Call for Evidence

Biotech Act II

June 10, 2026

Contents

Introduction

Biomanufacturing encompasses multiple sectors, including health and bioeconomy applications. All sectors are critical for support within Biotech Act Part II, with the same global manufacturing supply chain risks on the horizon.

Industrial biotechnology (bioeconomy) is Europe's most dynamic but also most exposed manufacturing mechanisms - as the world moves quickly to scale and dominate existing and new supply chains. It is the fastest-growing subsector of the EU economy by gross value added, growing at 5.3% per year in 2022. This is more than twice the 2.6% EU economy average, while all-biotech GVA grew at 4.7% over the same period. Industrial biotechnology employment expands 7.5 times faster than the EU average. Each job supports 3.4 further jobs across the broader economy. Across all biotech sectors, productivity stands at €160,000 GVA per person employed. 2.85 times the EU average, higher than finance, ICT, or automotive.[1]

Yet this sector is structurally exposed and not yet mature within the EU (likewise in other global regions which are also now racing to maximise their capacity). Between 2015 and mid-2025, EU biotech companies received €25 billion in venture capital against €219 billion in the United States. Sixty-six of sixty-seven EU health biotech companies that went public over the last six years were listed on non-EU exchanges.[2] Novel Food approval for fermentation products can take up to six years in the EU versus approximately one year in the United States or Singapore. Biocontrol products can require seven to eight years for EU authorisation against two to three years in competitor markets.[3]

Biotech Act Part I, published on 16 December 2025, addresses some elements of health biotechnology and food simplification. It does not explicitly address biomanufacturing. By the Commission's own design, it defers industrial biotechnologies (a substantial component of biomanufacturing), the level playing field, and horizontal enablers to a second act. Seven Member States have formally demanded an ambitious Act II.[4] Fourteen supported a broad scope at the November 2024 Competitiveness Council.

An opportunity for Europe: Global performance from a strong base

The EU has established itself as a strong biomanufacturing region, driven by significant conventional sectors adapting to future ambitions and its incredible innovation base. Its momentum to date has been driven by a framework of individual strategies and legislations and the EU must now adopt the higher level strategy and policy focus on biomanufacturing that other global regions have established, if it is to consolidate its innovation and production excellence. With the Biotech Act II, this very opportunity exists and the EU can mobilise to ensure competitive future across multiple sectors.

EU-Level Performance

The 2025 WiFOR Institute's study, covering all 27 Member States from 2008 to 2022, reports direct GVA from EU biotechnology at €38.1 billion in 2022, nearly doubled since 2008. A total footprint of €75.1 billion when indirect and induced effects are included.

Industrial biotech leads on growth. Its GVA grew at 5.3% per year, more than twice the 2.6% EU economy average. Industrial biotech employment grew 7.5 times faster than the EU average. Each direct job generated 3.4 further jobs, the highest employment multiplier of all biotech sectors. The sector's trade surplus reached €51.7 billion in 2022: a sevenfold increase since 2008, with export growth of 10.6% annually against 4.3% for total EU exports.[1]

Conventional statistics systematically undercount industrial and agri-food biotechnology. They count only dedicated biotech R&D companies, missing the far larger population of companies that use biotechnology as a production tool across agri-food, chemicals, cosmetics, and materials.

A new methodology developed by Assobiotec and the Politecnico di Milano traces biotechnology use across all sectors of the Italian economy, not just dedicated biotech R&D companies, and illustrates the scale of this gap.

While traditional surveys counted fewer than 1000 biotech companies in Italy, the new approach identified nearly 6,000. A sevenfold difference.[5] Neither France nor Germany, Europe's largest industrial biotech

[1]WifOR Institute, Measuring the Economic Footprint of the Biotechnology Industry in the European Union, March 2025

[2]European Commission, COM(2025) 1022, European Biotech Act Proposal, 16 December 2025

[3]EuropaBio, Biomanufacturing: Europe's Industrial Future, February 2025 - Novel Food regulatory timeline

[4]Council of the EU, Non-paper from DK, NL, FI, EE, LV, LT, PT delegations on the EU Biotech Act, February 2026

[5]Assobiotec-Federchimica / Osservatori Digital Innovation, Politecnico di Milano, Il Biotech in Italia 2025: Numeri, storie e trend, December 2025

economies, have an equivalent national mapping study. The same structural gap almost certainly exists across all Member States. The true economic footprint of industrial biotechnology is considerably larger than any current EU-level aggregate captures.

Examples of National Biotech Value Chain Footprint

Fermentation - According to France Fermentation, the French fermentation sector generates around €1.8 billion in annual revenue, across 25 production sites, employing over 10,000 people, with €700 million in exports. The sector consumes approximately 780,000 tonnes of sucrose and 320,000 tonnes of glucose syrup annually, supplying yeast and bacterial cultures essential to food and beverage production, as well as amino acids, vitamins, probiotics, flavours, biofertilisers and biocontrol agents. *France Fermentation estimates that the addressable market for innovative fermentation products that could be industrialised in France exceeds €3 billion*.

Bio-based Chemicals and Materials - Germany's chemical industry uses bio-based feedstocks for an estimated 6 to 15% of its inputs, generating approximately €3 billion in bio-based value added and employing around 25,000 people in bio-based chemical production. This footprint is real, but it has not yet translated into production scale in the most strategically important emerging categories. As illustration, globally, bio-based plastics represent only 1% of total plastic production, and Asian producers are on track to exceed 70% of the global capacity by the end of this year.[6] At the moment, Germany has no large-scale bio-based plastics production plant.

Cosmetics - Bio-based active substances, enzymatically produced molecules, precision fermentation ingredients, and bio-sourced surfactants are displacing petrochemical and conventionally extracted botanical ingredients across skincare, haircare, and fragrances. *Cosmetics already represents 30% of the French bio-sourced products market by volume*. [11] The European ingredients footprint spans enzymatic active ingredients (e.g., Italy's PlantaRei company, that has achieved 80% CO_2 reduction versus conventional chemical synthesis[7]), bio-sourced surfactants (BEGOODN, recipient of €4.06 million, France 2030), and fermentation-derived aromas and specialty esters (CALIPSO, €4.19 million, France 2030).

[6]Beck-O'Brien, M., Bringezu, S. et al., Monitoring the German Bioeconomy: Status, performance, trends and implications for sustainable development, SYMOBIO / Thunen Institute, University of Kassel, December 2024

[7]ADEME / France 2030, Bilan thematique: Produits biosources et biotechnologies industrielles, Edition 2025

The innovation pipeline is strong, and Europe currently has world leading fermentation capacity

Europe leads the world in quality of biotech research, producing more *top-cited publications in agricultural, industrial, and health biotechnology than the United States or China*.
In industrial-specific infrastructure, *Europe hosts twice the precision fermentation capacity of the United States,* 479 demo and pilot biomanufacturing plants (90 dedicated to industrial biotech), and 2,362 biorefineries.[3] However, this position is changing.

Risks and Opportunity

A global industrial re-orientation for biomanufacturing is underway and China is not the only country to have recognised that industrial biotechnology is a strategic industry requiring fast State policy.

India's BioE3 Policy (Biotechnology for Economy, Environment and Employment), approved by the Union Cabinet in August 2024,[8] represents the first dedicated biomanufacturing policy framework from the world's most populous country. It targets a $300 billion bioeconomy by 2030, up from $130 billion in 2024 and $10 billion in 2014. The proposal has six designated thematic sectors including high-value bio-based chemicals, biopolymers and enzymes, smart proteins and functional foods, and climate-resilient agriculture. The policy *establishes 16 biomanufacturing hubs and a Bio-RIDE financing scheme (INR 9,197 crore, approximately €1 billion),* integrating bio-foundries with scale-up infrastructure in a model *explicitly designed to bridge the pilot-to-commercial gap that European policy has not yet solved*.

New Zealand's Gene Technology Bill, introduced to Parliament on 17 December 2024,[9] is set to end a near-30-year effective ban on GMO releases that since 1998 had permitted only three unconditional environmental releases. The bill replaces the Hazardous Substances and New Organisms framework with a dedicated Gene Technology Regulator, a *risk-tiered approval system, and explicit international alignment with trading partners*. The Health Select Committee revised draft was published in October 2025. Its second reading is pending. *New Zealand is unlocking gene technology for agriculture, food, and biomanufacturing applications at precisely the moment Europe remains constrained by its own GMM and Novel Food frameworks*.

To highlight, that this comes of the back of March 2023's **United States' White House Bold Goals for US Biotechnology and Biomanufacturing report** and its formal target of producing *at least 30% of its chemical demand through biomanufacturing pathways within 20 years*.

