EUROPEAN
COMMISSION

Brussels, 20.3.2024
COM(2024) 137 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU

1. Introduction

Biotechnology[1] **and** its application to manufacturing bio-based products, **biomanufacturing**[2] can be part of **the solution to address many societal and environmental challenges**, such as climate mitigation and adaptation, access to and sustainable use of natural resources, restoration of vital nature systems, food supply and security, and human health. Biotechnology and biomanufacturing **are key for the competitiveness** and the modernisation of our economy due to their high growth potential and increased labour productivity. They also strongly **enhance the EU's open strategic autonomy and resilience** by reducing industry's dependency on fossil-based input and other sources of raw materials, and increase circularity. They help advance the European Health Union and achieve the European Green Deal objectives.

Biotechnology has also been identified as **a critical technology from the economic security perspective**[3]**,** given its cross-cutting nature. It is also one of the technologies prioritised in the Strategic Technologies for Europe Platform (STEP) regulation[4].

Biotechnology and biomanufacturing are important enablers for the bioeconomy at large, which cover all sectors and systems that rely on biological resources, their functions and principles (ecosystems, animals, plants, micro-organisms and derived biomass, wood, including organic waste). At the same time, biotechnology and biomanufacturing depend on the wider bioeconomy for their inputs, and to some extent as an outlet for their products. They also have strong links with healthcare and especially the pharmaceutical industry.

The EU has an innovative and competitive biotech industry, whilst AI is set to accelerate many biotech innovations and developments. At the same time, the potential of biotechnology and biomanufacturing has also been recognised by other countries[5]. Moreover, the EU has a strong domestic supply of renewable raw materials, such as wood. Today, the EU is well-endowed with human talent, research and innovation results and capacities to further develop bio-based manufacturing and biotechnologies.

However, to promote EU industrial competitiveness and its sustainability, greater efforts are needed to create the right environment for this sector to grow. European biotech and

---

[1] According to the OECD, biotechnology is defined as the application of science and technology to living organisms, as well as parts, products and models of them, to alter living or non-living materials for the production of knowledge, goods and services. Advanced biotechnologies are geared towards various application areas, being the main ones medical and pharmaceutical ("red" biotechnology), agri-food ("green" biotechnology), and industrial and environmental ("white" biotechnology), with the marine biotechnology (so-called "blue") gaining increased attention.

[2] The use and conversion of biotechnology and biological resources into chemicals, products and energy.

[3] Commission Recommendation (EU) 2023/2113 of 3 October 2023 on critical technology areas for the EU's economic security for further risk assessment with Member States.

[4] Proposal for a Regulation of the European Parliament and the Council establishing the Strategic Technologies for Europe Platform ('STEP') and amending Directive 2003/87/EC, Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/24, COM/2023/335 final.

[5] With the publication of their "Bold goals for US biotechnology and biomanufacturing" report, the US has defined an industrial strategy for biotechnology and biomanufacturing, setting goals in five fields: climate, food and agriculture, supply chains, health and cross-cutting. China has also identified biotechnology as a key sector in its Made in China 2025 strategy. India, which is growing robustly in biotechnology, has unveiled a Biotechnology strategy as part of its own "Make in India" campaign, and the UK, with its "Life Science Strategy", intends to give a new push to its biotechnology sector.

biomanufacturing companies need a supportive regulatory framework and more financing opportunities to thrive in Europe[6].

This Communication summarises the current challenges and barriers for biotechnology and biomanufacturing and proposes actions to address these challenges in a timely manner, in line with the Communication on the Long-term competitiveness of the EU[7]. It also explores ways to foster engagement and collaboration, including through international dialogue and cooperation.

2. Overview of the sector

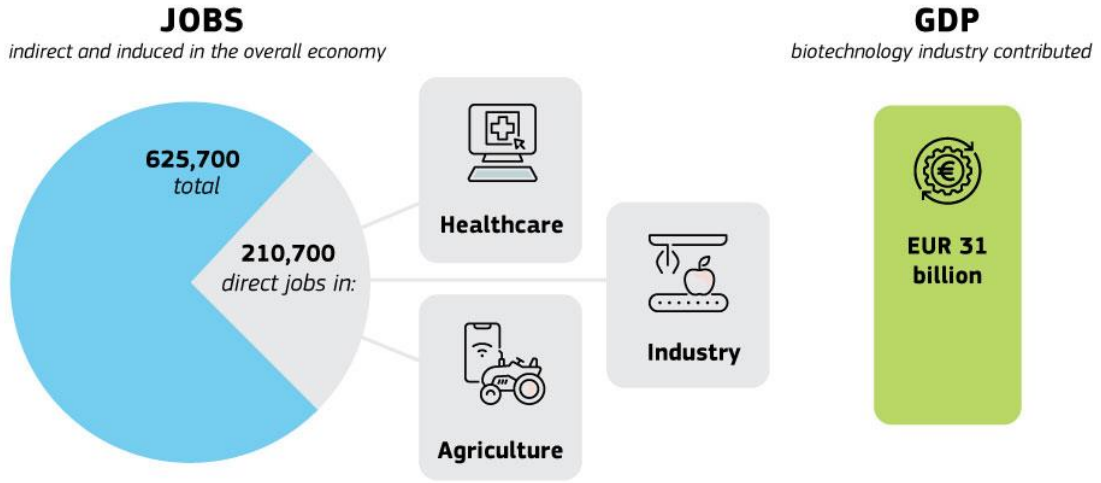
The overall global biotechnology market size[8] was EUR 720 billion in 2021 with a growth rate of more than 18% annually. The US dominates this market by contributing 60% of the global value[9], followed by the EU (12%) and China (11%). It is characterised by intense technological competition, with a R&D intensity that is higher than in other R&D-intensive fields such as pharmaceuticals or digital products and services[10]. The sector is inherently research-driven, often involving cutting-edge equipment, technologies, techniques and knowledge[11] that require substantial and continuous investments to stay at the forefront of scientific and technological advancements. The development of biotechnological products often involves lengthy and complex processes, and additional investments before the products reach the market to secure the intellectual property protection and fulfil the regulatory requirements.

