

## Completing the picture: A modernised European Union for Industrial Biotechnology

### Introduction:

Industrial biotechnology, encompassing the use of DNA and microorganisms, is one of the EU's most dynamic and enabling technologies. It is deeply embedded across a wide range of sectors, including those currently under pressure from supply chain disruption and inflation.

Applications such as microbial fermentation are central to Europe's transition towards a sustainable, competitive and resilient bioeconomy. They offer transformative potential across applications including industrial processes and manufacturing, agriculture, food and environmental remediation. By reducing reliance on fossil-based inputs and helping to simplify complex supply chains, industrial biotechnology strengthens Europe's resilience to global supply shocks.

However, despite its maturation, this technology remains highly exposed to international competition, as other regions rapidly scale biomanufacturing capabilities and consolidate their positions global value chains.

To maintain and strengthen its leadership, the EU must now complete the legislative and ecosystem progress initiated in the current mandate, especially through a dedicated legislative vehicle such as the EU Biotech Act II. Progressive legislation that addresses access to feedstock, development of capacity and creation of market pull, must be combined with simplification and harmonisation within the world-leading safety standards for which the EU is renowned.

### EFIB Den Haag Statement – A modernised European Union for Industrial Biotechnology

Since its launch in 2021, the annual EFIB Statement has set out key priorities to advance policy and market maturity for industrial biotechnology in the EU. Important progress has been made, with legislative developments such as the EU Biotech Act I and the Food and Feed Safety Simplification Omnibus beginning to reflect sector needs.

Building on the progress, the 2026 EFIB Statement outlines the next steps required to fully mature the industrial biotechnology ecosystem, focussing on regulatory frameworks, stakeholder engagement, and financing conditions to secure the EU's role in global markets and supply chains.

## **Ask 1 - Modernising regulation and policy: A dedicated, horizontal EU Regulation for microorganisms**

The EU should establish a dedicated, horizontal EU Regulation on microorganisms, reflecting established and state-of-the-art scientific knowledge, delivering a cohesive approach across relevant sector-specific legislation.

Such a horizontal Regulation would apply across sectors (excl healthcare applications into patients, which has a highly specific regulatory framework) and across contained use & deliberate release, covering all categories of microorganisms.

It would provide legal certainty and enable safe microbial innovations to reach the EU single market with greater confidence for investors and innovators.

*Ask: A dedicated, comprehensive EU framework for microorganisms that creates confidence and coherence for innovation, investment and EU resilience.*

## **Ask 2 - Education and awareness: Future-looking stakeholder engagement and representation**

Effective policymaking must reflect societal needs and expectations. In biotechnology, however, debates often remain shaped by outdated narratives that no longer reflect today's scientific, economic or consumer realities.

At a time when global competitors are advancing rapidly, continued hesitation risks undermining the EU's ambitions and competitiveness. Policymaking must therefore actively engage citizens, stakeholders and innovators in a forward-looking dialogue that supports informed decision-making.

*Ask: Policymaking platform that engages and represents consumer, stakeholder and citizen voices for the future*

## **Ask 3 - Financing innovation: Delivering a mature funding and collaborative framework**

The EU has excelled in building an innovation foundation for industrial biotechnology, despite more challenging market pathways compared to other global regions. This has produced waves of innovators, from the start-ups breaking the innovation frontier through to mature global companies delivering biotechnology at scale across sectors.

The financial and collaborative ecosystem has a role to support these maturing technologies and enable market delivery. This requires an evolution of funding and collaborative mechanisms.

The EU Biotech Act has created a strategic project framework for healthcare biotechnology delivery and this can be extended into industrial biotechnology through the upcoming Act Part II. This can be further reinforced through extending eligible costs within collaborative projects to beyond TRL 7 - reflecting the needs of late stage innovators, especially in smaller companies.

*Ask: Create a mature funding and projects ecosystem for industrial biotechnology close to market.*