

Fraunhofer Group for Health
Fraunhofer Group for Resource Technologies and Bioeconomy

Biotechnology as a Strategic Pillar for European Sovereignty, Competitiveness, and Resilience

Europe faces the existential task of shaping its future, and biotechnology sits at the very heart of that challenge. The continent's scientific leadership, industrial competitiveness, and strategic sovereignty in critical sectors, from pharmaceuticals and food security to advanced materials and climate resilience, are increasingly at risk. Fragmented national approaches, underinvestment in scaling infrastructure, regulatory incoherence, and the rapid rise of competing biotech superpowers in the United States and China demand a decisive, unified European response. This is precisely why the EU Biotech Acts are not merely desirable, they are necessary.

Biotech Act I must lay the regulatory and structural groundwork: harmonizing the fragmented European biotech landscape, reducing barriers to market entry, aligning the incentive frameworks of the MDR, AI Act, and sector-specific regulations, and establishing the investment conditions needed to retain and scale European biotech innovation. Without this foundation, European research excellence will continue to be commercialized elsewhere. Biotech Act II must go further, addressing the full breadth of biotechnology's transformative potential across all sectors of the economy. Limiting the scope to a narrow subset of applications would be a strategic mistake. Fraunhofer calls on the Commission to honour the commitment to propose Biotech Act II without delay and without compromise on ambition. Biotechnology and the critical enabling infrastructure of biomanufacturing cannot be afterthoughts in a piecemeal legislative process. A partial strategy will produce partial results and Europe cannot afford that. Together, the two Acts must form a coherent, interlocking framework that covers the entire biotechnology value chain: from fundamental research and clinical translation, through industrial scaling and circular material flows, to resilient agricultural systems and sovereign digital health infrastructure. Only a strategy that is comprehensive, well-funded, and regulatory-coherent will be capable of positioning Europe as the global leader in the bioeconomy of the 21st century.

The following areas are of the highest strategic relevance for European competitiveness:

- Pharmaceuticals, diagnostics, personalized medicine, and medical technology
- Industrial fermentation, bio-based raw materials, enzymatic processes, and circular chemistry
- Climate-resilient agriculture, biological plant protection, and sustainable food systems
- Insect-based bioprocesses and novel protein sources

1. Healthcare and Biomedical Innovation

Novel Drug Classes: Driving Medical Breakthroughs and Strengthening Europe as a Pharmaceutical Hub

Conventional drug discovery has long been constrained by its focus on target structures with clearly defined binding pockets, such as enzymes or receptors. An estimated 80% of all disease-relevant target molecules in the human proteome are considered "undruggable" due to the absence of accessible binding sites or because they function via large-scale interaction surfaces, including transcription factors, scaffold proteins, and protein-protein interactions. New drug classes are fundamentally disrupting this paradigm:

- Targeted protein degradation (PROTACs, molecular glues) enables degradation of disease-critical proteins via the ubiquitin-proteasome system, granting access to previously inaccessible targets and circumventing resistance mechanisms.
- RNA-based therapeutics intervene at the mRNA level, bypassing the need for a conventional protein binding pocket. Advances in targeted delivery, such as GalNAc conjugates and lipid nanoparticles, are accelerating clinical translation.
- Gene and cell therapies address the genetic root causes of previously incurable diseases or modulate immune responses directly.
- Next-generation biologics, including bispecific antibodies and nanobodies, expand the therapeutic arsenal through novel mechanisms, including targeted immune cell recruitment.

For Europe to remain internationally competitive as a pharmaceutical hub, the development of novel drug classes through AI-assisted molecular design, genetic engineering, and advanced biotechnological processes is essential. The economic stakes are immense.

Policy Recommendation: The EU Biotech Act should establish targeted, interdisciplinary large-scale funding programs with direct structural linkages to preclinical and clinical development pipelines in the pharmaceutical industry. Regulatory pathways for novel modalities must be clarified and harmonized across Member States to prevent Europe from losing ground to international competitors.

2. 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 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 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—whether as emulsifiers, specialty lipids, polymer building blocks, or high-value food and feed ingredients. Microbial cascades and cell-free systems further enable the valorization of previously untapped biomass streams, significantly increasing resource efficiency.

Policy Recommendation: The EU Biotech Act 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. Flexible access and co-

funding models should enable high utilization rates, industrial application, and rapid transfer into regional value chains.

