European Economic and Social Committee

OPINION

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Biotech Act

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)

Proposal for a Directive of the European Parliament and of the Council amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs

(mandatory referral)

(COM(2025) 1022 final)

(COM(2025) 1031 final)

CCMI/257

Rapporteur: **Joan ROGET ALEMANY**

Co-rapporteur: **Thomas STUDENT**

Advisor	Joan COMELLA (advisor to the rapporteur, Group I)
Legislative procedure	EU Law Tracker
Referral	European Parliament 14/1/2026
Legal basis	Articles 114 and 294 of the Treaty on the Functioning of the European Union
European Commission documents	2025/0406 (COD) COM(2025) 1031 final
Section responsible	Consultative Commission on Industrial Change
Adopted in section	10/3/2026
Adopted at plenary session	18/3/2026
Plenary session No	604
Outcome of vote (for/against/abstentions)	208/0/0

1. RECOMMENDATIONS

1.1 To unleash the transformative power of health biotechnology and protect the EU's strategic independence, the biotechnology sector needs to be reinforced through focused investments in research, innovation and production. For the EESC, reducing reliance on external political developments means committing to stronger, more resilient capabilities within the EU. This transformation should comply with social, environmental and industrial values, making sure that the EU's innovations benefit people, competitiveness and sustainability alike.

1.2 The EESC believes that, in the EU, the European Medicines Agency (EMA) should be the sole agency/authority for licensing pharmaceuticals.

1.3 The EESC welcomes the concept of regulatory sandboxes and recommends that 'social acceptability' also be tested. Sandboxes will undoubtedly allow the EU to reduce the current innovation gap. The EESC recommends aligning the definition of 'sandbox' with that of the EMA.

1.4 The EESC firmly believes that SPCs should be granted for one year if three conditions linked to key concerns are fulfilled: i) the product is innovative; ii) it is produced in the EU; and iii) it has a significantly different mechanism of action and a level of safety and effectiveness at least equivalent to that of any medicinal product authorised in the EU for the same disease.

1.5 The EESC welcomes the 'capital booster' financial pilot that will be launched with a duration of two years and a guarantee of EUR 5 billion, with the aim of mobilising up to EUR 10 billion in additional investment. This 'capital-booster' should become a permanent tool for late-stage financial support. We welcome the very important role that the European Investment Bank will play in channelling funding. The Committee believes that capital and risk capital require harmonised EU regulation to ensure that investors see the EU as a safe place and decide that this is the place to stay. To maintain the EU's long-term strength as a biotechnology hub, cooperation between academia and industry must be actively encouraged. Stronger partnerships and technology transfer mechanisms between universities, research centres and companies should be promoted through targeted funding and tailored support programmes aligned with social, environmental and industrial policy goals. The Commission should regularly monitor progress and evaluate results.

1.6 The defined 'digital by default' principle facilitates management and information exchange and regulates the use of AI in clinical trials. This necessary regulatory framework must be simple, clear, harmonised and predictable. The EESC highlights the importance of better integrating biotech into the European digital agenda and AI strategies. The EESC deems it necessary to once again stress the importance of human decision-making.

1.7 The EESC welcomes the Biotech Act's focus on biosafety. Annex I of the proposal includes a list of sensitive technologies and synthetic sequences that will be subject to control measures and require traceability and international cooperation to prevent improper or malicious uses (such as bioterrorism). In the case of products of concern, the EESC strongly recommends using

procedures similar to those for ‘drug precursors’. Mechanisms should be established to license which end users should be allowed to receive products of concern.

1.8 While the EU Health Biotechnology Support Network aims to build on and complement existing national and EU structures, avoiding any duplication, the EESC recommends additional support measures in financing.

1.9 The EESC believes that the EU must increase support for clusters. Therefore, the Committee suggests that EU institutions and bodies (such as financial, regulatory and other institutions necessary for supporting collaboration and the development of research and industrialisation) should set up offices in European clusters. Further measures for helping clusters reach a competitive size should be put in place, for example to integrate biotech in regional smart specialisation strategies, create biotech parks, establish bio-incubators, or set up open-access infrastructures for manufacturing.

1.10 For the EESC, simplification cannot and must not become a synonym for deregulation; the health and safety of the EU’s workers are on the line. The EESC would firmly reject any attempt to weaken the hard-won protections for workers, the environment and occupational health and safety. True simplification should reinforce the regulatory framework, ensuring that industrial innovation advances hand in hand with fairness, transparency and accountability.

