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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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)

{COM(2025) 1022 final}

Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
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 Union market, of biotechnology innovations, products and services, (iii) while safeguarding high standards for the protection of human health, animal health, patients and consumers, and the environment, ethics, quality, food and feed safety, and biosecurity. The appropriate legal basis is therefore as follows: • Article 114 of the Treaty on the Functioning of the European Union ('TFEU') which allows the Union to take measures that increase harmonisation and remove fragmentation to create a level playing field within, and fully exploit the scale of, the Union single market, so that the health biotechnology and biomanufacturing sectors can thrive. In accordance with Article 114(3) TFEU, the proposal seeks to achieve the objective of a high level of health and safety protection. • Article 168(4) TFEU, which mandates the Union to contribute to the achievement a high level of human health protection through the adoption - in order to meet common safety concerns - of (i) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; (ii) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; and (iii) measures setting high standards of quality and safety for medicinal products and devices for medical use. • Article 173(3) TFEU which allows the Union to decide on specific measures in support of action taken in the Member States to ensure the conditions necessary for the competitiveness of the Union's industry, excluding any harmonisation of the laws and regulations of the Member States. This article provides the legal basis for up an EU health biotechnology investment facility, setting establishing the framework basis for future Union financial support together with implementing partners, to support the financing of, and investments in, companies and projects falling within the scope of the European Biotech Act.
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In these areas the Union's competence is **shared** with the Member States. The proposal respects Member States' exclusive competences, such as in the provision of health services.
*Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU[1]. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU[2] sets out the areas where competence is shared*

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN

between the Union and the Member States. Article 6 TFEU[3] sets out the areas for which the Unions has competence only to support the actions of the Member States.

2. Subsidiarity Principle: Why should the EU act?

2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[4]:

- Has there been a wide consultation before proposing the act?
- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?

Extensive stakeholder consultations were carried out in view of the preparation of the proposal.

- A **call for evidence** (14 May - 11 June 2025) gathered 222 valid individual contributions from a wide range of stakeholders: business associations[5] (63), companies (50), non-governmental organisations (NGOs) (44), academic and research institutions (20), **public authorities in the EU (14),** EU-citizens (14) and other categories (17).
  - **As part of the public authorities, one had an international scope, 8 had a national scope, and five had a regional scope.**
- A **public consultation** (4 August - 10 November 2025) collected a total of 359 contributions. The contributions considered for the analysis[6] were submitted by 91 companies/businesses, 61 business associations, 47 NGOs, 44 academic/research institutions, 54 EU citizens, 9 non-EU citizens, **21 public authorities,** 2 trade unions, 2 consumer associations, and 1 environmental organisation[7], while 27 additional respondents identified themselves as 'Other'.
  - **As part of the public authorities, 8 had a national remit and 8 a regional scope, 2 were local authorities and 3 were international organisations.**
  - A strong majority of respondents to the public consultation agreed that biotechnology and biomanufacturing products can positively impact the EU economy and the society, also recognizing its contribution to the environment.
- Targeted consultation activities have been conducted, including in the context of an external study. announced in the Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' (Action 1)[8].
  - Consultation activities related to the **analysis of regulatory problems and challenges faced by the biotechnology sector**, and on the mapping of applicable EU and national legislations to biotechnologies (interviews, surveys and workshops).
  - For the **analysis of the impacts of identified policy provisions**, evidence on their impacts has been collected. On **clinical trials**, evidence has been collected through interviews, surveys and workshops. Evidence on the impacts of options on **genetically modified microorganisms** has been collected through **interviews.**

The Explanatory Memorandum contains a section on the principle of subsidiarity.

[3] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN
[5] 3 respondents that selected trade unions are analysed together with business associations as representing the industry.
[6] 4 trade unions were analysed under business associations.
[7] In the statistics, the 2 trade unions, 2 consumer organisations and the environmental organisation are reflected with the respondents who identified themselves as 'other'.
[8] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU, COM(2024) 137 final.

2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?

The objectives of the proposal cannot be achieved by Member States acting alone, as the issues tackled are of a cross-border nature and are not limited to single Member States or to several Member States. The proposed actions focus on areas where there is a demonstrable value added in acting at Union level due to the scale, speed and scope of the efforts needed.

