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European Commission

CALL FOR EVIDENCE FOR AN IMPACT ASSESSMENT

This document aims to inform the public and stakeholders on the Commission's future legislative work so they can provide feedback on the Commission's understanding of the problem and possible solutions, and give us any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	European Biotech Act
LEAD DG (RESPONSIBLE UNIT)	DG SANTE - D
LIKELY TYPE OF INITIATIVE	Legislative: proposal for a regulation of the European Parliament and of the Council
INDICATIVE TIMETABLE	Q3 2026
ADDITIONAL INFORMATION	Biotech and biomanufacturing - Your Europe

This document is for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described, including its timing, are subject to change.

A. Political context, problem definition and subsidiarity check

Political context

A new **European Biotech Act** was announced in the political guidelines for the European Commission 2024-2029. This new act should make it easier to bring biotech from the laboratory to the factory and then onto the market. Biotechnologies[1], supported by AI and digital tools, can help to modernise entire parts of our economy, from farming and forestry to energy and health. In the EU, biotechnology reached a gross value added in 2022 of €38.1 billion: the highest contribution came from medical and pharmaceutical biotechnologies and the fastest growing area was industrial biotechnology (Measuring the economic footprint of the biotechnology industry in the European Union). Yet, the EU is currently not reaping the full potential of biotech: European companies are not competitive enough and face barriers and complexity when translating innovation into products, bringing them to the market, and reaching their final users.

The Communication on biotechnology and biomanufacturing (published in March 2024) identified challenges and barriers for biotechnology and biomanufacturing in several sectors: medical and pharmaceutical, agricultural, food and feed, industrial and environmental, and marine biotechnology. It stressed the need for greater efforts to provide the right environment for the biotech sector to grow, to promote EU competitiveness and sustainability, while acknowledging its relevance as a critical technology from the viewpoint of economic security. More recently, the Competitiveness compass for the EU indicated that the European Biotech Act will provide a forward-looking framework conducive to innovation in areas such as health technology assessment and clinical trials and, more generally, for leveraging the potential that biotechnologies can bring to our economy.

This initiative is part of a broader Strategy for European Life Sciences, which looks at how the EU can support the green and digital transitions and develop high-value technologies. Several other EU policy initiatives are also particularly relevant for the sector. These include the future EU bioeconomy strategy and action plan, the European Innovation Act, the EU start-up and scale-up strategy and the European strategy for AI in science, plus initiatives that have already been adopted or are ongoing, such as the European industrial strategy, the Union of skills, the Savings and investments union, the EU Economic security strategy and the Energy Efficiency Directive.

Problem the initiative aims to tackle

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

The biotech sector is research-driven and fast-moving. To thrive, it requires substantial and continuous public and private investment, a conducive regulatory environment, an adequate ecosystem, advanced infrastructures, reliable supply chains and skilled workforces.

While, overall, the EU has a relatively strong position globally when it comes to fundamental research in biotech, this **does not translate into products** or improved industrial processes which can then be brought to the market. As a result, the EU is not realising the full potential that biotech can contribute to the EU's economy, sustainability and security. European companies are not competitive enough and face several market and regulatory barriers which have been identified in the Commission's communication entitled 'Building the future with nature: boosting biotechnology and biomanufacturing in the EU' and in the reports by Mario Draghi[2] and Enrico Letta.

The main drivers identified across biotech sectors are:

