EuropaBio Response to the Commission Public Consultation on the Single Market Strategy 2025

EuropaBio, the industry association for biotechnology in Europe, welcomes the opportunity to contribute to the development of the Single Market Strategy 2025. Biotechnologies play an essential and significant role in the delivery of EU goals for competitive, healthy, resilient and sustainable economies and societies. Applications are integrated throughout our industrial and social ecosystems, and it is a hallmark of success, demonstrating EU growth and benefit through innovation.

With a global biotech and biomanufacturing race underway, a truly integrated Single Market is key to secure European competitiveness, prosperity, resilience, and leadership. EuropaBio believes the Single Market Strategy 2025 must be translated into concrete actions, including an ambitious EU Biotech Act, that delivers on the needs of biotech innovators in the EU.

We highly welcome the Strategy's aim to make the EU simpler and faster by reducing regulatory and administrative barriers, particularly for start-ups and SMEs, to accelerate time-to-market and economic growth. To address the needs of the biotech industries, EuropaBio recommends the following:

Simplify and harmonise regulatory frameworks across member states

Regulatory fragmentation across Member States hinders the development and deployment of biotech products across the EU. Today, biotech innovators have to navigate a complex and inconsistent framework between Member States which is slowing down or preventing products from reaching the European market. We urge the Commission and the Member States to simplify and harmonise regulatory requirements by accelerating product approval timelines and increasing support for innovators. There is also a need to boost the capacity of regulatory networks and accelerate the digital transition to streamline processes and reduce delays (see examples in the Annex).

Strengthen Intellectual Property (IP) Protections

Biotechnology innovation relies heavily on robust IP rights. IPR enable innovators to raise capital to support development and access to market. Even as European innovators face challenges with access to investments, ensuring the protection of biotech innovation in Europe and globally is essential. Ensuring strong and predictable IPR for biotech, including for proprietary data submitted to regulatory agencies and protection for certain products, as well as ensuring a level playing field on the global market are essential to a world-class biotech and life science ecosystem.

Tailored Support for Small and Mid-sized Companies

Within the ecosystem, smaller companies are the forefront of biotech discovery and innovation. Simplified access to funding, reduced bureaucratic burdens, fee reductions and targeted capacity-building initiatives will enable smaller biotech innovators to scale and innovate more effectively. While simplification measures will already bring significant benefits to smaller companies, tailored support

should be explored to ensure those innovators can fully benefit from the Single Market, including by adopting sector-specific definitions of SMEs that reflect company maturation cycle within industries.

Building a Next Generation Ecosystem

The biotech ecosystem is highly productive with a labour productivity and job creation rates outperforming other industries such as the digital or financial sector.[1] Building a next generation ecosystem with skilled and high-quality employment, globally resilient value chains, and integration and benefit within all Member States will require the full benefits of the Single Market.

Involve Stakeholders in Policymaking

The biotechnology sector welcomes deeper engagement in shaping policies that affect its operations. We urge the Commission to establish dedicated platforms for dialogue with biotech stakeholders, ensuring our insights inform future strategies and legislation.

[1] Measuring the Economic Footprint of the Biotech Industry in Europe Data-Update 2021.pdf pp. 10 & 12.

Annex – Examples of Regulatory Burden on Biotech Innovators

Industrial Biotech[2]		Health Biotech	
Regulation 1829/2003 on genetically modified food and feed products	Uneven implementation of Regulation 1829/2003 is jeopardizing the Single Market's ability to function properly for fermentation products. Food and feed products produced from Genetically Modified Organisms are regulated by Regulation 1829/2003, with the presence of viable cells as the only regulatory criterion determining whether products fall in scope of this regulation. However, an uneven enforcement of the regulation for fermentation products not in scope has resulted in numerous RASFF alerts with immediate withdrawal of products from the EU market leading to significant economic repercussions for manufacturers.	**Regulation (EC) No 536/2014 on clinical trials**	Inconsistent implementation between Member States, including on the use of prolongation and coordination and consistency between and across ethic committees, is creating significant burden on sponsors.
Regulation (EU) 2015/2283 on novel foods	The recent proposed bans on the sale of cultivated meat by Italy and Hungary have the potential to disturb the free movement of goods as companies would be faced with restrictions on their products in specific national markets. These national bans are also unjustified as they fully overlook the existing product authorisation procedure in the Novel Foods Regulation 2015/2283 and ultimately undermine European and national competitiveness.	**Regulation (EU) 2021/2282 on health technology assessment**	Implementation of the Regulation is leading to significant unpredictability for health technology developers on assessment timeline, selection criteria, and fit-for-purpose guidelines for ATMPs and OMPs. Concerns remain about sustainability of the network, including availability of slots for JSC and the resources to carry out JCA on all products falling into scope. Significant hurdles remain to enable EMA and HTA processes to run fully in parallel, including ensuring no duplication of data between processes and Member States. Current