Furthermore, the drivers identified are shared across the Member States, affecting the functioning of the single market and the global competitiveness of European companies. Moreover, access to finance is scattered across the EU and EU companies lack the capacity to access private finance at a competitive scale, including at later stages of development. Similarly, European biotechnology clusters are scattered across the EU, without sufficient continental scale to compete globally. The development and deployment of AI solutions for biotechnology remains limited, also due to the low level of storage, access and sharing of data relevant for biotechnology in the EU, including across borders. Lastly, there is also a clear need across the EU to attract, reskill and upskill the workforce.

Moreover, while several Member States have taken action to boost innovation in biotechnology, the above-mentioned bottlenecks persist; improvements are expected to take considerably more time and without achieving the levels needed to compete at global level. For example, access to finance would remain scattered at EU level. The growth of clusters in the EU would also remain limited, without sufficient benefits from cross-border connections.

Finally, important regulatory barriers faced by European biotechnology companies stem from Union legislation. Therefore, with a view to enable the effectiveness of the substantive measures put forward in this proposal, it is proposed to simplify Union legislation in the area of health and of food and feed safety to make it easier to innovate and place biotechnology products and services on the Union market and to enhance legal clarity.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

The proposed measures aim at tackling **two main drivers,** i.e. the **complexity** of the regulatory frameworks leading to slow time to market in comparison to a rapidly evolving and high-risk biotechnology sector, as well as the **fragmentation** in the biotechnology and biomanufacturing enablers, resulting in difficulties for EU stakeholders to scale-up.
The regulatory drivers are likely to persist without intervention. Given that they stem from EU legislations, national action would not be relevant and EU action is more appropriate. The market drivers are not expected to be sufficiently tackled through national action. Member States will still be able to take complementary action and their competences are respected.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

First, important regulatory barriers faced by European biotechnology companies stem from Union legislation, including authorization procedures at EU level. In the health area especially, given that diseases do not know borders, these common EU provisions constitute a cross-border issue that affect all Member States and can be streamlined at EU level.
Second, the market drivers identified are shared across the Member States (see section 2.2.), affecting the functioning of the single market and the global competitiveness of European companies. The proposed Act ensures the smooth functioning of the internal market in the health

biotechnology and biomanufacturing sector, while maintaining a high level of protection of health and of the environment.
(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[9] or significantly damage the interests of other Member States?
The proposed regulatory changes concern measures directly affecting the internal market as regards biotechnology products. The proposed changes concern legislation at EU. Absence of EU level action would not allow to address the regulatory complexities, uneven interpretations and high costs stemming from EU legislation, which are likely to persist without intervention. Therefore, national action would not be relevant and EU action is more appropriate. With regards to EU industrial policy measures, whilst several Member States have taken action, challenges and barriers persist. Improvements in this policy area are expected to take considerably more time and without achieving the levels needed to compete at global level, thus compromising the overall objective of ensuring the functioning of the internal market and support the Union's competitiveness.
(c) To what extent do Member States have the ability or possibility to enact appropriate measures?
First, Member States' ability to enact national measures is limited to the areas framed in the amended legislations. Second, Member State can continue to develop national policies on the enabling factors to R&D and the industrial base in their countries; the proposal does not affect their competences in these areas (e.g. access to finance, education, etc.). The proposal also respects Member States' exclusive competences, such as in the provision of health services.
(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?
The problems and drivers have been observed across the national, regional and local levels of the EU. This includes the regulatory barriers stemming from EU legislation, which are similar in all Member States given that the related fields have been harmonised. The drivers hindering the EU biotechnology and biomanufacturing sector (e.g. access to finance, skills, taxation, etc) are also similar in all Member States. These challenges might however have different intensities in different Member States and at regional and local levels.
(e) Is the problem widespread across the EU or limited to a few Member States?
First, biotechnology and biomanufacturing can be carried out anywhere in the EU. Second, the driver related to the complexities of the regulatory frameworks has a clear EU dimension as they are caused by shortcomings in the existing Union legislation. Third, the drivers related to the fragmentation in the biotechnology and biomanufacturing enabler factors have been observed across the EU.
(f) Are Member States overstretched in achieving the objectives of the planned measure?

