

## A Biotech Act that works for food innovation

The EU Biotech Act presents a unique opportunity to position Europe as a global leader in biotechnology and biomanufacturing. To achieve this, the Act must provide a strategic framework that unlocks the full potential of Europe's scientific excellence and industrial capacity **across all areas of biotechnology, including food applications.**

Realising this potential will require tackling the structural barriers that hamper biotech innovation and deployment, such as **regulatory uncertainty, limited access to finance, and infrastructure gaps.** These challenges are interlinked across health and industrial applications, and cannot be solved in isolation. A coordinated EU response under the Biotech Act would unlock mutual benefits and accelerate progress across the entire biotechnology landscape.

Within this broader effort, **food biotechnology** can be a critical driver of the EU's competitiveness. Recent [McKinsey analysis](#) projects that the global market for advanced biotechnology beyond pharmaceuticals could grow from \$200-300 billion today to \$700 billion-\$1.1 trillion by 2040, with food biotechnology – and processes like **precision and biomass fermentation** – representing **\$130-395 billion** of this potential. Given its potential to reduce emissions, relieve pressure on land use, and strengthen Europe's strategic autonomy, food biotechnology will become crucial to achieving the EU's long-term climate and industrial objectives.

**To support food biotechnology,** the EU should pursue the following priorities through and beyond the Biotech Act:

- 1. Give the Biotech Act the scope and ambition Europe needs**
- 2. Close the funding gap through targeted public investment**
- 3. Ensure a clear and evidence-based path to market for food biotech innovations**
- 4. Future-proof funding and policy priorities beyond the Biotech Act**

### 1. Give the Biotech Act the scope and ambition Europe needs

The Biotech Act must translate Europe's growing political momentum around biotechnology into a cross-sectoral policy vision. There's a clear consensus on the need for a comprehensive, coordinated approach to fully unlock the potential of biotechnology. The European Commission's [Life Sciences Strategy](#) already calls for a holistic approach to biotechnology, while a European Parliament's [own-initiative report](#) and recent Council [conclusions](#) urge that **the Biotech Act capture the full breadth of the biotechnology and biomanufacturing industry, including its food applications.** Failure to include food biotechnology risks leaving a central pillar of the EU's innovation capacity underdeveloped and the EU losing its competitive edge to international competitors.

The next step is to turn that consensus into action. The Biotech Act should follow the example of initiatives such as the Net-Zero Industry Act and the Chips Act, serving as an industrial policy instrument that combines regulatory streamlining, targeted investment, and long-term political commitment to a key strategic sector.

## 2. Close the funding gap through targeted public investment

To translate Europe's scientific strength into economic impact, the Biotech Act must help close the financing and scale-up gap that continues to hinder industrial biotechnology, including food biotech. Financing high-risk, early-stage projects remains one of the sector's biggest barriers. These projects often face high capital costs, uncertain returns, and long payback periods, making them unattractive to traditional private investors. **Public funding and risk-sharing mechanisms** are therefore essential, particularly to support the transition from pilot-scale innovation to industrial-scale production.

In the alternative protein sector, specifically, capital expenditure (CAPEX) for self-owned demonstration

facilities typically ranges from \$1 million to \$ 20 million, while commercial-scale facilities can cost between \$15 million and \$150 million or more. Research estimates that investments should reach €2.7 billion annually from 2025 to 2050 to expand the EU's fermentation capacity from 7.5 million to 505 million litres for proteins produced from biomass and precision fermentation<sup>1</sup>. Europe has a strong foundation, with [almost half of the world's food-grade fermentation capacity](#). But as the sector grows, investment in infrastructure must accelerate.



**€2.7 billion in annual investment will be needed through 2050 to scale the EU's capacity for fermentation-enabled proteins from 7.5 to 505 million litres.**

### 2.1 Mainstream food biotechnology in EU funding programmes and instruments

While (food) biotechnology is recognised as a strategic technology, it still lacks dedicated funding programmes. The Biotech Act should commit the EU to expanding support for industrial biotechnology, including food biotechnology, through a diversified mix of grants, guarantees, and equity tools spanning the full innovation cycle, from research and innovation to deployment and commercialisation.

