

Fraunhofer Group for Resource Technologies and Bioeconomy

Europe's Biotechnology Imperative: Turning Legislative Intent into Industrial Impact and European Resilience

Europe's future will be shaped by what it does in biotechnology. From food security and advanced materials to climate resilience and circular chemistry, Europe's scientific leadership, industrial strength, and strategic autonomy face mounting pressure. Fragmented national approaches, gaps in scale-up infrastructure, and regulatory complexity, paired with rapid advances in the United States and China, underscore the need for coordinated action. Central to any credible response is research and innovation: sustained funding for fundamental and applied science, strong translational programs, pilot and demo facilities, and a regulatory framework that speeds safe adoption. The impact of the Biotech Act II will hinge on how effectively R&I is prioritized across the full pipeline, from discovery to deployment to determine whether legislative intent becomes industrial reality.

Scope, Ambition, and Coherence

Biotech Act II must address the full breadth of biotechnology's transformative industrial, agricultural, and environmental potential, the domains of white, green, and yellow biotechnology that underpin Europe's bioeconomy, food sovereignty, and industrial decarbonization. The Commission's framing of Biotech Act II as a complement to Biotech Act I is the right approach, but the ambition must be commensurate with the scale of the challenge. Limiting scope, delaying delivery, or compromising on funding commitments would be a strategic mistake. A partial strategy will produce partial results and Europe cannot afford that.

Critically, Biotech Act II must be designed in close coherence with Biotech Act I. Shared enabling infrastructures (biomanufacturing platforms, AI-driven process optimization, fermentation facilities, and system analysis capacities) serve both health-oriented and industrial biotechnology. Regulatory frameworks, investment signals, and data governance architectures must be harmonized across both Acts to prevent contradictions, duplication, and compliance fragmentation. The two Acts must together form a coherent, interlocking legislative architecture covering the entire European biotechnology value chain.

Investment Architecture and ECF Alignment

To translate Biotech Act II from legislative intent into measurable industrial impact, its objectives must be hardwired into the European Competitiveness Fund (ECF) policy windows. The ECF should recognize bio-based industrial value chains, biomanufacturing infrastructure, and circular biotechnology systems as strategic European assets, eligible for ECF funding on par with other deep-tech priorities. This alignment will channel capital to near-term deployable, high-TRL, drop-in solutions that integrate into existing value chains, reducing time to market and deployment risk. An ecosystem approach is essential: robust SME, startup and scaleup support must be paired with the catalytic role of large industrial actors, whose pilot and large-scale capabilities, operational efficiency, and value-chain synergies accelerate implementation and amplify impact. Without this structural anchoring, even the best-designed legislation will not generate the sustained investment momentum required for scale.

Within this financing architecture, positive, milestone-based incentives that reward transfer-readiness and technical feasibility can improve predictability and speed of uptake. To bridge the commercialization gap, a stage-gated startup roadmap from TRL 4–7 translation to

scale-up, with predictable support and financial tools, can de-risk progression. Strategic coordination is essential, including an IPCEI on Biotechnology to mobilize cross-border investment and state aid for biomanufacturing assets, and stronger continuity across FP10 (Pillar II), the EIC and the ECF to ensure a connected pipeline from research to market. Incentive design should reflect not just technologies but also organizational capability, encouraging focused 1:1 collaborations between research and technology organizations (RTOs) and companies, including short- to mid-term demonstration, transfer, and commercialization projects that ensure industrial relevance.