The competitive challenge from China, however, operates at a different order of magnitude. Where India and New Zealand are building enabling frameworks, China is executing a State-directed industrial campaign that is already eliminating European producers in specific molecule categories. And that is explicitly designed to expand.

China's Long-Term Biomanufacturing Strategy

China's 14th Five Year Plan for Bioeconomy Development (2021–2025)[10] was China's first dedicated bioeconomy plan, identifying biomanufacturing as one of four strategic priorities alongside biomedicine, bio-breeding, and bioenergy. The **15th Five Year Plan (2026–2030)** escalates this. A critical terminological signal: *"biotechnology" has been progressively replaced by "biomanufacturing" in the preparatory documents.[11] This is a deliberate shift from R&D to industrial-scale execution*. Biomanufacturing is *placed in the "future industries" tier alongside quantum computing, 6G, and brain-computer interfaces, receiving national procurement support, venture capital incentives, and an R&D super-deduction rate of 200%* (companies can deduct twice their actual R&D spend from taxable income.)[7] China's Ministry of Industry and Information Technology has separately announced a dedicated 15th FYP biomanufacturing sub-plan, with flagship product identification and AI-enabled production cases.[12]

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[8]India Department of Biotechnology, BioE3 Policy (Biotechnology for Economy, Environment and Employment), approved Union Cabinet 27 August 2024.

[9]New Zealand Gene Technology Bill, introduced in Parliament 17 December 2024; Health Select Committee revised draft published October 2025.

[10]China Daily, 14th Five-Year Plan for Bioeconomy Development, May 2022.

[11]Central Committee of the CPC, 15th Five-Year Plan Recommendations, October 2025

[12]China Briefing from Dezan Shira and Associates, dedicated 15th FYP biomanufacturing sub-plan, 2025–2026

Three Categories of Biomanufacturing Threat to the EU

The following categories demonstrate the speed of progress in other global regions and direct impact on EU lead companies. This is still early enough in global positioning for biomanufacturing, that the EU can strengthen its position for key products, unlike other sectors where manufacture has now consolidated to such an extent as to prevent the EU from being able to enter these markets. Biomanufacturing is the technology platform where we can still consolidate a significant global footprint, and Biotech Act II will be pivotal.

1. Already Displaced - China already dominates global production of key fermentation-based molecules, including amino acids (L-glutamate, L-lysine, L-threonine, L-tryptophan), citric acid, vitamin C, vitamin B-series compounds, industrial enzymes and probiotics, all of which are consumed in Europe and a major part of the human and animal food chains. [3]

In citric acid, China produced approximately 2.6 million tonnes in 2024, representing around 60% of global production, accounting for roughly 71% of global export volume. [13] In vitamin C, concentration is even more pronounced: China accounts for around 80% of global production capacity, leaving EU consumption overwhelmingly import-dependent on Chinese suppliers. [14]

In methionine, where Europe still retains significant production, Asia already accounts for nearly half of global capacity, with China at roughly 35% and expanding, while leading European producers are under increasing competitive pressure.

This displacement reflects structural advantages in fermentation economics, corn-based glucose integration, and sustained, state-backed capacity scaling.

2. Manufacturing process Conversion in Progress - The glufosinate case is the clearest completed example and a template for what follows. Glufosinate is one of the world's most widely used broad-spectrum herbicides. It is applied post-emergence in genetically modified soybeans, corn, canola, and cotton engineered to tolerate it, and used for pre-planting burndown weed control across these and other crops. It is the primary alternative to glyphosate where resistance has developed, making it critical to global food production and weed resistance management. The global market was valued at approximately $2.8-2.9 billion in 2025.[15]

Historically, glufosinate was produced via chemical synthesis, yielding equal proportions of the active **L-isomer** and inactive **D-isomer**, with roughly half the output effectively wasted. Chinese producers developed **enzymatic biocatalytic processes** that selectively produce only **L-glufosinate**, delivering a quality, yield and cost advantage simultaneously at industrial scale.

By May 2024, Glufosinate ammonium prices had collapsed to ~38,000 yuan/tonne, 50% below the prior year and the lowest in nearly a decade.[16] The product continues to be used in export markets globally and is now supplied exclusively from China.

This template is now in motion for lactic acid and PLA (where fermentation produces pure optical isomers impossible to replicate via chemical synthesis), succinic acid, polyhydroxyalkanoates and second-generation biosurfactants.

European companies, including the former DSM/Roquette Reverdia succinic acid joint venture (discontinued as Chinese capacity drove global prices below European production costs) have already experienced the pattern - state-backed overcapacity arrives, prices collapse, and European scale-up investment cases disappear.[17]

3. China's Next-Generation Targets: Europe Is Not Competing - China's 15th FYP explicitly targets microbial proteins, functional food ingredients via precision fermentation, and synthetic biology platforms[14] markets that do not yet exist at industrial scale globally.

China is building production capacity now, while European innovators in precision fermentation face up to six-year Novel Food approval cycles, absent scale-up financing, and no strategic procurement to anchor demand. China's synthetic biology infrastructure, including the Shanghai synthetic biology cluster, one of

[13]IndexBox, Global Citric Acid Market Overview, November 2025

[14]Market.us, Global Vitamin C Market Size, Share, And Business Benefits by Grade, October 2025

[15]Mordor Intelligence, Glufosinate Market Report, 2025

[16]ECHEMI, China: the price of Glufosinate ammonium TK hit a new low in ten years, May 2024

[17]Bioplastics magazine, DSM and Roquette cancel joint venture Reverdia, February 2019

the world's largest, is being built to enable programmable cell factories producing any molecule at industrial scale on demand.

European industry has independently reached the same conclusion about where the opportunity lies. The AB4S coalition, whose members include Evonik, Lallemand, and L'Oréal, quantified a $1.1 trillion global market opportunity for advanced biotechnology in its inaugural report with McKinsey,[18] and in its Molecule Manifesto published March 2026 identified terpenes, peptides, non-catalytic proteins, and hydroxy acids as the four priority molecule families ready for immediate commercial scale-up.

The overlap with China's strategic targets is not coincidental. Both assessments point to the same conclusion: the race to industrialise these molecule categories is already underway. Europe has the science and the companies. It does not yet have the policy conditions to compete at scale.
The following table maps some of the principal bio-based molecules referenced above, their applications, China's production position, and current European industrial presence.

Molecule	Key applications	China's position	European presence
Amino acids (L-lysine, L-glutamate, L-threonine)	Animal feed, food flavouring, pharmaceuticals, infusion therapies	China dominant globally; large-scale integrated facilities with subsidised glucose supply	Evonik (Germany) and CJ BIO Europe active but under sustained price pressure; margins shrinking vs Chinese production costs
Citric acid	Food/beverage acidulant, cleaning agents, pharmaceuticals, cosmetics	2,6M t/yr output, 60% world capacity, 71% exports	No significant EU commodity-scale production remaining; European players displaced
Vitamin C (ascorbic acid)	Food fortification, pharmaceuticals, cosmetics, animal feed	>80% of global production capacity and >80% exports	EU overwhelmingly import-dependent; no domestic production at industrial scale
Methionine	Poultry and swine feed (essential amino acid; birds cannot synthesise it)	Asia 64% of global capacity; China 35% and expanding through new enzymatic routes	Evonik (Germany) is the largest non-Asian producer
Glufosinate	Broad-spectrum herbicide: post-emergence use in GM soybeans, corn, canola, cotton; critical alternative where glyphosate resistance has developed	Chinese enzymatic L-isomer process delivers higher purity at lower cost; drove global price collapse to ~38,000 yuan/t (May 2024, -50% YoY)	July 2024 - Europe's last large-scale producer; EU now import-dependent for export-market supply
Lactic acid / PLA	PLA bioplastics packaging; food preservation; cosmetics (AHAs); pharmaceuticals; surgical sutures	Dominant in commodity lactic acid; expanding PLA capacity rapidly; fermentation produces chirally pure L-isomer that chemical synthesis cannot match	Corbion (Netherlands) key EU lactic acid producer; Futerro (Belgium) and TotalEnergies Corbion are PLA - cost pressure from China.
Succinic acid	Bioplastics); pharmaceuticals; food additives; surfactants; 1,4-BDO precursor	State-backed overcapacity reduced global prices below European production cost floors	EU producers declining in number, with other facilities under review.