In 2018 in the EU[12], biotechnology contributed directly EUR 31 billion to its overall GDP, created 210,700 direct jobs in healthcare, industry and agriculture, as well as supported 625,700 jobs (indirect and induced) in the overall economy. Between 2008 and 2018, the biotechnology industry grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the EU. Its labour productivity is very high. The products and solutions that biotechnology and biomanufacturing companies are creating can have a significant impact in different areas of application. For example, enzyme technology allows creation of lactose-free and sugar-reduced dairy products while laundry detergents contain enzymes, which break down fats, oils and protein chains. This allows washing clothes at lower temperatures, therefore reducing energy consumption.

Biotechnology also contributes to enhance economic security by providing substitute products and materials in critical sectors. This Communication complements the Communication on

[6] In the EU, the latest strategy focusing exclusively on biotechnology dates back to 2002: Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, Life sciences and biotechnology - A Strategy for Europe, 2002/C 55/03.
[7] Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, Long-term competitiveness of the EU: looking beyond 2030, COM(2023) 168 final.
[8] https://www.biospace.com/article/biotechnology-market-size-to-worth-around-us-3-44-trillion-by-2030/
[9] https://www.statista.com/statistics/1246614/top-countries-share-of-global-biotech-value/
[10] https://www.oecd.org/innovation/inno/keybiotechnologyindicators.htm
[11] Such as gene editing, synthetic biology, bioprinting and bioinformatics.
[12] EU27 adjusted values, EuropaBio study: "Measuring the economic footprint of the biotechnology industry in Europe", December, 2020, https://www.europabio.org/wp-content/uploads/2021/02/201208_WifOR_EuropaBIO_Economic_Impact_Biotech_FINAL.pdf

Advanced Materials for Industrial Leadership[13] in the production of advanced materials with renewable resources and responds, among others, to the need to facilitate the substitution of Critical Raw Materials (CRMs) with alternative advanced materials. Materials derived from biotechnology are included as one of the potential solutions for this challenge.



2.1. Biotech for health

Biotechnology has revolutionised healthcare since the first biotechnologically manufactured medicines in the 1980s, such as synthetically produced insulin. Today, many biotechnological medicines are on the market and bring life-saving therapies to patients.

As well as being a key sector for investment and competitiveness, a thriving EU biotech ecosystem is of strategic importance for the effectiveness of healthcare and resilience of health systems in times of strain such as public health emergencies. It can help to address challenges linked to ageing (such as disease prevention, personalised medicines, regenerative medicine and chronic illness) and antimicrobial resistance. A robust EU biotech ecosystem can contribute to the security of supply of both innovative and generic medicines in line with the objectives of the Communication on addressing medicine shortages in the EU[14].

2.2. Biotech applications in food and feed - biotech for food security

Biotechnology can help reduce the EU's external dependencies including in the agri-food sector. It can also contribute to a better protection of health and the environment by, for example, reducing crop and food losses and enabling a more efficient and reduced use of natural resources and input materials (chemical synthetic pesticides or mineral fertilisers). It

[13] Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions: "Advanced Materials for Industrial Leadership", COM(2024) 98 final.

[14] Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions "Addressing medicines shortages in the EU", COM(2023) 672 final.

also allows for feed and foodstuffs with improved environmental and health traits (e.g., with reduced saturated fats or allergens or with increased disease fighting nutrients). Innovation in biotechnology can be an important building block in the efforts to reduce the overall environmental footprint of agri-food production systems making them more resilient and supportive to reach the EU's climate neutrality goal and to provide more sustainable and some healthier foodstuffs.

2.3. Biotech and manufacturing for more added value with less resources in the sustainable wood-based sector

Biotechnology can strengthen the resilience of forests[15] to the effects of climate change, including severe droughts and forest fires. In the case of biomanufacturing, the forest sector offers sustainably produced, renewable and recyclable raw materials that can be used for high-value innovative products, such as batteries or healthcare and pharmaceuticals applications (e.g., nanocellulose-based wound dressings). Furthermore, wood can be used to replace fossil-based or non-renewable materials, for example, in the production of construction materials and textiles and to substitute chemicals.

2.4. Marine biotech applications responding to global challenges

Marine biotech has led to several pharma innovations by providing medicines treating cancer, cardiovascular diseases, pain and viral infections and by contributing to environmental remediation solutions such as cleanup of oil spills, plastic pollution, or wastewater treatment. Other market segments of interest for marine biotech include cosmetics, enzymes, chemicals, and bio-fertilisers. Hundreds of new compounds from the marine realm are being found every year that open up new biotechnical pathways, with the algae sector having a particularly broad spectrum of application[16].

EXAMPLES OF BIOTECH APPLICATION IN DIFFERENT AREAS

- Biotech for clean water: Based on modified enzymes, PFS[17] is the first patented enzyme-carrying filtration system capable of removing a large range of organic pollutants from wastewater. It can be easily installed in most of wastewater treatment facilities. Compared to alternative purification methods, PFS is very cost-efficient and requires no energy to run.
- Biorefineries for sustainable batteries: Biorefineries can nowadays transform wood into innovative high value-added products in several sectors: biochemicals, insulation foams, bio composites, engineered foams etc. One European company[18] is developing batteries made from hard carbon powder (refined lignin[19]) with a scalable model for commercial production.

[15] Examples of biotechnologies used in the forestry sector more commonly involve genomic tools to identify networks of genes that produce the most robust phenotypes for specific environmental conditions, with proposed benefits including increased fire resistance in trees and assisting trees to better adapt to changing climates.
[16] Towards a Strong and Sustainable EU Algae Sector, COM(2022) 592 final.
[17] PFS has been developed by Pharem Biotech, with the support of Horizon 2020.
[18] Stora Enso: from trees to batteries: https://www.storaenso.com/en/products/lignin/lignode
[19] Lignin is a type of polymer found in the cell of terrestrial plants, from 20% to 30% of a tree composition and it can be a component for a broad range of innovative products.