The following areas are of the highest strategic relevance for European competitiveness under Biotech Act II:

Biotechnology Domain	Key Application Areas
White Biotechnology	Industrial fermentation, bio-based raw materials, enzymatic processes, circular chemistry
Green Biotechnology	Climate-resilient agriculture, biological plant protection, sustainable food systems
Yellow Biotechnology	Insect-based bioprocesses, novel protein sources

Industrial Biotechnology and Bio-based Raw Materials

Biotechnological Proteins and Fats: Raw Materials for European Industrial Sovereignty

A critical bottleneck for European industry and the food sector is the supply of proteins and fats, creating deep dependencies on imported, volatile, or environmentally harmful raw materials. Biotechnological processes unlock new, resilient sources of functional proteins and lipids that serve as novel, circular building blocks for food, chemicals, materials, cosmetics, and specialty applications. Key technologies include precision fermentation, microbial oils, single-cell proteins, and the use of fungi, yeasts, bacteria, plants, insects, and algae. Europe needs integrated platforms that replace increasingly scarce plant-based resources and petrochemical fats, enabling a reliable raw material base independent of global market disruptions. Decentralized fermentation infrastructure, locally available waste feedstocks, short supply chains, and AI-based process control create economically and ecologically robust systems that stabilize food supply chains while simultaneously providing strategic raw materials for the chemical and manufacturing industries. Europe's high regulatory and quality standards are not merely compliance burdens; they represent a genuine competitive advantage that drives international demand for bio-based products produced on the continent. Biocatalytic refining and functionalization of biotechnologically produced raw materials represents a unique European selling point: proteins and fats can be precisely tailored to industrial specifications, such as emulsifiers, specialty lipids, polymer building blocks, or high-value food and feed ingredients. Microbial cascades and cell-free systems further enable valorization of previously untapped biomass streams, significantly increasing resource efficiency and reducing dependence on fossil-derived or low-quality imported inputs. This directly addresses one of the core problems identified in the Call for Evidence: the EU industry's excessive dependence on virgin fossil feedstock. Precision fermentation and microbial production platforms offer proven, scalable pathways toward de-fossilization of chemical and materials value chains, precisely the transition

that Biotech Act II is mandated to accelerate. In this context, projects that valorize biomass side-streams and CO₂ as feedstocks, supported through complete “waste-to-product” value-chain demonstrations and drop-in outputs, can shorten time-to-market and reduce risk. To underpin scalability, standards defined at the design stage can enable consistent “waste-to-product” transitions and interoperability across sectors.

Policy Recommendation: Biotech Act II should support the establishment of scalable platforms for precision fermentation, microbial oils, and single-cell proteins, and systematically open existing decentralized fermentation infrastructures across Europe. The ECF should designate these platforms as strategic industrial assets eligible for structural co-funding. Flexible access and co-funding models must enable high utilization rates, industrial application, and rapid transfer into regional value chains. Inclusion of 1:1 RTO–company collaboration mechanisms for short- to mid-term demonstration and transfer can ensure industrial relevance. Structured knowledge sharing under clear confidentiality frameworks can speed transfer while protecting IP.

Biotechnology-Derived Materials: Enabling Europe's Industrial Transformation

The transition away from fossil-based plastics and petrochemicals toward bio-based, circular, and regionally available material systems is one of Europe's defining industrial transformation challenges and a core focus area for Biotech Act II. Biotechnology offers scalable, high-quality alternatives that directly respond to the market fragmentation and competitiveness deficits identified in the Call for Evidence:

- Bio-based monomers and polymers produced via fermentation, enzyme technology, and cell-based platforms replace petrochemically derived polyamides, polyesters, and polyurethanes, creating new, climate-relevant raw material pathways and reducing fossil feedstock dependency across the chemicals, plastics, textiles, and construction sectors identified as priority lead markets in the Call for Evidence.
- Biotechnological recycling platforms, from enzymatic depolymerization to microbial degradation and re-biopolymerization, enable recovery of textiles, packaging, and PET streams into high-quality secondary materials, creating genuine closed-loop systems and new markets for specialty polymers and green chemicals.
- Targeted polymer functionalization via enzymatic modification yields materials with advanced properties: stimuli-responsive polymers, novel additive chemistry, and specialty polymers for electronic, industrial, and high-performance applications, creating differentiated European product categories that compete on quality and sustainability rather than price alone.
- Bio-based alternatives to PFAS through functionalized biopolymers address one of Europe's most pressing environmental and regulatory challenges across industrial, packaging, and consumer applications, opening significant new market opportunities as PFAS restrictions tighten.
- Market uptake depends not only on supply but also on demand signals: calibrated market-pull tools, such as blending quotas and product and material specifications in priority markets, can accelerate adoption without compromising safety.

