European Parliament
2024-2029

Committee on Public Health
Committee on Industry, Research and Energy

2025/0406(COD)

14.7.2026

AMENDMENTS
603 - 857

Draft report
Vytenis Povilas Andriukaitis, Wouter Beke
(PE789.987v01-00)

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 regulation
(COM(2025)1022 – 2025/0406(COD))

AM_Com_LegReport

Amendment 603
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) In view of the potential for cross-border and systemic benefits of high impact health biotechnology strategic projects, on the basis of its case-by-case assessment, a permitting authority can conclude that the public interest served by the project overrides the public interests related to nature and environmental protection and that consequently the project can be authorised, provided that all relevant conditions set out in Directives 2000/60/EC[22] , 2009/147/EC[23] or 92/43/EEC[24] of the European Parliament and of the Council, or in Union legislative acts on nature restoration, are met.	***deleted***

[22] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1. ELI: http://data.europa.eu/eli/dir/2000/60/oj.

[23] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds, OJ L 20, 26.1.2010, pp. 7-25. ELI: http://data.europa.eu/eli/dir/2009/147/oj.

[24] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 22.7.1992, p. 7. ELI: http://data.europa.eu/eli/dir/1992/43/oj

Or. en

Amendment 604
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) In view of the potential for cross-border and systemic benefits of high impact health biotechnology strategic projects, on the basis of its case-by-case assessment, a permitting authority can conclude that the public interest served by the project overrides the public interests related to nature and environmental protection and that consequently the project can be authorised, provided that all relevant conditions set out in Directives 2000/60/EC[22] , 2009/147/EC[23] or 92/43/EEC[24] of the European Parliament and of the Council, or in Union legislative acts on nature restoration, are met.	***deleted***

[22] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1. ELI: http://data.europa.eu/eli/dir/2000/60/oj.

[23] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds, OJ L 20, 26.1.2010, pp. 7-25. ELI: http://data.europa.eu/eli/dir/2009/147/oj.

[24] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 22.7.1992, p. 7. ELI: http://data.europa.eu/eli/dir/1992/43/oj

Or. en

Amendment 605
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) In view of the potential for cross-border and systemic benefits of high impact health biotechnology strategic projects, on the basis of its case-by-case assessment, a permitting authority can conclude that the public interest served by the project overrides the public interests related to nature and environmental protection and that consequently the project can be authorised, provided that all relevant conditions set out in Directives 2000/60/EC[22] , 2009/147/EC[23] or 92/43/EEC[24] of the European Parliament and of the Council, or in Union legislative acts on nature restoration, are met.	***deleted***

[22] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1. ELI: http://data.europa.eu/eli/dir/2000/60/oj.

[23] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds, OJ L 20, 26.1.2010, pp. 7-25. ELI: http://data.europa.eu/eli/dir/2009/147/oj.

[24] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 22.7.1992, p. 7. ELI: http://data.europa.eu/eli/dir/1992/43/oj

Or. en

Amendment 606
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) In view of the potential for cross-border and systemic benefits of high impact ***health*** biotechnology strategic projects, on the basis of its case-by-case assessment, a permitting authority can conclude that the public interest served by the project overrides the public interests related to nature and environmental protection and that consequently the project can be authorised, provided that all relevant conditions set out in Directives 2000/60/EC[22] , 2009/147/EC[23] or 92/43/EEC[24] of the European Parliament and of the Council, or in Union legislative acts on nature restoration, are met.	(30) In view of the potential for cross-border and systemic benefits of high impact biotechnology strategic projects, on the basis of its case-by-case assessment, a permitting authority can conclude that the public interest served by the project overrides the public interests related to nature and environmental protection and that consequently the project can be authorised, provided that all relevant conditions set out in Directives 2000/60/EC[22] , 2009/147/EC[23] or 92/43/EEC[24] of the European Parliament and of the Council, or in Union legislative acts on nature restoration, are met.
[22] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1. ELI: http://data.europa.eu/eli/dir/2000/60/oj.	[22] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1. ELI: http://data.europa.eu/eli/dir/2000/60/oj.
[23] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds, OJ L 20, 26.1.2010, pp. 7-25. ELI: http://data.europa.eu/eli/dir/2009/147/oj.	[23] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds, OJ L 20, 26.1.2010, pp. 7-25. ELI: http://data.europa.eu/eli/dir/2009/147/oj.
[24] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 22.7.1992, p. 7. ELI: http://data.europa.eu/eli/dir/1992/43/oj	[24] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, OJ L 206, 22.7.1992, p. 7. ELI: http://data.europa.eu/eli/dir/1992/43/oj

Or. en

Amendment 607

Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ten months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to eight months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to three months should be permitted.	***deleted***

Or. en

Amendment 608
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ten months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to eight months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to three months should be permitted.	(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ten months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to eight months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to three months should be permitted. ***The permitting process start should trigger the***

	needed GxP inspection and certification processes, where applicable, in order for the health (high impact) strategic projects to be fully operational.

Or. en

Justification

Streamlined permitting process is necessary but without the subsequent GxP inspections and certification processes, would fall short of overcoming operational obstacles.

Amendment 609
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ***ten*** months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to eight months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to ***three months*** should be permitted.	(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ***six*** months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to eight months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to ***one month*** should be permitted.

Or. en

Amendment 610
Kristoffer Storm

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*

(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ***ten*** months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to ***eight*** months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to ***three months*** should be permitted.	(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ***six*** months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to ***four*** months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to ***one month*** should be permitted.

Or. en

Amendment 611
Angelika Winzig

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ***ten*** months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to ***eight*** months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to ***three months*** should be permitted.	(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ***six*** months from the acknowledgement of a complete application, for biotechnology health strategic projects, and to ***four*** months, for high impact health biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to ***one month*** should be permitted.

Or. en

Justification

The proposed evaluation timeline is excessively long and ill-suited to the pace of biotechnology innovation, and the additional three-month extension would further undermine the competitiveness of strategic projects.

Amendment 612
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ten months from the acknowledgement of a complete application, for biotechnology ***health*** strategic projects, and to eight months, for high impact ***health*** biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to three months should be permitted.	(31) To ensure predictability and administrative efficiency, the overall duration of the permit-granting process should be limited to ten months from the acknowledgement of a complete application, for biotechnology strategic projects, and to eight months, for high impact biotechnology strategic projects, given the need to prioritise the speed of their implementation over any other type of biotechnology project. In exceptional and duly justified circumstances an extension of up to three months should be permitted.

Or. en

Amendment 613
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Manuela Ripa, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) Member States whose territories are concerned by health biotechnology strategic projects or high impact health biotechnology strategic projects should take all appropriate measures to facilitate their timely and effective development and deployment. Such measures should include the provision of administrative support,	(32) Member States whose territories are concerned by health biotechnology strategic projects or high impact health biotechnology strategic projects should take all appropriate measures to facilitate their timely and effective development and deployment. Such measures should include the provision of administrative support,

upon the request of project promoters, as well as, without prejudice to Union competition law, of public financial and technical support, with a particular attention paid to SMEs, start-ups and scale-ups.

upon the request of project promoters, as well as, without prejudice to Union competition law, of public financial and technical support, with a particular attention paid to SMEs, start-ups and scale-ups***, including tailored support for non-commercial sponsors such as university hospitals, with the objective of minimising administrative complexity and avoiding disproportionate costs associated with regulatory procedures, particularly for cross-border coordination of regulatory procedures, including support for parallel or joint assessments under the Clinical Trials Regulation***.

Or. en

Amendment 614
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) Member States whose territories are concerned by ***health*** biotechnology strategic projects or high impact ***health*** biotechnology strategic projects should take all appropriate measures to facilitate their timely and effective development and deployment. Such measures should include the provision of administrative support, upon the request of project promoters, as well as, without prejudice to Union competition law, of public financial and technical support, with a particular attention paid to SMEs, start-ups and scale-ups.	(32) Member States whose territories are concerned by ***biotechnology strategic projects, high impact*** biotechnology strategic projects or ***pan-European*** high impact biotechnology strategic projects should take all appropriate measures to facilitate their timely and effective development and deployment. Such measures should include the provision of administrative support, upon the request of project promoters, as well as, without prejudice to Union competition law, of public financial and technical support, with a particular attention paid to SMEs, start-ups and scale-ups.