- Grants: Existing instruments should be leveraged more intentionally, for example, through the creation of an **EIC Industrial Biotech STEP call** and (food) biotech-focused calls in **Horizon Europe work programmes**. Upcoming programmes, such as **FP10**, should also be designed with industrial biotech and its various applications (including food) in scope.
- Guarantees: A dedicated **Industrial Biotech window under InvestEU**, as well as future instruments like the **European Competitiveness Fund**, should be mobilised to de-risk private financing.
- Equity: The upcoming **Scale-up Europe Fund** and similar mechanisms should explicitly include industrial biotechnology companies among their eligible beneficiaries.

<sup>1</sup> Systemiq, "Fermenting the Future: The Opportunity of Precision & Biomass Fermentation for the EU" (pre-published version available on request)

## 2.2 Strengthen the EIB mandate to support food biotech scale-up

The EIB's latest [report](#) on investment gaps in the bioeconomy acknowledges that “bioeconomy investments are often considered too risky or not profitable enough in the short term to attract sufficient private financing.” The report further notes that “barriers to financing can be alleviated with more targeted financial products [...] specifically designed for bioeconomy sectors,” adding that such instruments can be blended with private capital to de-risk investment. A separate EIB [report](#) on scaling bio-based industries highlights that food and feed ingredients have strong growth potential, provided that additional capital is mobilised to support their deployment.

Although the EIB has taken important steps to support the bioeconomy, the majority of its portfolio remains concentrated in agriculture and forestry, with limited support for food innovation and food biotechnology. In this context, establishing dedicated programmes for industrial biotechnology, including food biotechnology, would fill a critical gap in the EU's financial architecture and bring the sector in line with practices in other strategic sectors.

- The Biotech Act should mandate the Commission and the European Investment Bank (EIB) Group to create an **Industrial Biotech Fund, backed by ring-fenced guarantees under InvestEU and the future European Competitiveness Fund**.
- In addition, a joint **EC-EIB Biotech Finance Lab** should be established to convene investors, innovators, and policymakers to co-design financing solutions.

## 2.3 Launch an “Advanced Fermentation” Flagship Initiative

Europe faces an acute shortage of pilot and first-of-a-kind (FOAK) infrastructure for fermentation technologies. The Commission's [Life Sciences Strategy](#) already commits to “support the scale-up and uptake of sustainable advanced fermentation by promoting innovation through public-private partnerships and supporting the scaling-up of startups and SMEs.”

Building on this commitment, the Biotech Act should establish an **Advanced Fermentation Flagship Initiative** that recognises fermentation as a cross-sector enabling technology. The initiative, potentially structured as a public-private partnership, should **support pilot and FOAK fermentation facilities, including food-grade facilities**, as well as facilitate regional **“Advanced Fermentation Valleys”** to pool infrastructure, supply chains, and skills.

## 2.4 Set out EU-wide manufacturing and infrastructure targets

The Biotech Act should set **indicative EU-level targets for industrial biotechnology infrastructure** – for example, aggregate biomanufacturing capacity to be achieved by 2035 or 2040 and benchmarks for new pilot and FOAK facilities. Clear targets, similar to those in the Net-Zero Industry Act, can signal policy stability by demonstrating that biotechnology is a strategic industrial priority and attract private investment.

### 3. Ensure a clear and evidence-based path to market for food biotech innovations

Food biotechnology will only thrive if regulation reflects its realities. The existing EU regulatory landscape for food biotech provides a robust, science-based framework for food safety, but is often criticised for its [slow](#) and [costly](#) implementation, which discourages start-ups and scale-ups from prioritising the European market. Targeted improvements should be sought via the Biotech Act to ensure the process for European innovators is more predictable and transparent while maintaining high safety standards.

#### 3.1 Advance process-based reforms to the premarket authorisation process for innovative producers



**Singapore and the US lead in food biotech approvals with clearer, faster pathways, while the UK is actively developing new regulatory approaches to support innovation.**

**To remain competitive, the EU should pursue targeted interventions that enable timely market access and enhance dialogue between innovators and regulators.**

As noted in a [recent academic paper](#), the EU path to market for new food biotechnologies is characterised by substantial delays and inconsistencies. Authorisation timelines often exceed statutory limits by months or years, reflecting procedural inefficiencies and variable submission quality. These delays make it difficult for companies to forecast market entry and revenue, creating financial uncertainty. Against this backdrop, the EU has become a high-risk market for start-ups and SMEs, where potential returns are outweighed by the costs associated with prolonged regulatory processes.

