

Cefic position paper on biotechnology and biomanufacturing

Biotechnology and biomanufacturing are crucial for the EU industry, driving economic growth, innovation, and sustainability. While the EU still plays a relevant role in the biotech and biomanufacturing field, its position is weakening, as witnessed by the various relocations of industries to third countries. Effective measures to support and strengthen this key industry should therefore be rapidly introduced.

A set of measures is necessary to speed up innovation, reduce uncertainty, deploy, and anchor biomanufacturing capacity in the EU while maintaining high safety standards. Cefic recommends:

- 1) Establishing uniform definitions for biotechnology and biomanufacturing and securing market conditions.
- 2) Ensuring policy coherence and clearly defining the scope and objectives of the Biotech Act.
- 3) Targeted policy modification to modernize the approach to GMOs.
- 4) Implementing regulatory sandboxes and increasing support and funding towards industrialisation.
- 5) Developing skills and boosting data initiatives.

1) Establishing uniform definitions for biotechnology and biomanufacturing and securing market conditions

Definitions and terminology

We welcome the European Commission's development of multiple policy measures to promote and support the growth of biotechnology and biomanufacturing. Cefic proposes the following series of definitions aimed at clarifying each relevant term, which is necessary to establish a common semantic understanding of terms such as biotechnology and biomanufacturing:

- **Biotechnology** applies science and technology to living organisms, as well as parts, products, and models of them, to alter living or non-living materials to produce knowledge, goods, and services.
- For biomanufacturing, we call to adopt the following definition as proposed by IBISBA. **Biomanufacturing** is the commercial-scale industrial production of goods using biotechnology as a core process component. We additionally propose that this term includes the upstream and downstream operations that lead to the production of marketable goods and services (i.e., preparation of feedstocks for product manufacturing and post-production purification or formulation of products suitable for commercialisation).

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- **Engineering biology** is the design, construction, and/or assembly of the components of living systems to achieve an intended function or outcome. It includes the use of approaches such as genetic engineering and metabolic engineering.
 - **Synthetic Biology** is the systematic deployment of engineering principles to design (or profoundly redesign) and engineer biological systems, endowing these with novel biological functions that are inaccessible when using conventional genetic engineering methods, or even creating new-to-nature functions.

Finally, the EU should adopt a “bio-based materials and products” definition which reflects the existence of different business & manufacturing models, and their related output, namely including bio-based and bio-attributed materials & products, which can be wholly or partly derived from biomass. In particular:

- **Bio-based products** are those for which the share of bio-based content can be measured via established radiocarbon methods (¹⁴C tracing). These may be fully or partially bio-based.
- **Bio-attributed products** are those for which the use of bio-based feedstocks, substituting part of the raw material needed in the manufacturing process, has been attributed to the product via the mass balance method and is certified according to a third-party certification scheme.

Secure market conditions for European biomanufacturing

There is a real risk that European biomanufacturing will be increasingly offshored to 3rd countries with a more competitive framework in place. To secure Europe’s leadership in this field, it is essential to provide a clear and supportive regulatory environment and improve the conditions that allow industries to thrive by ensuring:

- **Access to key feedstocks for fermentation:** Biomanufacturing depends significantly on the consistent supply of high-quality fermentation substrates, such as sugars, whose prices can be highly volatile. First-generation feedstocks are often costly due to factors such as trade barriers, while subsequent generations tend to remain more expensive than their fossil-based counterparts due to technological aspects.
- **Competitive low-carbon energy:** biomanufacturing and the whole bioeconomy need access to competitively priced low-carbon energy. Still today, many of the enabling sectors remain heavily exposed to fossil-based energy at a cost that is 2-3 times higher than 3rd countries.

2) Ensuring policy coherence & clearly defining the scope and objectives of the Biotech Act

The Biotech Act should explicitly recognise the strategic importance of securing Europe’s capacity in biomanufacturing and biotechnologies, and **create the right conditions to keep industrial capacities on European soil**. Cefic shares the overall objective of the Act to improve the size and competitiveness of the biotechnology and biomanufacturing sector in the EU while maintaining high safety standards, but highlights that biotechnology serves as a multi-sectoral tool and that regulatory differences and investment profiles are unique to each sector.