Or. en

Amendment 615

Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) Member States whose territories are concerned by health biotechnology strategic projects or high impact health biotechnology strategic projects should take all appropriate measures to facilitate their timely and effective development and deployment. Such measures should include the provision of administrative support, upon the request of project promoters, as well as, without prejudice to Union competition ***law***, of public financial and technical support, with a particular attention paid to SMEs, start-ups and scale-ups.	(32) Member States whose territories are concerned by health biotechnology strategic projects or high impact health biotechnology strategic projects should take all appropriate measures to facilitate their timely and effective development and deployment. Such measures should include the provision of administrative support, upon the request of project promoters, as well as, without prejudice to Union ***environment, social and*** competition ***laws***, of public financial and technical support, with a particular attention paid to SMEs, start-ups and scale-ups.

Or. en

Amendment 616
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) The Commission should complement the action of the Member States in support of ***health*** biotechnology strategic projects, closely cooperating with them, including through the European ***Health*** Biotechnology Steering Group established by this Regulation, to ensure synergy and optimal outcomes. In particular, the Commission should assist project promoters in identifying relevant funding opportunities available under existing Union funding programmes, including through actions of the EU ***Health*** Biotechnology Support Network established in this Regulation with the	(33) The Commission should complement the action of the Member States in support of biotechnology strategic projects, closely cooperating with them, including through the European Biotechnology Steering Group established by this Regulation, to ensure synergy and optimal outcomes. In particular, the Commission should assist project promoters in identifying relevant funding opportunities available under existing Union funding programmes, including through actions of the EU Biotechnology Support Network established in this Regulation with the purpose of assisting

purpose of assisting biotechnology actors in navigating regulatory health biotechnology procedural pathways and identifying funding, scaling up and networking opportunities across the Union. Further, to strengthen the Union's biotechnology innovation ecosystem, the Commission should also promote measures that enhance access of small and medium-sized enterprises, start-ups and scale-ups to research and technological infrastructures, including those funded through Union programmes.

biotechnology actors in navigating regulatory health biotechnology procedural pathways and identifying funding, scaling up and networking opportunities across the Union. ***The Support Network should provide high-quality, specialised and measurable services, including regulatory navigation, funding identification, project preparation and referral to relevant Union and national bodies.*** Further, to strengthen the Union's biotechnology innovation ecosystem, the Commission should also promote measures that enhance access of small and medium-sized enterprises, start-ups***, spin-offs*** and scale-ups to research and technological infrastructures, including those funded through Union programmes.

Or. en

Amendment 617
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) High impact health biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact health biotechnology strategic projects ***could*** be given ***particular consideration*** for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments.	(34) High impact health biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact health biotechnology strategic projects ***shall*** be given ***priority*** for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments***, with monitoring and full transparency on the allocation of funds, and outcomes of funded projects***.

Or. en

Justification

Designation of a high-impact project may not be sufficiently attractive or provide a meaningful incentive if funding remains uncertain. Where full funding cannot be guaranteed, prioritisation under Union programmes is therefore essential. Furthermore, improved access to funding must be accompanied by strong transparency mechanisms, robust monitoring, and clear reporting requirements when financial support is provided under Union programmes, instruments and as foreseen by the European Investment Bank Group.

Amendment 618
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) High impact health biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact health biotechnology strategic projects could be given particular consideration for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments.	(34) High impact health biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact health biotechnology strategic projects could be given particular consideration for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments***, with monitoring and full transparency on the allocation of funds, and outcomes of funded projects***.

Or. en

Amendment 619
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) High impact ***health*** biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact ***health*** biotechnology strategic projects could be given particular consideration for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments.	(34) High impact biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact biotechnology strategic projects could be given particular consideration for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments.

Or. en

Amendment 620
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) High impact health biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact health biotechnology strategic projects ***could*** be given ***particular consideration*** for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments.	(34) High impact health biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact health biotechnology strategic projects ***shall*** be given ***priority*** for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments.

Or. en

Amendment 621
Kristoffer Storm

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) High impact health biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact health biotechnology strategic projects ***could*** be given ***particular consideration*** for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments.	(34) High impact health biotechnology strategic projects should benefit from financial, technical and administrative support measures. In addition, in order to ensure that Union resources for biotechnology are channelled towards the actions that have the potential to deliver the most benefits at Union level, high impact health biotechnology strategic projects ***shall*** be given ***priority*** for financial support, in the context of the preparation, adoption and implementation by the Commission of work programmes for the relevant Union programmes, funds and instruments.

Or. en

Amendment 622
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The scale and nature of the Union support for high impact ***health*** biotechnology strategic projects might require long-term coordination and large-scale public and private investment. In this context, public-private partnerships play a key role in pooling expertise, sharing risks and accelerating the uptake of innovation. Consequently, the Commission could envisage to propose in the future the establishment of appropriate legal entities to mobilise investments, coordinate research and innovation activities and	(35) The scale and nature of the Union support for high impact biotechnology strategic projects might require long-term coordination and large-scale public and private investment. In this context, public-private partnerships play a key role in pooling expertise, sharing risks and accelerating the uptake of innovation. Consequently, the Commission could envisage to propose in the future the establishment of appropriate legal entities to mobilise investments, coordinate research and innovation activities and

support for the industrial deployment of biotechnology and biomanufacturing capacities across Member States, while ensuring close alignment with Union policy objectives. Those legal arrangements could take the form of European Partnerships where the Union together with private and/or public partners, acting in full compliance with competition rules, commit to jointly supporting the development and implementation of a programme of activities, including those related to market, regulatory or policy uptake.	support for the industrial deployment of biotechnology and biomanufacturing capacities across Member States, while ensuring close alignment with Union policy objectives. Those legal arrangements could take the form of European Partnerships where the Union together with private and/or public partners, acting in full compliance with competition rules, commit to jointly supporting the development and implementation of a programme of activities, including those related to market, regulatory or policy uptake.

Or. en

Amendment 623
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) With a view to ensuring that the most favourable provisions apply cross-frameworks, the provisions of this Regulation regarding the permit granting process, the priority status of ***health*** biotechnology strategic projects and of high impact ***health*** biotechnology strategic projects and the administrative, technical or financial support for such projects should apply without prejudice to more favourable provisions laid down in other Union legislation.	(36) With a view to ensuring that the most favourable provisions apply cross-frameworks, the provisions of this Regulation regarding the permit granting process, the priority status of biotechnology strategic projects and of high impact biotechnology strategic projects and the administrative, technical or financial support for such projects should apply without prejudice to more favourable provisions laid down in other Union legislation.

Or. en

Amendment 624
Ondřej Knotek, Viktória Ferenc

Proposal for a regulation
Recital 36 a (new)

Text proposed by the Commission	*Amendment*
	(36a) Participation in clinical trials conducted in more than two Member States remains uneven across the Union, resulting in disparities in patients' access to innovative medicinal products and limiting opportunities to strengthen clinical research capacity in certain Member States. In order to promote a more balanced geographical distribution of such clinical trials and to enhance the representativeness of clinical evidence generated within the Union, marketing authorisation applicants should be incentivised to include Member States that are persistently underrepresented in clinical trials conducted in more than two Member States. To that end, where a clinical trial conducted in more than two Member States includes one or more such Member States, the marketing authorisation applicant should benefit from a targeted derogation from the requirement to demonstrate that the medicinal product containing a new active substance is distinctively different or that the medicinal product has a mechanism of action that is distinctively different.