1.11 Every biotechnology application must undergo strict and independent evaluation before entering the EU market, fully accounting for biosecurity and bioethical concerns. The EESC expects the EU to acquire the resources needed to ensure that those evaluations and approvals do not suffer unnecessary delays that deny ill people the chance of a cure.

1.12 The EESC underlines that preventive medicines and access to them should be sufficiently recognised as an important element of the biotech ecosystem in the EU. The Biotech Act should strengthen the infrastructure for vaccine research by expanding the number of eligible clinical trial centres and interconnecting them by improving their coordination and collaboration.

1.13 The EESC welcomes the proposed improvements to the EU clinical trial system and urges the co-legislators to at least maintain the level of ambition of the Commission proposal.

1.14 The EESC recommends that dedicated fast-track pathways and proportionate requirements for paediatric and rare-disease trials must be considered in the Clinical Trials Regulation, while maintaining robust standards for evidence. The same level of attention should be provided to women and individuals from diverse backgrounds.

1.15 The EESC stresses that innovation involving genetically modified microorganisms must fully respect the precautionary principle. Any regulatory streamlining should remain conditional on a case-by-case risk assessment, effective traceability and environmental monitoring proportionate to open uses, safeguarding health, ecosystems and agricultural diversity, including organic farming. Risk-based approaches should therefore ensure detectability, reversibility and environmental post-release oversight (particularly when microorganisms may interact with soils, water or food chains).

1.16 For a successful implementation of this Biotech Act, the EESC recommends systematically integrating the EU biotech strategy in all related policy initiatives like the Clean Industry Deal, the European Competitiveness Fund, the pharmaceutical strategy, the Critical Medicines Act, the bio-economy strategy and the Competitiveness Compass, among others.

1.17 The EESC calls for an inclusive dialogue between all stakeholders to increase public understanding, disseminate accurate information and ensure the responsible deployment of innovations. In this respect, it is also important to coordinate the work of national medical ethics committees to align their visions and strengthen their impact.

2. EXPLANATORY NOTES

Arguments in support of recommendation 1.1

2.1 As of 2021, the global market size for biotechnology has reached approximately EUR 720 billion, with a robust annual growth rate exceeding 18%. The US dominates this market, contributing 60% of the global value, followed by the EU (12%) and China (11%).

2.2 Biotechnology products that are researched, developed and produced in the EU under fair and responsible conditions boost both security of supply and long-term economic growth. Such contributions deserve steady support through fair and forward-looking policies. That is why social, green and industrial criteria should be clearly built into State-aid and public-procurement rules. Those who create industrial value, safeguard jobs and strengthen the EU's supply chains should be seen not just as contributors, but as key partners in shaping a stronger and more self-reliant European future.

Arguments in support of recommendation 1.2

2.3 Having only the EMA taking such decisions will certainly reduce the time taken to deliver innovative medicines to patients who need them to improve their lives and overcome serious illnesses. Reducing the quite high number of different national regulations will allow EU research and innovation institutions to invest their time in seeking solutions to problems that worry EU citizens.

Arguments in support of recommendation 1.3

2.4 Regulatory sandboxes allow for innovation and a research mindset in an appropriate environment without fear since there are balanced mechanisms to avoid unnecessary risks.

Arguments in support of recommendation 1.4

2.5 Tying this innovation incentive (SPCs) to very restrictive and cumulative requirements would further harm patients' chances of being given a solution to their illnesses through innovative treatments in the EU. Another consequence of extreme requirements would be the further growth of the innovation gap with more advanced countries.

However, care must be taken to ensure that the supplementary protection certificate is granted only for medicines that deliver genuine therapeutic innovation.

Introducing a criterion relating to the mechanism of action and to comparative effectiveness makes it possible to prevent purely formal modifications of an existing medicine from leading to an extension of protection without any real benefit or added safety for patients.

Arguments in support of recommendation 1.5

2.6 EU venture capital investment makes up only 7% of the world total, with the US making up 63%, and China 14%. Of the 67 EU biotechnology firms choosing to list, 66 do so on non-EU stock exchanges (2019-2025).

2.7 Today, much of the industrialisation in this sector is taking place outside of the EU because of the heterogeneity of financial regulations in the EU, poor scalability conditions and the lack of long-term stability in financial regulations.

