

LSMA recognizes the importance of REACH in protecting human health and the environment. The upcoming REACH revision presents both challenges and opportunities for the European Life Sciences sector, a critical driver of innovation, healthcare, and Europe's strategic autonomy. LSMA believes a proportionate and targeted approach to chemical legislation is essential to balance environmental protection with maintaining a thriving Life Sciences industry in Europe.

Essential Use and Proportionality: Balancing Performance and Regulation

This balance hinges on a clear understanding and application of the "essential use" concept. While well-intentioned, the proposed shift from "suitable" to "acceptable" alternatives introduces ambiguity. For LSMA and our customers, *performance is paramount*. Alternatives that compromise efficacy, particularly in the pharmaceutical and biopharmaceutical sectors, are unacceptable and disruptive to the high quality of healthcare that patients in Europe expect. Lengthy revalidation and uncertain global regulatory re-approval processes can create critical supply chain disruptions and jeopardize patient access to essential medicines.

A thriving Life Sciences sector, particularly in developing non-healthcare applications, is fundamental to the innovative capacity of a broad range of R&D-intensive industries, including automotive, aerospace, electronics, and food. Moreover, it is critical in mitigating current and future health threats and securing Europe's strategic autonomy in healthcare and related fields. Chemical uses in Life Sciences applications and manufacturing should be explicitly recognized as "essential" under REACH and be accompanied by proportionate controls and assurances in the exemption and derogation considerations under Chapters VII and VIII of REACH. This recognition is crucial for maintaining Europe's leadership in Life Sciences manufacturing.

Streamlining Overlapping Regulations: Enhancing Efficiency and Competitiveness

To further support this objective, the One Substance One Assessment (OSOA) package must streamline overlapping regulations. Clarifying the interface between REACH, RoHS, POPs, and the Biocidal Products Regulation (BPR) is essential to avoid duplicative regulation and ensure substances used in Life Sciences, often under highly regulated conditions, are appropriately categorized and exempted from redundant and disproportionate regulatory burdens. Clear legal definitions and guidelines will enhance competitiveness and support contributions to both public health and environmental sustainability.

Specific Recommendations

To achieve this proportionate and streamlined regulatory framework, LSMA urges the European Commission to consider the following specific points in the REACH revision to achieve its objective of protecting human health and the environment while ensuring the good functioning of European Society:

1. Polymers: Tailored Requirements for Essential Materials

Given the significant use of polymeric materials in Life Sciences, polymers manufactured or imported below one tonne per year, and polymers with specific properties or uses should be excluded from notification and registration requirements. Instead of this consideration, Polymers Requiring Registration should be phased in gradually for polymers used in Life Science products and in their manufacturing to minimize supply chain disruption and delay innovation of healthcare-related products.

2. Small Quantity Exemptions: Reducing Administrative Burden

A system for exemptions from REACH authorizations for small-quantity uses is essential. The cost of authorization for minimal potential emissions is disproportionate and hinders innovation. A simplified AoA, proportionate to the quantity used or risk posed, should be introduced. Consequential

amendments to Article 58 (exempting essential uses and substances below one tonne), Article 56 (limiting the inclusion of substances in articles to quantities of one tonne or more with foreseeable releases), and Article 60 (mandating consideration of EU strategic autonomy in healthcare during authorization decisions and requiring simplified AoA criteria for healthcare and related SR&D) are necessary.

3. Generic approach to risk management (GRA): A Phased and Targeted Approach

The GRA should be implemented gradually, prioritizing sectors with high production volumes and exposure potential. Life Sciences, characterized by small-quantity, highly regulated applications, require additional time for substance phase-out. Exemptions from GRA should be introduced for substances below sector-specific quantity thresholds (e.g., one ton for Life Sciences), or where trained professionals can be expected as the main users. Restrictions on substance groups must identify each substance having evidence of equivalent hazard and avoid disproportionate burdens on smaller companies.

4. SR&D Exemption: Fostering Innovation and Research

The SR&D exemption must be maintained, clarified, and expanded. The definition of "controlled conditions" should be broadened to include all work performed by trained professionals aware of relevant safety requirements, distinct from "strictly controlled conditions." Furthermore, the exemption should apply to both substance and article usage, as well as necessary preparatory steps like manufacturing or assembly, with these provisions clearly enshrined in legal text, not merely guidance. Harmonization of the SRD exemption, as defined under REACH, across EU chemicals legislation is crucial.

5. Professional Uses: Clear Definitions for Effective Regulation

Clear, differentiated definitions of "industrial uses" and "professional uses" are needed within REACH to distinguish the reduced risk associated with smaller-scale professional uses in industrial, clinical, academic, and applied laboratories and to improve clarity on industrial/professional use derogations.

6. Authorisation and Restriction Procedure: Ensuring Access to Essential Substances

Most uses of substances within the Life Sciences sector are lower volume and are managed by strict OSH, environmental and institutional measures to control exposures and releases in line with European Union legislation. Additionally, the market applications for Life Sciences products are essential to several critical industry sectors such as healthcare, food and feed preparation, environmental monitoring, R&D-related sectors and applied sciences (e.g., forensics). To secure these critical supply chains, Life Science products must be considered equally essential.

The forthcoming REACH revision should exempt all essential uses from authorization and restriction, including necessary proceeding steps. To support this, evidence of low or no emissions, adequate controls, and products with no intended or foreseeable releases should be prioritized as key criteria for exemption. For small quantities used in PPORD, similar exclusions as those afforded to SR&D activities should apply, further minimizing the need for authorization. Where, despite these criteria, an application for authorization is deemed mandatory, the AoA should be simplified, emphasizing the uncertainties in product/process revalidation and attaining global regulatory reapprovals. Transparent and predictable reviews of essential uses of small volumes of substances under controlled conditions will aid in the resilience and strategic autonomy of European Life Sciences supply chains without increasing risk to humans or the environment.

7. Conclusion: A Collaborative Path Forward

A proportionate and targeted REACH revision is crucial for the continued success of the European Life Sciences sector. By addressing the specific concerns outlined in this paper, the European Commission

can ensure that REACH effectively protects human health and the environment while preserving the competitiveness, innovation, and strategic importance of the Life Sciences industry in Europe. LSMA stands ready to collaborate with the Commission to achieve this shared goal.

About LSMA

The Life Science Manufacturers Association (LSMA) is the unified voice of diverse companies powering the Life Science industry, dedicated to fostering a thriving ecosystem where innovation flourishes and critical technologies are accessible globally. As the industry's advocate, LSMA engages with policymakers to shape supportive policies that contribute to healthcare, sustainability, and the European economy. Uniquely positioned to address regulatory challenges, particularly concerning substitution, LSMA advocates for a proportionate approach recognizing the unique characteristics of Life Science applications, often involving highly sophisticated products critical to essential uses. Substitution in these areas is subject to lengthy procedures requiring extensive research, development, testing, validation, and regulatory approvals. By fostering collaboration, supporting innovation, and ensuring regulations are tailored to the industry's specific needs, LSMA aims to drive sustainable progress and maintain Europe's leadership in life sciences.

For further information and inquiries, please get in touch with the LSMA at info@lsma.org or visit their website at www.lsma.org.