

European Biotech Act

2025/0406(COD) - 16/12/2025 - Legislative proposal

PURPOSE: to establish an EU Biotech Act to strengthen the competitiveness, resilience and strategic autonomy of the Union's biotechnology and biomanufacturing sectors,

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Biotechnology is one of the fastest growing sectors in the EU. It currently accounts for more than 900 000 jobs – 75% of which are in the health sector - and contributes close to EUR 40 billion to the European economy. Biotech can revolutionise healthcare, as a source of ground-breaking new treatments and therapies, more precise diagnoses and personalised medicines. However, the EU lags behind other global regions when it comes to translating its worldclass science and innovation into commercially viable products, and even more so in manufacturing such products at scale.

The proposed Biotech Act will increase Europe's biotechnology potential by supporting the transition of innovative ideas from laboratory to market. It will explore new means of funding and investment for biotech companies, through a new health biotech investment pilot to be developed in cooperation with the EIB Group. It will aim to boost bio-manufacturing via targeted support.

CONTENT: the Commission proposal on a European Biotech Act establishes a **comprehensive EU framework** to strengthen the competitiveness, resilience and strategic autonomy of the Union's biotechnology and biomanufacturing sectors, with a particular focus on health-related applications. It introduces measures to facilitate investment, innovation and scale-up of biotechnological and biomanufacturing activities, including improved access to funding, infrastructure and skills.

The general objective of this Regulation is threefold:

- (i) to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector, from research to production;
- (ii) to create the conditions for the development and timely placing on the EU market, of biotechnology innovations, products and services;
- (iii) to safeguard high standards for the protection of human health, animal health, patients and consumers, the environment, ethics, quality, food and feed safety, and biosecurity.

This general objective translates into the following specific objectives:

- strengthen the biotechnology sector and reinforce the EU's research, development and production capabilities, by establishing a framework for the recognition of, and support measures for, strategic health biotechnology projects and high impact strategic health biotechnology projects;
- **support funding of, investments in,** and access to capital for, biotechnology companies and projects, including through the setting up of an EU health biotechnology investment pilot to fill the gap in spending on biotechnology innovation;

- improve the **EU manufacturing capacity** of, and expertise in **biosimilars**, including through international cooperation;
- facilitate the application of **AI into the EU's biotechnology and health technology** manufacturing ecosystems and frameworks, in line with the Regulation (EU) 2024/1689;
- ensure a legislative framework that encourages innovation and takes account of technological and scientific developments and progress, by establishing provisions for health biotechnology products;
- prevent the **misuse of biotechnologies** and strengthen **biodefence** capabilities;
- enable the effectiveness of the above-mentioned measures through a legislative framework conducive to the use of biotechnology innovations, by amending Union legislation in particular on clinical trials, veterinary medicinal products, food and feed safety and related legislation.

Budgetary implications

Without prejudice to the outcome of the negotiations on the next Multiannual financial framework (MFF) proposal, strategic health biotechnology projects and high-impact strategic biotechnology projects may be supported by Union programmes, funds and instruments, in accordance with the objectives set out in the regulations establishing those funds and programmes. A contribution is expected to come from the 'health, biotechnology, agriculture and bioeconomy' window under the European Competitiveness Fund which, according to the proposal of the Commission, would receive a total allocation of EUR 20.4 billion over the MFF 2028-2034.

Two agencies, EMA and EFSA are proposed to be reinforced in staff and financially to conduct tasks related to these projects. The necessary financial resources will be compensated from applicable programmes under the agencies' headings in the 2028-2034 MFF and where possible by additional income to be generated from third parties.