The proposal should therefore recognise the distinct challenges faced by, e.g., chemical and pharmaceutical innovations due to varying regulatory requirements, development processes, and production setups. We call for a **clear harmonisation in the wider framework** regulating bioeconomy, circular economy, and life sciences to ensure coherence and coordination, particularly necessary where shared values exist, such as in strain development or early development phases.

The ultimate goal of the Act should be to create a framework able to **accommodate continuously evolving frontiers of knowledge and understanding**, without being too prescriptive. Any new or updated regulatory requirements should be proportional to the actual risks involved, based on scientific and technical evidence, and take into account economic factors, thereby maintaining a balance between fostering innovation, increasing competitiveness, and ensuring safety.

To achieve a successful Biotech Act that reflects the needs of biomanufacturing sectors, we suggest the following:

- Avoid overregulation and tackle fragmented policies, **cross-check existing regulations**, and thoroughly analyse potential overlaps or conflicting requirements within a clearly set timeline.
- Future regulatory systems should have a unified point of entry and either a single pathway that considers all potential applications or more pathways that anticipate the much broader range of products that emerge from engineering biology. Further, to decrease the risk of products being passed between multiple regulatory committees, there should be one or more regulatory bodies that are capable of reviewing a full spectrum of options, with input from relevant specialist agencies.
- **Streamline, accelerate, and harmonize the EU's marketing authorization procedures** so that innovations can be efficiently and swiftly placed on the market. Refrain from revising whole permits or market authorizations when introducing a new product and instead use simplified measures or solely notification systems (for example, simplified approval for biomanufacturing activities which already hold a permit in one Member State).
- Apply product-based instead of process-based risk assessments.
- Offer assistance to public authorities in **expediting the permit-granting process** (i.e., financial resources or skill development initiatives), similar to the announced technical support instrument in the Startup and scale-up strategy.
- **Enhance the recently created biotech and biomanufacturing hub** beyond a gateway, extend the portfolio of products covered beyond human health, veterinary medicinal products, food and feed, and finally consider integrating it with the Knowledge Centre for Bioeconomy.
- **Enhance the dialogue between industry and authorities** by designating an expert committee or an EU authority to issue nonbinding recommendations to applicants to decide which organisms should be within the scope of the regulation, following the US example of ["Am I regulated?" approach](#).

3) Targeted policy modification to modernize the approach to GMOs

Following the scientific evidence, also highlighted by EFSA, that potential risks associated with a new variety of organisms (plants, microorganisms, ...) are related to the phenotypic traits and not the technique used for the development, Cefic emphasizes the need to focus biotech regulation on the product and not on the process. We call for targeted amendments to the existing policy framework as follows:

- **Deliberate Release Directive:** clarify requirements and specifications of what a long safety record entails, enabling differentiated (simplified) regulatory procedures for risk assessment and management whenever sufficient experience with a particular GMO has been gained. We propose a product-oriented interpretation: it is not the mutagenesis technique itself that has a long safety record, but rather the products introduced to the market or released into the environment after additional breeding and variety registration. According to this

interpretation, additional techniques and methods of genetic modification, such as CRISPR-Cas, should be considered as yielding organisms to be excluded from the directive.

- **Regulation 503/213 and Directive 2018/350:** transform the Annexes listing requirements for the execution of risk assessments into implementing acts, to allow quicker adaptation to technological and scientific development.
 - Appropriate procedures and guidelines should be available for submitting applications for products containing viable Genetically Modified Microorganisms (GMMs).
 - Environmental risk assessment should account for cases of products that require persistence in the environment to yield effects (i.e., bio-fertilizers, bio-remediation).
- **“Opt-Out” Directive:** should be reformed to an “opt-in” procedure. In such a scenario, whenever a qualified majority is not reached in the standing committee, Member States could still allow for the use of GMOs on their territory.

4) Implementing regulatory sandboxes and increasing support and funding towards industrialisation

Regulatory sandboxes, scale-up, and financing

Considering the fragmentation of the EU policy landscape, the announced 28th regime under the Start-up and scale-up strategy should be utilized to harmonize regulations for developers of new biotechnological solutions, especially when involving different and potentially conflicting national regulatory frameworks. It is important to note that regulatory sandboxes should be leveraged only when the legal situation is unclear or meaningful legislation has yet to be created, as they can provide a stopgap solution to determine and impose the relevant rules in real time.

