chain. In this context, it is important to address the complexity and length of Extended Safety Data Sheets (eSDS), which often contain many pages and make it difficult for users to extract the most critical safety information.
- Simplifying eSDS is essential to improve accessibility and ensure effective communication of vital details. Exposure scenarios could be removed as a tool of communication, while the SDS should provide concise, clear and actionable advice. This approach would better meet the practical needs of downstream users and is supported by sector proposals aimed at enhancing communication efficiency without compromising safety.
- The potential of, and make optimal use of, digital tools to communicate hazard and safety should be assessed. There should be opportunities to simplify the supply chain communication and the improvement of (extended) safety data sheets (SDS) via improved tools for communication following a pragmatic approach for companies, including harmonised electronic formats such as QR codes.

THE 'ESSENTIAL USE' CONCEPT (EUC)

- When implementing the Essential Use Concept (EUC), there is a risk of moving away from the risk-based approach and creating additional burden both for companies and authorities. The mere presence of a hazardous substance in a process or product is not a sufficient reason to apply the essentiality assessment. Therefore, the EUC could only be a valid solution if applied in a targeted manner, i.e., in case of proven risks to the health and environment, difficulties in managing these risks and if no acceptable alternatives or substitutes exist.
- The definition of "essential use" must not be arbitrarily determined by regulators but should be shaped through societal debate and political decisions, involving industry, SMEs, civil society, and academia. Essentiality is a dynamic concept that must adapt to emerging technologies. The criteria for defining essential use should be broad and substance-specific, considering functionality, societal needs, sustainability, and safe use as well as technological and economic aspects.
- The automatic application of the EUC based solely on hazard classifications could lead to regrettable substitutions, where more sustainable materials are replaced by less effective or environmentally harmful alternatives. This approach could contradict the EU Green Deal objectives and damage the EU's industrial competitiveness. Additionally, this approach could slow down regulatory processes by requiring granular assessments of essentiality for each substance, further straining limited resources.

ENFORCEMENT OF EU CHEMICALS LEGISLATION

- Evidence of enforcement of EU chemical legislation[1] shows a high rate of non-compliance, particularly with imported goods/products and online sales. Weak enforcement risks jeopardizing human health and environment protection, as well as competitiveness of EU companies that are investing in compliance but are facing unfair competition from third countries.
- The advice on enforceability developed by the ECHA Enforcement Forum is not fully considered in the final decision-making. 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.
- The growing complexity of legislation and simplistic assessments makes it difficult for enforcement authorities to target inspections where needed the most, especially when faced with a significant number of imports.
- If enforceability gaps are identified, the European Commission should find a solution to solve it e.g., launching a CEN request for harmonized test method development, ensuring there is laboratory capacity to check imports.

[1] https://cefic.org/news/data-confirms-an-urgent-need-to-step-up-enforcement-of-chemicals-legislation-for-imported-goods-and-online-sales/

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