The Biotech Act should aim to make the EU regulatory process more efficient without entirely reopening it. Targeted, process-based updates could remove unnecessary burdens for producers and be implemented quickly and efficiently. These could include:

- **Guidance:** Pre-submission guidance should clearly define testing and data requirements for different production platforms, including concrete examples to aid applicants. EFSA's 2024 revision of the [Novel Food guidance](#) is a step forward, but further alignment with best practices is needed. For example, Singapore's [Requirements for the Safety Assessment of Novel Foods](#) tailors guidance to specific food biotech production methods and is revised on a regular basis to keep pace with rapid innovation in the sector. These changes could be achieved without regulatory amendments, provided there was clear instruction to EFSA in the Biotech Act.
- **Pre-submission consultations:** Consultations for producers as covered in the General Food Law (GFL) Regulation have a very narrow scope, focusing only on administrative matters despite producers' need for substantive feedback on study design and technical requirements to inform applications. A formalised pre-submission consultation process, based on a systematised version of EFSA's [call for expressions of interest for SME advice](#) or examples from food regulators in [Australia and New Zealand](#) and [the US](#), would help companies engage early with regulators, clarify safety dossier requirements and prevent bureaucratic delays. Extending the scope of pre-submission advice would require Article 32a (1) of the GFL Regulation to be amended to include wording allowing applicants to ask technical and scientific questions and to secure non-binding feedback on study design from EFSA during the submission process.

- **Clarity on amending applications:** The Act should instruct EFSA to clarify routes for safety dossiers to be amended during and after product authorisations to reflect product development. The dynamic nature of the food biotech sector means products submitted for approval may be refined as production processes improve and scale-up occurs. The Act should direct EFSA to outline which changes can be made within existing applications and which require new dossier submissions, providing examples of these to aid clarity. This non-regulatory intervention would avoid wasted regulatory effort on outdated dossiers and unnecessary trade-offs for producers between dossier submission and product innovation.

### 3.2 Clarify the regulatory status of GMM products

In combination with the upcoming EU Food and Feed Simplification Omnibus, the Biotech Act should deliver **a harmonisation of approaches to levels of residual DNA in fermentation products produced with GMMs**. As [noted by experts](#), the presence of recombinant DNA in a product does not constitute a safety risk in itself. Modern fermentation products are produced under containment with premises and work processes designed to prevent the release of GMMs into the environment, as well as the production of final products that do not contain any live GMM cells. The Commission should:

- Clarify that the **10 ng/g threshold is an analytical limit of detection**, not a regulatory trigger, and ensure consistent interpretation across Member States.
- **Reject zero-tolerance approaches for residual DNA** that impose disproportionate costs and administrative burdens on the advanced fermentation industry.
- **Prevent duplicate pre-market authorisation requirements for GMM products** under multiple EU frameworks, which duplicates work and costs for applicant companies with no benefit to consumer safety.

### 3.3 Enable testing spaces for new and innovative technologies

The Commission aims to accelerate the transition of biotech products from lab to market, yet limited testing opportunities, especially for SMEs, prevent producers from trialling innovations and generating data for scale-up. **Regulatory sandboxes** could address this by allowing technologies to be tested under strict supervision, helping regulators and producers build expertise together without lowering safety standards.

**The Biotech Act should enable regulatory sandboxes in food biotech by providing Member States with the legal clarity to design national sandboxes within a common framework.** This could be done by amending GFL Regulation Article 3 (8) to clarify that 'placing on the market' does not include the pre-market, non-commercial testing of food and feed in a controlled environment, and providing explicit encouragement to Member States to pursue opportunities for sandbox development within the Act.

To properly support the food biotech sector, **these sandboxes should be equally applicable across all regulated food and feed product categories, including novel foods and products regulated under the GM Food and Feed Regulation**, ensuring that the full range of production technologies benefit from the opportunities that sandboxes provide.



**The benefits of sandboxes are broad. For regulators**, understanding innovative products helps refine risk assessment approaches and proactively identify gaps in expertise. **For innovators**, they offer a space to develop products in line with regulation while allowing flexibility where existing frameworks don't yet account for new technologies. They also help producers prepare stronger applications, thereby contributing to a more efficient regulatory process.