2.8 Despite a strong landscape of universities and research institutes, there is a clear gap between excellent basic research and market-ready innovation: the 'translation gap'. This gap weakens the industry's global competitiveness.

Arguments in support of recommendation 1.6

2.9 Commission guidelines for AI throughout the lifecycle of a medicinal product avoids duplications and ensure regulatory coherence. Regulation must be easy to carry out in all Member States. Maintaining human decision-making is important to evaluate benefits and risks and protect patient safety.

Arguments in support of recommendation 1.7

2.10 The objective is to ensure that biotechnology is used for legitimate purposes without compromising public health or safety. There is reasonable concern regarding trading risks, and many EU biotech companies, start-ups and SMEs should not be shouldered with the burden of the responsibility of what their customers do.

Arguments in support of recommendation 1.8

2.11 A lot of work will need to be done to initiate and implement the necessary cultural change to make the EU stronger through joint collaboration between entities with diverse cultures.

Arguments in support of recommendation 1.9

2.12 When asked why so many global – and many European – financial players decide to industrialise innovation projects in the US, the answer is linked to the attractiveness of clusters like those in Boston and South San Francisco. The attraction is linked to their size and the culture developed there, which fosters all key elements, from talent to financing.

2.13 Additionally, given the restrictions on freedom of research in the United States, the European Union should highlight its values to attract talent.

Arguments in support of recommendation 1.10

2.14 The EU's strength is linked to its social responsibility towards its citizens – from employees to patients. It is not easy to find the right balance, and the EU is unique in finding it.

Arguments in support of recommendation 1.11

2.15 Various stakeholder groups such as academic/research institutions, NGOs, representatives of companies (including SMEs) and public authorities underlined slow and complex regulatory frameworks that lead to long authorisation/approval processes, thereby hindering innovation and delaying market access.

Arguments in support of recommendation 1.12

2.16 To foster innovation throughout the EU health sector and ensure its attractiveness, the Biotech Act should focus not only on treatment, e.g. innovative therapies, but also on preventive medicines, including immunisation. The Regulation should consistently recognise prevention as a strategic goal in health biotechnology.

Arguments in support of recommendation 1.13

2.17 Clinical trials are an important scientific method for developing medicines to solve problems caused by not-yet solved illnesses or even improve existing treatments.

2.18 The global share of commercial clinical trials in the European Economic Area has halved, from 22% in 2013 to 12% in 2023. During the same period, China's share tripled from 5% to 18%.

2.19 China and the US approve clinical trial applications within 60 days, while EU multinational trials average 113 days – delaying time-to-market, patient access and returns on investment. Clinical trials take up a significant proportion of the patent protection period, which may in some cases reduce the incentive to innovate.

Arguments in support of recommendation 1.14

2.20 Standard clinical trial requirements are not feasible for ultra-rare paediatric indications where trials designed to be adaptive and decentralised are required. This will reduce the time it takes for vulnerable people to access medicines. International and European experience shows that directly involving patients, caregivers and paediatric experts improves feasibility, relevance for end users and regulatory acceptability in rare-disease and paediatric trials.

2.21 There is a risk that minority groups may be discriminated against in healthcare efforts, including through the new use of AI to decide which research paths need attention.

Arguments in support of recommendation 1.15

2.22 There is a limited knowledge of microbial diversity, microbiome interactions and horizontal gene transfer. Precaution therefore remains scientifically justified.

Arguments in support of recommendation 1.16

2.23 It is important that the EU Biotech Act is complementary to already existing policies, and that biotech is integrated in the European industrial policy toolbox. Regulatory fragmentation must be avoided. The development of coherent regulatory and industrial policy pathways are key for addressing all stages of the biotech value chain, for making Europe a global hub for biotech, and for creating economic and societal added value. It is also important to harmonise regulations across EU Member States to ensure coherence and coordination among regulatory efforts and to make biotech products accessible to all.

Arguments in support of recommendation 1.17

2.24 Actions and campaigns that highlight the social and environmental contribution of biotech solutions while also addressing society's concerns are important for the social acceptance of biotech. Raising public awareness and acceptance about opportunities and risks of healthcare biotechnology is key for avoiding public misinformation and polarisation on topics like GMOs, gene or immunotherapies, vaccines and novel foods.