[9] https://europa.eu/european-union/about-eu/eu-in-brief_en

First, the first Pillar of the proposed Act aims at making the EU regulatory framework streamlined and fit-for-purpose for the rapidly evolving biotechnology and biomanufacturing sector. In this context, the proposed Act is expected to allow Member States to perform their implementation and enforcement tasks in a more cost-efficient and consequently a more proportionate manner.
Second, with regards to EU industrial policy measures, Member States will incur costs related to the implementation of certain measures however these are expected to be proportionate with objectives being achieved.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

There is an overall strong support from Member States to reinforce the EU health biotechnology and biomanufacturing, and to ensure patients and users can benefit from innovations placed on the EU market. In September 2025, EU Member States urged the Commission to unlock the potential of biotechnologies, by reducing fragmentation and simplifying the EU regulatory framework across policy areas[10].

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

A large market with a streamlined and fit-for-purpose regulatory framework is the best possible way to support biotechnology to reach the market. It also ensures the same level of the protection health and of the environment across the Union.
Coordinated action at EU level on the enabling factors for a competitive EU biotechnology and biomanufacturing sector, are expected to yield higher benefits than national measures to ensure the smooth functioning of the EU single market. Stakeholders will be equipped with targeted tools to for biotechnology and biomanufacturing to efficiently scale-up. These respect national competences.

(a) Are there clear benefits from EU level action?

A large market with a streamlined and fit-for-purpose regulatory framework is the best possible way to support biotechnology to reach the market. It also ensures the same level of the protection health and of the environment across the Union.
Furthermore, comprehensive coordinated action at EU level on the enabling factors for a competitive EU biotechnology and biomanufacturing sector in the integrated single market (e.g. the set-up of strategic projects at EU level), are expected to yield higher benefits than national measures at lower scale.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

The development of biotechnology and biomanufacturing is costly, therefore it is more cost-efficient for operators to operate in a larger market with uniform regulatory frameworks. The measures streamlining and clarifying the regulatory framework and reducing administrative burden will allow to place products on the market in shorter time best achieve this objective through action at EU level.
The measures supporting the enabling factors for biotechnology and biomanufacturing in the EU aim at enhancing the functioning of the EU Single Market, which can be met more efficiently at EU level.

[10] Council of the European Union, A call for action on life sciences for the Union's competitiveness - Council conclusions (approved on 30 September 2025) (13323/25)

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

The first pillar of the proposal focuses on the EU regulatory frameworks. Although the covered areas are already harmonised at EU level, the proposed Act aims at streamlining and clarifying already existing Union legislation, also addressing the observed diverging national interpretations or additional national requirements, hampering the smooth functioning of the internal market. The other measures aim at equipping the EU with targeted tools to for biotechnology and biomanufacturing to efficiently scale-up.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The first Pillar of the proposal will amend existing Union legislation. Member States will keep the competences as the implementation and enforcement of the planned measures.
The additional measures aim at ensuring the smooth functioning of the Single Market and the competitiveness of the EU through complementary action at EU level. These objectives cannot be sufficiently achieved through national measures. National competences are not impacted.

(e) Will there be improved legal clarity for those having to implement the legislation?

The first Pillar specifically addressed the implementation challenges of the amended EU legislation. The additional measures will apply to the whole Single Market and will provide stakeholders with the tools and enhanced predictability to operate in the EU.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

The selected measures under the industrial policy and substantive part of the proposal are targeted at the specific areas of interventions listed below:

- The provisions on strategic health biotechnology projects and high-impact strategic health biotechnology projects are proportionate to the aims pursued, including by recognising the first category of projects at Member State level, and the second category at Union level on the basis of an assessment at Member State level. Moreover, the recognition of such projects is based on clear criteria tailored to ensure that projects that contribute substantially to the Union's competitiveness, resilience, and security fall within the enhanced support regime. Moreover, the recognition of such projects does not restrict Member States' ability to support additional projects through other instruments. Member States benefit from flexibility as regards the authorities that they intend to designate to recognise strategic health biotechnology projects and assess applications for high-impact strategic health biotechnology projects. This flexibility also applies to the single points of contact and the provision of administrative, technical, and financial support, in line with Union law and the national systems. Accelerated permitting timelines apply only to recognised projects and are designed to streamline procedures without lowering any environmental, health or safety standards.
- Similarly, measures aimed at supporting networking among health biotechnology clusters are limited to what is necessary to foster synergies in the internal market, while the EU

Health Biotechnology Support Network is aiming to build on existing national and EU structures wherever possible.