**A strong example is the UK [regulatory sandbox](#) for cell-cultivated products**, which enables producers to co-design consumer safeguards and regulatory pathways with the regulator. [Positive feedback](#) highlights that it meets a critical need for businesses and regulators on emerging technologies.

#### 4. Future-proof funding and policy priorities beyond the Biotech Act

For the EU to remain competitive and resilient in the global biotech landscape, the Biotech Act should establish governance structures for oversight, strategic review, and collaboration, ensuring the EU can respond effectively to geopolitical, technological, and market trends.

##### 4.1 Create a “Biotech for Europe Platform”

The Biotech Act should establish a permanent **Biotech for Europe Platform to steer policy and funding priorities**. The Platform should be chaired by the Commission, with participation from Member States and stakeholders from industry, the research community, and civil society. It would monitor progress under the Act and, similar to the Net-Zero Europe Platform, could help coordinate EU and national funding and policies for biotech.

##### 4.2 Publish a regular Biotech Competitiveness Review

The Commission should commit to publishing a **Biotech Competitiveness Review** every two to three years, **benchmarking Europe's performance against that of its global peers** (e.g., the US, China) **on key indicators such as access to finance, regulatory efficiency, and biomanufacturing capacity**. A dedicated Biotech Competitiveness Review would ensure that Europe systematically monitors its relative position, identifies gaps, and takes corrective action (including investment) to avoid falling behind and to secure long-term global leadership in this strategic sector.

#### About the Good Food Institute Europe

The Good Food Institute Europe is a nonprofit and think tank helping to build a more sustainable, secure and just food system by diversifying protein production. We champion the science, policies and investment needed to make alternative proteins delicious, affordable and accessible across Europe.

By advancing plant-based foods, cultivating meat from cells and producing ingredients through fermentation, we can boost food security, meet our climate targets and support nature-friendly farming. GFI Europe is powered by philanthropy.

Pauline Grimmer  
Policy Manager

 [paulineg@gfi.org](mailto:paulineg@gfi.org)

## Annex: Overview of GFI Europe’s policy recommendations

<p><b>Give the Biotech Act the scope and ambition Europe needs</b></p>	<ul style="list-style-type: none"> <li>• Ensure the Biotech Act includes food biotechnology in its scope.</li> </ul>
<p><b>Close the funding gap through targeted public investment</b></p>	<ul style="list-style-type: none"> <li>• Expand existing EU funding instruments for food biotechnology, including through an EIC Industrial Biotech STEP call, an Industrial Biotech window under InvestEU, and dedicated calls under Horizon Europe and FP10.</li> <li>• Leverage future mechanisms such as the Scale-up Europe Fund and the European Competitiveness Fund to de-risk financing.</li> <li>• Establish an Industrial Biotech Fund between the European Commission and the European Investment Bank (EIB), supported by ring-fenced InvestEU guarantees.</li> <li>• Create an EC-EIB Biotech Finance Lab to connect investors, innovators, and policymakers and co-design financing solutions.</li> <li>• Launch an “Advanced Fermentation” Flagship Initiative to support the build-out of pilot and first-of-a-kind (FOAK) fermentation facilities, including food-grade facilities.</li> <li>• Define EU-level targets for biomanufacturing capacity, similar to targets under the Net-Zero Industry Act.</li> </ul>
<p><b>Ensure a clear and evidence-based path to market for food biotech innovations</b></p>	<ul style="list-style-type: none"> <li>• Provide clear pre-submission guidance defining testing and data requirements for all production platforms.</li> <li>• Expand pre-submission consultations under the General Food Law (GFL) to allow technical and scientific queries and non-binding EFSA feedback.</li> <li>• Instruct EFSA to clarify how safety dossiers can be updated during and after authorisation to reflect ongoing product development.</li> <li>• Clarify the regulatory status of GMM products.</li> <li>• Establish regulatory sandboxes for food biotechnology by providing Member States with the necessary legal clarity to develop national frameworks under the GFL regulation.</li> </ul>
<p><b>Future-proof funding and policy direction beyond the Biotech Act</b></p>	<ul style="list-style-type: none"> <li>• Create a “Biotech for Europe Platform” to steer policy and funding priorities.</li> <li>• Publish a regular “Biotech Competitiveness Review” to benchmark Europe’s progress against global peers on access to finance, regulatory efficiency and biomanufacturing capacity.</li> </ul>