1. European companies in particular SMEs, spin-offs and start-ups have a hard time expanding within the single market because of a **complex regulatory framework that is perceived as slow and burdensome**. There are several cases where implementation of the relevant EU regulatory framework diverges among Member States. In addition, in certain instances, the EU regulatory framework, including the regulatory science that enables risk assessment, is neither sufficiently tailored to the specificities of the highly innovative and fast-developing biotechnology sector nor up to date. This results in diverse regulatory environments that are complex to navigate for companies and that can hinder the development or commercialisation of biotech products. Barriers at national or regional levels can further delay or hinder market entry of innovative products.
2. The growth and development of biotech companies in Europe is hindered by **market fragmentation, risk capital constraints, and scattered innovation support**. EU companies lack sufficient access to risk-tolerant capital and there is a lack of coordinated investment (private and public) to support the translation of innovation into products and the scaling-up of production for innovative biotech products. Despite increases over the last decade, the share of global venture capital funds raised in the EU is only 5%, compared with 52% in the United States and 40% in China.
3. The EU does not tap into **the full potential of its scale**, not only in terms of market size, but also when it comes to pooling capacities to make it more competitive globally. Typically, national interests often lead to support for local champions, resulting in a fragmented landscape. Many biotech clusters exist throughout the EU. Some **clusters** cover various technologies and provide a full range of activities that bring together different stakeholders (e.g. from academic research to support SMEs, spin-offs and start-ups). Others, however, are mostly of regional relevance, do not cover all the steps from laboratory to market, duplicate efforts at low scale, do not fully use their capacities, or have limited resources. Fragmentation in this area means Europe's biotech is punching below its weight.
4. Another important factor is that biotech products are complex to develop. Manufacturing them requires highly specialised equipment and a highly qualified and multidisciplinary workforce. **In the EU**, there is a **mismatch between the labour supply and the biotech and biomanufacturing skills required**. This, combined with the fast-developing nature of this field, calls for greater efforts to attract suitable candidates to the biotech workforce and for upskilling and frequent reskilling to improve retention of staff. In addition, academics and scientists active in research for innovative technologies are often poorly connected to the industry ecosystem and/or lack the necessary entrepreneurial skills to create companies and develop commercial products.
5. **AI and big data** – including access to supercomputing capacity and to large, integrated, high-quality datasets – offer huge potential for all sectors underpinned by biotechnology, provided that appropriate safeguards are put in place (e.g. in terms of biosecurity). But the potential of AI and data is not yet fully exploited in the biotech sector.

In addition, the EU is a global leader in **biomanufacturing**, particularly in biological medicines, which generate high economic value, create highly skilled jobs, and attract further investment in manufacturing and R&D. However, global competition for such investment is intensifying and supply chains remain subject to disruption, which poses an unprecedented challenge for the EU in maintaining its leading position and, ultimately, for its economic security.

The challenges described above affect all those involved in the biotech value chain but, in particular, spin-offs, start-ups and SMEs. Without action at EU level to provide the right environment, the EU biotech sector will not thrive in a

[2] On the pharmaceutical sector, the Draghi report flags four major elements: (1) lesser and fragmented public R&D investment in the EU; (2) lesser private R&D investment in the EU and a weaker supporting environment; (3) a slow and complex regulatory medicines framework in the EU; (4) the complex emergence of a European Health Data Space (EHDS).

competitive global market. **Companies that can bring their products to the market faster and more easily in other regions may simply do so – and ultimately move, innovate, invest, grow and generate employment there**. As an illustration, the share of clinical trials conducted in the EU has fallen over the last decade from 25% to 19%. European biotech companies face an opportunity gap, with the United States having twice as many early-stage venture capital deals and three times as many late-stage deals. Over the last six years, 66 of the 67 biotech companies going public have targeted the US NASDAQ rather than European stock markets.

Without intervention at EU level, the competitiveness gap of the EU will probably widen. In that sense, the EU is likely to fall behind its competitors in bringing innovations to the market, supporting start-ups, scale-ups and other SMEs, and, overall, in profiting from the potential benefits that biotechnology can bring to the economy and society as a whole. Furthermore, if no action is taken, dependencies on third countries would increase.

Basis for EU action (legal basis and subsidiarity check)

Legal basis

The legal basis for this initiative is expected to be **Article 114** (establishment and functioning of the internal market) and **Article 179** (strengthening its scientific and technological bases by achieving a European research area) of the Treaty on the Functioning of the European Union.
The principle of subsidiarity will be respected.

Practical need for EU action

The problems and drivers identified are shared across EU Member States and affect the single market and the competitiveness of European companies, as well as European research and innovation. For instance, there is a need to promote an ecosystem for the entrepreneurial economy, including creating a supportive environment to raise private finance for EU companies at a competitive scale. Biotech clusters need to be significant and meaningful on a continental scale to compete globally. Supporting the storage, access and sharing of data across the EU and facilitating access to sufficient supercomputing capacity will also be critical for the development and deployment of AI solutions for biotech. Greater efforts to attract, reskill and upskill workers in the biotech sectors are needed throughout the EU. Lean and streamlined regulatory and risk assessment frameworks need to support the functioning of the internal market. Some of the legislation applicable to biotechnology is already harmonised at EU level and any further streamlining should therefore also be undertaken at that level.

Several Member States have taken action to boost innovation in this field, but the bottlenecks have only been partly addressed. What is now needed is coordinated intervention of a sufficient scale at EU level, while respecting the competencies of Member States.