- Biotech for greener and more productive agriculture: Biocontrol agents (BCA) provide alternative solutions to chemical pesticides. They rely on natural means to control pests, such as parasitism, predations, or other mechanisms to protect crops. Biotech can help to produce more effective and cost-efficient BCA enhancing the properties of organisms, such as fungi. One of its applications is increasing natural plant defences for vineyards. Microalgae-based biorefineries are already being developed to extract nutrients from wastewater to produce biostimulants, biopesticides, and biofertilisers. It is expected to increase crop yield compared to existing cultivation cases with chemical inputs.
- Biotech for health: Based in part ongroundbreaking research in Europe, mRNA therapeutics allowed the discovery of mRNA-based vaccines for COVID-19 saving millions of lives. In addition to vaccines against infectious diseases, RNA therapeutics are being developed to treat cancer as well as rare and cardiovascular diseases.
- Biotech and sustainable carbon sources: In the chemical industry more than 90% of annual carbon demand (about 450 million tonnes CO_2) is supplied by fossil carbon[20]. Alternative feedstocks, like sustainable biomass, recycled waste and CO2 captured from biogenic sources could instead be used for the manufacturing of polymers, plastics, solvents, paints, detergents, cosmetics and pharmaceuticals, contributing to emission reduction, resource efficiency and strategic autonomy.

The 2012 EU Bioeconomy strategy, updated in 2018, set the foundation for a more innovative, resource-efficient and competitive society that reconciles food security with the sustainable use of renewable resources for industrial purposes, while ensuring environmental protection. Given its important role in supporting the green transition, the bioeconomy will continue to be key for ensuring the EU's competitiveness and resilience. Therefore, there is a need to adjust the EU policy on bioeconomy taking into account the current societal, demographic and environmental challenges, reinforcing its industrial dimension and its links to biotechnology and biomanufacturing to contribute to a stronger EU economy. In that sense, in 2025, this Communication will be complemented by a review of the EU Bioeconomy Strategy.

3. Challenges

The EU biotech and biomanufacturing sector is facing several challenges that need to be addressed for it to realise its full potential.

3.1. Research and technology transfer to the market

Europe is strong in life sciences[21] and leads on high-quality publications covering health, agriculture, and industrial biotech[22]. However, many research results are not developed further for the market. In the case of health-related and blue biotech, the of cutting-edge-research into products and treatments is less successful in the EU compared to the US and China. Worldwide

[20] https://renewable-carbon.eu/publications/product/the-renewable-carbon-initiatives-carbon-flows-report-pdf/
[21] World University Rankings 2022 by subject: life sciences | Times Higher Education (THE)
[22] "CWTS Leiden Ranking 2022," CWTS Leiden Ranking, accessed October 2022.

growth in health biotech R&D (which concentrates most of the investments in biotech) since 2012 can be largely attributed to the entry and activity of US firms[23].

Biotech research is scattered across Member States and only a limited number of centres of excellence ranking among the top worldwide have emerged[24]. Additionally, professionalised mechanisms for the technology transfer from universities and research centres to the market are not well developed or systematic. This makes the use of their biotech discoveries and advances by EU companies more challenging.

3.2. Regulatory complexity

Innovative biotechnologies and products may encounter regulatory obstacles at both Member State and EU levels when entering the market. Biorefineries that do not meet the requirements outlined in the Net-Zero Industry Act[25] often face lengthy permitting and authorisation procedures (e.g., building permits, environmental authorisations, industrial risk analyses) before they can become operational. Biotechnologies and products that fulfil these requirements will benefit from the streamlined administrative and permit-granting processes under that regulation. Investing in and building new modern/innovative biorefineries is a long-term and capital-intensive undertaking. Another example is the approval of a biological plant protection product in the EU which takes up to three times as long as in the US. Similarly, developers of biotech health products have difficulties in navigating the complex EU and national-level regulatory environment and the intrinsic complexity characterising those innovative treatments.

3.3. Access to finance

Access to finance is key for the development of a vibrant biotech industry. Given the long-term financing needs of biotech companies, and uncertainty surrounding the return on their investments, traditional, loan-based bank financing (which is prevalent in the EU) is in most cases not suitable to meet the needs of this industry. Biotech companies need to look to capital markets for the funds they need, and would thus benefit from further progress on the Capital Markets Union.

At the earliest stages of development, biotech firms need venture capital financing to get their ideas off the ground. The great uncertainty as to the feasibility and success of novel products means that investments into biotech firms carry high risk as well as long investment horizons.

The scale-up stage of financing is the most problematic for biotech firms in the Union. The fragmentation of EU capital markets results in many small-to-medium sized equity funds that invest mostly nationally. Early-stage venture capital at smaller amounts has become more available in the EU but still lags behind other main economic regions, while access to larger amounts of later-stage venture capital in the growth phase remains a major obstacle. To

[23] EU Industrial R&D Investment Scoreboard (2023), p. 50, Table 17 as well as Section 3.2.2 Health industries. A similar, albeit less pronounced US dominance is observed for the (non-biotech) pharmaceutical sector.

[24] See https://www.nature.com/nature-index/institution-outputs/generate/all/global/all (key words: region: "global", sector: "all"; subject or journal group: biological sciences).

[25] Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net Zero Industry Act), COM(2023) 161 final.

adequately fund later-stage biotech firms, the EU is in dire need of larger and deeper pan-European funds which can facilitate large rounds of private investment.

Finally, at later stages of their development, biotech companies could seek financing by accessing public stock markets. However, these markets are still dispersed across Member States which leads to fragmented liquidity and consequently higher cost of capital for listing companies.

3.4. Skills

European biotech and biomanufacturing companies face rapidly evolving skills needs. Compared to other products, biotech products are more complex to develop and their manufacturing requires highly specialised equipment and a highly qualified and multi-disciplinary workforce. In light of this and in the context of the European Year of Skills, continuing training, up- and re- skilling are particularly important to meet the constantly evolving industry needs, in line with the EU target that 60% of adults participate in training each year by 2030[26]. Deep expertise is required in life sciences-related fields but also in digital technologies (AI, big data, robotics), in regulatory frameworks and in quality assurance and control. For some biotech products, especially in the field of medicines, centres of excellence and specific skills are needed for the final administration of the product to patients.

In addition, the EU is at risk of losing these skills because researchers and companies are attracted to other parts of the world with more supportive environments to develop their biotech projects.

3.5. Value chain obstacles

Businesses encounter value chain obstacles, and struggle to find sufficient sustainable feedstock to move from fossil to renewable raw materials on a larger scale. EU industrial bio-based systems rely heavily on imports such as oilseeds, cork, pulp, algae, (intermediate) chemicals, textile fibres, as well as animal and vegetable oils. At the same time, some EU-sourced alternatives may be available that are not yet fully exploited, such as organic waste and by-products. Whilst the demand for biomass is increasing it is estimated that the supply of sustainable biomass falls 40-70%[27] short compared with projected demand by 2050[28]. This makes the use of additional renewable carbon sources such as recycled waste or captured carbon necessary.