Biotechnology-Derived Materials for Health, Industry, and Medical Technology

The transition away from fossil-based plastics toward bio-based, circular, and regionally available material systems is one of Europe's defining industrial transformation challenges. Biotechnology offers scalable, high-quality alternatives:

- 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.
- Biotechnological recycling platforms, from enzymatic depolymerization to microbial degradation and re-biopolymerization, enable recovery of textile, packaging, and PET streams into high-quality secondary materials, creating genuine closed-loop systems.
- Targeted polymer functionalization via enzymatic modification yields materials with advanced properties: stimuli-responsive polymers, novel additive chemistry, and specialty polymers for medical, electronic, and high-performance applications.

For the healthcare sector, key pharmaceutical precursors, excipients, and (bio)polymer building blocks must be producible locally within robust, scalable, and circular production structures. This is a prerequisite for supply security. The development of sustainable bio-based alternatives to PFAS in medical applications, leveraging functionalized proteins with high biocompatibility and biostability, is a priority for both health and environmental policy.

Policy Recommendation: The EU Biotech Act 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, and clear regulatory pathways are essential to bring bio-based materials, PFAS alternatives, and critical medical precursors into industrial application at scale.

3. 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 processes for recovering nitrogen, phosphorus, and organic materials from wastewater and agricultural waste streams through fermentation and purification technologies, producing high-quality nutrient solutions for plant production and urban supply systems.
- 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 and reducing dependence on pesticides and synthetic fertilizers. The EU's evolving regulatory framework for NGTs must be science-based and proportionate.

- 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.
- 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.

Policy Recommendation: The EU Biotech Act 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 and a harmonized, science-based regulatory framework, particularly for NGTs, are necessary to close regional material cycles, reduce import dependencies, and strengthen European food sovereignty.

4. Digitalization, AI, and Connected Healthcare

Biosensors and Point-of-Care Diagnostics

Comprehensive healthcare requires diagnostics and treatment monitoring that are fast, reliable, and suitable for everyday use, available where people live, whether at home, in care facilities, or in primary care practices, regardless of geography. Innovative biosensors and point-of-care diagnostics enable early detection and continuous biomarker monitoring, reducing the burden on cost- and labor-intensive centralized systems. For AI-driven healthcare processes, the reliability of input data from biotechnological assays is foundational. Robust preanalytics, standardization, and quality controls are therefore central requirements. Standardized digital interfaces enable integration of measured values into digital health infrastructures along care pathways, from initial assessment through follow-up monitoring, across primary care, hospital, and long-term care settings. Cross-cutting priorities such as prevention and gender-specific medicine (including women's health) can be systematically addressed through such platforms.

Policy Recommendation: The EU Biotech Act should support the establishment of patient-centered, modular real-world laboratories as innovation ecosystems for testing, validating, and scaling biosensor and point-of-care solutions across European health systems.

Digital Operating Rooms and Medical Robotics

The dual demographic shift in European healthcare, characterized by an aging, increasingly multimorbid population and a growing shortage of skilled workers, demands targeted deployment of digital technologies, AI, and robotics. Digital twins, tracking technologies, and autonomous assistive robots already demonstrate significant potential: intelligent decision support, increased precision and efficiency, and improved access to cutting-edge care for broad patient populations. Medical robotics is emerging as one of the world's most dynamic growth markets. Europe with its innovation-driven, SME-dominated industry meeting excellent academic research is ideally positioned to lead in this field.

Despite these strengths, three EU regulations, the Medical Device Regulation (MDR), the AI Act, and the Machinery Regulation, currently create significant barriers to market access, particularly

for medical robotics. Real-world laboratories offering regulatory relief, supported by competent authorities during the R&D phase, can break down existing transfer barriers and enable reliable translation from research to clinical application. A further major obstacle is the lack of interoperability between medical devices and IT systems. Although standards such as FHIR, DICOM, and SDC exist, their practical implementation remains inadequate. Explainable, secure AI and robotics systems connected via standardized, interoperable interfaces are necessary to deliver innovative solutions that enhance quality, safety, access, and resilience in healthcare.

Policy Recommendation: The EU Biotech Act, in coordination with the MDR, AI Act, and Machinery Regulation, should mandate the establishment of real-world laboratories for medical AI and robotics. Networked, interoperable surgical ecosystems and robotic assistance systems should be promoted, and regulatory coherence across the three frameworks must be improved.

AI as a Key Technology in Biotechnology and Health Research

Healthcare faces compounding challenges: demographic change, workforce shortages, increasingly complex clinical pictures, fragmented IT landscapes, and resource constraints. AI-based medical devices, digital applications, and AI-accelerated R&D workflows are essential to ensuring quality, access, and efficiency.

