Ref. Ares(2026)5917902 - 10/06/2026

Feedback on the Biotech Act II

Input from EIC Engineered Living Materials (ELMs) Portfolio Projects: REMEDY, Biorobot-Miniheart, BIOACTION, FUNGATERIA, NEXTSKINS, Bio-HhOST, ISOS, LoopOfFun

The EIC Engineered Living Materials (ELMs) portfolio welcomes the European Commission's initiative to develop the Biotech Act II. It strongly supports its ambition to strengthen industrial biotechnology and biomanufacturing across the European Union. The EIC ELMs portfolio comprises 10 collaborative projects bringing together leading universities, research institutes, SMEs, and innovation actors across Europe. The portfolio represents a broad European ecosystem at the forefront of engineered living systems, synthetic biology, engineering biology, advanced biomanufacturing, and bio-based innovation.

ELMs are an emerging class of bio-based and biomanufactured materials that integrate living cells into functional material systems. ELMs can provide sensing, responsiveness, self-repair, adaptation, carbon utilisation, low-energy manufacturing, and circularity functionalities, in agreement with the EU bioeconomy strategy, that are difficult or impossible to achieve with conventional fossil-based materials. Due to their versatility, ELMs have potential applications across multiple strategic sectors, including construction, healthcare, environmental remediation, energy systems, textiles, agriculture, food systems, advanced manufacturing, and circular materials. The Biotech Act II presents a major opportunity for Europe to establish global leadership in industrial biotechnology by enabling emerging platform technologies such as ELMs to scale from research to industrial deployment.

1. Strengthening Europe's industrial biotechnology and biomanufacturing ecosystem

Europe has a strong scientific base in synthetic biology, biotechnology, advanced fermentation, and bio-based materials. However, emerging technologies such as engineered living materials still face significant barriers when transitioning from laboratory research to industrial deployment.

The EIC ELMs portfolio recommends:

- Integration of full-cycle innovation support covering discovery, prototyping, pilot production, demonstration, and early industrial deployment for high-risk industrial biotechnology platforms.
- Structured access to shared infrastructures, including pilot-scale biomanufacturing facilities, advanced characterisation platforms, AI-enabled design tools, digital twins, and high-throughput experimentation infrastructure.
- Standardised testing and validation frameworks specifically tailored to bio-based and engineered living materials. These should cover durability, functionality, safety, and biodegradation performance under application-relevant conditions. Those harmonised testing protocols would enable comparability across projects and sectors, reduce uncertainty for industry stakeholders, and accelerate regulatory evaluation and market uptake.
- Support for interdisciplinary skills combining biotechnology, synthetic biology, nanotechnology, materials science, AI, engineering, circular design, and biomanufacturing.
- Stronger European foresight and monitoring mechanisms for emerging biotechnology platforms to enable early assessment of societal, environmental, industrial, and regulatory implications.
- Support for AI-assisted design and predictive modelling tools that accelerate development and reduce industrial scale-up timelines for bio-based products.
- Continuing to improve the communications involving all the actors in the value creation chain to achieve effective and coherent messages about bio-based systems.
- Support multi- and interdisciplinary educational initiatives to access up-to-date new knowledge and developments, including internationalization.

- Support for European biofoundries, living material testbeds, and shared repositories of well-characterised biological parts, strains, matrices, protocols, and safety data to accelerate reproducibility, standardisation, and scale-up of engineered living materials.

2. Creating lead markets and accelerating industrial uptake

A major challenge for engineered living materials and other industrial biotechnology products is achieving widespread market uptake. Fossil-based products continue to benefit from mature value chains, economies of scale, and indirect incentives that disadvantage emerging bio-based alternatives.

The EIC ELMs portfolio recommends:

- Demand-side incentives and public procurement mechanisms that stimulate uptake of sustainable biomanufactured products.
- Progressive minimum bio-based and/or recycled carbon content requirements in selected industrial sectors where technologically feasible.
- Recognition of ELMs and advanced bio-based materials as strategic technologies contributing to de-fossilisation, circularity, and industrial resilience.
- Support for demonstration projects and first industrial deployment facilities that bridge the gap between pilot scale and market adoption.
- Strengthening of real-world pilot environments involving end-users and value chain actors to complement technological demonstration and validate performance, usability, and acceptance under realistic conditions.
- Support for user-centric pilot applications that bridge the gap between technological feasibility and market adoption, particularly for novel bio-based materials with unfamiliar functional or sustainability characteristics.
- Harmonised standards, terminology, and certification frameworks for bio-based and living materials across Member States to reduce fragmentation within the single market.

Potential lead markets for ELM-enabled products include construction materials, coatings, textiles, packaging, environmental remediation systems, specialty chemicals, biomineralisation applications, energy applications, and low-carbon manufacturing systems.

3. Improving investment predictability and scale-up financing

Engineered living materials often require long development timelines, interdisciplinary infrastructure, and high upfront scale-up investments. Current investment mechanisms remain insufficient for infrastructure-intensive deep-tech biomanufacturing technologies.

The EIC ELMs portfolio recommends:

- Dedicated public-private investment instruments for advanced biomanufacturing technologies, which require mechanisms suited to long industrial development timelines.
- Long-term funding continuity from EU-supported research to industrial demonstration and commercial deployment.
- Financial de-risking mechanisms for first-of-a-kind industrial biotechnology facilities.
- Support for SMEs and start-ups developing disruptive ELM manufacturing technologies.
- Identification and implementation of necessary measures to prevent the loss of strategically important biotechnology intellectual property and industrial know-how outside Europe.