The utilization of heterogeneous waste streams as feedstocks is becoming a new economic segment that simultaneously strengthens regional processing infrastructure and advances Europe's circular economy objectives, directly aligned with the Circular Economy Act and the sustainability criteria dimension outlined in the Call for Evidence.

Policy Recommendation: Biotech Act II should expand regional biotechnology-based materials and recycling platforms, building on existing EU initiatives and infrastructure such as Fraunhofer's Circonomy Hubs®. Open-access frameworks, co-funding mechanisms through the ECF, and clear regulatory pathways, including streamlined permitting and authorization timelines, are essential to bring bio-based materials and PFAS alternatives into industrial application at scale.

Resilient Agricultural and Food Systems: Biotechnological Solutions for Food Security and Climate Resilience

Securing European food systems amid geopolitical uncertainty, growing import dependence, and accelerating climate change constitutes a strategic challenge of the highest priority. Europe possesses the necessary infrastructure, scientific expertise, and industrial capacity to build truly resilient agricultural systems, but must urgently accelerate research investment, regulatory modernization, and public acceptance. Key biotechnological levers include:

- Nutrient recovery biotechnology: Scaling fermentation and purification processes for recovering nitrogen, phosphorus, and organic materials from wastewater and agricultural waste streams, producing high-quality nutrient solutions for plant production and urban supply systems, directly reducing dependence on imported synthetic fertilizers and aligning with the fertilizers simplification work referenced in the Call for Evidence.
- New Genomic Techniques (NGTs): The responsible use of NGTs is strategically essential for accelerating the availability of pathogen-resistant, climate-adapted, and high-yielding crops, minimizing crop losses while reducing dependence on pesticides and synthetic fertilizers. The EU's regulatory framework for NGTs must be science-based and proportionate, and Biotech Act II should provide the policy clarity needed to unlock European NGT-based breeding capacity at scale.
- RNAi-based plant protection: RNA interference as a bio-based plant protection principle enables highly specific, residue-free pest control, reduces chemical pesticide dependence, and simultaneously protects biodiversity, soil, and water quality.
- Automated and AI-supported production systems: Vertical farming process chains, robot-assisted harvesting technology, and AI-driven growth control systems ensure stable yields under extreme conditions while strengthening regional value creation and reducing land-use pressure.
- Circular nutrient modeling: Mathematical multiscale models (reactor–process–plant) and scale-up routes support the transfer of circular agriculture technologies to pilot and demonstration scale, closing biological and technical nutrient cycles efficiently and providing the evidence base required for investment decisions.

Policy Recommendation: Biotech Act II should provide targeted support for integrated demonstration and scaling platforms encompassing biotechnological nutrient recovery, NGT-based crop improvement, RNAi-based biopesticides, and automated agricultural systems. Coordinated EU investment, including through the ECF, and a harmonized, science-based regulatory framework, particularly for NGTs and plant protection products, are necessary to close regional material cycles, reduce import dependencies, and strengthen European food sovereignty. This approach is strengthened by early standard setting for “waste-to-product” transitions and funding of full value-chain demonstrations that couple feedstock preparation, production, and purification.