- On access to funding, the interventions focus on measures mobilising public funding and private capital; public funding needs to be in line with State aid rules.
- The proposed interaction modalities with Member States in the context of a Steering Group allows for priorities to be adjusted, including by ensuring that the support measures for strategic health biotechnology project and high-impact strategic health biotechnology projects remains closely aligned with the Regulation's general objective.

The proposed amending provision aimed at reducing the time-to-market of biotechnology products and services focus on certain sectoral Union legislation where room for simplification of regulatory and administrative complexities has been identified. Simplification relates to changes that are necessary with a view to secure the effectiveness of the substantive provisions put forward in this proposal and will improve the legal clarity, certainty, and overall efficiency of the concerned EU legislative frameworks.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The initiative does not go beyond what is necessary to achieve the objectives of the proposal and is appropriate to achieve them. The choice of the legal instrument is justified. The proposal respects and does not modify the competences of Member States.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

As indicated in question 2.3., the first pillar of the proposal aims at streamlining and clarifying existing Union legislation, also addressing the observed diverging national interpretations or additional national requirements that hamper the smooth functioning of the internal market. Action at EU level is therefore more appropriate than national interventions and the proposal does not go beyond what is necessary to achieve this objective.
Moreover, the other pillars of the proposed Act aim at addressing the market drivers identified. Whilst several Member States have taken action, the absence of coordinated action at EU level is not expected to bring fast improvements and at the necessary levels to compete at global level. National action would not be sufficient to achieve the objective general and specific objective of the proposal.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

The proposal takes the form of a Regulation of the European Parliament and of the Council.

A regulation is the most suitable legal instrument for Pillars 1 to 4, given the need for a uniform application of the new rules, in particular the conditions and procedure for recognising heath biotechnology strategic projects and high-impact health biotechnology strategic projects, and for their administrative, technical and financial support, and also more broadly for companies and non-profits active in the relevant biotechnology sectors across the internal market. This is also the case for Pillar 5, regarding the provisions on biotechnology health products, given that they aim to ensure a dialogue and more flexibility across the Union legislative frameworks in the area of health. The choice of a regulation as a legal instrument is also appropriate for pillar 6 because only a regulation,

with its directly applicable legal provisions, can provide the necessary degree of uniformity needed to boost EU biodefence and biosecurity and prevent biotechnology misuse.

In all cases, the choice of the instrument is justified considering that the pillar 7 establishes provisions amending several existing Union regulations in the area of health and food and feed safety.

Lastly, a regulation is appropriate for the provisions regarding on evaluating this Regulation which do not need to be transposed through national measures and are directly applicable.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument og approach?)

The first pillar of the proposal has an internal market component, and therefore it leaves limited scope for national action in order to ensure the smooth functioning of the internal market. Member States' ability to enact national measures remains limited to the areas framed in the amended legislations and is unchanged.
With regards to the other pillars, Member States can develop complementary national, regional and local policies to support biotechnology and biomanufacturing, including in the areas covered by the act, based on their needs.
The proposal does not modify the repartition of competences between the Union and Member States.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

For the Union level, without prejudice to the outcome of the negotiations on the next MFF proposal, strategic health biotechnology projects and strategic health high-impact biotechnology projects may be supported by Union programmes, funds and financial instruments, in accordance with the objectives set out in the regulations establishing those funds and programmes.

For the national and regional level, authorities might incur costs related to establish single points of contact with adequate staff and provide administrative support to project promoters for the permit granting procedures of Health Biotechnology Strategic Projects.

Costs are expected to be commensurate to the benefit that countries and regions are expected to receive from streamlined, more coherent procedures and improved coordination, reducing duplication of administrative work, and supporting more consistent regulatory decisions across the Union, as well as, from the investment that strategic health biotechnology projects, the strategic health high-impact biotechnology projects and the EU investment facility might attract in the respective countries (e.g. establishment of biomanufacturing infrastructures, set up and growth of start-ups and scaleups with subsequent economic value and employment generation).

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

The proposed measures enabling biotechnology and biomanufacturing to scale-up in the Union aims at complementing national initiatives. Member States will continue to be able to take action in these areas, taking into account the diversity of their national biotechnology industry.