Biomanufacturing-related innovations frequently do not reach industrial scale, which is necessary for making the related products competitive. To tackle this aspect, the EU should:

- Establish a funding instrument tailored to the commercialisation & replication of scaled-up facilities, bridging the gap between innovation and market deployment.
- Continue and increase CBE-JU funding by using the newly dedicated Competitiveness Fund chapter on Health, Biotech, Agriculture & Bioeconomy, the European Scale-up Fund, and updating the scope of the joint undertaking by dedicating it to high-TRL projects ($\geq$ TRL 6).
- Strengthen Multi-Party Collaborations: to encourage knowledge transfer and leverage expertise in innovative technologies such as synthetic biology, bioinformatics, or biocatalysis, it is necessary to strengthen and promote collaboration between universities and industries.
- Consider the potential contribution of the European Defence Fund, given the relevance of biomanufacturing for defence applications.
- De-risk the scaling up of new biomanufacturing innovations by further strengthening and investing in (existing) open-access infrastructures.
- Mobilise EU financial instruments such as the Innovation Fund, European Investment Bank, to support industrial projects, reduce investment risks, and reinforce Europe’s strategic autonomy in biomanufacturing and bioeconomy.
- Ensure a more coordinated and harmonised approach to research and innovation funding at different levels (i.e. regional, national).
- Ensure better and strategic mobility of funding across Europe, especially on a cross-regional basis, by extending the remit of existing regional funding mechanisms.

The role of defence

As also reported by NATO in their Summary of Biotechnology and Human Enhancement Technologies Strategy, **biotechnology offers opportunities to enhance defence and security** by:

- Decreasing strategic dependencies on strategic competitors and potential adversaries by using synthetic biology and biomanufacturing.
- Leveraging unique properties of biotech materials for military platforms and infrastructure, including those that are stronger, lighter, self-healing, less toxic, more efficient, and/or faster to manufacture than current alternatives.

To further help advance the use of biotechnology and biomanufacturing for defence applications, consideration should be given to the creation of projects specifically tailored to biomanufacturing under the EU Permanent Structured Cooperation (PESCO). Following the example of the US Defense Advanced Projects Agency (DARPA), the EU should consider leveraging the existing testing and scale-up infrastructure to also develop high-value chemicals and compounds for a wide range of defence needs, while at the same time bolstering the civilian industrial uses.

5) Developing skills and boosting data initiatives

Skills and consumer engagement

Developing EU-wide biotech competencies and education pathways and competencies from secondary education through university, as well as support for programs offering on-the-job training and experiential learning opportunities, are crucial for public support for these technologies. Cefic proposes that the Commission ensure the following actions under the European Research Act (2026):

- In collaboration with Member States, **promote inclusion** of biotech and biomanufacturing principles already at the high school level.
- Establish a European **minimum framework of competencies** in biotechnology and biomanufacturing to serve as a basis for the creation of EU-harmonized university-level courses.
- Overcome sectoral competition for talent and brain drain: The EU is experiencing a loss of top scientific talent to countries like the US, Canada, and China, driven by better funding, salaries, and research opportunities. Nature reports that 90% of German academics are on temporary contracts, and countries like Spain and Italy face hiring freezes, pushing young researchers abroad.
- Offer **specialized European master's degrees** focused on biotech and biomanufacturing by leveraging the European university alliances, and include biotech and biomanufacturing as a key technological domain for innovative joint European study programs.
- To improve consumer engagement, develop a detailed action plan to **effectively communicate the nature of biotechnology, biomanufacturing, and their products**, highlight their benefits, and demonstrate how they can address EU climate challenges while building public confidence and acceptance of these technologies and products.

Use of data and artificial intelligence

To speed up innovation, Cefic asks for the establishment of a “data initiative”, which would allow biotechnology and biomanufacturing developers **access to high-quality, secure, and wide-ranging datasets** that can drive biomanufacturing development, together with AI-enhanced design facilitating

in-silico metabolic engineering strategies. Such an initiative should build on existing platforms and systems and could speed up dramatically the design and selection of promising pathways leading to the development of new strains and the related process development (e.g., by AI-based literature mining and enzyme library design).