3. PROPOSED AMENDMENTS TO THE LEGISLATIVE PROPOSAL OF THE EUROPEAN COMMISSION

Amendment 1
linked to recommendation 1.4
Amendment to *Article 27* of COM(2025) 1022 final

Text proposed by the European Commission	EESC amendment
1. […] provided that the marketing authorisation applicant demonstrates that all of the following conditions are met: (a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union; (b) ***the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease;*** ***(c) the clinical trials evaluating the efficacy of the medicinal product and supporting its marketing authorisation were conducted in more***	1. […] provided that the marketing authorisation applicant demonstrates that all of the following conditions are met: (a) the medicinal product contains a new active substance distinctly different from that of any authorised medicinal product in the Union; (b) at least a manufacturing step ***(***excluding packaging, quality testing and Certification***)*** is performed in the Union. ***(c) the medicinal product has a mechanism of action distinctly different and shows a level of safety and efficacy which is at least equivalent to that of any authorised medicinal product in the Union for the same disease***.

than two Member States; ***(d)*** at least a manufacturing step**,** excluding packaging, quality testing and certification is performed in the Union. 2. The European Medicines Agency ('the Agency') shall assess.	2. The European Medicines Agency ('the Agency') shall assess…

Reason
The main concern that prompted the Biotech Act is the fact that the EU is losing ground in both research and the industrialisation of innovative bioproduction resulting from that research. Therefore, there must be three regulatory conditions for support tackling these issues: supporting both innovative products and their production in the EU.

Amendment 2

linked to recommendation 1.7

Amendment to *Recital 87* of COM(2025) 1022 final

Text proposed by the European Commission	**EESC amendment**
There are divergent requirements in Member States… This lack of harmonisation creates additional costs for economic operators, especially for those with strong security systems in place, and might distort competition within the internal market as well as potentially create barriers to trade and innovation.	There are divergent requirements in Member States… This lack of harmonisation creates additional costs for economic operators, especially for those with strong security systems in place, and might distort competition within the internal market as well as potentially create barriers to trade and innovation ***and endanger public health and safety.***

Reason
The lack of harmonisation is an internal cost borne by EU producers that hampers the availability of innovative medicines. This burden delays the market entry of innovative medicines that are developed to cure more people.

Amendment 3

linked to recommendation 1.7

Amendment to *Article 44* of COM(2025) 1022 final

Text proposed by the European Commission	**EESC amendment**
7. Paragraphs 1 to 7 shall also apply by analogy to persons that are not economic operators, except in the case where the biotechnology product of concern is supplied to a person that is employed by the same legal entity.	***7. A system similar to the licences that exist for other chemical products of concern (like drug precursors) shall be established within four years. An economic operator that makes available on the Union market, including through online marketplaces, biotechnology products of concern shall, for each transaction, check and report the licence of the prospective***

	customer and record the transaction, including the quantities ordered. ***8.*** Paragraphs 1 to ***8*** P shall also apply by analogy to persons that are not economic operators, except in the case where the biotechnology product of concern is supplied to a person that is employed by the same legal entity.

Reason
This is necessary to ensure that products of concern do not end up in the wrong hands. Otherwise, the EU may one day regret not putting in place a serious certification process to protect the European population from malware players, bioterrorism, etc. The EU is diverse and it is certainly difficult for start-ups and SMEs to be able to check the real activity of potential end customers in different countries.

Amendment 4

linked to recommendation 1.13

Amendment to *Article 6* of COM(2025) 1022 final

Text proposed by the European Commission	**EESC amendment**
	4. Member States and the Commission shall ensure that centres of excellence and manufacturing infrastructure supported under this Regulation include dedicated capacity for paediatric and rare-disease therapies, including age-appropriate formulations, dosing and delivery devices, as well as hospital-based and point-of-care manufacturing solutions for ultra-rare indications.

Reason
This amendment is needed to ensure that centres of excellence and supported manufacturing infrastructure truly meet paediatric and rare-disease needs, where current market incentives are structurally insufficient. Because around 80% of rare diseases have paediatric onset and many programmes for advanced therapy medicinal products are for ultra-rare diseases with only a few hundred patients EU-wide, generic volume-driven models do not deliver age-appropriate formulations, devices or small-batch capacity. By requiring dedicated paediatric and rare-disease capacity, including hospital-based and point-of-care manufacturing, the amendment tackles these market and infrastructure failures and reinforces the Biotech Act's goals for EU health resilience and equity for high-need paediatric and rare-disease patients.

Brussels, 18 March 2026.

The President of the European Economic and Social Committee
Séamus BOLAND