[18]Advanced Biotech for Sustainability (AB4S) coalition / McKinsey & Company, Harnessing the Economic and Environmental Benefits of Advanced Biotechnology, March 2025

Molecule	Key applications	China's position	European presence
PHAs / PHB	Biodegradable packaging; agricultural mulch films; biomedical devices; slow-release coatings	Chinese producers (Bluepha, Ecomann) rapidly scaling; dominating emerging market before EU reaches commercial production	POLYPROD (France 2030) — EU's first industrial-scale PHA facility, still pre-commercial; Biomer (Germany) in niche pharmaceutical/medical grades only
Biosurfactants	Detergents; cosmetics and personal care; industrial cleaning; food emulsification; enhanced oil recovery	China scaling rapidly via industrial biotechnology; cost advantages in rhamnolipid and sophorolipid production	Evonik (Germany, rhamnolipids) and Holiferm/Unilever (UK/EU, sophorolipids) R&D leadership strong; industrial scale still limited; BEGOODN (France 2030, €4M) under development
Microbial / precision fermentation proteins	Alternative proteins; functional food ingredients; animal feed; cosmetics actives	15th FYP explicit strategic target; state-backed biofoundries and biomanufacturing hubs under construction now	EU innovators technically strong but face ~6yr Novel Food approval cycles; limited EU industrial-scale production; risk of China pre-empting market before EU regulatory pathway opens

The consequence of inaction for EU industrial and supply chain resilience

Competition lost: China moves first, Europe will be dependent

When China converts chemical production to biotechnological routes, three simultaneous advantages compound the displacement effect:

- **Cost convergence:** at the Chinese fermentation scale, with integrated glucose and other supply chains and state-financed facilities, biotech routes are now cost-competitive with, or even cheaper than, chemical synthesis at the European scale.
- **Selectivity advantage:** fermentation produces specific optical isomers with high efficiency that chemical synthesis cannot. This creates quality and regulatory advantages that premium markets reward, as glufosinate demonstrated.
- **IP accumulation:** first-mover commercialisation builds proprietary strain libraries, process datasets, and downstream processing know-how, creating durable competitive barriers for later European entry.

China is explicitly building to capture European demand. Its 15th FYP identifies bio-based chemicals and materials as strategic targets. Its state-industrial model, based on subsidised facilities, integrated glucose supply chains and 200% R&D super-deductions, is designed to produce at cost floors that European producers cannot match without equivalent structural support.

The scenario is not hypothetical: Europe is replicating its gas dependency and AI lag uptake. This time in bio-based molecules critical to food security, packaging, textiles, and pharmaceutical supply chains where it still has a scientific lead.

Capacity erosion is near irreversible

The erosion is already measurable. Germany's broader bioeconomy employment fell approximately 11% between 2010 and 2017, a structural decline during a period of rising global demand for bio-based products. This was not a cyclical contraction but a symptom of shifting capacity location.

Capacity loss is irreversible in ways that financial data does not (yet) capture. When biomanufacturing facilities close, they terminate contracts with specialist process engineers, dissolve supplier relationships built over decades and end an accumulated body of fermentation and downstream processing knowledge that cannot be reconstituted in the short or medium term.

It is extremely difficult to establish long term capacity without the right market conditions. France's France 2030 programme, the EU's most ambitious industrial biotech investment to date, at €433.3 million across 20 projects, has funded a comprehensive pipeline. Yet, only one project, NACRE, operates at true commercial scale. The others remain at demonstrator or pre-commercial stage, waiting for the financing and market conditions that would justify full industrial commitment.

The Valley of Death and Company EU exit

The funding gap between public research grants and the capital needed to reach commercial scale is the single most consistently cited barrier by European industrial biotech companies. It is not a new problem, however without a comprehensive Biotech Act Part II, there are limited structural solutions.

European innovators reaching the scale-up stage face a structural choice: accept non-European capital on terms that typically require relocating headquarters, list on non-European exchanges, or abandon scale-up entirely. The financing gap for health biotechnology is documented in the Commission's Act Part I proposal, with health-biotech VC at €25 billion in the EU, compared to €219 billion in the US over the past decade.

The industrial biotech financing gap is structurally similar but lacks a documented figure, in part, because, as mentioned earlier in this report, industrial biotech is systematically undercounted in existing statistics.

The challenge is not only capital. Regulatory timelines for industrial biotech applications are a structural barrier to commercialisation that compounds the financing gap.

Application	EU approval	US / Singapore approval	EU disadvantage
Novel Food (fermentation products)	**~6 years**	**~1 year**	**6× longer**
Biocontrol products	**7-8 years**	**2-3 years**	**3× longer**

Source: EuropaBio, Biomanufacturing: Europe's Industrial Future, February 2025 - citing IBMA 2024 (biocontrol) and EuropaBio analysis (Novel Food).

Any company operating globally is structurally incentivised to launch in the US or Singapore before seeking EU approval for fermentation-derived products. This is a commercial reality that progressively drains European industrial biotech of first-mover advantage, scale-up rationale, and investor confidence. Science created in Europe is systematically commercialised elsewhere.

Narrowing Innovation Pipeline Narrows - reduced translation

Germany's patent specialisation index is already comparatively low and declining in biotechnology, biopharmaceuticals, plant breeding, and microbiomes, the areas most relevant to industrial biotech's next generation.

These are leading indicators. Industrial biotech process expertise is not transferable from research publications. When production erodes, the knowledge base that would enable the next generation of process improvement erodes with it.

Europe's lead in research publications will not protect its industrial position if the commercial infrastructure to convert that science into manufacturing knowledge is progressively eroded.

Biotech Act II: Building beyond Biotech Act I

The EU Biotech Act Part I plays a key role in strengthening the biotech ecosystem, primarily in health.

However, the biomanufacturing challenge described in this document is almost entirely beyond the scope of Part I, including for health. The following categories of industrial biotechnology policy are entirely outside the scope of Biotech Act Part I and will not be addressed by secondary instruments or delegated acts.

Topics to address beyond Biotech Act Part I		
Production	**Financing**	**Markets & Trade**
Industrial biomanufacturing facilities	Gap for industrial scale-up	Market creation tools for bio-based products
Cross-border biomanufacturing corridors	EU Taxonomy eligibility for bio-based production	Trade defence mechanisms calibrated to bio-based sectors
Feedstock access frameworks for industrial fermentation		Export frameworks for products not authorised in the EU
Process innovation for fermentation & downstream processing		
Regulatory reform for GMM-based industrial production		
Cross-cutting: Talent and Skills critical to deliver Act Part I and II and biomanufacturing at scale		

Regulatory Fragmentation and Member State mandate for resolution

The Member State non-paper identifies a specific and illustrative failure. If a food additive is produced using a GMO microorganism, two regulatory frameworks apply simultaneously: Regulation 1333/2008 (food additives) and Regulation 1829/2003 (GMO food and feed).

Each requires a separate, case-specific risk assessment conducted by different agencies on different timelines that do not necessarily align. A single product faces duplicated assessment, extended timelines, and the risk of contradictory conclusions.

The political foundation for fixing it is unambiguous. Fourteen Member States supported a broad Biotech Act at the November 2024 Competitiveness Council. In February 2026, Denmark, the Netherlands, Finland, Estonia, Latvia, Lithuania, and Portugal submitted a formal non-paper calling on the Commission to address precisely this.

Member States have called for a Biotech Act Part II that results in harmonised GMO regulations across the Single Market; coordinated risk assessment procedures across EFSA, ECHA, and EMA; long-term public-private financing for industrial biotech scale-up; market demand stimulation through procurement and standards; and national security provisions for strategic biotechnology inputs.

The EU Biotech Act II in focus

Achievements should have a tangible impact and can be clearly measured through manufacturing and trade indicators. It should enable all sectors across bioeconomy and health, building on advances for health innovation within the Biotech Act Part I.

For growing and large companies, whether in the EU or seeking to expand into the EU, this includes addressing issues such as market access and reliable access to feedstock, as these are key factors in investment decision-making. For smaller (often pre-revenue) innovators, achieving investment-critical milestones is essential, and both market access and viable feedstock supply help mitigate investor headwinds in markets where investments and access to capital are smaller.

The Biotech Act Part II, with a focus on biomanufacturing, can address bottlenecks for all companies innovating towards scale-up.

A biomanufacturing focus also allows the EU to strengthen its position as an exporter of high value/ quality biomanufactured products across multiple sectors. This will help reinforce its position within key global supply chains at a time when supply has become a geopolitical asset, while not losing sight of the fact that EU companies generate substantial revenues through exports. The Act can maximise export capability, including for products not authorised within the EU, which creates additional barriers and complexity for companies and leads to significant fragmentation across member States.

The EU is still a leader in biomanufacturing process innovation, although this will change as other regions fulfil their ambitions for biomanufacturing scale. The Act provides an opportunity to build and connect expertise across all sectors, ensuring it is recognised as a global leader in process innovation. Biotech Act I creates a promising template for ATMPs, which can be amplified across Europe's biomanufacturing hubs.