Or. en

Amendment 625
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Biotechnology undertakings, especially SMEs, start-ups and scale-ups, and non-profits face challenges in navigating the regulatory processes, financing, scaling up and networking	(37) Biotechnology undertakings, especially SMEs, start-ups and scale-ups, and non-profits face challenges in navigating the regulatory processes, financing, scaling up and networking

opportunities in the Union. To address those challenges, the Commission should manage, coordinate and support an EU Health Biotechnology Support Network, composed of national and regional antennas, leveraging and complementing existing structures such as the European Enterprise Network. The Network should assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the legislative framework, health biotechnologies regulatory pathways and funding opportunities at Union and national level. Moreover, the EU Health Biotechnology Support Network should provide support for health biotechnology strategic projects and enhanced assistance for high impact health biotechnology strategic projects. The Commission should make available to the Network an AI powered interactive tool to assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the regulatory framework and pathways and funding opportunities at EU and national level.	opportunities in the Union. To address those challenges, the Commission should manage, coordinate and support an EU Health Biotechnology Support Network, composed of national and regional antennas, leveraging and complementing existing structures such as the European Enterprise Network. The Network should assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the legislative framework, health biotechnologies regulatory pathways and funding opportunities at Union and national level***, while campaigning for the Union to lighten the regulatory load, which has a major adverse impact on the competitiveness of these undertakings***. Moreover, the EU Health Biotechnology Support Network should provide support for health biotechnology strategic projects and enhanced assistance for high impact health biotechnology strategic projects. The Commission should make available to the Network an AI powered interactive tool to assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the regulatory framework and pathways and funding opportunities at EU and national level.
	Or. fr

Amendment 626
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Biotechnology undertakings, especially SMEs, start-ups and scale-ups, and non-profits face challenges in navigating the regulatory processes, financing, scaling up and networking	(37) Biotechnology undertakings, especially SMEs, start-ups***, spin-offs*** and scale-ups, and non-profits face challenges in navigating the regulatory processes, financing, scaling up and networking

opportunities in the Union. To address those challenges, the Commission should manage, coordinate and support an EU ***Health*** Biotechnology Support Network, composed of national and regional antennas, leveraging and complementing existing structures such as the European Enterprise Network. The Network should assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the legislative framework, health biotechnologies regulatory pathways and funding opportunities at Union and national level. Moreover, the EU ***Health*** Biotechnology Support Network should provide support for ***health*** biotechnology strategic projects and enhanced assistance for high impact ***health*** biotechnology strategic projects. The Commission should make available to the Network an AI powered interactive tool to assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the regulatory framework and pathways and funding opportunities at EU and national level.

opportunities in the Union. To address those challenges, the Commission should manage, coordinate and support an EU Biotechnology Support Network, composed of national and regional antennas, leveraging and complementing existing structures such as the European Enterprise Network. The Network should assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the legislative framework, health biotechnologies regulatory pathways and funding opportunities at Union and national level. Moreover, the EU Biotechnology Support Network should provide support for biotechnology strategic projects and enhanced assistance for high impact ***biotechnology strategic projects and pan-European high impact*** biotechnology strategic projects. The Commission should make available to the Network an AI powered interactive tool to assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the regulatory framework and pathways and funding opportunities at EU and national level.

Or. en

Amendment 627
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Biotechnology undertakings, especially SMEs, start-ups and scale-ups, and non-profits face challenges in navigating the regulatory processes, financing, scaling up and networking opportunities in the Union. To address	(37) Biotechnology undertakings, especially SMEs, start-ups and scale-ups, and non-profits face challenges in navigating the regulatory processes, financing, scaling up and networking opportunities in the Union. To address

those challenges, the Commission should manage, coordinate and support an EU Health Biotechnology Support Network, composed of national and regional antennas, leveraging and complementing existing structures such as the European Enterprise Network. The Network should assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the legislative framework, health biotechnologies regulatory pathways and funding opportunities at Union and national level. Moreover, the EU Health Biotechnology Support Network should provide support for health biotechnology strategic projects and enhanced assistance for high impact health biotechnology strategic projects. The Commission should make available to the Network an AI powered interactive tool to assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, in navigating more efficiently the regulatory framework and pathways and funding opportunities at EU and national level.	those challenges, the Commission should manage, coordinate and support an EU Health Biotechnology Support Network, composed of national and regional antennas, leveraging and complementing existing structures such as the European Enterprise Network. The Network should assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, ***and non-profits*** in navigating more efficiently the legislative framework, health biotechnologies regulatory pathways and funding opportunities at Union and national level. Moreover, the EU Health Biotechnology Support Network should provide support for health biotechnology strategic projects and enhanced assistance for high impact health biotechnology strategic projects. The Commission should make available to the Network an AI powered interactive tool to assist developers and project promoters, in particular SMEs, start-ups, and scale-ups, ***and non-profits*** in navigating more efficiently the regulatory framework and pathways and funding opportunities at EU and national level.

Or. en

Amendment 628
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 37 a (new)

Text proposed by the Commission	*Amendment*
	(37a) Emphasises the urgent need to streamline administrative and regulatory procedures and to develop mechanisms for mobilising public and private capital for biotechnology SMEs.

Or. fr

Amendment 629
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission.	(38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission. ***To ensure structured discussions, a representative of the Member States and a representative of the Commission should co-chair. Member States should be able to appoint additional expert representatives to accompany the permanent Member State representative in order to support the different tasks of the Steering Group. The representatives of relevant stakeholders, including healthacre, patients and industry representatives, could, at the discretion of the Steering Group be invited to meetings to provide expertise or participate as observers, where this is relevant and appropriate.***

Or. en

Amendment 630
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) The European ***Health*** Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission.	(38) The European Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission. ***Where appropriate, the Commission should be able to invite relevant Union bodies, agencies, experts and stakeholders to support the work of the Steering Group, including in specific subgroups, while ensuring the protection of confidential and commercially sensitive information.***

Or. en

Amendment 631
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission.	(38) The European Health Biotechnology Steering Group ('the Steering Group')***, made up of experts with considerable experience in the field, recognised at European level and selected on the basis of professional criteria,*** should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission.

Or. ro

Amendment 632
Dario Nardella, Georgia Tramacere, Giorgio Gori

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission.	(38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission***, and from representative organisations of the pharmaceutical and health biotechnology industries***.

Or. en

Justification

For future looking biotechnology, input and experience from industry is needed, while Member States and the Commission retain the decision-making role.

Amendment 633
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation,	(38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation,

foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission.	foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission***, and from representatives of the pharmaceutical and health biotechnology industries***.

Or. en

Amendment 634
Angelika Winzig

Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission.	(38) The European Health Biotechnology Steering Group ('the Steering Group') should be established to provide advice to the Commission and to the Member States with a view to facilitate the implementation of this Regulation, foster cooperation with the Commission and among the Member States, and the exchange of best practice. The Steering Group should be composed of representatives from all Member States and the Commission***, and representatives of the pharmaceutical and health biotechnology industries***.

Or. en

Amendment 635
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) Member States should provide to	(39) Member States should provide to

the Steering Group, on an annual basis, an overview of the health biotechnology strategic projects and of the high impact health biotechnology strategic projects that they recognise, as well as of the existing and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices.	the Steering Group, on an annual basis, an overview of the health biotechnology strategic projects and of the high impact health biotechnology strategic projects that they recognise, as well as of the existing and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices. ***In particular, Member States should report on obstacles affecting the development, validation, regulatory acceptance and uptake of NAMs, including scientific, technical, infrastructural, skills-related and regulatory barriers, as well as examples of enabling practices. In addition, Member States should report on emerging opportunities in NAM development that may require future financial, skills, and infrastructural investment.***

Or. en

Justification

Including a specific reporting requirement on obstacles to NAM uptake and emerging opportunities would improve the evidence base for Union-level coordination and policy action. It would allow systematic identification of recurring barriers across Member States (particularly those related to validation, regulatory acceptance, infrastructure and skills) thereby supporting targeted measures to accelerate the integration of NAMs into research, innovation and regulatory frameworks.