CO₂ use for gas fermentation or algae production in the EU ETS

Current emissions accounting frameworks recognize only a limited number of CO₂ utilization pathways. Most biological conversion routes, including gas fermentation and algae cultivation, generally do not qualify for emissions reductions because the carbon is expected to be re-released and permanence requirements are not met. As a result, industrial operators, such as steel plants converting off gases biotechnologically into chemicals, receive no emissions credit for doing so. This represents an investment barrier for one of biotechnology's most promising decarbonization pathways. Projects exploring the use of carbon dioxide (CO₂) are investigating whether captured CO₂ can be used to cultivate algae (micro or macroalgae). The goal is to utilize CO₂ as a material and thereby contribute to climate protection. Therefore, the question arises whether, and under what conditions this CO₂ utilization can lead to a reduction or elimination of obligations under the EU Emissions Trading System (EU ETS). The current EU ETS is based on accounting for greenhouse gas emissions released to the atmosphere rather than on a lifecycle assessment of the overall environmental impact of a product or process. Every ton of CO₂ is thus considered an emission and is subject to the requirement to purchase certificates. Subsequent use, compensation, or offsetting are generally not eligible for credit under the EU ETS. Normally in algae production, CO₂ is absorbed through photosynthesis and converted into biomass. However, this binding is biologically and temporally limited. In practice, the carbon bound in algae is regularly released again during further use, e.g. in energy production (biofuels), use as animal feed or food, chemicals, decomposition, or composting. Therefore, the CO₂ used is emitted with a time lag under the EU ETS, and the obligation to for emission certificates remains fully in effect. Currently, exempting CO₂ quantities from the scope of EU ETS is only possible in exceptional cases, namely when the CO₂ is technically captured before it enters the atmosphere, the carbon remains bound long-term (without foreseeable re-emission), and the CO₂ quantities are clearly measured, accounted for, reported, and verified according to EU ETS regulations. This scenario does not regularly occur in microalgae production, as it involves temporary biological storage. Therefore, algae are not considered a permanent CO₂ sink within EU ETS. Algae-based systems are part of the biogenic carbon cycle and differ fundamentally from permanent storage pathways such as CCS or mineralization. However, two important distinctions should be noted when assessing CO₂ use in algae production. First, the source of CO₂ matters. Biogenic CO₂, for example from fermentation processes, biogas plants, or direct air capture, originates from the short-term carbon cycle and is generally treated differently from fossil CO₂. Nevertheless, the extent to which its utilization should affect ETS obligations remains a regulatory question. Second, the product matters. Where algal biomass flows into short-lived energy carriers such as biogas or biofuels, the above assessment holds. Yet where the carbon is incorporated into long-lived materials, bio-based plastics, textile fibres, or specialty chemicals, it remains bound across product lifetimes. This is functionally equivalent to other recognized CCU pathways and should be treated accordingly under the regulatory framework.

Comparison of different Co2 Pathways in ETS assessment:

CO ₂ Pathways	ETS assessment
CO ₂ → algae → biomass/ energy	ETS required

CO ₂ → algae → short-term products	ETS required
CO ₂ → mineralization (carbonates)	Potentially ETS-exempt
CO ₂ → geological storage (CCS)	Recognized as ETS-relevant

The use of CO₂ for algae production does not replace the EU ETS. The CO₂ used is generally considered emitted. A reduction in the certificate requirement is not possible under current law. While CO₂ use for algae production can be beneficial from a funding, research, and climate policy perspective, it does not exempt the user from the ETS. These conclusions apply primarily to fossil CO₂ sources and short-lived end products; biogenic CO₂ streams and long-lived carbon-binding products warrant differentiated regulatory treatment.

Policy recommendations: Biotech Act II should advocate for a revision of the relevant emissions accounting and carbon reporting frameworks, including under the EU ETS and the Carbon Border Adjustment Mechanism (CBAM) to potentially extend the ETS exemptions. This would increase investments in the (biotechnological) utilization of CO₂-rich streams. This is crucial to also enable further innovations regarding long-term uses and of the bound CO₂. In particular, the revision should consider:

- Differentiated ETS treatment for biogenic and DAC-derived CO₂ streams, reflecting their distinct role within the carbon cycle compared with fossil carbon sources.
- Differentiated ETS treatment by end-product permanence: Where carbon remains bound in long-lived materials, such applications may approach the permanence characteristics of certain recognized CCU pathways and therefore warrant consideration within future ETS accounting rules.
- Establish clear MRV (monitoring, reporting, and verification) requirements for durable algal products to ensure environmental integrity while enabling investment.