Regulatory frameworks remain the core driver of innovation and biomanufacturing. In addition to modernised frameworks within the EU, the Biotech Act provides an opportunity to monitor and respond to global trends, seeking alignment for effective regulation, especially with partner regions where strong trade links are in place.

Finally, the Biotech Act can play a coordinating role for biomanufacturing within priority value chains across the EU. It can help to build manufacturing pathways across Member States, recognising the strengths of different regions and enabling their frictionless contribution of capacity and skills into supply chains, whilst upholding national priorities for safety and innovation growth.

Biotech Act II: Challenge/Evidence – Asks - Outcome

1. Dedicated, horizontal EU Regulation on microorganisms Call for Evidence contribution: Predictability for investment, simplification		
Challenge/evidence	**Ask**	**Outcome**
Incremental progress towards use of microorganisms does not address structural barriers needed to enable the broad deployment of microbial innovation. It does not address the scale or speed of structural progress required to fully enable the EU's microbial biomanufacturing position globally The current GMO Framework in particular, including Directive 2001/18/EC and Directive 2009/41/EC, and the current definition of genetically modified microorganisms (GMMs), remains predominantly process-based and has unevenly kept pace with scientific and technological. In the case of Directive 2001/18/EC, this misalignment has been recognised by the European Commission, having resulted in an absence of genetically modified microbial products (beyond medicinal uses) on the EU market, while other global regions have enabled their use in a wider range of applications. As a result, Europe faces a growing innovation gap and risks undermining its sustainability and competitiveness objectives.	The EU should create a dedicated, horizontal EU Regulation on microorganisms. The Regulation will apply across sectors (incl. food/feed and environmental applications, but excluding advanced therapies in health). It will apply across both contained use and deliberate release conditions. It will cover all types of microorganisms (i.e. based on Categories 0, 1 and 2 microorganisms). A product-based definition of GMMs should be introduced as part of this framework. The definition of GMMs within the GMO framework and broader EU legislative frameworks should be revised and aligned with this product-based definition. The following elements create a comprehensive microorganism framework that comprehensively serves microbial applications within biomanufacturing and which incorporates current progress other legislative proposals.	The outcome is a coherent, predictable and transparent framework for the use of microorganisms that will place the EU on an equivalent industrial framework as other major biomanufacturing regions, whilst preserving the current high safety standards expected by consumers and innovators. It enables predictable biomanufacturing innovation, market access and scale, with the result that investment can increase at all TRL stages. This results in early rapid growth of innovative SMEs, EU market access as primary (rather then secondary or tertiary) option, and consolidated investment into EU biomanufacturing capacity.

	CATEGORY 0	CATEGORY 1	CATEGORY 2
DESCRIPTION	Microbial wild-type strain or microbial strain mutated using conventional methods	Genetically modified microbial strain without (functional) foreign DNA Safety equivalence with the parent strain or microbial species.	Genetically modified microbial strain with introduction of (functional) foreign DNA.
STATUS PATHWAY FOR ASSESSMENT & APPROVAL	RA & EC approval under sectoral product legislation	RA & EC approval under sectoral product legislation or Notification to EU MS relevant body and entry into an EU registry when placing on the market not subject to sectoral product legislation for an EC approved equivalent strain	**Contained use** RA & EC approval under sectoral product legislation **Placing on the market** RA & EC approval under GMO legislation + under sectoral product legislation
PROCESS FOR CONTAINED USE STRAIN CHANGES	If (sectoral) product authorisation has already been granted, review of documentation on changes to the strain by an independent certifier. Old and new strain should be Cat. 0 or 1.		If (sectoral and/or GMO) product authorisation has already been granted, approval of changes to the strain through notification procedure to EC and relevant EU authority
LABELLING OF COMMERCIAL /FINAL PRODUCT	No GMO labelling		**Contained use** No GMO labelling **Placing on the market** GMO labelling

*foreign DNA = DNA sequences not present in the pangenome of the subject species, or originating from a species that the subject species could not conceivably exchange genetic material with.

Interplay with current GMO Framework - The requirements outlined in the proposed Regulation should be adapted according to the above categories. For microorganisms falling under the introduced Cat. 2, additional requirements as should be outlined in the proposed GMO Framework, informed by the Directives 2001/18/EC,2009/41/EC and Reg. 1829/2003, could apply (e.g., GMO labelling and traceability).

Fast-track notification procedure for Cat. 1 microorganisms - For Cat. 1 microorganisms placed on the market which are being proposed to be not subject to risk assessment and may require approval under sectoral product legislation, only a notification to Member States designated relevant competent authority(ies) should be introduced under the new Regulation. This notification should be in a standardised format, requiring an appropriate, proportionate and well defined

	data set and should be subject to a corresponding maximum processing period to be defined in the Regulation. The notification could also require publication in an **EU register of notified microorganisms**. **Notification procedure for changes to Cat. 2 microorganisms used in containment already subject to sectoral product authorisation -** Changes to a Cat. 2 microorganism used in production under containment should only be subject to a notification procedure when sectoral product legislation is also applicable. The relevant notification submission should contain a detailed description of the changes to the microorganism, any changes to the production process and the final product, and provide possible risks to human and animal health and the environment and appropriate mitigating factors. In the proposed regulation, the placing on the market of products containing Cat. 2 microorganisms will require full product authorisation as is required under current GMO legislation and where relevant sectoral legislation should apply. **EU register of microorganisms -** A centralised EU register should be created to list notified Cat. 1 and authorised/approved Cat. 2 microorganisms, ensuring transparency, traceability and legal certainty for operators and regulators. **Labelling and traceability obligations -** Labelling requirements applicable to the microorganisms should be aligned to the categories (as cited above) based on risks. Labelling and traceability measures could be limited to Cat. 2 microorganism/products containing them (to be) placed on the market but may not apply to Cat. 0 and 1 microorganisms. In addition to a dedicated microorganisms framework, sectoral legislation must also unlock microbial applications, including those involving GMMs, by removing restrictive provisions such as the restriction linked to the intentional addition of GMMs in the new Regulation 2026/405 on Detergents and surfactants.	

2. Legal clarity and harmonisation across Member States Call for Evidence contribution: Simplification, Predictability for investment		
Challenge/evidence	**Ask**	**Outcome**
The EU regulatory framework lacks legal clarity and harmonised interpretation across Member States, notably regarding feed additives for export, the status of food cultures, and key regulatory definitions. The removal of the export provision from Directive 70/524/EEC in Regulation (EC) No 1831/2003 has led to divergent interpretations on feed additives not authorised in the EU but produced for third-country markets, undermining investment decisions and global competitiveness. For food cultures, despite their recognised status as food ingredients under Regulation (EC) No 178/2002 and Regulation (EU) No 1169/2011, some Member States classify certain uses as food additives under Regulation (EC) No 1333/2008. This issue has remained unresolved for over two decades, despite repeated discussions in expert groups and SCoPAFF, leading to inconsistent enforcement. More broadly, unclear and non-harmonised definitions (e.g. “bio-based”, “fermentation-derived”, plant extracts) result in divergent classification and authorisation outcomes. Ongoing discussions in SCoPAFF illustrate both the persistence of these ambiguities and the limitations of non-legally binding interpretations. The consequence of such regulatory and definitions weakness and ambiguity is that the	The EU should provide targeted legislative clarification to address persistent divergences: • Reintroduce a definition and provisions for feed additives intended for export only in Regulation (EC) No 1831/2003. • Explicitly exclude food cultures from Regulation (EC) No 1333/2008 by adding them to the list of exemptions. • Clarify and harmonise key regulatory definitions to ensure consistent classification across Member States. • Establish a legal basis for SCoPAFF interpretations to ensure their consistent and effective application.	This would ensure harmonised interpretation across Member States, strengthen legal certainty, and support more predictable investment and innovation. It would also improve competitiveness, facilitate market access for innovative products, and enable more coherent EU decision-making. The reinstatement of the export provision from Directive 70/524/EEC will directly improve the competitiveness of biomanufacturing in the EU for export. This is an essential action that helps to reduce the global economic headwinds against EU biomanufacturing (including tariffs) and reinforce a positive environment for investment into capacity within the EU. The exclusion of food cultures from Regulation 1333/2008 will resolve a decades-old single market issue and ensure full SM operation for a major economic activity. The clarification of definitions will support single market operation and make an important contribution to transparency and consistency for consumers. The legal basis for SCoPAFF interpretations would resolve a substantial single market barrier and support Member State expertise and resourcing and effective operation of a committee that has struggled to adjust to the