Amendment 636
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) Member States should provide to the Steering Group, on an annual basis, an overview of the health biotechnology strategic projects and of the high impact health biotechnology strategic projects that they recognise, as well as of the existing and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices.	(39) Member States should provide to the Steering Group, on an annual basis, an overview of the health biotechnology strategic projects and of the high impact health biotechnology strategic projects that they recognise, as well as of the existing and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices. ***In particular, Member States may report on obstacles affecting the development, validation, regulatory acceptance and uptake of NAMs, including scientific, technical, infrastructural, skills-related and regulatory barriers, as well as examples of enabling practices. Member States may also report on emerging opportunities in NAM development that may require future investment in skills, infrastructure and funding.***

Or. en

Amendment 637
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) Member States should provide to the Steering Group, on an annual basis, an overview of the health biotechnology strategic projects and of the high impact health biotechnology strategic projects that they recognise, as well as of the existing	(39) Member States should provide to the Steering Group, on an annual basis, an overview of the health biotechnology strategic projects and of the high impact health biotechnology strategic projects that they recognise, as well as of the existing

and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices.	and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices***, and include new strategic projects that may be proposed over time, which may complement existing ones***.

Or. ro

Amendment 638
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) Member States should provide to the Steering Group, on an annual basis, an overview of the ***health*** biotechnology strategic projects and of the high impact ***health*** biotechnology strategic projects that they recognise, as well as of the existing and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices.	(39) Member States should provide to the Steering Group, on an annual basis, an overview of the biotechnology strategic projects and of the high impact biotechnology strategic projects that they recognise, as well as of the existing and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices.

Or. en

Amendment 639
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) To ensure effective governance and learning across the Union, the Steering Group should periodically review systemic challenges in the financing and deployment in particular for high impact ***health*** biotechnology strategic projects and recommend corrective measures to the Commission and to Member States.	(40) To ensure effective governance and learning across the Union, the Steering Group should periodically review systemic challenges in the financing and deployment in particular for high impact biotechnology strategic projects and recommend corrective measures to the Commission and to Member States.

Or. en

Amendment 640
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(40a) The European Biotechnology Steering Group should support the translation of research and innovation results into industrial deployment and market uptake, in particular in the area of health, including by promoting coordination between research, investment and demand-side measures and by identifying barriers to scale-up and market creation in the Union. To that end, the Steering Group should be able to establish dedicated working groups, in particular on Union biomanufacturing capacity, to support the mapping of capacity and the identification of key bottlenecks and supply-chain vulnerabilities, and on biotechnology capital markets, to support the coordination of Union, national and private financing, in cooperation with the

European Investment Bank Group, national promotional banks and institutions and relevant institutional investors. The Steering Group should also support regulatory convergence by identifying divergent national implementation practices, administrative bottlenecks and cross-framework regulatory challenges affecting biotechnology, particularly in the area of health, and by providing advice, best practices and recommendations to the Commission and the Member States

Or. en

Amendment 641
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 40 a (new)

Text proposed by the Commission	*Amendment*
	(40a) Companies receiving financial support should be subject to dissuasive and proportionate penalties in cases of non-compliance with their contractual conditions. Non-compliance by an undertaking receiving financial support for a health biotechnology strategic project should result in appropriate corrective measures and sanctions, including the suspension, termination, or full or partial recovery of the financial support granted, or the exclusion from future support measures, in particular where the undertaking fails to ensure the availability or affordability of the resulting products across the Member States.

Or. en

Amendment 642
Michalis Hadjipantela

Proposal for a regulation
Recital 41

Text proposed by the Commission	*Amendment*
(41) Given the capital-intensive nature of biotechnology and the high probability of non-commercialisation of individual projects, access to finance is a structural bottleneck for the sector. To boost the potential of biotechnology to contribute to the Union's competitiveness, resilience and the creation and maintenance of quality jobs, sufficient funding tailored to the sector's risk profile needs to be mobilised across the financing life cycle.	(41) Given the capital-intensive nature of biotechnology and the high probability of non-commercialisation of individual projects, access to finance is a structural bottleneck for the sector***. The particularly long development cycles of health biotechnology further compound this challenge, requiring financing instruments that provide stability over extended time horizons and that are designed to support long-term planning and investment***. To boost the potential of biotechnology to contribute to the Union's competitiveness, resilience and the creation and maintenance of quality jobs, sufficient funding tailored to the sector's risk profile needs to be mobilised across the financing life cycle. ***Such funding mechanisms should be open to the full range of actors capable of contributing to Union industrial capacity, innovation and strategic resilience, including SMEs, start-ups, scale-ups, mid-caps and other biotechnology companies explicitly contributing to the objectives of this Regulation.***

Or. en

Amendment 643
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Margarita de la Pisa Carrión

Proposal for a regulation
Recital 41 a (new)

Text proposed by the Commission	*Amendment*

(41a) The benefits of biotechnology innovation for patients with rare diseases can only be fully realised where diagnosis is timely and effective referral pathways are in place. As the average diagnostic delay for rare diseases in the Union often exceeds four years, investment in advanced diagnostics, genomic technologies and newborn screening programmes is essential to support a competitive European biotechnology ecosystem. Without prejudice to Member States' competence for the organisation of their healthcare systems, the Union should support the development of guidance on screening criteria, facilitate structured dialogue between diagnostic developers and regulatory authorities, and promote more efficient and predictable assessment pathways for innovative diagnostic technologies. In doing so, it should build on existing initiatives, including the European Reference Networks established under Directive 2011/24/EU and the European Joint Programme on Rare Diseases. Strengthening diagnostic pathways for rare diseases will improve patients' timely access to diagnosis and treatment while fostering biotechnology innovation and investment across the Union.

Or. en

Amendment 644
Aurelijus Veryga

Proposal for a regulation
Recital 41 a (new)

Text proposed by the Commission	*Amendment*
	(41a) Recognises that advances in advanced therapy medicinal products, including CAR T-cell therapies, offer significant potential to improve patient outcomes in areas of unmet need;

emphasises that timely patient access depends on healthcare systems having sufficient capacity, expertise and effective care pathways, including qualified treatment centres and strong referrals infrastructure; notes that capacity constraints and fragmentation continue to create disparities in access across the Union; stresses, therefore, the importance of Union support for investments in healthcare infrastructure, specialised workforce capabilities and coordinated care networks to facilitate the delivery of these therapies and strengthen the Union's leadership in advanced therapies.

Or. en

Amendment 645
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 41 a (new)

Text proposed by the Commission	*Amendment*
	(41a) Achieving the objectives of this Regulation requires not only stronger research, development and manufacturing capacities, but also healthcare systems that are able to effectively absorb and deploy biopharmaceutical innovation. In this contect, public expenditure on innovative biopharmaceuticals should be considered as a long-term strategic investment in health system sustainability, resilience and societal wellbeing, rather that solely as a short-term cost. A more investment-oriented perspective on health and pharmaceutical spending can support better alignment between industrial, health and fisical policies at Union and national level, therefore stimulating biotech innovation through its entire lifecycle.

Or. en

Amendment 646
Stine Bosse, Katri Kulmuni, Billy Kelleher, Martin Hojsík

Proposal for a regulation
Recital 41 a (new)

Text proposed by the Commission	*Amendment*
	(41a) Rare diseases play a crucial role in driving scientific progress and innovation that subsequently benefit broader patient groups. Promoting research and development of innovative therapies for rare diseases therefore generates societal value beyond the immediately treated population, this includes driving high skilled labour and clinical stewardship. A strategic approach to biotechnology uptake should recognise this multiplier effect and support investment frameworks that enable healthcare systems to accommodate innovation in areas of unmet medical need.

Or. en

Amendment 647
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Recital 41 b (new)

Text proposed by the Commission	*Amendment*
	(41b) In the case of rare diseases and paediatric conditions, delayed diagnosis, fragmented referral pathways and newborn screening approaches, and limited coordination between specialised centres can prevent eligible patients from benefiting from authorised innovative therapies. Strengthening early diagnosis, including through appropriate use of

genomics and newborn screening, and supporting effective coordination between referral and treatment centres, including across Member State borders, are therefore critical to enable timely and equitable uptake of biotechnology innovations. The lack of timely and appropriate diagnosis for such conditions also places pressure on EU healthcare systems as a whole.