3.6. Intellectual property

Intellectual property (IP) allows biotech innovators to protect research results and to recover the large upfront capital investments needed. It is also frequently a critical asset which emerging biotech start-up companies can offer to secure financing.

[26] This is one of the three EU headline targets for 2030 of the European Pillar of Social Rights Action Plan. https://op.europa.eu/webpub/empl/european-pillar-of-social-rights/en/

[27] depending on the projected demand scenarios

[28] "The European biomass puzzle – Challenges, opportunities and trade-offs around biomass production and use in the EU": https://www.eea.europa.eu/en/newsroom/news/biomass-in-europe

Biotech patents represent about 5% of total IP5[29] patents filed between 2001 and 2020[30]. The vast majority of the biotech patents are related to industrial and medical applications combining more than 96% of all patents analysed. The USA is leading in the development of biotech patents (39.6% of total biotech patents in 2020) followed by the EU with 18.3% and China catching up quickly (10.4%).

3.7. Public acceptance

In spite of their many benefits, public awareness and acceptance of biotechnology and bio-manufactured products in the EU needs further attention. Relevant frameworks need to give robust assurances to citizens about responsible use, safety and sustainibility. This will be a key objective of the possible EU Biotech Act. It also calls for well-informed engagement and discussion with civil society.

Moreover, biotechnology and bio-manufactured products are usually more expensive than their fossil-based competitors and, at the same time, their societal and sustainability benefits are not apparent for many consumers.

3.8. Economic security

Biotechnology was identified as one of the ten critical technology areas for European economic security, based on its enabling and transformative nature, the potential risk of civil and military fusion of some biotechnologies, and the risk of their misuse for human rights violations. It is currently subject to an ongoing assessment of the risks to technology security and technology leakage conducted jointly by the Commission and the Member States. The assessment has been mapping out strengths to protect and vulnerabilities to address across the main application areas and identified priority risk scenarios, including possibilities of misuse of biotech. Based on this exercise, the Commission and the Member States will identify precise and proportionate risk mitigation measures to ensure that the EU remains at the forefront of technological innovation in biotech, safeguards its economic security, and maintains strong cooperation with the broadest possible range of like-minded partners.

4. Opportunities and way forward

4.1. Leveraging research and boosting innovation

A more integrated approach to the technology transfer process in Member States can significantly benefit biotech and biomanufacturing companies. This implies actions in three interconnected domains: (i) technology transfer capacity building (including through training, knowledge development and sharing), (ii) technology transfer financing and (iii) design of innovation ecosystems through research organisations, technology transfer offices and

[29] IP5 includes: the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the US Patent and Trademark Office (USPTO) and the National Intellectual Property Administration of People's Republic of China (NIPA).

[30] Grassano, N., Napolitano, N., et al. (2024). Exploring the global landscape of biotech Innovation: preliminary insights from patent analysis. Luxembourg: Publications Office of the European Union (forthcoming).

Research[31] and Technology Infrastructures[32]. Technology centres[33] are a key tool to accelerate technology transfer reducing the time-to-market for innovative products. In the EU there are at least 130 mapped technology centres active in biotechnology and biomanufacturing[34].

The approach could build upon the experience of regions in designing their innovation strategies, 'smart specialisation strategies'. Several EU regions have identified biotechnology in their smart specialisation strategies.[35] As a result, the strategies enhance close-to-market research and innovation capacities in biotechnology and develop the necessary skills.

To help to identify drivers and bottlenecks of innovation and of technology adoption, the Commission has launched a study to investigate the EU's position compared to other global leaders in emerging biotechnology generation and transfer to the biomanufacturing industry.

To facilitate a more productive use of Research Infrastructures, the Commission will explore ways to accelerate the development and use of the Industrial Biotechnology Innovation and Synthetic Biology Accelerator (EU IBISBA)[36] as a trusted digital repository and service network for the sector.

Artificial Intelligence and use of data

There is an unprecedented amount of data available in biotechnology today. Artificial intelligence (AI) applied to bio-based industry allows companies to automate a wide range of processes helping them to streamline and scale up their operations. AI image analysis or deep learning can be used to analyse microbiomes, screen phenotypes, and develop rapid diagnostics in a vast range of applications. The use of AI-based systems to predict best metabolic pathways for biosynthesis and virtually test several variables can speed up bioprocesses' development. The application of AI allows personalized healthcare solutions enabling the development of customized treatments and diagnostics.

Generative AI holds a particular promise. For example, it can generate new or analyse existing gene sequences to help understand complex genetic diseases or facilitate drug discovery and support protein and peptide engineering for biotechnological and therapeutic purposes and synthetic biology applications, such as the production of sustainable fabrics. For instance, one significant contribution[37] AI has made to advancing scientific knowledge to date is the creation of the most complete database of predicted 3D structures of human

[31] Research Infrastructures are facilities that provide resources and services for research communities to conduct research and foster innovation. They include major scientific equipment or sets of instruments, collections, archives or scientific data, computing systems and communication networks.
[32] Technology infrastructures are facilities, equipment, capabilities and support services where industrial players can find support to commercialise new products, processes and services, in full compliance with EU regulations.
[33] Technology Centres are public or private organisations carrying out applied research and close-to-market innovation. Technology Centres typically provide the following services to SMEs: access to technology expertise and facilities for validation, demonstration, proof of concept / lab testing, prototype development and testing, pilot production and demonstration/ pilot lines / pre-series, product validation / certification.
[34] Technology Centre Mapping tool launched by the Commission through the European Monitor of Industrial Ecosystems (EMI) project: https://monitor-industrial-ecosystems.ec.europa.eu/technology-centre/mapping.
[35] S3 CoP Observatory (europa.eu): https://ec.europa.eu/regional_policy/assets/s3-observatory/index_en.html
[36] IBISBA provides a single access point to researchers from academia and industry to integrated services for end-to-end bioprocess development (e.g., process optimization, data services, analytics or protein discovery and engineering).
[37] This is a result of a collaboration between the European Molecular Biology Laboratory and Deep Mind.

proteins and the prediction of a protein's shape computationally rather than determining it experimentally through years of laborious and often costly techniques.