4. Sustainability, circularity, and strategic autonomy

Engineered living materials can contribute substantially to Europe's climate, circularity, and strategic autonomy objectives by reducing dependence on virgin fossil feedstocks and enabling low-energy manufacturing pathways.

The EIC ELMs portfolio recommends:

- Developing harmonised sustainability assessment methodologies adapted to emerging biotechnology and living material systems, including life-cycle assessment methodologies appropriate for early-stage technologies.

- Promoting circular-by-design approaches for bio-based and engineered materials, including the integration of biodegradability, disassembly, and material recovery considerations at the design stage.
- Supporting systematic assessment of realistic end-of-life pathways for bio-based and engineered materials, including industrial composting, home composting, recycling, and controlled degradation, while accounting for regional infrastructure conditions across the EU.
- Supporting pilot-scale validation of circular use cases and end-of-life scenarios to enable the effective implementation of circular material concepts beyond laboratory conditions.
- Supporting technologies that enable self-repair, extended material lifetime, recyclability, biodegradability, and closed-loop manufacturing systems.
- Promoting industrial biotechnology approaches that reduce dependency on critical raw materials and imported fossil-derived inputs.

5. Regulatory simplification and enabling frameworks for emerging biotechnologies

Emerging biotechnology platforms such as engineered living materials often face fragmented and unclear regulatory pathways because they combine characteristics of materials, biotechnology products, engineered biological systems, and manufacturing technologies. Regulatory frameworks should more clearly differentiate between living materials, non-living bio-based materials, and materials derived from genetically modified organisms, as these categories may present fundamentally different risk profiles. Materials that are biologically produced but do not contain viable organisms in the final product should be assessed differently from living or replicating systems. The current lack of differentiation can create significant barriers to industrial translation and market entry.

The EIC ELMs portfolio recommends:

- EU-wide regulatory sandboxes for industrial biotechnology and emerging engineered living materials.
- Early continuous regulatory dialogue mechanisms between innovators, regulators, and industry to clarify applicable frameworks during development and scale-up phases.
- Harmonised terminology, definitions, regulatory assessments' requirements and approval pathways for emerging biotechnology-enabled material systems across the EU, including materials with genetically modified microorganisms.
- Shifting from a process to product and from a risk-only to a risk-benefit approach in the regulatory approval of materials with genetically modified microorganisms.
- Simplified and accelerated permitting procedures for pilot and demonstration-scale industrial biotechnology facilities.
- Coordinated regulatory guidance for biohybrid and living material systems whose functions combine material performance with biological activity or biologically derived engineered components.
- Regulatory preparedness for emerging biotechnologies incorporating AI-assisted design, synthetic biology, engineered biology, engineered microorganisms, and advanced fermentation systems.
- Development of risk-proportionate regulatory frameworks that distinguish ELMs from conventional GMO applications where appropriate, ensuring that assessment and approval requirements reflect the specific characteristics, exposure pathways, and risk profiles of ELM systems.
- Development of proportionate, risk-based regulatory guidance for contained or localised applications of engineered living materials, including systems designed with genetic safeguards, kill-switches, auxotrophy, physical containment, or other containment-by-design strategies.

6. Clear and transparent governance, ownership and stewardship structures

The Biotech Act II should not focus solely on accelerating innovation and scaling biomanufacturing. It should also address the governance and ownership structures that determine who controls critical biotechnology capabilities, data assets, manufacturing infrastructure, and intellectual property to ensure the public good. The Act should promote transparent governance, resilient public ownership

models, public return on public investment, and stewardship of strategically important biological and data resources to strengthen Europe's long-term competitiveness, resilience, and technological sovereignty.

Conclusion

The Biotech Act II can become a cornerstone of Europe's industrial competitiveness, strategic autonomy, and circular bioeconomy transition. Engineered Living Materials represent a highly promising industrial biotechnology platform with the potential to support de-fossilisation, low-carbon manufacturing, circularity, and resilient European value chains across multiple sectors.

To fully unlock this potential, the Biotech Act II should:

- Support multi- and interdisciplinary educational initiatives to access up-to-date new knowledge and developments
- Support full-cycle industrial biotechnology innovation from research to market deployment.
- Create lead markets for sustainable bio-based and biomanufactured products.
- Improve investment predictability and scale-up financing for deep-tech biomanufacturing.
- Strengthen shared infrastructures, interdisciplinary skills, and industrial ecosystems.
- Establish harmonised and adaptive regulatory frameworks for emerging biotechnology platforms.
- Accelerate industrial deployment through regulatory simplification, standards, and demand-side incentives.
- Reinforce Europe's strategic autonomy by reducing dependence on fossil-based and imported industrial inputs.

The Act should also promote responsible innovation, transparency and public engagement to build trust in biotechnology-enabled materials and ensure that societal, ethical, safety and environmental considerations are addressed from the earliest stages of development. To further support industrial adoption, targeted approaches for risk communication and user engagement should be strengthened. Transparent communication on safety, environmental impact, and performance is critical to foster public trust in bio-based and living materials. This is particularly important for emerging material systems incorporating biological components or novel functionalities, where acceptance and perception may significantly influence market uptake. With these measures, Europe can position itself as a global leader in industrial biotechnology and next-generation bio-based manufacturing technologies.