Or. en

Amendment 648
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 41 b (new)

Text proposed by the Commission	*Amendment*
	(41b) Rare diseases play a crucial role in driving scientific progress and innovation that subsequently benefit broader patient groups. Promoting research and development of innovative therapies for rare diseases therefore generates societal value beyond the immediately treated population, this includes driving high skilled labour and clinical stewardship. A strategic approach to biotechnology uptake should recognise this multiplier effect and support investment frameworks that enable healthcare systems to accomodate innovation in areas of unmet need.

Or. en

Amendment 649
Aurelijus Veryga

Proposal for a regulation
Recital 41 b (new)

Text proposed by the Commission	*Amendment*
	(41b) Rare diseases play a crucial role in driving scientific progress and innovation that subsequently benefit broader patient groups. Promoting research and development of innovative therapies for rare diseases therefore generates societal value beyond the immediately treated population, this includes driving high skilled labour and clinical stewardship. A strategic approach to biotechnology uptake should recognise this multiplier effect and support investment frameworks that enable healthcare systems to accommodate innovation in areas of unmet need.

Or. en

Amendment 650
Aurelijus Veryga

Proposal for a regulation
Recital 41 c (new)

Text proposed by the Commission	*Amendment*
	(41c) The objectives of this Regulation cannot be achieved solely through the strengthening of research, development and manufacturing capacities. The effective uptake and use of health biotechnologies within healthcare systems is equally essential to ensure that innovation translates into tangible benefits for patients, public health and economic sustainability. Persistent delays between Union authorisation and real-world access, as well as variations in clinical practice and infrastructure across Member States, risk undermining the Union's competitiveness and the societal value of biotechnology innovation.

Or. en

Amendment 651
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 41 c (new)

Text proposed by the Commission	*Amendment*
	(41c) The objectives of this Regulation cannot be achieved solely through the strengthening of research, development and manufacturing capacities. The effective uptake and use of health biotechnologies within healthcare systems is equally essential to ensure that innovation translates into tangible benefits for patients, public health and economic sustainability. Persistent delays between Union auhorsation and real-world access, as well as variations in clinical practice and infrastructure across Member States, risk undermining the Union's competitiveness and the societal value of biotechnology innovation.

Or. en

Amendment 652
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 41 d (new)

Text proposed by the Commission	*Amendment*
	(41d) In the case of rare diseases and pediatric conditions, delayed diagnosis, fragmented referral pathways and newborn screening approaches, and limited coordination between specialised centres can prevent eligible patients from benefiting from authorised innovative therapies. Strengthening early diagnosis, including through appropriate use of genomics and newborn screening, and

supporting effective coordination between referral treatment centres are therefore critical to enable timely and equitable uptake of biotechnology innovations. The lack of appropriate diagnosis also places pressure on the healthcare system as a whole.

Or. en

Amendment 653
Aurelijus Veryga

Proposal for a regulation
Recital 41 d (new)

Text proposed by the Commission	*Amendment*
	(41d) In the case of rare diseases and paediatric conditions, delayed diagnosis, fragmented referral pathways and newborn screening approaches, and limited coordination between specialised centres can prevent eligible patients from benefiting from authorised innovative therapies. Strengthening early diagnosis, including through appropriate use of genomics and newborn screening, and supporting effective coordination between referral and treatment centres are therefore critical to enable timely and equitable uptake of biotechnology innovations. The lack of appropriate diagnosis also places pressure on the healthcare system as a whole.

Or. en

Amendment 654
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 41 e (new)

Text proposed by the Commission	*Amendment*
	(41e) Certain health biotechnologies, including advanced therapy medicinal products, require highly specialised infrastructures and clinical expertise. Efficient uptake of such therapies depends on clear pathways for patient identification, referral and transfer between recognised centres of excellence. Enhanced coordination mechanisms between referral and treatment centres can support consistent clinical decision-making, optimise resource use and improve patient outcomes across the Union.

Or. en

Amendment 655
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 42

Text proposed by the Commission	*Amendment*
(42) To address key challenges in the functioning of Union capital markets, the Commission is implementing the Savings and Investment Union (SIU) Strategy. The SIU will reduce market fragmentation, create better investment opportunities for citizens and help to expand funding options for businesses. In particular, it will seek to improve access to equity and debt financing for all companies, including startups and scaleups, strengthen the role of venture capital and institutional investors and better align Union public funding instruments with SIU objectives. Recent Commission guidance on legislative programmes[25] also clarifies that the biotechnology sector can be the target of Union, national and regional legislative	***deleted***

programmes via reference to the Competitiveness Compass, supporting favourable prudential treatment of investments made under such programmes.

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[25] C(2025) 7231 final

Or. en

Amendment 656
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Recital 42 a (new)

Text proposed by the Commission	*Amendment*
	(42a) Europe's competitiveness depends not only on scientific excellence but also on its capacity to finance biotechnology companies throughout their development, enabling them to scale, manufacture and remain within the Union.

Or. en

Amendment 657
Stine Bosse, Katri Kulmuni, Billy Kelleher, Martin Hojsík

Proposal for a regulation
Recital 43 a (new)

Text proposed by the Commission	*Amendment*
	(43a) Advanced therapy medicinal products for the treatment of rare diseases are often administered at a limited number of highly specialised centres, so that access for many patients depends on treatment in a Member State other than that of affiliation. Where Member States so choose, the voluntary joint procurement of orphan medicinal

products provided for under [Regulation (EU) …/… of the European Parliament and of the Council … (the Critical Medicines Act), reference to be added after adoption, cf. COM(2025) 102 final] may improve the availability of such therapies for the participating Member States, thereby supporting cross-border access for their patients to treatment at centres of excellence for advanced therapies recognised under this Regulation located in another Member State. To that end, those centres of excellence should facilitate the cross-border movement of patients seeking such diagnosis and treatment, in accordance with the pathways for planned cross-border healthcare established by Directive 2011/24/EU and Regulation (EC) No 883/2004.

Or. en

Amendment 658
Stine Bosse, Katri Kulmuni, Billy Kelleher, Sigrid Friis

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment ***Pilot*** to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles.	(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment ***Facility*** to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles***, including support for Moonshot programmes advancing innovation in rare diseases,***

women's health, and NAMs across the innovation and regulatory value chain*.* ***For the purposes of this Regulation, biotech-specific risk profiles shall take into account: (a) the stage of regulatory development of the company or project, including submission for market approval to a relevant regulatory authority, whether within or outside the Union; (b) prior regulatory approval granted by a competent authority in a jurisdiction outside the Union whose regulatory standards are comparable to those of the Union, including in the areas of food safety, human health and animal health; and (c) demonstrated manufacturing readiness at advanced pilot or industrial scale. Biotechnology companies active across all sectors of application, including food and feed biomanufacturing, fermentation-derived ingredients, and bio-based industrial inputs, shall be assessed against those criteria on equal terms. The Commission and the EIBG shall operationalise these factors in the pilot's operational design in accordance with Article 22(3).***

Or. en

Justification

The term 'biotech-specific risk profiles' is currently undefined, leaving the implementing partner free to apply generic risk frameworks that disregard regulatory milestones. This amendment sets the minimum statutory content of the term and requires equal treatment across all biotechnology sectors of application, consistent with the broadened scope of Amendment 1 and the new European Biotechnology Scale-Up Fund (cf. Article 22a introduced by Amendment 164 in the rapporteurs' text). For Member States with significant agri-food and fermentation industries, the equal treatment requirement ensures public investment is not skewed to a single sub-sector.