Companies applying AI to biotechnology and biomanufacturing can benefit from the measures proposed in the AI package[38], especially from the setting up of AI Factories which will give privileged access to supercomputers to AI startups and the broader innovation community. Companies could also benefit from the strengthened support to the Common European Data Spaces, and the launch of "GenAI4EU", a landmark initiative that has earmarked approximately EUR 500 million to stimulate the uptake of generative AI across all of the Union's fourteen industrial ecosystems, including biotechnology.

The European Health Data Space Regulation (EHDS) once applicable will standardise health data across the EU to allow for better use for research, innovation, and public health policies (the "secondary use of health data"). While protecting patients' fundamental right to privacy, the EHDS will facilitate access to and use of health data, including their use for the purposes of R&D for health biotech in particular, in a secure and trustworthy setting.

The '1+ Million Genomes' (1+MG) initiative[39] aims to enable secure access to genomics and the corresponding clinical data across Europe for better research, personalised healthcare and health policy making. Its Genomic Data Infrastructure will establish a federated data infrastructure for genomic and clinical data across Europe. Since November 2023, the 1+MG initiative is in its second (scale-up and sustainability) phase, implementing the technical infrastructure, initial infrastructure operation with research pilots in clinical use-cases, and connection of the infrastructure to EHDS. By 2026, 15 countries will have an operational infrastructure in place. An integrated cross-country data infrastructure can be used to expand to collection of new biomarkers (e.g. lifestyle/environment biomarkers beyond health, such as air quality, labour characteristics) and more comprehensive datasets needed for precision medicine and longevity research.

The Commission will take the following actions to foster the application of big data and AI in biotech and biomanufacturing companies:

- In the context of the GenAI4EU initiative, support structured exchanges with stakeholders to **accelerate the uptake of AI**, and in particular Generative AI, in biotech and biomanufacturing and raise awareness with those stakeholders of facilitated access to the EuroHPC supercomputers for AI startups and the science and innovation community.
- Support the **development of advanced Generative AI models for healthcare**, leveraging data and tools such as multi-modal data and human health 'Virtual Human Twin'[40] modelling, existing cross-border data infrastructures[41] and other relevant data sources, supported under the Horizon Europe and Digital Europe programmes and using Euro HPC supercomputing capacities.

[38] Commission launches AI innovation package: https://ec.europa.eu/commission/presscorner/detail/en/ip_24_383
[39] European '1+ Million Genomes' Initiative: https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes
[40] European Virtual Human Twins Initiative: https://digital-strategy.ec.europa.eu/en/policies/virtual-human-twins
[41] Such as 1+ Million Genomes Initiative; European Cancer Imaging Initiative: https://digital-strategy.ec.europa.eu/en/policies/cancer-imaging

4.2. Stimulating market demand

To succeed on the market, bio-based products need to prove their sustainability and lower environmental impact when compared, for instance to petrochemical products. The Life Cycle Assessment (LCA) is the key methodology for assessing the environmental impacts of products. While different LCA approaches have been developed, the Commission recommends the Product Environmental Footprint (PEF) approach which was last reviewed in 2021. In its next periodical revision (in 2025-2026), in light of recent scientific developments, the Commission will **review the assessment of fossil-based and bio-based products to ensure equivalence of treatment and incorporate methodologies for carbon storage in construction materials**.

To accelerate the substitution of fossil feedstock and to stimulate the demand and market uptake of bio-manufactured products, the Commission will conduct an in-depth impact assessment of the feasibility of **bio-based content requirements in specific product categories and in public procurement.** Such requirements could be established, in line with the EU's international commitments, through delegated acts under the new Ecodesign for Sustainable Products Regulation. In addition, the Commission will explore how bio-manufactured non-food products could profile themselves better through **labelling of bio-based products**. In the growing movement towards sustainability and eco-friendly choices, labelling and certification of bio-manufactured non-food products play a pivotal role in building consumer trust. Voluntary labelling, based on objective sustainability criteria for bio-based feedstock, would allow biotech and biomanufacturing industries to reliably inform consumers about the bio-based content and sustainability of their products[42].

This can be done by supporting the circular bioeconomy model and stimulating the use of captured CO_2 as a new carbon resource, as recognised in the Communication towards an ambitious Industrial Carbon Management for the EU[43]. The Innovation Fund, for example, supports projects capturing CO_2 from the atmosphere or from mixed waste and turning it into a valuable resource. Furthermore, the Sustainable Carbon Cycles Communication has set out the goal of at least 20% of the carbon used in the chemical and plastic products to come from sustainable non-fossil sources by 2030.

Providing a stable, predictable, and balanced IP framework for protecting and valorising biotech innovation and facilitating access to it, especially to smaller actors across the value chain such as primary producers and SMEs, is crucial for ensuring a vibrant biotech ecosystem in the EU. The launch of the unitary patent ('UP') system in 2023, as well as the upgrade of the current EU regime for supplementary protection certificates (SPCs), proposed in the context of the Commission's 'patent package' of 2023[44], will support ground-breaking innovation in biotechnology. Innovators across the EU, including in biotech, need to reap the full benefits of these initiatives, therefore the swift adoption of the 'patent package' is essential.

---

[42] Any future sustainability criteria for bio-based feedstock beyond energy should be consistent with the sustainability criteria for energy products included in the recast Renewable Energy Directive 2018/2001.
[43] Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, Towards an ambitious Industrial Carbon Management for the EU, COM(2024) 62 final.
[44] Intellectual property: harmonised EU patent rules: https://ec.europa.eu/commission/presscorner/detail/en/ip_23_2454

4.3. Streamlining regulatory pathways, including permitting and authorisation

Further action at EU level is needed to improve conditions for moving from "lab to fab" creating a level playing field for companies in the internal market for the commercialisation of mature biotech innovation.

The Commission will assess how **EU legislation and its implementation could be further streamlined to reduce any fragmentation, explore potential simplification, and shorten the time for biotech innovations to reach the market; as well as regulatory obstacles that arise at national or other governance levels which impede an effective single market**. To this end, the Commission will launch a study that will map key current industrial bio-based value chains, analyse the regulatory framework and the impact of relevant legislation, and thereby lay the foundations for a possible EU Biotech Act[45].

