

## EU biotech and biomanufacturing Initiative

### Key asks for Industrial Biotechnology

The EU biotech and biomanufacturing initiative is a unique opportunity for the EU to take urgent and immediate actions to support the scale up of the EU biotech and biomanufacturing sector. This must be coupled with a regulatory environment that encourages investments in research and development, fosters innovation and market access. The EU must also provide incentives that attract the best in class for skills, in both business and biomanufacturing.

The EU biotech and biomanufacturing sector contributed circa 35 Bn EUR to the EU (+UK) economy with 224.600 direct jobs in 2021, representing a Gross Value Added (GVA) of 3.2% for the whole biotech sector (3.7% for industrial biotech) compared to an overall of 2.1% GVA for the total EU (+UK) economy.

Industrial biotechnology uses enzymes, microorganisms and living cells to make biobased products from renewable raw materials. This is a key enabler of the EU's transition from a fossil-based economy to a green and competitive bioeconomy in multiple sectors, including chemicals, pharmaceuticals, food and feed, fragrances, detergents, paper and pulp, textiles, and bioenergy. A global technology race is underway in the industrial biotechnology sector. The winners will lead global manufacturing and trade in several sectors. Their economies will be more competitive, sustainable, and resilient. By reducing their dependency on non-renewable resources and harnessing a broader range of food and feed production technologies, they will strengthen their strategic autonomy and food security.

Building on its strong science and research base, and the EU Commission's recent announcements on its ambition for European leadership in new technologies, Europe now needs to create impact from these good intentions and to reinforce its competitiveness. We have identified specific key asks for a globally competitive EU Industrial biotechnology sector that delivers sustainable innovative solutions. We call on these specific key asks to be considered in the forthcoming European Commission Biotechnology and Biomanufacturing initiative alongside [5 common cross-sectoral principles](#).

#### 1. Need for harmonised national and EU frameworks for enabling biotechnology (principle 1)

The EU needs to develop a 'whole Europe' approach to harmonise and align the framework for biotechnology and biomanufacturing in a similar manner to countries such as the US, China, India that have all developed national frameworks combining strategy, policy, and fiscal incentives. With that in mind, we call for the creation of an **EU office of biotechnology** across all European Commission directorates that can support the implementation of the EU biotechnology and Biomanufacturing Initiative and monitor related policy developments to ensure coherence therefore avoiding potential unintended divergence. Because of the broad strategic opportunities that biotech offers, a coordinated effort across all industrial sectors and their policy directorates will be crucial for the success of the initiative and for the development of safe and sustainable biotech solutions.

We also recommend exploring the development of specific vehicles i.e. EU own resources to create a level playing field for innovative products, such as a sustainable non-fossil levy (similar to a Plastics Levy on recycled plastic waste) and/or a **mechanism for VAT that recognises sustainable products**. We also recall the requirement for EU Member States in the EU's Eighth Environment Action Programme ((EU) 2022/591) to strengthening environmentally positive incentives as well as phasing out environmentally harmful subsidies in line with EU and international commitments.

## 2. Address regulatory hurdles to accelerate market access and enhance global competitiveness (principles 2 & 3)

The EU needs to undertake a **comprehensive review of its regulatory approach to biotech and biomanufacturing** to significantly accelerate market access to products as it is currently experiencing disproportionately low or lack of adequate approval process for certain biobased products compared to other regions. For example, the lack of harmonised approach in the implementation of the legislation<sup>1</sup> applying to fermentation products, as well as the lack of testing procedure capability for novel foods, such as cultivated meat, currently hinders their development phase. There is also the recognition that the GMO framework is no longer fit for purpose and needs to be adapted to scientific and technical progress<sup>2</sup>. Sectorial legislation, such as the proposal on Sustainable Use of Pesticides Regulation, does not address the approval timelines of biocontrol products, despite incentivising their use, while the Farm to Fork Strategy does not provide biotech pathway alternatives for the target of pesticide reduction by 50%. Despite high-level political ambitions, all these legislative inconsistencies and inadequacies combined with higher CAPEX, energy prices in Europe and higher subsidies for biotech in other regions currently result in increased manufacturing relocation outside the EU thus leading to reduced supply chain security and resilience.

As part of the comprehensive review of regulatory approach to biotech, possible solutions to explore include the **development of codes of practices** (e.g. the Dutch authorities have issued a Code of Practice which allows tasting based on a safety assessment performed by a company relying on an independent expert-committee); **EU market pull measures** and **biobased targets** in product legislation; and **EU public procurement programmes** (e.g. similar to the USDA "BioPreferred" programme<sup>3</sup>) to guarantee a minimum level of demand for bio-based products.