Amendment 659
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles.	(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles. ***For the purposes of this Regulation, biotech-specific risk profiles shall take into account: (a) the stage of regulatory development of the company or project, including submission for market approval to a relevant regulatory authority, whether within or outside the Union; (b) prior regulatory approval granted by a competent authority in a jurisdiction outside the Union whose regulatory standards are comparable to those of the Union, including in the areas of food safety, human health and animal health; and (c) demonstrated manufacturing readiness at advanced pilot or industrial scale. Biotechnology companies active across all sectors of application, including food and feed biomanufacturing, fermentation-derived ingredients, and bio-based industrial inputs, shall be assessed against those criteria on equal terms. The Commission and the EIBG shall operationalise these factors in the pilot's operational design in accordance with Article 22(3).***

Or. en

Justification

The term 'biotech-specific risk profiles' is undefined, leaving the implementing partner free to apply generic risk frameworks that disregard regulatory milestones.

Amendment 660
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles.	(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles. ***The Investment Pilot should contribute in particular to reducing financing gaps affecting SMEs, start-ups and scale-ups established in the Union, especially those developing technologies addressing unmet medical needs, advanced therapies and technologies contributing to strategic health resilience.***

Or. en

Amendment 661
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health	(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health

Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles.	Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles. ***The Pilot should support health biotechnology projects across the lifecycle of products, technologies and manufacturing processes, including development, scale-up, industrial deployment and manufacturing of biosimilars and other follow-on biological medicinal products.***

Or. en

Amendment 662
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles.	(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles. ***The Pilot should support health biotechnology projects across the lifecycle of products, technologies and manufacturing processes, including development, scale-up, industrial deployment and***

manufacturing of biosimilars and other follow-on biological medicinal products.

Or. en

Amendment 663
Aura Salla

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles.	(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles. ***The Pilot should strengthen the scale-up potential of companies established in the Union, thereby contributing to the Union's strategic autonomy.***

Or. en

Amendment 664
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of	(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of

biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles.

biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles***, and it should also ensure, along with the relevant bodies, that a workforce specialised in this field is available over the medium and long term***.

Or. ro

Amendment 665
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles.	(44) Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles***, while ensuring synergies and avoiding any overlap with the European Innovation Council***.

Or. en

Amendment 666
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44a) Regulatory approval granted by a competent authority in a comparable jurisdiction outside the Union constitutes objective evidence of reduced investment risk for the purposes of eligibility assessments under the pilot established by Article 22 and the Fund established by Article 22a. Comparable jurisdictions include Singapore and the United States, where regulatory standards for food safety, human health and animal health are broadly equivalent to those of the Union. Submission for market approval to a relevant regulatory authority, whether within or outside the Union, shall be recognised as a material risk-reducing milestone. Companies that have obtained third-market approval or submitted for market approval shall not be classified as pre-commercial entities for the purposes of eligibility under Article 22 or Article 22a.

Or. en

Justification

Neither the Commission text nor the draft report requires third-country regulatory approval to be treated as evidence of reduced risk, so a company holding approval from a comparable authority may be assessed identically to a pre-commercial start-up, misallocating public risk capital. This recital establishes third-market equivalence and prevents the pre-commercial classification of qualifying companies, applying the principle to both the pilot (Article 22) and the rapporteurs' new Scale-Up Fund (Article 22a, introduced by Amendment 164). Comparable jurisdictions are named as Singapore and the United States. The intention is not least to ensure that European innovators who are already taking part in regulatory approval processes in third country jurisdictions are not unfairly disadvantaged when bringing their products to the market also in the EU.

Amendment 667
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44a) The Pilot should support health biotechnology projects across the lifecycle of products, technologies and manufacturing processes, including development, scale-up, strategic and critical industrial deployment and manufacturing of biosimilars and other follow-on biological medicinal products.

Or. en

Justification

The funding architecture should not be limited in practice to early stage or breakthrough innovation. To deliver competitiveness, resilience and access, the Pilot should also de-risk late-stage development, scale-up and manufacturing capacity, including the follow-on biologic sector, where investment decisions depend on predictable support for expensive and complex development and production pathway

Amendment 668
Stine Bosse, Katri Kulmuni, Billy Kelleher, Vlad Vasile-Voiculescu

Proposal for a regulation
Recital 44 b (new)

Text proposed by the Commission	*Amendment*
	(44b) A resilient and equitable Union health ecosystem would benefit from marketing authorisation holders and other undertakings coming forward, on a voluntary basis, with contribution models that support innovation and patient access across the Union. Such voluntary contributions could, in particular, help sustain the European Reference Networks for rare and complex diseases; to support reductions or waivers of the fees payable to the European Medicines Agency by

small and medium-sized enterprises and by developers of medicinal products originating in academic and not-for-profit research; and to support cross-border access for patients to Centres of Excellence for advanced therapy medicinal products, so that patients with rare conditions, and in particular children should have equal access to reach specialised treatment irrespective of the Member State in which they reside. The Commission should therefore find ways to ensure a firm, sustainable, and long-term financial contribution from the innovative pharmaceutical industry to the abovementioned areas of investment as well as for the industry to contribute to the EU Biotechnology Investment Facility established by this Regulation. Undertakings that benefit substantially from the Union market and from the incentives established by this Regulation, including the extension of the supplementary protection certificate, are well placed to contribute to the conditions on which continued innovation and equitable access depend. Any such contributions should remain genuinely voluntary and transparent, and should complement Union and national funding rather than substitute for it.

Or. en

Amendment 669
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 44 c (new)

Text proposed by the Commission	*Amendment*
	(44c) The EU Biotechnology Investment Facility established under this Regulation should be designed and implemented in a manner consistent with the Union's objectives for the Investment and

Pensions Union, in particular by creating risk-sharing mechanisms and blended finance instruments that are compatible with the long-term liability structures and investment horizons of institutional investors, including pension funds and insurance undertakings. For health biotechnology in particular, the Facility should not operate in isolation but should serve to synergise, leverage and crowd in the full range of available Union, national and private funding sources, so that public resources catalyse rather than replace private investment. To that end, the Facility should seek complementarity and coordination with, among others, the European Competitiveness Fund and in particular its Health, Biotech, Agriculture and Bioeconomy window, together with the ECF InvestEU Instrument; Horizon Europe and the financial instruments of the European Innovation Council; the EU4Health programme; the Strategic Technologies for Europe Platform (STEP) and the projects bearing its Sovereignty Seal; the Innovation Fund and the Digital Europe programme where relevant to biomanufacturing and digital manufacturing technologies; the Union's shared-management funds, namely the European Regional Development Fund, the Cohesion Fund, the European Social Fund Plus and, for cross-border projects, the instruments of European Territorial Cooperation; the Just Transition Fund in regions affected by industrial transition; the InvestEU Programme and, as it succeeds it, the ECF InvestEU Instrument; and the resources of the European Investment Bank Group and of national promotional banks and institutions. In pursuing such synergies, the Facility should have regard to the successive stages of the EU multiannual financial framework, ensuring continuity between the instruments in force and their successors, and should draw on the experience of STEP in steering funding across multiple Union programmes

towards strategic technologies.

Or. en

Amendment 670
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) The Health Biotechnology Investment Pilot would aim to mobilise a substantial amount of capital, from the EIBG, Union budget, public national schemes and private sector investors (including institutional investors), to narrow the sector investment gap, currently estimated at EUR 40 billion annually, amounting to EUR 400 billion for the next 10 years, and ensure the sector's long term competitiveness and strategic autonomy.	(45) The Health Biotechnology Investment Pilot would aim to mobilise a substantial amount of capital, from the EIBG, Union budget, public national schemes and private sector investors (including institutional investors), to narrow the sector investment gap, currently estimated at EUR 40 billion annually, amounting to EUR 400 billion for the next 10 years, and ensure the sector's long term competitiveness and strategic autonomy***, and also to encourage the development of skills in key fields and cross-border cooperation, thereby helping to reduce innovation disparities between Member States***.