In that context, targeted simplifications to the regulatory framework, focusing on specific areas such as harmonized requirements for low-risk biotechnologies and streamlining/simplifying approval processes for certain product categories, will be explored. Issues of implementation will also be considered, for instance, to ensure clarity about applicable regulatory frameworks in fast developing areas or products or technologies that do not easily fit an existing category. This would foster innovation in the EU by improving clarity and predictability for the industry and help to upscale relevant biomass production in the EU. In addition, the adoption of the new Regulation on plants produced by certain new genomic techniques is essential for the EU to benefit from the biotechnology potential in the agri-food area.

The Commission will further **promote the establishment of regulatory sandboxes that allow to test novel solutions in a controlled environment for a limited amount of time** under the supervision of regulators as a way of bringing more of them quickly to the market. This has already been proposed for breakthrough therapies under the reform of the pharmaceutical legislation.

To respond to current needs and to help biotech companies bringing innovative products to the market, the Commission will make full use of existing structures such as the European Enterprise Network to work towards establishing an **EU Biotech Hub**, **an operational tool for biotech companies to navigate through the regulatory framework and identify support to scale up**.

[45] One possible question would be the possible generalisation to non-medical biotech of approaches under the Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment, OJ L 458, 22.12.2021, p. 1.

European leadership for health biotech

In the last 30 years, biotech transformed the pharmaceutical industry and enabled the development of breakthrough therapies that are lifesaving or that significantly improve the quality of life of patients and their families. The development of biotech in Europe also continues to positively contribute to the region's economic well-being. In 2018, healthcare biotech's total direct GDP contribution was EUR 29.0 billion, and the sector contributed to over 175,000 direct jobs in the EU[46]. However, the existing regulatory framework governing the development and use of biotech-based medicinal products ("biopharmaceuticals") is complex and can include multiple legislations covering medicinal products, advanced therapies, medical devices and in vitro diagnostics, substances of human origin, genetically modified organisms, and clinical trials, both at the national and EU level.

Reform of the pharmaceutical legislation

The Commission proposed a revision of the EU pharmaceutical legislation[47] that includes the necessary elements to ensure that the EU regulatory system is flexible enough to accommodate new innovative biotechnological medicines that are safe and effective. At the same time, the reform aims to create a regulatory environment in which the EU can continue to innovate and be a global leader in pharmaceutical biotechnology, including in Advanced Therapy Medicinal Products (ATMPs)[48] by proposing new provisions, such as **regulatory sandboxes; providing clarifications on the interface and interaction with other legislative frameworks** to help developers navigate the regulatory requirements, especially for combination products; exploring new possibilities for **scaling up or scaling out of biomanufacturing capacities;** proposing clearer rules on the **use of the hospital exemption[49] for ATMPs**. In parallel, a study is currently taking stock of the application of the hospital exemption under the ATMP regulatory framework and the practical experiences across the EU with developing and making available innovative biotech products in the hospital setting.

Swift adoption of the proposals for the reform of the pharmaceutical legislation is therefore key to facilitating health biotechnology in Europe.

Adding to the support of biomanufacturing in Europe, the Commission is supporting the development of innovative manufacturing technologies through the EU4Health Work Programme 2024. In addition, the Commission **will launch a study to identify how best to leverage existing assets and infrastructures for health biotechnology**, including those

[46] WiFOR Institute (2020), Measuring the Economic Footprint of Biotechnology in Europe: https://www.wifor.com/uploads/2021/03/201215_WifOR_EuropaBIO_Economic_Impact_Biotech_FINAL.pdf

[47] https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation_en

[48] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 provides the overall framework on ATMPs.

[49] The hospital exemption allows for the use of an ATMP without a central marketing authorization. The ATMP should be prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient.

developed under Joint Undertakings, with the aim to boost biomanufacturing capacity within the EU.

Collaboration on national responsibilities

Before any medicine can be authorised, evidence needs to be generated through clinical trials. Clinical trials on biopharmaceuticals and ATMPs are still hindered by differences in national requirements and additional national regulations. The Clinical Trial Regulation (CTR)[50] entered in application in 2022; with transition to the new framework still ongoing, it is yet to realise its full potential in terms of harmonising and facilitating the conduct of clinical trials in the EU. In close partnership with Member States, the European Medicines Agency and relevant stakeholders, the Commission is working on the further harmonisation, improvement and streamlining of the clinical trial processes in the EU under the Accelerating Clinical Trials in Europe (ACT EU) initiative[51]. By the end of 2024, the Commission will **launch a study on the implementation of the CTR in order to assess its impact on European clinical research and to prepare the required report on the CTR's functioning.** The Commission will assess whether a revision of the legislation is necessary and consider any further necessary steps, such as clinical trial hubs to help overcome cross-border fragmentation and build capacity.

Based on the objective of affordability set in the EU pharmaceuticals strategy and developed in the group of National Competent Authorities on Pricing & Reimbursement and public healthcare payers, the Commission will further encourage voluntary collaboration on effectiveness analysis, pricing and reimbursement of medicines. This may include biotech products and biosimilars with a view to ensure that these products address the needs of the health systems.

4.4. Fostering public and private investments

The EU has a broad range of financing instruments to support biotechnology and biomanufacturing such as Horizon Europe, including the Circular Bio-based Europe Joint Undertaking (CBE JU) and the Innovative Health Initiative Joint Undertaking (IHI JU); EU4Health; the Innovation Fund; and now also the Strategic Technologies for Europe Platform (STEP). Cohesion Policy alone has funded about 3 700 close-to-market biotech research and innovation projects in various regions since 2014[52]. In terms of availability of **information on funding opportunities**, the **Sovereignty Portal** established under the STEP Regulation, will include information on the ongoing and upcoming calls for proposals and calls for tender available under 11 EU funding programmes including for biotech.

To develop and scale up innovations with the potential to create new markets, the Commission **will advocate the inclusion of specific challenges on biotech and biomanufacturing in the co-creation and comitology process for the European Innovation Council (EIC) accelerator Work Programme 2025**. Further targeted support for breakthrough technologies

[50] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC 2

[51] Actions include methodology guidance, improving data analytics and the creation of a Union level group of ethics committees enabling cooperation to work towards alignment of national requirements.

[52] Projects co-funded by the EU (europa.eu): https://kohesio.ec.europa.eu/en/projects

under the European Innovation Council, including through equity investments, will also be explored. As and when climate-relevant biotech and biomanufacturing innovation approaches high technology readiness levels at sufficient scale and variety, the Commission will also examine whether and how the Innovation Fund can support its deployment and take-up on the market, notably by using the Fund as a service to leverage national funds.