B. Objectives and policy options

The overall objective of the initiative is to **improve the size and competitiveness of the biotechnology sector** in the EU while maintaining high safety standards.

The new European Biotech Act will aim to ensure that the EU makes the most of the biotech revolution for the benefit of society, the environment and the economy. The new Act will make it easier to develop and bring to market products across all biotech sectors in the EU.

The impact assessment will explore the following five areas:

1. **Speed and streamlining**: 'time-to-market' is an essential parameter for the successful translation of innovation into commercial products. This is especially relevant for start-ups with limited cash-flow and a lack of alternative sources of revenue. Where appropriate, the regulatory environment for biotech needs to be simplified, including the procedures for risk assessments. The aim is to facilitate and speed up the development and approval of biotech products and to bring them to the market faster and more easily, without compromising safety for health and for the environment or biosecurity standards. Several activities to address this goal have been initiated through proposals already adopted by the Commission, such as the reform of pharmaceutical legislation (e.g. proportionate risk assessment and reduced market access timelines, sandboxes) and the proposed legislation on plants obtained by certain new genomic techniques. Best practices for accelerated time-to-market at EU, national and regional levels need to be promoted, in particular for the most innovative and promising technologies.
2. **Financing**: having access to sufficient capital is key to supporting the process of translating innovation into product development and the scaling-up of production capacities. Risk-tolerant capital is essential for the development of the biotech industry at seed phase, scale-up stage (especially the medium and late-stage venture capital phase), and at later stages of development (e.g. generating access to public equity financing

via stock markets). Existing public activities, incentives and funding schemes offered under Commission programmes or by EU agencies, together with other EU or national measures, could also be improved.

3. **Scale**: tapping into the potential of the EU in terms of both scale of production and market size can help to ensure that companies - in particular spin-offs, start-ups and other SMEs - thrive in Europe. It can help them to complete the development, production and deployment of their products in the EU. Further options could be to look at possible support for the development, operation, governance and coordination of biotech clusters or centres of excellence in the EU. Biomanufacturing in particular will be looked at, with a view to exploring how the EU and Member States can deploy targeted incentives to attract and retain investment in high-tech biomanufacturing. This includes investing in infrastructure, streamlining permitting processes, fostering a globally competitive regulatory environment, and supporting innovation in sustainable manufacturing. An open, competitive and at-scale business environment will be essential to keep the EU ahead in the global race.
4. **Skills**: specific measures will be considered to improve the upskilling and reskilling of the workforce in the biotech area. This is to ensure that companies have access to adequately trained staff and to equip academic developers with the necessary entrepreneurial skills to create and grow a company. Possible initiatives could include programmes to attract top global talent in R&D, manufacturing engineers and serial entrepreneurs.
5. **Use of data and AI in the biotech sector**: access to data, storage services and computing resources is essential for biotech research and innovation and for the development of AI tools and solutions to support the development of biotech products. AI plays an increasingly large role in biotech, for example by speeding up drug discovery or mitigating the misuse of biotechnology. The health biotech sector requires access to anonymised real world health data in Europe by leveraging initiatives and legal frameworks, such as the European Health Data Space (EHDS). Having access to supercomputing capacity and AI testing facilities (known as 'AI Factories') is essential to enable biotech companies and organisations to use data effectively. Targeted projects and tailored programmes at EU level have the potential to facilitate and push forward the development and adoption of digital solutions and AI in all biotech sectors, while ensuring that biotechnology is not used for malicious purposes.

In addition, the White paper for European defence - readiness 2030 emphasises the strategic importance of biotech in the global technology race. Specific biotech applications will therefore be looked at from the viewpoint of **security and defence** (e.g. dual-use technologies) when exploring potential policy measures.

The initiative is expected to result in a proposal for a regulation which could be accompanied by non-legislative actions.

C. Likely impacts

The impact assessment will look at ways of tackling the underlying drivers that can best support increased innovation and competitiveness of the EU biotech sector.

This could lead to EU companies active in the biotech area bringing to market an increased number of products from the R&D phase, and to an increased number of products being fully developed and eventually manufactured by EU companies. The economic impacts are likely to be significant and will be assessed thoroughly.

The initiative will also aim to modernise the EU biotech sector by supporting its adoption of AI, facilitating its shift towards biotech production and boosting its competitiveness compared with other regions. The impact assessment will also pay particular attention to the needs of SMEs, spin-offs and start-ups, as these are the backbone of the biotech revolution and are expected to benefit the most from the initiative.