For AI to achieve its full potential, it requires accessible, high-quality, and sovereign health data. In the context of the European Health Data Space (EHDS), Fraunhofer advocates:

- Privileged data access for trusted research actors, including non-university institutions such as Fraunhofer Institutes, Helmholtz Centers, and SMEs engaged in research
- National and European AI real-world labs as practical innovation ecosystems, designed from the outset to comply with the AI Act, Biotech Act, and MDR
- Digital patient models integrating individual health data from wearables to large clinical devices, enabling personalized medicine at scale
- AI-automated production of personalized therapies (e.g., CAR-T cell manufacturing) to reduce cost and increase accessibility
- Removal of regulatory incoherence between the AI Act, MDR, and Biotech Act, which currently creates compounding compliance barriers

Policy Recommendation: The EU Biotech Act should establish real-world labs as practical innovation ecosystems to bring AI-based medical devices, pharmaceuticals, and digital applications rapidly into clinical practice. Privileged data access for trusted actors within the EHDS framework and elimination of overlapping regulatory barriers are prerequisites.

5. Cross-Cutting Enabling Measures

Biomanufacturing: Scaling Infrastructure as Europe's Strategic Foundation

Europe was once the globally recognized pioneer in biomanufacturing. However, the end-to-end infrastructure for development, scale-up, and industrial implementation of bio-based processes is being rapidly dismantled through divestment, posing a serious threat to European competitiveness. Without scaling capability, research results remain confined to low Technology Readiness Levels, and the step into industrial production, necessary for economic success, fails to materialize. Priority investments are needed in:

- Modular, AI-controlled, decentralized process facilities that strengthen supply chain resilience and generate regional value
- Utilization and networking of existing biomanufacturing infrastructures across Europe as the most capital-efficient levers 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 energy and resource efficiency gains
- Model-based risk analyses and hybrid scale-up concepts enabling early industrial decision-making and avoiding misallocation of investment

Policy Recommendation: The EU Biotech Act 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 involving multiple industry partners.

System Analysis, Assessment, and Bioinnovation: The Evidential Foundation for Policy

Sound policy decisions on Europe's biotech 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, including the generation of societal acceptance. Essential analytical components include:

Analytical Tool	Purpose
Life Cycle Assessment (LCA)	Robust, comparative evaluation of climate, resource, 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, competitive dynamics
Material Flow and Circularity Analysis	Integration of products and processes into circular economy systems

Policy Recommendation: The EU Biotech Act should institutionalize independent, cross-sectoral system analysis capacity as a neutral steering instrument, providing an evidence base for coordinating policymakers, industry, and investors across Member States.

Translation Alliances: Bridging the Valley of Death

Despite Europe's outstanding basic research and internationally competitive industry, the transfer of scientific findings into practical innovations remains insufficiently systematic. Collaboration between research, industry, healthcare, and regulatory bodies occurs sporadically, and long-term horizontal collaboration models along value chains are largely absent. Fraunhofer

proposes the establishment of translation alliances for biomedicine as public-private collaboration infrastructures, integrated into a European framework. Within this structure: Partners from science, industry, healthcare, and regulation contribute expertise and infrastructure to accelerate product development
Novel collaboration models and early AI integration shorten development timelines
The overarching goal is to bring more ideas from research into application more quickly.

The Fraunhofer Proof-of-Concept Initiative, in collaboration with university medical centers, Helmholtz centers, and the pharmaceutical industry, provides a proven foundation. A Fraunhofer-wide Trust Center and clinical trial platform extends this to the medical technology sector, which is heavily SME-dominated and particularly exposed to translation risk. The European-level ambition: strengthen the healthcare industry's innovative capacity and increase its gross value added from approximately €100 billion to around €150 billion per year by 2030, alongside the creation of highly skilled jobs.

Policy Recommendation: The EU Biotech Act should support the establishment of translation alliances as public-private cooperation structures, with dedicated translation funds to jointly accelerate the transfer of research results into application.

The EU Biotech Act presents Europe with a defining opportunity – to consolidate its scientific strengths, address structural vulnerabilities, and assert technological sovereignty in one of the most consequential sectors of the 21st century. Fraunhofer urges European policymakers to translate the Act's ambitions into concrete, adequately funded, and regulatory-coherent measures across all five cross-cutting enabling dimensions outlined above. The challenges are real. So are the solutions. What is needed now is political will, coordinated investment, and institutional architecture to implement them on a European scale.