Cefic Bio-based cluster position on the Biotech Act call for evidence

SUMMARY

Biotechnologies are crucial for the EU chemical industry, driving economic growth, innovation, and sustainability.

Cefic shares the overall objective of the Biotech Act to improve the size and competitiveness of the biotechnology and biomanufacturing sector in the EU while maintaining high safety standards and to ensure that the EU makes the most of the biotech revolution for the benefit of society, the environment, and the economy.

Cefic recommends that the EU Commission take into account the following considerations to ensure the establishment of a thorough EU Biotech Act.

1. Provide clear definitions of biotechnology and biomanufacturing
2. Make the Act multi-sectoral
3. Ensure clear delineation of the different policies' roles, scope, and interconnections
4. Protect patents and intellectual property

Biotechnologies are crucial for the EU chemical industry, driving economic growth, innovation, and sustainability. They facilitate the production of biomass-derived chemicals and products, mitigate environmental impact, and advance healthcare through innovations such as mRNA vaccines and personalized medicines. In agriculture, biotechnology enhances crop yields and promotes environmentally friendly practices.

Cefic urges the EU Commission to consider the following aspects to ensure a comprehensive EU Biotech Act.

First things first: a common understanding of the terms and their interrelation

The European Commission is preparing an array of policy measures designed to support the growth of biotechnology and biomanufacturing. To ensure that policymakers are provided with consistent and comprehensible terminology, there is a need for a common semantic understanding of the different terms, such as biotechnology and biomanufacturing.

Cefic proposes to refer to the following definitions.

BIOTECHNOLOGY

> *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* [1].

[1] Friedrichs, S. and B. van Beuzekom (2018), "Revised proposal for the revision of the statistical definitions of biotechnology and nanotechnology", *OECD Science, Technology and Industry Working Papers*, No. 2018/01, OECD Publishing, Paris

BIOMANUFACTURING

For biomanufacturing, we call to adopt the following definition, as proposed by the Industrial Biotechnology Innovation and Synthetic Biology Accelerator (IBISBA).

> *Biomanufacturing is the commercial-scale industrial production of goods using biotechnology as a core process component* [2].

We additionally propose to adopt the full interpretation of IBISBA, suggesting that *since biomanufacturing refers to the overall process, one can consider that this term includes the upstream and downstream operations (i.e., preparation of feedstocks for product manufacturing and post-production purification and formulation of products suitable for commercialisation, respectively) that lead to the production of marketable goods and services* [3].

The Biotech Act objective and scope: make the Biotech Act multi-sectoral

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 and to ensure that the EU makes the most of the biotech revolution for the benefit of society, the environment, and the economy.

Ultimately, establishing a favourable policy environment will lead to the creation of a single market for sustainable products, retaining current business, and avoiding further offshoring to third countries[4] whilst scaling up biomanufacturing and biotechnologies in Europe.

Concerning the scope of the Act, Cefic wishes to highlight the following.

- Biotechnology serves as a multi-sectoral tool, unrelated to any specific application area. More information is available at Annex 1.
- Regulatory differences and investment profiles are unique to each sector (e.g., pharma with GxP, clinical trials vs. chemical sector).

The proposed Biotech Act should reflect this and should:

- Encompass all biotechnologies and the whole biomanufacturing sector.
- Seek harmonization where shared values exist, such as in strain development or early development phases.
- Strike a balance between commonalities and differences among sectors, recognizing the distinct challenges faced by, e.g., chemical and pharmaceutical innovations due to varying regulatory requirements, development processes, and production setups.

Ensure clear delineation of the different policies' roles, scope, and interconnections

The Act is a piece in the puzzle of legislation supporting the wider bioeconomy, circular economy, and life sciences, and should be developed with this in mind. Therefore, we call for a clear delineation of the different policies' roles, scope, and interconnections. The European

[2] Marie Ancelin, Vitor A.P. Martins dos Santos, John P. Morrissey, Michael J. O'Donohue, Merja Penttilä, James C. Philp, Addressing semantic ambiguity in biotechnology: Proposals from the European research infrastructure IBISBA, New Biotechnology, Volume 88, 2025, Pages 83-88, ISSN 1871-6784

[3] Ibid 2

[4] See, for example, Europe loses last antibiotic ingredient plant as production shifts to China | Caliber.Az – Last visit June 2025

Commission should address how this coordination can be achieved to ensure coherent and collaborative efforts rather than isolated initiatives.

Patents and intellectual property

Given the heavy reliance on innovation within biotechnology and biomanufacturing, special attention should be given to protecting patents and intellectual property. Unclear patent protections can undermine research, development, and technology transfer, thus hindering progress in the field.

Clarity is a commercial benefit, and so, certainty that a particular area of biotechnology is well and sensibly regulated serves the growth of the field as a whole.

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Oleochemicals Europe

BioChem
Europe

EFG
European Fermentation Group

efcg
EUROPEAN FINE CHEMICALS GROUP

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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, in support of our ask towards a multi-sectoral Biotech Act, 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 need 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.

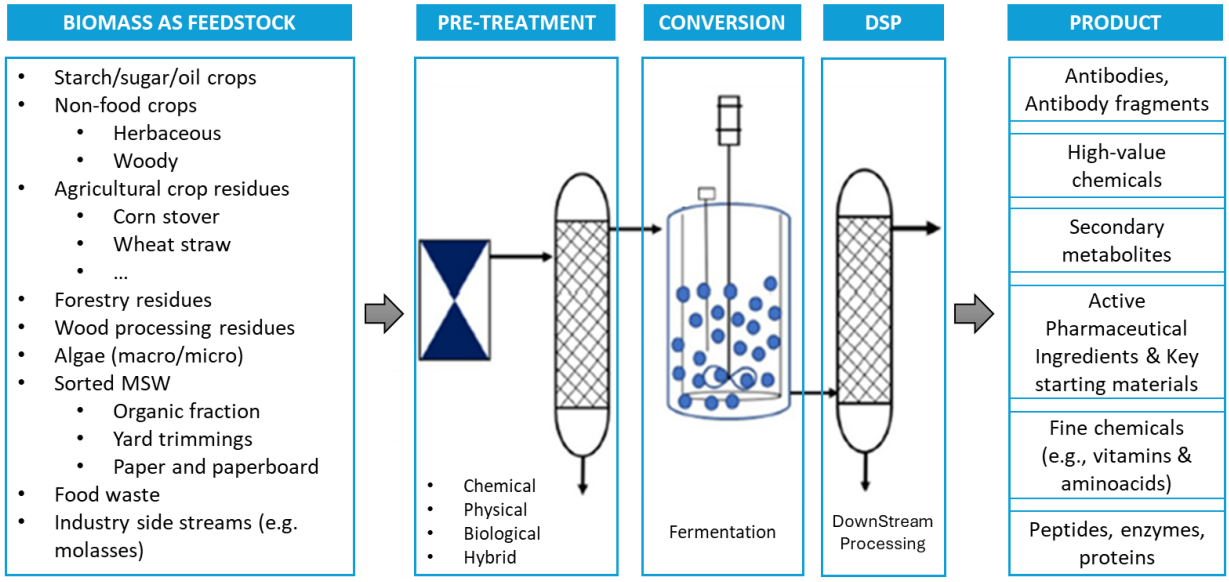

Figure 1 - Schematic representation of a typical biomanufacturing process. Different types of feedstocks that can be used and different types of products resulting from such a process are reported to highlight the diversity of sectors covered by biotechnology and biomanufacturing.