Or. ro

Amendment 671
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) The ***Health*** Biotechnology Investment ***Pilot*** would aim to mobilise a substantial amount of capital, from the EIBG, Union budget, public national schemes and private sector investors (including institutional investors), to	(45) The Biotechnology Investment ***Facility*** would aim to mobilise a substantial amount of capital, from the EIBG, Union budget, public national schemes and private sector investors (including institutional investors), to

narrow the sector investment gap, ***currently estimated at EUR 40 billion annually, amounting to EUR 400 billion for the next 10 years, and*** ensure the sector's long term competitiveness ***and*** strategic autonomy.	narrow the sector investment gap, ensure the sector's long term competitiveness***,*** strategic autonomy***, support Europe's strategic autonomy, resilience, and clean transition, and build investor and capital markets confidence in the future of the European biotech sector***.

Or. en

Amendment 672
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 46

Text proposed by the Commission	*Amendment*
(46) The Health Biotechnology Investment Pilot should be tailored to biotechnology risk profiles and lifecycle needs on the Union market. It should be possible to include newly created and established instruments, encompassing advisory services, direct and indirect individual investments, direct and indirect intermediated financing or portfolio financing. The detailed instruments, eligibility and risk parameters, and indicative allocations should be specified in the operational design of the Pilot.	(46) The Health Biotechnology Investment Pilot should be tailored to biotechnology risk profiles and lifecycle needs on the Union market***, including the specific capital needs of late-stage development, technology transfer, process validation, commercial-scale biomanufacturing, analytical testing infrastructure and the upgrade or expansion of existing manufacturing sites***. It should be possible to include newly created and established instruments, encompassing advisory services, direct and indirect individual investments, direct and indirect intermediated financing or portfolio financing. The detailed instruments, eligibility and risk parameters, and indicative allocations should be specified in the operational design of the Pilot***, including for projects that strengthen Union biosimilar development and manufacturing capacity***.

Or. en

Amendment 673
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 46

Text proposed by the Commission	*Amendment*
(46) The ***Health*** Biotechnology Investment ***Pilot*** should be tailored to biotechnology risk profiles and lifecycle needs on the Union market. It should be possible to include newly created and established instruments, encompassing advisory services, direct and indirect individual investments, direct and indirect intermediated financing or portfolio financing. The detailed instruments, eligibility and risk parameters, and indicative allocations should be specified in the operational design of the Pilot.	(46) The Biotechnology Investment ***Facility*** should be tailored to biotechnology risk profiles and lifecycle needs on the Union market. It should be possible to include newly created and established instruments, encompassing advisory services, direct and indirect individual investments, direct and indirect intermediated financing or portfolio financing. The detailed instruments, eligibility and risk parameters, and indicative allocations should be specified in the operational design of the Pilot.

Or. en

Amendment 674
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46a) Rare diseases, orphan medicinal products and advanced therapy medicinal products face persistent financing gaps, in particular between basic research and human clinical trials. The Union should therefore assess and, where appropriate, support portfolio-based and risk-sharing financing approaches that aggregate diversified research and development pipelines, including rare disease and orphan medicine projects, in order to improve the risk-return profile for investors and mobilise long-term capital. Such approaches may include Research-Backed Obligations or equivalent debt-based instruments, credit enhancement

mechanisms, blended finance and other structures supported by the European Investment Bank Group, the European Investment Fund, national promotional banks and institutions and relevant Union programmes. Those instruments should build on Union strengths, including the centralised regulatory framework, ERNs, patient registries, natural history data, biobanks and Union research and innovation programmes, while ensuring transparency, access commitments and public-interest safeguards.

Or. en

Amendment 675
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46a) Particular attention should be paid, in the design and implementation of the EU Health Biotechnology Investment Pilot, to areas characterised by a major public health and socioeconomic burden and persistent innovation gaps, including mental health conditions, where scientific complexity, fragmented delivery pathways and limited access to risk-tolerant capital have hindered the development and scale-up of innovative solutions.

Or. en

Amendment 676
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) The Pilot ***may*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .	(47) The Pilot ***should*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .

Or. en

Amendment 677
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) The Pilot ***may*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .	(47) The Pilot ***shall*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .

Or. en

Amendment 678
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) The Pilot ***may*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .	(47) The Pilot ***shall*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .

Or. en

Justification

More certainty is needed on the EU financial support to the programs, even though details will be provided under the MFF 2028-2034.

Amendment 679
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) The Pilot ***may*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .	(47) The Pilot ***shall*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .

Or. en

Amendment 680
Kristoffer Storm, Aurelijus Veryga

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) The Pilot ***may*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .	(47) The Pilot ***shall*** receive Union financial support through Union programmes. Pending the establishment of the Pilot, a scheme, also covering ongoing investment activities, launched with the support of the EIBG under the current Multiannual Financial Framework 2021-2027 and supported under the InvestEU programme, will mobilise up to 10 billion in investments in the biotechnology sector in 2026 and 2027 .

Or. en

Amendment 681
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) Union public equity markets for biotechnology remain shallow relative to global peers, which constrains late-stage financing and exit options for European start-ups and scale-ups. Stock exchanges are still largely fragmented across Member States, with limited specialised research coverage and dedicated market-making, prompting European scale-ups to list abroad. To address this bottleneck for a competitive Union biotechnology sector and complement the SIU strategy, which seeks to promote integration and increase the depth of Union capital markets, projects contributing to a Union late-stage capital booster pilot should be recognised by the Commission as high-impact ***health*** biotechnology strategic projects in accordance with the conditions laid down	(48) ***Union public equity markets for biotechnology remain comparatively underdeveloped and fragmented across Member States. Over six years, 66 out of 67 Union biotechnology companies that went public chose to list on non-Union stock exchanges, illustrating persistent structural disadvantages faced by Union-based innovators in a scale-up environment that remains too fragmented, slow and complex, and the need for faster, more coherent and simplified Union-level conditions for biotechnology companies to grow, scale and remain in Europe.*** Union public equity markets for biotechnology remain shallow relative to global peers, which constrains late-stage financing and exit options for European start-ups and scale-ups. Stock exchanges are still largely

in this Regulation.	fragmented across Member States, with limited specialised research coverage and dedicated market-making, prompting European scale-ups to list abroad. To address this bottleneck for a competitive Union biotechnology sector and complement the SIU strategy, which seeks to promote integration and increase the depth of Union capital markets, projects contributing to a Union late-stage capital booster pilot should be recognised by the Commission as high-impact biotechnology strategic projects in accordance with the conditions laid down in this Regulation.

Or. en

Amendment 682
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) Union public equity markets for biotechnology remain shallow relative to global peers, which constrains late-stage financing and exit options for European start-ups and scale-ups. Stock exchanges are still largely fragmented across Member States, with limited specialised research coverage and dedicated market-making, prompting European scale-ups to list abroad. To address this bottleneck for a competitive Union biotechnology sector and complement the SIU strategy, which seeks to promote integration and increase the depth of Union capital markets, projects contributing to a Union late-stage capital booster pilot should be recognised by the Commission as high-impact health biotechnology strategic projects in accordance with the conditions laid down in this Regulation.	(48) Union public equity markets for biotechnology remain shallow relative to global peers, which constrains late-stage financing and exit options for European start-ups and scale-ups. Stock exchanges are still largely fragmented across Member States, with limited specialised research coverage and dedicated market-making, prompting European scale-ups to list abroad. To address this bottleneck for a competitive Union biotechnology sector and complement the SIU strategy, which seeks to promote integration and increase the depth of Union capital markets, projects contributing to a Union late-stage capital booster pilot should be recognised by the Commission as high-impact health biotechnology strategic projects in accordance with the conditions laid down in this Regulation. ***Particular attention should be given to companies progressing innovative products through clinical***

development and towards manufacturing in the Union.