single market does not fully function for vital parts of EU food and feed chains, with no substantive reason why it should not be easily addressed and resolved		technical complexity of current demands of food approvals.
3. Improved authorisation procedures for EFSA Call for Evidence contribution: Simplification, Predictability for investment		
Challenge/evidence	**Ask**	**Outcome**
Current EU authorisation procedures are not sufficiently proportionate to risk, creating unnecessary burden and delays. Novel Food approval for fermentation products can take up to six years in the EU versus ~one year in the US/Singapore; analysis of 292 Novel Food applications (2018–2024) shows an average timeline of 2.56 years (±1.19), with many cases exceeding four years. Biocontrol products can require seven to eight years for EU authorisation vs two to three years in competitor markets; GM product approvals average around five years. More broadly, lengthy and unpredictable procedures, partly due to inconsistent use of "stop-the-clock" mechanisms and limited resources within EFSA, delay assessments, create bottlenecks, and reduce the overall efficiency and competitiveness of the EU system. While the Qualified Presumption of Safety (QPS) framework provides a well-established and valuable safety reference to streamline risk assessment, its scope is currently limited.	Harmonise the use of "stop-the-clock" by: • Defining clear criteria • Limiting iterative requests • Setting reasonable, clearly defined timelines for applicant response Ensure adequate resourcing and capacity within EFSA to deliver timely and efficient risk assessments. The Biotech Act II will undertake a review of EFSA operation, notably drawing on the EFSA performance evaluation and comparison with other regulatory agencies, and propose a framework for extended and efficient resourcing that maintains agency governance and independence. Further strengthen the early dialogue between innovators and regulators building on the extension of the pre-submission advice introduced in the Biotech Act I, by structuring the process and allowing for joint scientific advice. Develop qualified presumption of safety (QPS)-type publicly available lists for cell-based foods, including cell-types, media, or equipment components that are safe to use, as well as substances of concern (in processes or products, based on dialogues and results of safety reviews).	This would reduce unnecessary and unpredictable delays caused by broad, iterative or late-stage information requests, while maintaining high safety and scientific standards. Development of EFSA operational performance within established governance would have substantial benefits for EU food chain resilience and the position of the EU as facilitator of innovation and advancements through biomanufacturing, including: • Predictable dossier timelines – clarity for investment • Efficient processing of dossiers, with particular focus on innovation – incentivised EU application • Transparency for established safe/of concern components/processes and recognition of confirmed low risk innovation – accelerated innovation and investment

4. Structural improvements to the Novel Food Framework Call for Evidence contribution: Predictability for investment, simplification		
Challenge/evidence	**Ask**	**Outcome**
A key structural challenge in the Novel Food framework is the determination of novel food status, currently assessed at Member State level. The EU Novel Food Catalogue is a useful non-binding, but unfortunately insufficiently granular, tool. Its modernisation is essential to improve legal certainty, ensure harmonised interpretation across Member States, and enable efficient market access by avoiding repeated case by case assessments. This is a contributing factor to the significant barrier for novel foods within the EU, creating substantial delay and fragmentation of the single market and forcing the requirement for food innovators to seek first market authorization outside the EU. It reinforces the perception of a hostile environment for innovation within the EU. Animal cell lines used in cells culture systems, including cultured meat production, raise distinct scientific, technical, regulatory and safety assessment questions compared with GMMs. The current regulatory framework, in particular the Novel Food and the GMO frameworks, does not sufficiently reflect these specificities, including where new genomic techniques are used in the development of production cell lines.	Develop and introduce a more centralised and science-based EU approach, with earlier EFSA involvement where appropriate, to support consistent interpretation of novel food status across Member States Improve and modernise the Novel Food Catalogue: • Clear criteria, • Transparent, user-friendly and regularly updated format • Standardised detailed template for Member State reports Introduce adaptations to the Novel Food, GMO and new Microorganisms framework (see ask on *Dedicated, horizontal EU Regulation on microorganisms*) to better reflect the unique scientific and regulatory specificities of animal cell lines used in cell culture systems. These adaptations should include both legislative amendments and corresponding (EFSA) scientific guidance.	These improvements would reduce duplication, improve legal certainty and accelerate time-to-market for innovative products, while maintaining high safety standards. Clear timelines and procedural guidance would also be important to ensure predictability for applicants. A more consistent interpretation of novel food status will improv legal certainty and contribute to single market function and improve status for investment. A modernised Novel Food Catalogue will enable a transparent and harmonized EU approach for innovators, with reduced need for case-by-case assessments and double checks by both innovators and authorities. This will increase predictability and guidance for innovators, accelerate dossiers, resulting in improved status for investment.

5. Market implementation barriers & consumer understanding Call for Evidence contribution: Simplification, predictability for investment		
Challenge/evidence	**Ask**	**Outcome**
Regulatory requirements on labelling and market implementation are not sufficiently aligned with consumer understanding or market practices, creating avoidable barriers to product uptake. The use of technical or unfamiliar names of microorganisms and their products on food labels can confuse consumers and does not reflect how such products are commonly understood. The absence of early regulatory guidance on labelling creates uncertainty for applicants and can trigger late-stage changes, delaying market access and increasing costs for innovators, plus inefficient use of resources by regulators.	Amend labelling provisions to explicitly allow the use of non-technical or common microorganism or product names (including Latin names where appropriate), unless more precise naming is strictly necessary for safety reasons, in order to align with consumer understanding and market practice. Develop an updated EU definition of bio-based to include advanced biotechnologies (linked to ask on *Legal clarity and harmonisation across Member States)* Develop harmonised, meaningful and clear communication standards for biotech-derived and conventionally produced products	This would improve consumer understanding and acceptance, reduce regulatory uncertainty, and facilitate smoother and faster market uptake of authorised products. In supporting EU transparency and consistency for consumers, this enables the engagement and recognition of food and food ingredient processes and sources, for bio-based and other production pathways. It also contributes to a level playing field with fossil-derived products.
6. Institutional coordination and governance Call for Evidence contribution: Simplification, Predictability for investment		
Challenge/evidence	**Ask**	**Outcome**
Biotech-derived products, including live microorganisms, GMMs, NGT-derived organisms, enzymes and biostimulants frequently fall under more than one regulatory framework at once, spanning food, chemicals and medicines. Today there is no standing mechanism to ensure that EFSA, ECHA and EMA assess these products coherently. The result is parallel and sometimes inconsistent data requests, divergent methodologies, and outcomes that can differ for the same organism or molecule depending solely	Mandate structured cooperation between EFSA, ECHA and EMA. Establish a permanent cooperation mechanism, modelled on the "One Substance, One Assessment" approach and extended to biotech-derived products, rather than relying on case-by-case exchanges. Develop joint guidance on data requirements. Have the three agencies issue joint guidance setting out a single, coherent evidence framework, aligned with EU data-standardisation efforts. Align assessment methodologies and enable data reuse. Greater alignment of risk-assessment approaches, supported by interoperable data systems, so evidence can be reused across regimes.	This will enable consistent, coordinated assessment of products that fall under more than one framework, building on clear expectations, less duplication, and reduced uncertainty for applicants. Decisions will be consistent regardless of regulatory entry point, and more efficient use of scientific evidence. As an overall outcome, the EU regulatory framework will be more consistent, efficient and predictable, improving risk-assessment

on the regulatory entry point. This creates duplication and uncertainty for applicants and undermines the predictability that investment in EU biomanufacturing requires. A key example is the upcoming implementation of the General Pharmaceutical Legislation, where EMA will require direct engagement with ECHA, with outcomes critical for biomanufactured medicinal products within the EU.		quality, reducing duplication and uncertainty for applicants, and strengthening Europe's attractiveness for biotech investment.
7. Circularity & biomass use Call for Evidence contribution: Sustainability criteria		
Challenge/evidence	**Ask**	**Outcome**
Regulatory frameworks do not sufficiently enable the circular use of biological resources, limiting the uptake of secondary biomass and side streams in biotech production. In practice, barriers linked to classification, traceability and duplicative approvals constrain the safe use and valorisation of these inputs. Under the Waste Framework Directive 2008/98/EC, side streams may be classified as waste, requiring an end-of-waste determination before they can be used as a raw material in production processes. Under the Fertilising Products Regulation 2019/1009, the use of nutrient-rich side streams may be restricted depending on their origin and processing history. Current rules under Organic Regulation 2018/848 can unintentionally limit the use of safe	Introduce provisions enabling the safe use of secondary streams in biotech production and downstream valorisation, removing barriers linked to classification, traceability, and approval duplication. Provide clear, harmonised EU guidance on the use of side-streams in food-grade biomass fermentation, including rules for CO_2 and waste valorisation, to support circular bioproduction. Reassess existing food legislation that restricts the reintegration of food-derived waste into the food chain, where this undermines circularity objectives, while ensuring continued safety.	This would have multiple outcomes, including: • Enabling conventional manufacturing processes to meet sustainability goals and transition to net zero. • Echo industrial modernization in other global regions where use of sidestreams from conventional manufacture is now integrating into biomanufacturing. • Fully enable the circular use of renewable carbon feedstock, achieving maximum efficiency within theoretically available industrial inputs • Support the valorisation of side streams, reducing pressure for use of primary biomass • Enable more locally available circular feedstock, enhancing local