Cross-Cutting Enabling Measures

Regulatory Modernization and Harmonization

- A proportionate, risk-based, science-driven regulatory model, drawing on globally accepted practices (e.g., ICH Q9/Quality by Design), can provide predictable, shorter approval timelines for low-risk innovations without compromising safety.
- EU-wide procedural harmonization reduces fragmentation and allows authorities to rely on internationally accepted standards.
- Alignment of regulation with transparent, standardized sustainability assessment metrics improves comparability and market visibility in B2B and B2C markets.
- A reassessment of the legal definition of “waste” and related legislation can unlock residue recycling within resource-efficient, sustainable processes.
- Regulatory sandboxes and Europe-wide virtual/physical hubs can enable rapid validation of circular bioeconomy technologies.
- Framework conditions that facilitate market entry of circular bio-based products and processes, combined with a reduction of subsidies for non- or barely-sustainable products, can strengthen competitiveness.
- Market-pull tools, such as blending quotas and material specifications, can accelerate adoption where appropriate.

Biomanufacturing: Scaling Infrastructure as Europe's Strategic Foundation

Europe was once the globally recognized pioneer in biomanufacturing. This position is now under serious threat. The end-to-end infrastructure for the development, scale-up, and industrial implementation of bio-based processes is being rapidly dismantled through divestment, posing a serious threat to European competitiveness and directly causing the "Valley of Death" that prevents promising innovations from reaching industrial application. Without scaling capability, research results remain confined to low Technology Readiness Levels. This structural gap is one of the root causes of the investment predictability problems and the low market uptake of bio-based products identified in the Call for Evidence. The ECF must treat biomanufacturing infrastructure as a strategic European industrial asset. Priority investments are needed in:

- Modular, AI-controlled, decentralized process facilities that strengthen supply chain resilience and generate regional value across all biotech sectors.
- Utilization and networking of existing biomanufacturing infrastructures across Europe—the most capital-efficient lever for rapid market entry, especially for startups and spin-offs seeking to cross the Valley of Death.
- Digital and AI-supported models for process prediction, analytics, optimization, and shared data spaces, enabling faster learning curves and significant energy and resource efficiency gains.
- Model-based risk analyses and hybrid scale-up concepts enabling early industrial decision-making and avoiding misallocation of investment.
- Open-access pilot and demonstration facilities that give SMEs and startups the scaling capabilities they cannot afford to develop independently, directly addressing the SME-specific barriers highlighted in the Call for Evidence.
- Focused 1:1 RTO—company collaborations for short- to mid-term demonstration, transfer, and commercialization can ensure industrial relevance and speed.

Policy Recommendation: Biotech Act II should establish transfer-oriented public-private partnerships, coordinated by neutral research organizations such as Fraunhofer, to develop open biomanufacturing and scaling infrastructures to market readiness through consortium-based implementation structures. The ECF should provide structural co-funding for European biomanufacturing hubs as projects of strategic European interest. Regulatory sandboxes, as mentioned in the Call for Evidence, should be established with the explicit purpose of enabling rapid scale-up validation in real industrial conditions. This approach is reinforced by embedding a "transfer mindset" from the outset, adapting technologies to commercial needs, integrating alignment into project plans, and tracking progress via milestones.

System Analysis, Assessment, and Bioinnovation: Foundation for Policy

Sound policy decisions on Europe's biotechnology transformation require robust system analyses, efficient assessment methods, and validated innovation pathways. Technologies must not only be developed but systematically evaluated across ecological impact, regulatory feasibility, market potential, scalability, and business model viability. This closes the critical gap between research, industrial implementation, and political prioritization and is essential for generating the societal acceptance that bio-based industrial transformation requires.

Analytical Tool	Purpose
Life Cycle Assessment (LCA)	Robust, comparative evaluation of climate, resource, and environmental impact
Technology Assessment	Maturity, risk, investment requirements, regulatory feasibility
Business Case Modeling	CAPEX/OPEX, scaling logic, time-to-market, market potential
Geopolitical Foresight & Scenario Development	Early identification of supply chain risks and competitive dynamics
Material Flow and Circularity Analysis	Integration of products and processes into circular economy systems

This analytical capacity also provides the evidential basis for demonstrating that biotechnology investments under the ECF and Biotech Act II deliver measurable returns on European competitiveness, sustainability, and strategic autonomy, a prerequisite for sustained political and investor confidence.