In addition, we call for creating **a secure collaborative data space that pools datasets and resources together** (following the example of the Health Data Research UK sandbox). Hosted by one entity and allowing access to others, it would serve new combinations and uses of data, allow regulators or government agencies to test capabilities on actual datasets, and enable coalitions of actors to pool resources together through technologically enabled decentralised approaches (e.g., data collaboratives, fiduciaries, commons).

This initiative should be further compiled or integrated on a platform like the European Genomic Data Infrastructure, which could benefit from the announced Commission investment of EUR 25 million from the Digital Europe work program 2026 to boost the European genomic data infrastructure.

Annex 1 – Why a biotech act covering multiple sectors?

To illustrate the use of biotechnology across sectors and the integration of biotechnology and biomanufacturing within the broader bioeconomy, fermentation-based processes are a good example. Here, biotechnologically optimized microorganisms, designed to efficiently produce specific products, facilitate the generation of vital bio-based chemicals, enzymes, vitamins, amino acids, and Active Pharmaceutical Ingredients (APIs). These products have diverse applications such as home and personal care products, agrochemicals, pharmaceuticals, textiles, food & feed, and packaging.

Such a process can be summarized in a series of interconnected blocks, as shown in **Figure 1**.

While the fermentation in itself can be considered as the biotechnological core of the process, it could not be carried out without a feedstock to feed the microorganisms. The latter needs to be fed with a feedstock they find “palatable” to properly work. To this end, the biomass, coming from a variety of different sources, needs to be pre-treated and broken down to make its components accessible for microbial fermentation or other (bio)chemical processes, thus also showing the link with the broader bioeconomy.

The pre-treatment process is an example in which biotechnology can be again the protagonist, but can also be carried out using more conventional technologies like solvent extraction.

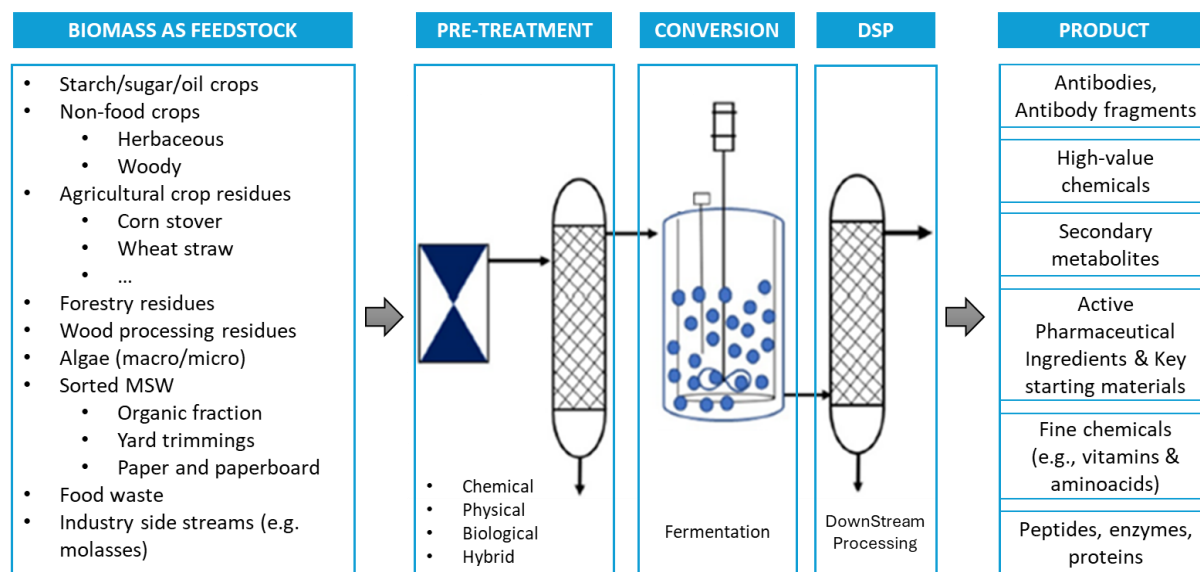


Figure 1 - Schematic representation of a typical biomanufacturing process. Different types of feedstocks that can be used and different types of products resulting from such a process are reported to highlight the diversity of sectors covered by biotechnology and biomanufacturing.