recycled nutrients and recovered resources, creating barriers to circular production and nutrient recovery despite broader EU sustainability objectives. As a result, a producer may be able to demonstrate that a recovered nutrient stream is safe, sustainable, and contributes to circularity, yet still be unable to use it in organic production because the input is not listed or authorised under the organic framework. This prevents the full deployment of fermentation as a circular technology, despite its potential to convert secondary biomass and residues into higher-value products across food and feed applications.		biomanufacturing capacity scale up, integrated industrial cluster design, reduce transport costs for materials and reduced pressure for producers to relocate towards carbon sources • Enable more efficient and sustainable bioproduction across the EU while maintaining high safety standards
8. Security of investment and scale-up finance Call for Evidence contribution: Predictability for investment, Non-legislative cross-cutting support measures		
Challenge/evidence	**Ask**	**Outcome**
Europe's risk capital remains comparatively limited and fragmented. The Draghi report identifies a significant scale gap, with 137 US venture funds exceeding USD 1 billion since 2013 compared with 11 in the European Union, while IMF analysis finds that venture funds raise substantially more capital in the US than in the EU. This shortfall is most acute at growth and scale-up stages and contributes to relocation: a substantial share of European high-growth firms have moved their headquarters abroad, primarily to the United States. In adjacent segments such as life sciences, global market	Explicit recognition of health biomanufacturing technology providers as innovation actors, with defined eligibility under the Act's industrial innovation, funding, infrastructure, and procurement instruments. Replicate/Extend BA I strategic projects into biomanufacturing for all sectors Extend EU funding instruments beyond Technology Readiness Level 7 and ensure coverage of both capital expenditure and compliance-related operating costs (including certification, verification and auditing), across relevant programmes such as the European Competitiveness Fund, Horizon Europe and the Innovation Fund. Address the growth-stage equity gap by mobilising institutional and private capital at scale through EU-level initiatives (including the Savings and Investments Union and the EIB Group's TechEU programme), and by establishing a dedicated biomanufacturing window within existing venture-scale instruments, with targeted access for SMEs and specialised service providers.	Strengthened access to growth and scale-up capital reduces reliance on non-EU funding markets, enabling European biotech firms to scale domestically rather than relocating at critical stages. Extension of biotechnology-suited project structures from BA I, creates a consistent and recognised structure for biotechnology and biomanufacturing across all sectors. Deployment-stage funding that extends beyond Technology Readiness Level 7 and covers compliance-related operating costs prevents validated processes from stalling

participation is similarly uneven, illustrating the broader structural gap in late-stage risk capital. Public funding is concentrated below deployment. Financial instruments thin out beyond Technology Readiness Level 7, and support generally covers capital expenditure but not the operating-expenditure costs associated with regulatory compliance (e.g. certification, verification and auditing). As a result, projects that are technically validated can stall before commercialisation due to insufficient financing for compliance and early market entry. The framing of biomanufacturing as a question of capacity rather than of technology has practical consequences. Funding instruments under Horizon Europe, IPCEI eligibility, European Innovation Council support, infrastructure programmes and innovation procurement are typically calibrated to downstream end product developers. The technology suppliers that enable those developers to scale, qualify and produce, are treated as suppliers rather than innovation actors. This lack of recognition stands in contrast to sectors such as medicines and medical devices, which benefit from explicit designation as public interest goods under dedicated EU legislation (e.g. in the PFAS context). Health biomanufacturing technologies, despite directly enabling these same public health outcomes, do not benefit from equivalent recognition and are therefore subject to inconsistent treatment under horizontal measures.	Link the introduction of new regulatory requirements (such as content quotas or certification obligations) to dedicated, matched funding that covers both capital and operating costs over the relevant compliance timeline, ensuring that regulatory demand is accompanied by the financial capacity for implementation. Investment and policy frameworks under the EU bioeconomy must explicitly recognize the strategic importance and specific constraints of biomanufacturing in the health sector Fiscal and funding policy should reflect the vastly different business models of industrial biotech vs health biotech. In parallel, clear governance of end-of-life bio-risk, including ownership and liability across circular supply chains, is needed to remove legal uncertainty that currently significantly inhibits uptake in health biomanufacturing (and likely other sectors).	before commercialisation, improving conversion from innovation to market. Recognition of biotechnology in the EU Taxonomy provides clearer investment signals, improves comparability with alternative technologies, and facilitates increased capital allocation from sustainable finance and institutional investors. Mobilisation of institutional capital through EU-level instruments expands the pool of patient risk finance, addressing structural fragmentation and increasing the availability of large-scale funding rounds within Europe. Linking regulatory obligations to dedicated funding reduces the risk that compliance costs act as a barrier to uptake, supporting faster and more predictable market deployment of bio-based solutions. A more coherent financing and regulatory framework across the scale-up phase improves investment predictability, strengthens Europe's competitiveness in global biotech markets, and supports retention of high-growth companies. Recognition of specific sector needs and legal commitments through product lifecycle, strengthens the impact from public (and Joint Undertaking) programmes and prevents exclusion of innovation in key points within the lifecycle of biomanufactured products.

There is limited awareness of how decarbonisation and circularity can realistically be achieved in the health sector, which is characterised by long innovation and validation cycles, strict regulatory requirements (e.g. GMP, product validation), and high safety thresholds. As a result, health biomanufacturing risks being marginalised within broader bioeconomy initiatives, despite the fact that the sector will ultimately be a major downstream adopter and integrator of innovations emerging from industrial biotechnology (biosolutions), translating them into regulated healthcare applications. Sustainable finance frameworks do not yet adequately reflect biotechnology. Under the EU Taxonomy, industrial biotechnology and fermentation processes are not clearly distinguished from conventional chemical processes, and bio-based applications are recognised only under restrictive conditions. While the Commission is revising the technical screening criteria, the current process is focused on simplification and burden reduction rather than the inclusion or refinement of additional activities, limiting the scope for addressing these gaps in the near term.		
9. From innovation to scale Call for Evidence contribution: Predictability for investment, Creating lead markets, Non-legislative cross-cutting support measures		
The current EU permitting framework does not provide timelines calibrated to biomanufacturing activities. While the Net-Zero Industry Act (NZIA) introduces maximum permit-granting timelines (12 and 18 months, or 9 and 12 months for net-zero strategic projects), these	Establish a distinct EU permitting category for biomanufacturing as an industrial activity in its own right, explicitly covering food, feed, chemicals, materials and environmental applications, and introduce binding, activity-specific permitting timelines (9–12 months) calibrated to biomanufacturing processes rather than	Predictable permitting on the activity's own terms, combined with shared scale-up infrastructure and a standing FOAK instrument, closes the key transition points where Europe's bio-based projects stall, enabling conversion of research and pilot