Policy Recommendation: Biotech Act II should institutionalize independent, cross-sectoral system analysis capacity as a neutral steering instrument, providing a shared evidence base for coordinating policymakers, industry, and investors across Member States. This should be explicitly integrated into the monitoring and evaluation framework of the Act.

Innovation and Translation Alliances: Bridging the Valley of Death in Industrial and Green Biotechnology

Despite Europe's outstanding fundamental research base and internationally competitive companies, the transfer of scientific findings into industrial innovations remains chronically insufficient. The Valley of Death between laboratory-scale discovery and commercial-scale application affects industrial and green biotechnology acutely. Long-term, horizontal collaboration models along biotechnology value chains are largely absent and this structural deficit directly contributes to the low market uptake and investment predictability problems identified in the Call for Evidence.

Fraunhofer proposes the establishment of European and national biotechnology translation alliances as public-private collaboration infrastructures, specifically focused on industrial, green, and yellow biotechnology. Within this structure:

- Partners from research, industry, agriculture, and regulation contribute complementary expertise and infrastructure to accelerate process and product development.
- Novel collaboration models and early AI integration significantly shorten development timelines from discovery to industrial deployment.
- Dedicated translation funds bridge the critical TRL 4–7 funding gap, where public research funding typically ends and private investment has not yet begun.
- The overarching goal: bringing more European biotechnology innovations from research into industrial application more quickly, strengthening European industrial value creation and reducing dependence on imported bio-based inputs.

Short- to mid-term 1:1 RTO–company demonstration and transfer projects can ensure industrial relevance and speed. Structured knowledge sharing under confidentiality agreements between innovators and manufacturers can accelerate transfer while safeguarding IP. Milestone-triggered startup roadmaps with stage-gated support can de-risk translation and scale-up through the TRL 4–7 corridor. Empowering research organizations as reliable providers of demand- and market-oriented sustainability technologies and services can strengthen the innovation-to-industry interface.

Policy Recommendation: Biotech Act II should support the establishment of biotechnology innovation alliances as public-private cooperation structures, with dedicated translation funds co-financed through the ECF. These alliances should explicitly target the TRL 4–7 gap in industrial and green biotechnology, preventing European innovations from being scaled and commercialized outside the continent. [Added: Incorporating milestone-based incentives that recognize transfer-readiness and technical feasibility can further improve outcomes.]

Citizen Engagement and Demand Creation

Public skepticism and low awareness of biotechnology's benefits remain key barriers to broader adoption. Online and in-person citizen dialogues, accessible information campaigns, and best-practice cases can build trust and understanding. Clear communication of the advantages of bio-based products helps consumers reassess their choices and articulate requirements. Early, opportunity-oriented involvement of stakeholders and the public further increases acceptance and enables broader application.

Conclusion

The Call for Evidence correctly identifies the core structural barriers facing European industrial biotechnology: insufficient market uptake, investment unpredictability, single market fragmentation, and regulatory frameworks poorly suited to emerging technologies. Credible, implementable solutions exist across all of these dimensions in industrial fermentation, bio-based materials, agricultural biotechnology, and the enabling infrastructure of biomanufacturing and translation. Collectively, these measures provide threefold benefits: resource resilience (including defense relevance), environmental sustainability, and economic competitiveness through lower raw material costs and accelerated bioeconomy deployment. But solutions require more than good legislation. They require adequate, sustained, and strategically coordinated investment. Biotech Act II must therefore be embedded in the ECF policy windows, designed in full coherence with Biotech Act I, and anchored as a strategic priority in FP10. Anything less will leave Europe's considerable biotechnology research strengths unrealized and cede leadership in one of the most consequential industrial transformation fields to competitors who have already made their strategic choices. The solutions are there. What is needed now is political will, coordinated investment, and institutional architecture to implement them on a European scale.

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