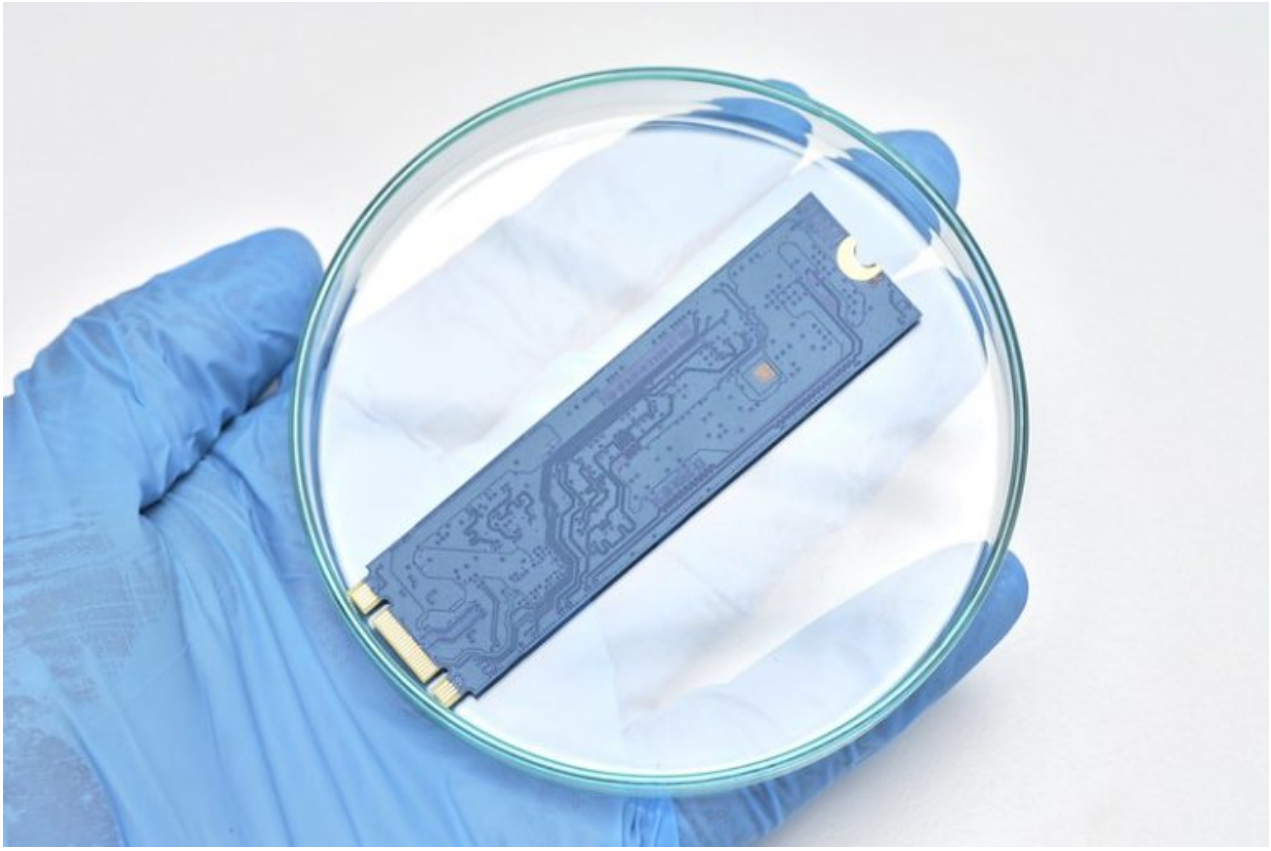
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Biotech Act : precaution sacrificed in the name of innovation?

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Publié le 25/02/2026, modifié le 09/03/2026

In a recent proposal for regulations claiming to "*strengthen the biotechnology and biomanufacturing sectors*", the European Commission wants to see these sectors governed by a policy that "*balance innovation with safety, equity and environmental protection*". However, the text mainly aims to promote industrial competitiveness and attractiveness to investors. It provides for faster authorisation procedures for "*biotechnology products*", a lighter regulatory framework and prioritisation of so-called "*strategic*" projects in order to reduce time to market.



On 2 July 2025, the European Commission announced its strategy for life sciences[1]. This includes several initiatives[2], among which is a proposal for a regulation to "*strengthen the biotechnology*[3] *and biomanufacturing*[4] *sectors*", the text of which was presented on 16 December 2025[5]. This

proposal is one of a series of new legislative initiatives relating to living organisms[6] and is part of an increasingly complex process of challenging the current regulatory framework[7]. The European Commission's approach is based primarily on its objectives of simplification and reduction of regulatory constraints, but it calls into question measures to protect health, the environment and certain citizens' rights. This proposed biotech regulation thus seeks to redefine priorities in order to continue to make living organisms a commodity at the service of multinationals and start-ups.

Which sectors are affected?

Officially focused on health biotechnologies, the proposed biotech regulation actually covers a broader scope, also affecting agriculture, food and industry. It is part of the Commission's European strategy for life sciences, which includes a strategy to promote start-ups and the bioeconomy.

On the health side, the proposed regulation concerns, among other things, "*innovative"* therapy medicinal products (Regulation 1394/2007), including gene (medical GMOs), cell and tissue therapies. It also covers industrial "*biomanufacturing*", fermentation processes, research and production infrastructure, access to biological and health data, and the use of digital tools and artificial intelligence throughout the development chain for these products.

