

The Life Science Manufacturers Association, comprising companies that develop products for R&D, biomanufacturing and biotechnologies wants to express its considerations regarding the approach presented in the second workshop of 1 October 2024 on the ongoing “Study on strengthening the role of substitution in the context of REACH and other EU chemicals legislation”.

- **Underlying Causes of Central Problem:** While the contractor's proposed list of substitution pathways provides a solid foundation, LSMA believes it's not entirely comprehensive. To address this, LSMA introduces the concept of Market/Value Chain Resistance to Change. This resistance is driven by:
 1. **Technical Concerns:** Market and regulatory agencies may express concerns about potential alterations in product performance, whether improvements or declines.
 2. **Regulatory Hurdles:** The industry may be reluctant to seek regulatory re-approvals throughout the value chain, both within the EU and globally.
 3. **Market Adoption Challenges:** Introducing novel technologies (beyond simple chemical substitution) often requires retraining, validation, and potentially significant capital investments in equipment and facility infrastructure.
- **Regulatory Framework:** A light regulatory framework, alongside voluntary substitution (as illustrated in option 4), would be welcome if the common early stages take due consideration of small volume and niche uses, including the potential for derogation in specific cases.
- **Substitution Centers:** The association questions the effectiveness of substitution centres for life science uses and their potential costs compared to authorization. While diverting difficult-to-assess uses into substitution processes could provide benefits, niche life science uses are unlikely to be prioritized because of the low-volume use/emissions. LSMA suggests a trustee arrangement for early disclosure of niche uses that would allow their early identification and potential exemption.
- **Collaborative Approach:** LSMA favours voluntary collaboration but worries about oversight without a light form of regulation. If this model becomes relevant for our sector, industry players may find traditional CBI protections inadequate. Complex upstream considerations and potential free riders could also hinder collaboration. More clarity and early industry consultation are needed on any regulatory framework that would mandate it.
- **Scope Definition:** To ensure effective implementation, the scope of the substitution or use requirements must be clearly defined. While the intended end uses are often low-volume applications, LSMA members may still be involved in high-volume uses of substances within their supply chains, such as formulation or down-filling. To address this, LSMA proposes proportional and representational inclusion of all actors in the value chain of the targeted substances within the scope of the substitution requirements.
- **Substitution Journeys:** LSMA criticizes the proposed substitution journey for omitting regulatory (re)approval processes and its oversimplification. The actual substitution process can involve multiple approvals at different stages and by numerous global players in the value chain.
- **Integration with Existing Legislation:** LSMA advocates for a streamlined regulatory framework encouraging proactive substitution efforts. This approach would be particularly applicable in sectors where sector-specific derogations or exemptions are impractical. We propose exploring potential relations with existing regulations, such as the Restriction of Hazardous

Disclaimer

This position paper has been prepared by the members of the LSMA in regard to the currently ongoing consultation process on *Strengthening the role of substitution planning in the context of REACH and other EU chemicals legislation* study by the European Commission. The content of this document is based on information known to us at the time of writing and may be subject to change.

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Substances (RoHS) and the F-Gases Regulation (FGR), to ensure a coherent and effective regulatory environment.

- **Incentivisation for participating in substitution:** To encourage proactive participation in substitution initiatives, particularly in anticipation of regulatory actions like REACH Annex XVII listings, LSMA recommends implementing a suite of incentives. This can include:
 - **Regulatory Flexibility:** Granting regulatory flexibility or exemptions for companies that demonstrate significant progress in substitution, such as expedited approval processes for new products or reduced testing requirements.
 - **Research Funding:** Providing grants or subsidies to support research and development efforts aimed at developing safer alternatives to targeted substances, especially for small and medium-sized enterprises (SMEs).
 - **Tax Benefits:** Offering tax deductions or credits for companies that successfully substitute targeted substances in their products or processes.

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