An InvestEU blending operation, HERA Invest, supported by the EU4Health programme, supports research and development (R&D) related to the most pressing cross-border health threats. HERA Invest provides a financing mechanism to promote advanced research and development of medical countermeasures and related technologies. It fills a vital gap in the field with EUR 100 million to support innovative SMEs with loans in the early and late phases of clinical trials.

The low number of specialist investors in the EU compared with other regions of the world is often perceived as a hurdle for the development and scale-up of European biotech. In that regard, the Commission will **explore possibilities to support the EIB Group in expanding the European Tech Champions Initiative**, leveraging additional Member State funds and attracting new investment players to provide competitive high-risk public investment in promising health biotech, focusing on the late-stage growth funding challenge and on strategic areas such as health security.

In line with the recent Eurogroup statement on Capital Markets Union, the Commission will launch **a study by the end of 2024 to identify barriers and ways to support the consolidation of investment funds**, **stock exchanges and post-trading infrastructure** in order to enable the development of the necessary scale, enhance the knowledge base, create deeper pools of liquidity and help lower the cost of financing for companies. Depending on the barriers and solutions identified, this could underpin action at Union level and/or initiatives by (subsets of) Member States or market players.

The forthcoming study of the European Investment Bank (EIB) on bioeconomy will quantify funding gaps, assess market needs and barriers and identify emerging innovative projects. On the basis of the study, the Commission will analyse whether improvements to the existing instruments can be made to better provide financial support to solutions based on biotechnology and biomanufacturing[53].

Due to the long innovation timelines, tax credits, which are compliant with State aid rules and coherent with other EU initiatives in the field of direct taxation, can incentivise private investment in biotechnology. This measure has already been adopted by some Member States; for example, in France a company can get a 30% tax credit for its R&I investments up to EUR 100 million and 5% for investments above EUR 100 million. The Commission will explore the effectiveness of introducing general or targeted tax credits for R&I activities.

At international level, external financing instruments such as the European Fund for Sustainable Development Plus (EFSD+) Open Architecture offer guarantee schemes to de-risk investments of European companies in Africa and Latin-America and the Caribbean.

[53] Under State aid rules, the Risk Finance Guidelines, the General Block Exemption Regulation (Article 21 on risk finance aid) and the research and development and innovation (R&D&I) framework provide ample opportunities for financial support to biotechnology and biomanufacturing.

4.5. Strengthening Biotech-related skills

The 'Pact for Skills', under the EU Skills Agenda, addresses the most pressing industry skills gaps with active involvement of industry and key actors in education and training. Large-Scale and Regional Skills Partnerships can play a significant role in providing upskilling and reskilling opportunities on biotech and biomanufacturing related topics for the working-age population, especially in the agri-food health and textile sectors, where Large-Scale Skills Partnerships are already in place[54]. A specific large-scale partnership for the biotech and biomanufacturing could also be explored, taking into account the particular skills challenges of an area in very rapid evolution. Such partnerships can be co-financed through the Blueprint Alliances activity of the Erasmus+ programme.

Moreover, the expanding number of dynamic European Universities alliances and Erasmus+ partnerships and alliances for innovation can also strengthen the development of high-level skills and competences required by the biotech sector.

Biotech industrial clusters and Regional Innovation Valleys can, thanks to the close collaboration centres, allow industry to advise universities on the design of the curricula and content for biotech related higher education courses, so that they can better adjust to the needs of EU biotechnology and biomanufacturing companies.

The STEP is a new budgetary tool with the objective to support the development of critical technologies and to address shortages of labour and skills in the three STEP sectors, including in the biotech sector. In the context of cross-industry labour and skills shortages, skills development is key and can be done through various education and training projects with the support of different stakeholders, especially social partners[55].

To grow and retain talent within the EU, attracting skilled third country nationals to work in the biotech sector can also help address skills gaps. Once operational, the EU Talent Pool will provide the first EU-wide platform to help match employers with skilled third country nationals needed on the EU labour market.[56]

In addition, the New European Bauhaus Academy will support upskilling linked to circularity and biotech and biomanufacturing in the built environment. The Commission will explore expanding the concept to other sectors that have a direct impact on the life of the citizens such as textiles.

---

[54] https://pact-for-skills.ec.europa.eu/about/industrial-ecosystems-and-partnerships/health_en, https://pact-for-skills.ec.europa.eu/about/industrial-ecosystems-and-partnerships/agri-food_en

[55] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and The Committee of the Regions: Labour and skills shortages in the EU: an action plan, COM(2024) 131 final.

[56] Proposal for a Regulation of the European Parliament and of the Council establishing an EU Talent Pool, COM(2023) 716 final.

Promoting circularity, sustainable sourcing of materials and depollution – biotech for green transition

Production of renewable bio-based materials and energy carriers from waste and biomass in an innovative, sustainable and circular way with the help of biotechnology can significantly contribute to the climate neutrality target by 2050, create green jobs and sustainable economic growth in regions across Europe.

Industrial biotechnology that uses microorganisms or their biological components will enable new processes that use less resources and energy and produce less waste and polluting emissions. Enzymatic or other biotechnology-based processes are also crucial for novel recycling technologies.

Environmental biotechnology can more effectively depollute waste streams, remediate contaminated soils. Environmental biotechnology may also help to reduce microplastics pollution.

Other types of biotechnology, combined with the application of our knowledge on **microbiomes**[57], can contribute to the fight against climate change. For example, bio-based systems can improve the detection and monitoring of chemical pollutants. Such systems could also lead to the development of alternative energy sources by engineering marine algae or bio-hybrid artificial photosynthesis systems and by providing an innovative carbon-capture solution while at the same time caring for biodiversity. The reduction of emissions can be further strengthened with the conversion of biomass and waste feedstocks into sustainable fuels.

To accelerate the application of biotechnology for climate and sustainability, the Commission will explore how to accelerate market approval of **sustainable, low-risk bio-pesticides and bio-based fertilisers.** Some of the living labs under the EU Mission "A Soil Deal for Europe" could be testbeds for such substances and their impact on soils and the results obtained could feed further actions[58]**.**

4.6. Developing standards

Standards are of utmost importance for biotechnology, biomanufacturing and the bio-based industries in general. Even though they are most often voluntary, they facilitate market access and innovation by influencing industry practices, guiding policies and by ensuring products or processes meet recognised benchmarks for quality, safety, and sustainability. It is therefore essential to further update and develop missing and outdated standards. The Commission will continue to **encourage the elaboration and updating of European standards for biotechnology and biomanufacturing**, with support of the European standardisation organisations and in compliance with EU competition rules. In this regard, the Commission in its Annual Union Work Programme for European Standardisation for 2024 has indicated its

[57] Microbiomes are defined as complex microbial communities from various environments and ecosystems such as soils, marine, gut etc.