[2] Industrial biotechnology uses enzymes and micro-organisms to make biobased products from renewable raw materials in sectors such as chemicals, food and feed, detergents, paper and pulp, textiles, and bioenergy.

			governance and transparency rules, including the role of the HTA Stakeholder Network, could be improved to facilitate dialogue and collaboration between authorities and stakeholders.
Regulation (EU) 2020/852 on Taxonomy and Delegated Regulation (EU) 2023/2486 (Environmental Delegated Act)	Inconsistent application of the sustainable finance Taxonomy framework has resulted in disincentives for bio-based products. The Environmental Delegated Act introduces a restriction on the use of primary biomass for bio-based plastic packaging. In the absence of criteria for other bio-based products, some Member States are extending this restriction, leading to decisions against financing biomanufacturing projects for other bio-based products. Restrictions on the use of primary biomass for bio-based products that were not anticipated in the Taxonomy framework prevent biotech companies from investing in Europe and create uncertainties for the biotech industry.	**Directive 2011/24/EU on cross-border healthcare**	Inconsistent implementation of the cross-border healthcare Directive is placing a disproportionate burden on patients requiring innovative therapies due to its complexity and inadequacy to meet their needs. Lack of information, high upfront payment for healthcare costs and uncertainty over reimbursement, and complex administrative barriers are faced by cross-border patients and carers which add to the burden of their condition.
Regulation (EC) No 178/2002 on general food law	We recognise the important role the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) plays in ensuring health and safety across the entire food supply chain. However, some committee discussions may be in conflict with provisions laid out in EU law, creating significant uncertainties for the industry and that could lead severe delays in implementation. These include: 1. The uneven enforcement of Regulation on food and feed products produced from Genetically Modified Organism, as referred to above, which was already discussed and concluded at SCoPAFF level in 2004. Some Member States asked for this to be rediscussed in SCoPAFF with a view to change the 2004 SCOPAFF conclusions and align with their own interpretation despite the Commission Legal Services having provided its	**Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products**	Inconsistent application of the transparency Directive remains an issue, recognised by the Commission study published in September 2024, and impacting its functioning. For the health biotech industry, non-adherence to timelines remains an issue. The Directive is also increasingly incoherent with today's market and new legislation such as the Health Technology Assessment Regulation.

	interpretation of the Regulation. This topic has been under discussion at SCoPAFF level since 2021. 2. The reinterpretation of the definition of the term 'natural' in the Flavourings Regulation (EC) No 1334/2008. This is driven by some Member States despite no lack of regulatory clarity. The topic has been under discussion since 2023. 3. The proposal to regulate certain uses of food cultures under two different regulatory frameworks (i.e. as food additives and as food ingredients). This proposal would create different requirements for food cultures. This topic has been under discussion since 2004.		
Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms	An improved regulatory approach for all microorganisms, including those which are used in a live form, is needed to generate an accessible pathway to market for these types of products. The current regulatory framework in this Directive is not suitable for these products and cannot currently be applied.	**Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (for medicinal products)**	For medicinal products, the inconsistent application of the Directive is leading to significant burden on the health biotech industry in the EU. Significant burden is placed on innovators preparing applications for therapies consisting or containing GMOs, including significant differences between Member States on data requirements, processes, and timing despite the use of a common application form as well as common request for additional information from competent authorities.