are designed around energy-system metrics, notably gigawatt capacity. Biomanufacturing output, typically expressed in tonnes or cubic metres, does not map onto these criteria. As a result, projects fall outside the calibrated thresholds and can, in practice, be subject to the longest applicable timelines. Moreover, eligibility is indirect: biomanufacturing is covered only as it contributes to climate or energy objectives and is not recognised as a distinct industrial activity. Similarly, the Industrial Accelerator Act (4 March 2026) extends streamlined permitting only to decarbonisation investments in energy-intensive industries (e.g. steel, cement, chemicals), leaving biomanufacturing applications in food, feed, materials and environmental services outside a dedicated fast-track regime. Investment constraints arise at two well-identified stages: the transition from pilot to demonstration and from demonstration to first-of-a-kind (FOAK) commercial deployment. Analysis by the European Investment Bank highlights structural financing gaps at these stages, reflecting high capital intensity, long development timelines and technology risk profiles that fall outside conventional venture finance models. The European Commission has estimated a substantial annual investment gap for the bioeconomy. In response, the B ioeconomy Investment Deployment Group (launched April 2026) aims to design blended finance, guarantee and risk-sharing instruments, with participation from the EIB Group, national	energy-based metrics, ensuring applicability beyond the indirect and limited coverage currently provided via net-zero or decarbonisation frameworks. Establish a standing EU-level FOAK financing instrument targeting the pilot–demonstration–first commercial transition, combining blended finance, public guarantees covering technology risk and revenue-risk mitigation (including offtake support), with stage-gated, milestone-based disbursement and a specific mandate to mobilise patient capital from commercial banks and institutional investors for capital-intensive projects with long payback periods. Develop a European network of open-access, multi-user biomanufacturing facilities at demonstration and early commercial scale, ensuring access for SMEs and scale-ups where dedicated plants are not economically viable and providing the industrial-scale capacity required to achieve cost competitiveness and overcome current scale-up bottlenecks. Align EU support frameworks with biomanufacturing development timelines by addressing the gap between time-limited startup eligibility and size-based scale-up criteria, ensuring continuity of support through demonstration and early commercialisation either by extending eligibility windows for capital-intensive deep tech or introducing a transitional bridge mechanism. Shift EU policy design from indirect support via climate or energy eligibility criteria to direct, activity-based treatment of biomanufacturing, ensuring that permitting, financing and support frameworks reflect sector-specific technical, economic and time-to-market characteristics.	leadership into commercial production capacity. Activity-specific timelines and direct regulatory recognition reduce uncertainty, accelerating project delivery and improving investment predictability across biomanufacturing value chains. A permanent FOAK financing framework mobilises patient capital at scale, lowering financing barriers for capital-intensive facilities and enabling first commercial deployments that are currently delayed or displaced outside the EU. Open-access, large-scale infrastructure increases utilisation efficiency, lowers entry barriers for SMEs and scale-ups, and supports industrial-scale validation necessary for cost competitiveness. Eligibility frameworks aligned with biotech development timelines ensure continuity of support through demonstration and early commercialisation, preventing firms from losing access to instruments before reaching revenue generation. Moving from indirect (climate- or energy-based) eligibility to activity-based support strengthens policy coherence and ensures that biomanufacturing is systematically integrated into EU industrial strategy.

promotional banks and specialised funds. However, participation from the “patient capital” tier, large commercial banks, pension funds and insurers, remains limited at this stage, constraining the scale and cost of capital available for FOAK deployment. Europe’s biomanufacturing ecosystem is strong at early stages, with extensive pilot and demonstration infrastructure. However, scale-up capacity remains insufficient. In particular, the availability of large-scale bioreactors required to achieve cost competitiveness is limited. This creates a structural bottleneck: SMEs, which typically operate at lower or variable volumes, cannot justify dedicated facilities, while the absence of shared large-scale infrastructure delays commercial deployment. Available analyses indicate that a substantial increase in biomanufacturing capacity will be required to meet projected demand by 2040.		
10. Create lead markets and a level playing field with fossil-based products Call for Evidence contribution: Creating lead markets, Predictability for investment		
Challenge/evidence	**Ask**	**Outcome**
Bio-based and biomanufactured products are central to Europe's industrial renewal, broadening the feedstock base, strengthening strategic autonomy and offering lower-carbon options across many value chains. They face a structural disadvantage that is not of their making: established products benefit from decades of process optimisation, mature supply chains and easy feedstock access, while bio-based routes contend with a persistent cost gap and weak market pull. At the same time,	Create a toolbox of market-pull measures, tailored by value chain. Provide a coherent set of demand-side instruments (content targets, labelling, public procurement, VAT and other tax measures, certificate and credit systems, and Contracts for Difference) and apply the right combination to each value chain (food and feed; chemicals, home and personal care; materials and plastics), rather than a one-size-fits-all approach. Make content targets technology-neutral. Where product-level content targets are used, define them at end-product or product-group level, and allow both bio-based and bio-attributed (mass-balance) content to count towards compliance.	Effective, proportionate demand signals that fit the maturity of each sector. Compliance pathways that reward genuine substitution without locking in a single technology. Investment flows to the most efficient routes, not only to physically bio-based ones. Dependable anchor demand that de-risks first-of-a-kind investment.

demand-side mandates introduced ahead of supply-side readiness risk imposing compliance burdens before sustainable feedstocks and intermediates are available at scale. The Biotech Act should therefore pair credible market-pull with attention to supply-side maturity, and treat bio-based and bio-attributed routes on equal terms.	Recognise bio-attributed (mass-balance) products as contributing equally to EU goals. Treat bio-attributed products as delivering the same benefits as physically bio-based products and as counting fully toward EU climate and circularity objectives. Scale public procurement to create early demand. Expand sustainable and green public procurement to build early markets for bio-based products beyond healthcare. Use fiscal incentives and buyer commitments to accelerate uptake. Deploy reduced VAT, targeted tax relief and aggregated buyer commitments to help close the cost gap and bring volumes to scale. Taxonomy criteria for sustainability finance, either within the current technical screening criteria revision, or by committing the next review cycle and related delegated acts including revisiting criteria for bio-based products • Distinguish between biotech and conventional processes in the EU Taxonomy framework • Removal of eligibility criteria for bio-based plastics which sets a precedent for other non-food applications)	*Outcome:* faster uptake, improving economics, and a self-sustaining market over time. **Overall outcome:** Fully open markets for biomanufactured products on a level playing field, giving industry the confidence to invest in Europe and accelerating defossilisation of EU value chains.
11. Sustainability, carbon accounting, and traceability that work in practice Call for Evidence contribution: Predictability for investment, Creating lead markets, Sustainability criteria		
Challenge/evidence	**Ask**	**Outcome**
Sustainability verification and accounting are fragmented (e.g., different rules in RED vs product-level approaches) and can create inconsistent incentives (including disincentives for recycling of biogenic carbon). Additional environmental impact categories beyond GHG face data availability and benchmarking challenges; poorly	Traceability: Leverage existing schemes (FSC, ISCC+, RSPO) and use the Digital Product Passport as a backbone. Adopt outcome-based, technology-neutral sustainability criteria: classify feedstocks by measurable sustainability performance and risk profiles, not fixed lists. Harmonise carbon accounting across relevant EU methodologies, ensuring biogenic carbon treatment does not penalise recycling and supports cradle-to-gate product carbon footprint approaches where appropriate.	Enhanced traceability without the requirement for stand alone novel schemes and integration alongside other technologies. Progress in sustainability that is responsive and adaptable alongside scientific and industrial progress SSbD that supports rather than constrains biomanufacturing decision-making.

designed rules risk becoming a de facto barrier to scale-up. For PEF/circularity accounting, the "assimilation benefit" of biogenic carbon through reuse cycles should be retained; carbon transfer penalties could disincentivise recycling. RED sustainability criteria (Article 29(2–7)) can be applied where relevant (e.g., biomethane/bionaphtha), but should not be applied horizontally to all feedstocks; existing frameworks (e.g., EUDR) should not be made more restrictive. On environmental categories beyond GHG: data availability constraints and unclear benchmarks; current PEF methodology does not adequately valorise sustainable feedstock choices.	If SSbD is used, keep it as guidance focusing on minimum performance thresholds and early regulatory predictability, not a prescriptive or mandatory labelling regime. Build verification on existing certification and chain-of-custody infrastructure, and operationalise traceability via Digital Product Passport to minimise reporting burden. Design any multi-impact requirements around practical data availability, with clear baselines and transitional phases.	
12. EU competitiveness and trade facilitation Call for Evidence contribution: Predictability for investment, Creating lead markets, Simplification, Non-legislative cross-cutting support measures		
Challenge/evidence	**Ask**	**Outcome**
Europe's biotech competitiveness depends on frameworks that are robust at home and compatible with global trade. Where verification and compliance systems are more restrictive or less predictable than those of trading partners, they risk distorting competition and pushing production outside the EU rather than raising standards. This matters strategically: • The EU is increasingly dependent on imports for key molecules across all sectors,	Ensure consistency between domestic and imported products. Use recognised certification schemes, mass-balance systems and, where appropriate, mutual-recognition agreements with trusted third-country frameworks, so that imports meet equivalent standards without creating duplicative or disproportionate verification burdens. Harmonise verification and enforcement at EU level. Adopt EU-wide, risk-based approaches that strengthen legal certainty and make enforcement more efficient, while avoiding unnecessary trade barriers Use strategic partnerships to keep supply chains open. Deploy trade partnerships and cooperation to remove barriers and safeguard innovation, including for feedstocks and intermediates.	Creation of a level playing field between EU and imported products, and verification that travels with the product across borders. Predictable, uniform application across Member States, lower compliance costs, and stronger investor confidence. Outcome: reduced strategic dependence, secure access to inputs, and protection of EU innovation in critical bio-based value chains.