## 3. Improve access to feedstock and recognition of sustainability (principles 2 & 3)

To secure long term investment commitments at the appropriate scale in the EU, it is also imperative to secure a reliable supply of sustainable feedstock for the bioeconomy. EU's ambition to de-fossilise its economy will only happen if the EU Commission sets the necessary safeguards for a sustainable use of EU primary biomass. This requires **defining sustainability criteria** as well as developing robust and updated sustainability methodologies which accurately measure the LCA (Life Cycle Assessment) credentials of innovative materials using alternative feedstocks and produced with innovative processes. We therefore urge the Commission to develop a proper **accounting mechanism for bio-**

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<sup>1</sup> Directive on the contained use of genetically modified micro-organisms (2009/41/EC and relevant sectoral legislation on e.g. food enzymes, feed additives, novel foods

<sup>2</sup> [EU COM Proposal for a regulation of the European Parliament and of the council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation \(EU\) 2017/625](#)

<sup>3</sup> <https://www.biopreferred.gov/BioPreferred/>

**based Carbon across key policies** such as EU Emission Trading System (ETS), coupled with a review of the **Product Environmental Footprint (PEF) methodology to account for biogenic Carbon**. It is also crucial to adapt the sustainable finance **Taxonomy framework to recognise the distinction between biotech and conventional processes**. Both the NACE and the CPA (Regulation 2008/451 - New statistical classification of products by activity) already have dedicated classification categories for biotech research activities and this should be extended to all biotech activities.

#### **4. Support infrastructure scale up and improve access to skills (principles 4 & 5)**

To promote the bioeconomy through the whole value chain, the EU must support both the creation of demonstration and pilot facilities as well as larger-scale commercial facilities using **financial commitments, public private partnerships, and mechanisms from across programmes over the long term** (e.g. Important projects of common European interest). These would need to be complemented by the **creation of specific education programmes and training centres of excellence** connected to manufacturing such as for example the Biotech campus Delft, the EU Biotech campus in Belgium and the National Institute for Bioprocessing Research and Training in Ireland<sup>4</sup>. There should also be a mechanism to ensure harmonisation and complementary between EU and national programmes.

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<sup>4</sup> [Biotech campus Delft \(https://www.biotechcampusdelft.com/\)](https://www.biotechcampusdelft.com/), the [EU Biotech campus \(https://biotechcampus.eu/\)](https://biotechcampus.eu/) and the [National Institute for Bioprocessing Research and Training](https://www.nibr.ie/) in Ireland (https://www.nibr.ie/)

## **EC Initiative on Biotechnology and Biomanufacturing: Principles for an impactful Europe**

### **February 7, 2024**

A global technology and market race is underway within biotechnology and biomanufacturing. Successful regions will lead innovation, manufacturing and trade across multiple sectors, with competitive and sustainable next generation economies and strong global trade presence.

Europe has long been recognised as a leader in biotechnology research and innovation. However, its transition into industrial application and manufacturing at scale is proceeding at a slower pace than other regions, with consequences already felt for citizen and economic benefit, investment, competitive global positioning, green transition targets and supply chain security.

The EU Initiative for Biotechnology and Biomanufacturing is a unique opportunity for the EU to build on its strong research and innovation base towards clear industrial, societal and market targets.

**Five core principles** should underpin goals for Europe's approach to biotechnology and biomanufacturing, not only within the proposed Initiative, but integral the European Union's implementation of industrial strategy across sectors. Principles should be embedded into consideration of legislations, ensuring convergence, rather than divergence, for innovation across frameworks.

- 1. Recognise societal and economic benefits from biotechnology and biomanufacturing, with a predictable and coherent policy framework throughout value chains that enables growth and transformation across sectors.**
- 2. Ensure competitive market access for biotechnology and biomanufactured products in Europe and allow European companies to be active contributors into globally resilient supply chains, with informed citizen confidence, including clear regulatory pathways for innovative advances.**
- 3. Unlock the full potential of Europe's Single Market for biotechnology processes and biomanufacturing, including for people, goods, services, and capital.**
- 4. Create Investment frameworks for biotechnology and biomanufacturing, including access to risk capital within Europe, to facilitate multi-scale production facilities and biorefineries and achieve pan-European capacity.**
- 5. Apply Innovation Principles within R&D priorities for biotechnology (including digital and AI advancement), enhance intellectual property protection and develop skills to accelerate industrial transition and production through innovation.**