The impact assessment will also consider social impacts on job creation, skills, and the potential benefits for European citizens from the access to new solutions, together with impacts on human and animal health.

The assessment of environmental impacts will focus, in particular, on protecting and restoring biodiversity and using it sustainably. The biotech sector has the potential to align competitiveness and sustainability objectives. By supporting the growth of the biotech sector, the initiative is expected to have significant environmental benefits, for example by replacing some fossil-based input by bio-based compounds while ensuring that energy demand is met in a sustainable way. It could also help to achieve the climate neutrality target by 2050 and EU energy objectives by 2030, while creating green jobs and supporting a sustainable economic growth in regions across the EU.

The initiative will be relevant for the entire EU, as the biotech sector, with its various specialisations, is diffused across all Member States and regions, some of which act as key innovation hubs that drive cross-border collaboration.

This initiative will also help to meet the UN **sustainable development goals** (SDGs), in particular SDG 9 'industry, innovation and infrastructure', SDG 3 'good health and well-being' and SDG 13 'climate action'. SDG 8 'decent work and economic growth', SDG 2 'zero hunger' and SDG 12 'responsible consumption and production' are also relevant for this initiative.

D. Better regulation instruments

Impact assessment

An impact assessment will be conducted to feed into the Commission's proposal, which is tentatively planned for Q3 2026. The impact assessment process will be initiated in Q2 2025. It will be conducted in line with the Better Regulation guidelines and toolbox.

The impact assessment will be informed by robust evidence and stakeholder consultations (including a Call for evidence and public consultation). It will also benefit from the findings of external studies. The impact assessment will include a description of the problems to be addressed and will explore and compare options under the five areas mentioned in Section B.

Consultation strategy

The consultation gives stakeholders an opportunity to share views and insights on the main challenges faced by the biotechnology and biomanufacturing sectors across the EU, the possible scenarios to facilitate the development, market entry and deployment of biotechnology products in the EU, and the likely economic, social and environmental impacts of potential measures. Stakeholders include citizens, innovators, entrepreneurs, researchers and academia, biotech companies from different biotech sectors and of different sizes, industry federations, NGOs and civil society, other users of biotechnologies, trade unions, policy makers and public authorities, investors, and venture capitalists active in biotech. Particular efforts will be made to reach out to **SMEs** and **local and regional authorities**.

The consultation process will include the following activities:

- **Call for evidence**: to be launched in Q2 2025, giving interested parties the opportunity to provide feedback in any of the 24 official EU languages (it will be available in all official EU languages on the Have your say webpage for 4 weeks);
- **Public consultation**: to be launched in Q3 2025, giving interested parties and the general public the opportunity to answer a web-based questionnaire in any of the 24 official EU languages (it will be available in all official EU languages on the Have your say webpage for 12 weeks);
- **Targeted consultation activities**, tailored to specific stakeholder groups.

In line with the Commission's Better Regulation policy to develop initiatives informed by the best available knowledge, **scientific researchers, academic organisations, learned societies, scientific associations and other stakeholder groups** with expertise in the biotechnology sectors will also be invited to submit relevant published and pre-print scientific research, analyses and data. The Commission is particularly interested in submissions that integrate the current state of knowledge in relevant fields. **Industry** (including all relevant biotech sectors) is also encouraged to submit views and evidence on the main challenges, obstacles and bottlenecks encountered with specific biotechnologies, notably those stemming from the EU legislative framework, and to identify gaps as appropriate.

The Commission will publicise the consultation via various channels. The input received from stakeholders will feed into the impact assessment:

- A **factual summary report** on the replies to the public consultation will be published on the Have your say webpage 8 weeks after the closure of the consultation.
- A **synopsis report** covering all consultation activities will accompany the impact assessment report.

Why we are consulting?

The consultation strategy aims to ensure that all stakeholders concerned have an opportunity to express their views and share insights on the main challenges faced by the sector across the EU, the measures proposed, and their likely impact.
Stakeholders' input will feed into the impact assessment for the future European Biotech Act.

Target audience

The consultation is addressed to citizens, innovators, entrepreneurs, industry, financial institutions, investors/venture capitalists, researchers/research organisations, civil society (including consumer, patient and environmental organisations), other users of biotechnologies (e.g. farmers and foresters), trade unions, national and regional authorities, and any other stakeholders.