The European Commission also wants to link this proposed biotech regulation with the one currently being negotiated on plants modified by NGTs (new genetic modification techniques). It states that this proposal is "*consistent with the vision for agriculture and food*" (General Food Law), a Commission communication[8] dated February 2025 in which it proposes to build *"a sustainable agri-food system... for current and future generations*". This communication considers NGTs to be "*keyfor accelerating the development of climate-change resilient, resource-saving, nutritious and high-yielding varieties, thereby contributing to the EU's food security and food sovereignty*...". According to the Commission, they "*can also yield microorganisms with positive impact on agricultural production, for example by reducing the need for synthetic fertilisers*".

This extension of the scope of the biotech regulation will not necessarily result in environmental and health risk assessments that are commensurate with the challenges at stake, at the risk of ignoring the precautionary principle.

Simplifying to optimise the industrial process

The text of the proposal describes biotechnology and biomanufacturing as "*essential to the competitiveness, strategic autonomy and economic security"* of the European Unionand a *"pillar of the Union's societal well-being in key areas such as health and food*". This observation stems from the text's central diagnosis that "*the EU lags behind other global regions when it comes to translating its world-class science and innovation into commercially viable products*". The Commission points out that this situation, described in particular by the Draghi report, which is very popular and forms the basis of the trend towards legislative "*simplification*"[9], too often leads companies to leave European territory to invest, develop, employ, create value and market their products elsewhere.

Risk assessment in the biotechnology and biomanufacturing sectors is not presented as an issue to be reinforced, but is implicitly seen as a factor slowing down progress. Thus, the biotech regulation introduces the concepts of "*strategic projects*" and "*high-impact strategic health biotechnology projects*", which benefit from priority treatment and enhanced administrative support. Any company developing an innovative project may ask a competent authority in a Member State

to designate its project as a "*strategic project*".

This objective of accelerating market access is being achieved in particular through experimental frameworks (regulatory sandboxes) that allow innovative products to be tested under adapted, *i.e.* reduced, regulatory conditions. Although these tests are to be supervised, the very principle of the system is based on a temporary derogation from the normal regulatory framework, which postpones risk assessment to a later stage after marketing. The simplification process also extends to the experimental procedures.

The Commission therefore does not see its proposed biotech regulation as a means of protecting citizens and the environment from the impacts of biotechnology, but rather as a tool for optimising the industrial process.

When innovation takes precedence over precaution

This priority given to innovation is particularly evident in the provisions relating to GMOs. Directive 2001/18/EC is explicitly mentioned, not to recall its protection objectives, but to suggest that its requirements and their implementation in Member States would slow down the conduct of clinical trials involving GMOs in the medical and veterinary fields. This proposed biotech regulation does not formally amend Directive 2001/18, but gradually circumvents its scope by stacking specific and derogatory regimes for veterinary medicinal products. This process had already begun with Regulation 2020/1043, which introduced derogations from the directive for clinical trials of medicinal products containing or consisting of GMOs and intended to treat or prevent coronavirus disease (COVID)[10].

The text continues this logic by amending Regulation 1394/2007 on advanced therapy medicinal products. It introduces the possibility of creating a category of "*advanced therapy medicinal products [or ATMPs] containing or consisting of genetically modified organisms presenting no or negligible risks*". They use techniques based on viral vectors, somatic cells or genetically modified material using NGTs. The Commission reserves the right to specify these categories by means of delegated acts in order to perpetuate the legislative framework for ATMPs. In concrete terms, it wants to be able to adopt such acts to amend Regulation 1394/2007 "*by clarifying the definition, without extending its scope, of what constitutes a tissue engineered product, in light of technical and scientific advancements in the field of ATMPs".* This mechanism would enable the Commission to amend the regulatory framework quickly, without in-depth legislative debate, while reducing the scope of the independent and prior risk assessment that is nevertheless essential in this still poorly understood field of life sciences.

Overall, the proposed biotech regulation places great emphasis on "*innovation*" (mentioned more than 200 times), while making no reference to *the* "*precautionary principle*", a cornerstone of European environmental law. Despite this, the European Commission continues to draw a clear political line, subordinating precaution to innovation and competitiveness.

What is the current status of the European procedure?

The proposed biotech regulation has now been submitted to the European Parliament and the Council as part of the ordinary legislative procedure. Amendments may be proposed, but the text is already part of a broader drive towards regulatory simplification, strongly promoted by the Commission and supported by a clear European industrial strategy.

The upcoming institutional debate on biotechnologies applied to living organisms will have to address a fundamental trade-off: how far is the European Union prepared to go in reducing risk

assessments and circumventing the precautionary principle, to the detriment of developing and maintaining a legislative framework that protects European citizens?

- + European Commission, "COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS - Choose Europe for life sciences - A strategy to position the EU as the world's most attractive place for life sciences by 2030" , 2 July 2025.
- + The document lists the "EU Strategy for Start-ups and Scale-ups", the "Savings and Investment Union" strategy, the Skills Union, the Medical Countermeasures Strategy, the Stockpiling Strategy, the Bioeconomy Strategy, etc.
- + Biotechnology is defined in the proposed regulation 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*".
- + Biomanufacturing is defined in the proposed regulation as "*industrial adoption of biotechnology*".
- + European Commission, "Proposal for a Regulation of the European parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)", 16 December 2025.
- + "The European Commission's legal initiatives", *Inf'OGM*.
- + "GMOs, seeds, pesticides, transparency... European law under attack!", *Inf'OGM*, 22 January 2026.
- + European Commission, "Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A vision for European agriculture and food – Working together to make our food and farming sector attractive for future generations – COM/2025/75 final", 19 February 2025.
- + European Commission, "The Draghi report on EU competitiveness", September 2024.
- + European Union, "Regulation (EU) 2020/1043 on the conduct of clinical trials on medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent coronavirus disease (COVID-19), and on the supply of such medicinal products – PE/28/2020/REV/1," 17 July 2020.

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