[58] EU Mission: A Soil Deal for Europe: https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/soil-deal-europe_en

intention to request the European standardisation organisations to develop and revise standardisation deliverables on biomaterials, bio-based, and wood-derived products.

4.7. Collaboration and synergies

As a way forward, the Commission will encourage the deployment of technologies related to biotechnological processes and biomanufacturing across EU regions through Regional Innovation Valleys (RIVs)[59]. These RIVs could become **sectoral centres of biotech excellence** in the EU on specific issues, such as biotech health security and biotech for food systems. The Commission would support authorities in charge of public national, regional, or local innovation policies and programmes to implement joint activities towards innovation, development and deployment in the area of biotech and biomanufacturing. This would be accompanied by the participation of the private sector and research and innovation actors.

Moreover, the Commission has in place important fora for collaboration such as the Enterprise Europe Network (EEN) and the European Cluster Collaboration Platform (ECCP), which can complement these efforts with advisory and matchmaking activities. The ECCP has at least 159 cluster organisations active in biotech which can be involved in these activities[60].

Additionally, bio-based value chains would benefit from a deeper integration of primary producers (e.g., farmers and foresters) as they are at the beginning of most bio-based value chains. At present, primary producers (farmers and forest managers) often only play the role of biomass suppliers, and do not always get sufficient benefits to guarantee their interest in long-term business relations.

4.8. Fostering engagement and international cooperation

International cooperation can leverage the EU's strengths in biotech through knowledge sharing and industrial collaboration. The Commission will **explore the possibility of launching international biotech and biomanufacturing partnerships with key international partners, such as the US, India, Japan, and South Korea,** to collaborate on research and technology transfer, and to explore possibilities for a strategic cooperation on regulatory and market access-related topics. Such cooperation could also address health and global food security aspects. Through the Global Gateway and in line with its Global Health Strategy, the Commission will advance existing partnerships with Africa, Latin America and the Caribbean on manufacturing health products aiming to diversify global supply chains, overcome shortages of critical health products and reduce the global burden of disease. More generally, the Commission will examine the level of trade barriers to biotech and biomanufactured products and the potential to lower them through its trade agreements.

Furthermore, the EU and the US will step up the work in the EU-US Trade and Technology Council and under the Science and Technology agreement to explore the opportunities of innovative and sustainable biotechnology and biomanufacturing solutions to address global challenges, such as climate change mitigation and adaptation, protecting biodiversity,

[59] One of the five flagship of the European Commission Communication "New European Innovation Agenda" (NEIA), COM(2022) 332 final

[60] These cluster organisations are mapped on the European Cluster Collaboration Platform: https://reporting.clustercollaboration.eu/industry .

improving health outcomes, and to partner up in addressing economic security risks on biotechnology.

The EU will continue working with its partners in the global UN policy frameworks such as the World Health Organisation, the Convention on Biological Diversity and its Cartagena Protocol on Biosafety, as well as the Kunming-Montreal Global Biodiversity Framework to ensure safe and sustainable use of biotechnology globally.

5. Conclusions

The extraordinary advances in life sciences, supported by digitalisation and AI, and the potential of solutions based on biology for solving societal issues make biotechnology and biomanufacturing one of the most promising technological areas of this century. They can help the EU to modernise its primary sector and industry, boost circularity and be more competitive and resilient, provide better healthcare to our citizens and succeed in its green transition.

A more coordinated approach for biotechnology and biomanufacturing policies will help realise their full potential. Strengthening our biotechnology and biomanufacturing competitiveness requires measures in the regulatory, industrial, economic and social dimensions. This includes significant investment in infrastructure and know-how and ensuring that it can reap the benefits of the EU single market.

The Commission will continue to follow-up and strengthen the EU level framework along the main actions:

- ***Action 1***: Simplified regulatory framework and faster access to market: to prepare for this the Commission will launch a study analysing how the legislation that applies to biotech and biomanufacturing could be further streamlined across EU policies, exploring targeted simplifications to the regulatory framework, including for faster approval and bringing to the market. The study will be finalised by mid-2025 and could lay the foundations for a possible EU Biotech Act.
- ***Action 2***: Better support for scale-up and ease of navigating regulations: the Commission will work towards establishing an EU Biotech Hub, an operational tool for biotech companies to navigate through the regulatory framework and identify support to scale up, by end of 2024.
- ***Action 3:*** Use of AI and generative AI: the Commission will support structured exchanges with stakeholders to accelerate the uptake of AI, and in particular Generative AI, in biotech and biomanufacturing (in the context of GenAI4EU). The Commission will also raise awareness of facilitated access to the EuroHPC supercomputers for AI startups and the science and innovation community, in the course of 2024.
- ***Action 4:*** Encourage more private investments: in order to remove obstacles to investments, the Commission will complete a study to identify barriers and ways to support the consolidation of investment funds, stock exchanges and post-trading infrastructure, by mid-2025.
- ***Action 5:*** More public investments to encourage private investments in the sector: the Commission will advocate the inclusion of biotech and biomanufacturing as part of the European Innovation Council (EIC) accelerator Work Programme 2025 to develop and scale-up innovations.
- ***Action 6:*** Enable fair comparison with fossil-based products: the Commission will further develop methodologies to ensure a fair comparison between fossil-based and bio-based products, in 2025. This will include reviewing the Product Environmental Footprint (PEF) to assess the environmental impact of products.
- ***Action 7:*** Bigger market for biotechnology and biomanufacturing: the Commission will deepen cooperation with international partners, such as the US, on biotechnology research, under the Science and Technology Agreements, by end 2024.
- ***Action 8:*** The Commission will review the EU Bioeconomy Strategy by end 2025. The review will take into account the current societal, demographic and environmental challenges, reinforcing the bioeconomy's industrial dimension and its links to biotechnology and biomanufacturing to contribute to a stronger EU economy.