European Biotech Act I :
Scope, Regulatory Framework, Market Landscape and Competitiveness Context

European Parliament

The European Commission proposed the "*Biotech Act I*" in December 2025. This is the **first standalone legislation regulating health biotechnology as a distinctive sector**. The legislation covers the whole lifecycle from research to market placement.

The goal of this new legislation is to make **biotech-based solutions affordable, competitive**, and **more rapidly available in the market.**

The European Commission has also announced a **second European Biotech Act for 2026**, covering biotechnology beyond health.

"Biotechnology" means 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, products and services. The proposed legislation particularly addresses health biotechnology.

The EU Biotech sector generated **EUR 75.1 billion** in economic footprint in 2022 and supported **nearly one million jobs**.

Issues of EU's biotechnology

Access to funding is the main bottleneck, while regulatory fragmentation is secondary to the capital gap

Complex regulatory framework

The current **regulatory framework that integrates biotechnology is very complex**. Despite its economic weight, the EU faces a structural competitiveness gap on commercial clinical trials. EC argues that complex and time-consuming regulatory barriers explain the decline.

Disparities across the EU

Almost every Member State has its own strategy on biotechnology. The Biotech Act I is intended to complement the Member States' national strategies which also highlights the disparities across the Union: major biotech hubs are in the North and West EU countries.

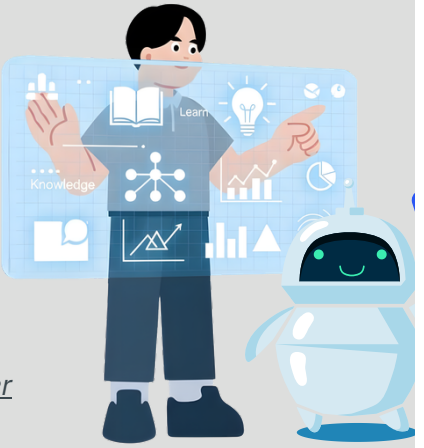
Access to funding

Biotech's high risk, capital intensive nature and lengthy development cycles makes funding difficult. The financing gap between the EU and US in late-stage R&D increases the risk of EU Biotech start-ups choosing to IPO abroad.

The institutions' proposals and objectives to enable progress :

- Proposes a **faster and easier adoption of biotechnologies** by reducing and simplify the regulatory framework
- Improve the functioning of the internal market to **strenghten competitiveness** of health biotechnology
- Make it easier to develop and test biotech products through **faster clinical research pathways**
- **Prevent misuse and increase the standards of protection** in the biotechnology market
- The Biotech Act I **aims to integrate AI** in the strategic sectors including pharmaceuticals and biotechnology

AI in biotechnology



Modern Biotechnology is **digitally intensive**, so the Biotech Act I should be read alongside the **EU cybersecurity framework**.

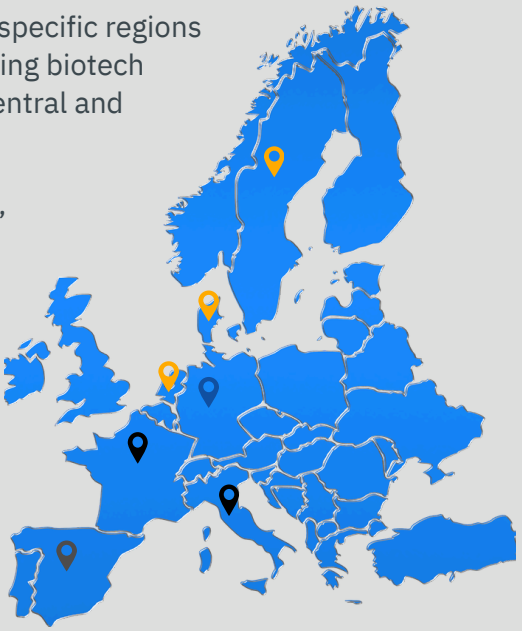
The "*Apply AI Strategy*" and the "*AI Continent Action Plan*" aim to integrate AI in the strategic sectors including **pharmaceuticals and biotechnology**.

Ransomware accounts for **54% of incidents in the health sector**. "*The Cyber Resilience Act*" sets lifecycle security requirements for products with digital elements.

The role of EU Member States in biotechnology

There can be some distinct competences which can be observed in specific regions due to the **existing industry and established economic base**. Leading biotech clusters are concentrated in Northern and Western Europe, while Central and Eastern Europe (CEE) are emerging.

Seven EU Member States stand out: Denmark, France, Spain, Italy, Germany, Sweden and the Netherlands.



Countries such as Denmark, Sweden and the Netherlands are specialised in **red biotechnology, meaning medical and pharmaceutical biotech**. These 3 countries have between 500 and 850 companies each concerning biotech.

The Netherlands **is one of EU's most connected hubs for life science and biotechnology innovation**.

Germany is among the EU's leading biotechnology countries and is specialised mostly in red (medical & pharmaceutical) and white (industrial & environmental) biotechnology.

Spain hosts 1,119 dedicated biotech companies. It is specialised in human health, and is considered the EU leader in clinical trial authorisation.

Central and Eastern European countries (CEE) are catching up through clusters connected to Western ecosystems, including the Baltic states, Bulgaria, and Poland.

This infographic was prepared by Garence CHAVE for the Policy Department for Transformation, Innovation and Health of The Directorate-General for Economy, Transformation and Industry (DG ECTI) and is based on the briefing "European Biotech Act I: Scope, Regulatory Framework, Market Landscape and Competitiveness Context" written by Kristin BECKER and Anne PLOEGER, at the request of the European Parliament's Committee on Industry, Research and Industry (ITRE).

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