including medicines, food, packaging and industrial supply chains, • Import dependence is growing for fermentation-based molecules such as vitamin C and citric acid. A trade-compatible, risk-based approach is therefore essential to both EU resilience and EU competitiveness.		
13. Global export simplification: DNA synthesis Call for Evidence contribution: Predictability for investment, Creating lead markets, Simplification, Non-legislative cross-cutting support measures		
Challenge/evidence	**Ask**	**Outcome**
It is essential for biosecurity and autonomy in a strategic capability that the EU has a resilient and responsible DNA manufacturing industry. It has a base of innovative DNA synthesis companies, many of which are highly advanced SMEs. However the EU does not have a competitive framework that enables these companies to compete against DNA synthesis services in regions including the US and China. This carries the very real risk that EU biomanufacturing is reliant on non-EU providers, losing the skills, economic contribution and autonomy for a critical technology. The export license submission and approval framework in the EU is not fit for purpose. It is highly fragmented across Member States, export control authorities and national frameworks are not fit for purpose to enable competitive trade. The EU has the opportunity to be a global leader within responsible and trusted DNA manufacturing, grown from European research excellence, however it does not have the	Harmonised export framework for the EU, with standardised templates across Member States Centralised EU-wide license platform – enables EU security and screening across non-EU purchasers Comprehensive guidance for full export license process and interaction across agencies (inc. Customs), standardised across Member States Maximum export licence approval time of 7 days Creation of trusted partner export framework for shared screening and expedited export licenses Global export licenses per country	Globally competitive position for EU DNA synthesis companies Increased investment and scale of DNA manufacturing within the EU Resilient and secure supply and biomanufacturing within the EU Global framework of trusted DNA synthesis partner countries Opportunity for EU to lead development of global biosecurity

commercial framework to deliver this. A safe, responsible, trusted and competitive region. Issues include: • Poorly functioning application platforms: Inefficient company operation • Unspecified approval times, often over 8 weeks, compared to other regions • Requirements to submit export licenses for individual orders within a larger batch • Limited or no guidance on requirements for export license applications, including process for corrective actions • No feedback or corrective pathways for declined export licenses • Illogical and poorly defined countries for permitted export • Limited or no framework or guidelines for reconciling discrepancies between agencies (customs vs company records) • Absence of EU-wide reporting framework for exported sequences to enable tracking of high risk patterns of purchase and assembly		
14. Biomanufacturing foresight body Call for Evidence contribution: Non-legislative cross-cutting support measures		
Challenge/Evidence	**Ask**	**Outcome**
It is a significant challenge to accurately assess EU biomanufacturing capacity across sectors within the EU, within the context of global supply chains and risks to EU resilience, security and competitiveness.	The EU creates a Biomanufacturing foresight body, which includes: • Member State representation • JRC monitoring of agreed targets for EU capacity • Industry reporting and engagement	A coordinated monitoring and foresight action for biomanufacturing will give the EU the vital and orderly framework required to achieve its ambitions in the long term. It will mobilise and engage Member States to recognize their biomanufacturing footprint

EuropaBio already publishes the WiFOr Study on the 'Measuring the Economic Footprint of the Biotechnology Industry in the European Union' based on Eurostat data, however this is a snapshot for the EU as a whole and not a comprehensive deep dive into critical supply chains or EU capacity. There is a need for a more coordinated framework to ensure that the EU's own stated ambition for biomanufacturing is accurately monitored, with foresight for trends that pose a risk and the ability to recommend remedial action at EU and MS level.	• Monitoring of long term global biomanufacturing market and production trends • Recommendations for EU own capacity within key supply chains • Recommendations for global trade partnerships in areas of key sensitivity • Biomanufacturing global innovation and capacity trends • Identification of global regulatory barriers, good practice and alignment priorities for EU biomanufacturing frameworks	and co-create a strong pathway for development, harmonization and growth.
15. EU Biomanufacturing corridors Call for Evidence contribution: Predictability for investment, Creating lead markets, Non-legislative cross-cutting support measures		
Challenge/Evidence	**Ask**	**Outcome**
The EU has enabled member States to focus on key technologies and sectors through frameworks such as Smart Specialisation Strategies and regional development programmes for many decades. It also has regional development funding programmes that partner emerging and mature regions in identified technology areas. This is supported further through impactful Joint Undertakings and IPCEI. With increased focus now on single market harmonization and lead market development, there is now an opportunity to formally tie all these elements together to genuinely test how value chains and supply chains for biomanufacturing can be meaningfully created across MS borders. This is a gap within the EU's	The EU has an opportunity to mobilise multiple tools in order to build seamless biomanufacturing corridors across Member States and leverage a biomanufacturing interface into legislative and financial tools created through the 2025-2029 mandate. Bioeconomy • Cross-border biomanufacturing corridors recognised across MS within priority value chains, including food, with MS alignment for frictionless process and transfer of materials/products. • Identify and engage logistics expertise and capacity availability and needs within corridors, with calls for expertise where gaps identified. • Alignment with Net Zero Industry Act and Industrial Accelerator Act. Health • Cross-border biomanufacturing corridors across MS • Cross-border industrial clusters integrating research centres, pilot-scale facilities, ATMP manufacturing hubs, and logistics infrastructure.	Such a programme delivers industrial KPIs linked to EU biomanufacturing ambitions, at the same time as securing resilience of supply and economic advances in Member States. It is a multi-faceted Initiative that allows Member States to identify their own strengths within an EU-wide biomanufacturing corridor, building on research and innovation excellence and driven by priority supply chains for Europe. It also helps to identify which elements of biomanufacturing are feasible within any 'preferred' programmes and which key aspects should be undertaken with closely

increasingly sophisticated armoury of tools for industrial support. Such a programme would be a test bed for the multiple legislative and non-legislative tools now becoming available, and combine real world industrial performance with validation of strategy and implementation.	• Build on Strategic Projects framework of Biotech Act I with expanded industrial supply chain coordination. • Cross-border infrastructure funding for cold chain and advanced therapy logistics. Skills and workforce mobility programmes will be embedded, including apprenticeships, fellowships, technicians, engineers.	aligned global partners and supported through trade arrangements.
16. EU Industrial Biotechnology Biomanufacturing Process Excellence Initiative Call for Evidence contribution: Non-legislative cross-cutting support measures, Creating lead markets		
Challenge/Evidence	**Ask**	**Outcome**
The EU has a significant foundation of excellence and skills in bioprocessing and is often a reason why complex innovation advances underpin novel biomanufacturing companies here. The current EU approach to the biomanufacturing of health biotechnologies (Biotech Act I) places a strong emphasis on expanding production capacity, while insufficiently recognising both the strategic importance of health biomanufacturing technologies themselves and the distinct role of health biomanufacturers. Advances in bioprocessing technologies, manufacturing platforms, and scale-up capabilities are critical determinants of efficiency, product quality and safety, speed of delivery, and supply resilience for medicines and diagnostics - yet innovation in these areas remains under-prioritised. The current EU position of excellence is not one that can be sustained without ambitious and proactive action, for two key reasons:	<u>Fermentation Process Innovation Initiative</u> • Dedicated Industrial programme focused on biomanufacturing through fermentation process innovation, to include upstream steps such as strain development and downstream processing. • Maximum integration through CBE JU and FP10, including EIC – roadmap for achievements • Creation of a commercial bioprocess innovation platform <u>EU ATMP Biomanufacturing Process Innovation Initiative</u> • Dedicated industrial programme focused on advanced therapy manufacturing technologies (automation, closed systems, AI-driven process optimisation). • Public-private partnerships for modular manufacturing standards and interoperable platforms. • Regulatory sandboxes for manufacturing innovations (GMP adaptation pathways). • Establish a legal mandate for the sector-aware application of horizontal regulation on health biomanufacturing technologies, through guidance, delegated acts or sector-specific provisions, to reflect the volume, validation	The EU maintains and strengthens a globally competitive position in excellence for next generation biomanufacturing. This continues to strengthen a global advantage that the EU has built over the decades. This has the dual effect of enabling 'fit for the future' employment profiles in diverse regions across the EU and supporting the commercial creation and growth of innovation resulting from EU research. Finally, it continues to deliver the EU ambition of high quality jobs within a knowledge-driven economy.

• All global regions have identified skills and process excellence as a bottleneck for competitiveness and have initiated programmes to address this. The EU focus on biomanufacturing in this mandate was initiated in part by the 2023 Executive Order from President Biden, which flagged skills and bioprocess excellence as a major focal point. • As other global regions focus on scale up and supply chain dominance in biomanufacturing, bioprocessing excellence will be integral to achieving their aims. Countries such as China have already pivoted into process and innovation excellence within healthcare and substantially reshaped global markets.	and pharmacopoeial constraints that horizontal frameworks do not currently capture.	