Or. en

Amendment 683
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) Union public equity markets for biotechnology remain shallow relative to global peers, which constrains late-stage financing and exit options for European start-ups and scale-ups. Stock exchanges are still largely fragmented across Member States, with limited specialised research coverage and dedicated market-making, prompting European scale-ups to list abroad. To address this bottleneck for a competitive Union biotechnology sector and complement the SIU strategy, which seeks to promote integration and increase the depth of Union capital markets, projects contributing to a Union late-stage capital booster pilot should be recognised by the Commission as high-impact health biotechnology strategic projects in accordance with the conditions laid down in this Regulation.	(48) Union public equity markets for biotechnology remain shallow relative to global peers, which constrains late-stage financing and exit options for European start-ups and scale-ups. Stock exchanges are still largely fragmented across Member States, with limited specialised research coverage and dedicated market-making, prompting European scale-ups to list abroad. To address this bottleneck for a competitive Union biotechnology sector and complement ***in a timely fashion*** the SIU strategy, which seeks to promote integration and increase the depth of Union capital markets, projects contributing to a Union late-stage capital booster pilot should be recognised by the Commission as high-impact health biotechnology strategic projects in accordance with the conditions laid down in this Regulation ***and within a reasonable timeframe so that these projects can be launched swiftly***.

Or. ro

Amendment 684
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 48 a (new)

Text proposed by the Commission	*Amendment*
	(48a) Biotechnology companies in the Union often face significant difficulties in accessing late-stage venture and scale-up financing, which are essential to bring innovative products from clinical or pilot stage to industrial deployment and manufacturing. This financing gap, sometimes referred to as the "valley of death", risks pushing promising Union biotechnology companies and technologies to relocate their scaling and manufacturing activities to third countries offering more favourable access to capital. In order to address this market failure and to strengthen the Union's industrial and technological capacity in biotechnology, a European Biotechnology Scale-Up Fund (EBSF) should be developed as a Union level fund-of-funds to mobilise long-term, risk-tolerant private and institutional capital, including from pension funds and insurance undertakings, through apporpriate risk-saharing mechanisms, and should crowd in rather than replace private financing with a view to increasing late-stage venture, growth and scale-up financing for biotechnology companies and projects established or active in the Union. The EBSF should build on the experience gained through the pilot referred to in Article 22 of this Regulation and should operate in complementarity with other relevant Union financing instruments, in particular the European Competitiveness Fund, InvestEU or its successor programmes, the European Innovation Council and the Strategic Technologies for Europe Platform or its successor instruments, so as to avoid overlap and ensure the coherent and efficient use of Union resources.

Or. en

Amendment 685
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 48 a (new)

Text proposed by the Commission	*Amendment*
	(48a) The EU biotechnology late-stage capital booster pilot should contribute to the establishment of a dedicated, specialised and cross-border platform and trading infrastructure for biotechnology securities in the Union, addressing the structural deficits identified in this Regulation, namely fragmented stock exchanges, absence of specialised research coverage, and limited market-making for biotechnology securities, that have driven European biotechnology companies to list on non-Union exchanges. The pilot should explicitly aim to create the conditions for a deep, liquid and integrated biotechnology capital market in the Union, drawing on the experience of specialist biotechnology markets in other jurisdictions and building on the objectives of the Savings and Investment Union (SIU).

Or. en

Justification

This recital anchors the late-stage capital booster pilot proposal in the Savings and Investment Union policy framework. This is the strongest language achievable within this Regulation's legal basis.

Amendment 686
András Tivadar Kulja

Proposal for a regulation
Recital 50

Text proposed by the Commission	*Amendment*
(50) The Commission has proposed a	(50) The Commission has proposed a

European Competitiveness Fund (ECF)[28] for the MFF period 2028-2034, aiming to increase European competitiveness, notably in strategic sectors and technologies along the investment journey. It is proposed to be structured along four policy windows reflecting strategic priorities crucial to Union competitiveness and resilience. It proposes funding to support the biotechnology sector through a 'Health, Biotech, Agriculture and Bioeconomy' window.

European Competitiveness Fund (ECF)[28] for the MFF period 2028-2034, aiming to increase European competitiveness, notably in strategic sectors and technologies along the investment journey. It is proposed to be structured along four policy windows reflecting strategic priorities crucial to Union competitiveness and resilience. It proposes funding to support the biotechnology sector through a 'Health, Biotech, Agriculture and Bioeconomy' window. ***Within the relevant Union funding programmes, including the European Competitiveness Fund, where appropriate, dedicated budgetary lines should support health biotechnology strategic projects that reinforce Union biomanufacturing capacity, including but not limited to biosimilar development and manufacturing projects.***

[28] As per Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP].

[28] As per Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP].

Or. en

Amendment 687
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 50

Text proposed by the Commission	*Amendment*
(50) The Commission has proposed a European Competitiveness Fund (ECF)[28]	(50) The Commission has proposed a European Competitiveness Fund (ECF)[28]

for the MFF period 2028-2034, aiming to increase European competitiveness, notably in strategic sectors and technologies along the investment journey. It is proposed to be structured along four policy windows reflecting strategic priorities crucial to Union competitiveness and resilience. It proposes funding to support the biotechnology sector through a 'Health, Biotech, Agriculture and Bioeconomy' window.	for the MFF period 2028-2034, aiming to increase European competitiveness, notably in strategic sectors and technologies along the investment journey. It is proposed to be structured along four policy windows reflecting strategic priorities crucial to Union competitiveness and resilience. It proposes funding to support the biotechnology sector through a 'Health, Biotech, Agriculture and Bioeconomy' window. ***Within the relevant Union funding programmes, including the European Competitiveness Fund, where appropriate, dedicated budgetary lines should support health biotechnology strategic projects that reinforce Union biomanufacturing capacity, including biosimilar development and manufacturing projects***
[28] As per Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP].	[28] As per Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP].

Or. en

Justification

An explicit reference to biosimilar medicines, biosimilar development and manufacturing as an integral part of 'biotechnology' is needed in the MFF/European An explicit reference to biosimilar medicines, biosimilar development and manufacturing as an integral part of 'biotechnology' is needed in the MFF/European Competitiveness Fund to safeguard a practical funding pathway for biosimilar strategic projects. This formulation remains compatible with the future basic acts while creating a clear policy steer for dedicated funding windows.

Amendment 688

Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 50

Text proposed by the Commission	*Amendment*
(50) The Commission has proposed a European Competitiveness Fund (ECF)[28] for the MFF period 2028-2034, aiming to increase European competitiveness, notably in strategic sectors and technologies along the investment journey. It is proposed to be structured along four policy windows reflecting strategic priorities crucial to Union competitiveness and resilience. It proposes funding to support the biotechnology sector through a 'Health, Biotech, Agriculture and Bioeconomy' window.	(50) The Commission has proposed a European Competitiveness Fund (ECF)[28] for the MFF period 2028-2034, aiming to increase European competitiveness, notably in strategic sectors and technologies along the investment journey. It is proposed to be structured along four policy windows reflecting strategic priorities crucial to Union competitiveness and resilience. It proposes funding to support the biotechnology sector through a 'Health, Biotech, Agriculture and Bioeconomy' window. ***Where appropriate, dedicated budgetary lines should support health biotechnology strategic projects that reinforce Union biomanufacturing capacity, including biosimilar development and manufacturing projects.***
[28] As per Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP].	[28] As per Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing the European Competitiveness Fund ('ECF'), including the specific programme for defence research and innovation activities, repealing Regulations (EU) 2021/522, (EU) 2021/694, (EU) 2021/697, (EU) 2021/783, repealing provisions of Regulations (EU) 2021/696, (EU) 2023/588, and amending Regulation (EU) [EDIP].

Or. en

Amendment 689
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 50 a (new)

Text proposed by the Commission	*Amendment*
	(50a) The Commission should support patient organisations, in particular under the European ECF, in carrying out independent education and awareness-raising activities for the patient community concerning biosimilar medicines. Such support should aim to improve understanding of biosimilar medicines, foster trust therein, and address hesitancy regarding their use, thereby contributing to their uptake across the Union.

Or. en

Amendment 690
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 50 a (new)

Text proposed by the Commission	*Amendment*
	(50a) The Commission should promote complementarities between Horizon Europe, InvestEU, the European Innovation Council, the European Investment Bank Group and national promotional banks in order to maximise the impact of Union investment.

Or. en

Amendment 691
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) Companies, projects and initiatives	(51) Companies, projects and initiatives

falling within the scope of this Regulation ***could*** be given ***particular consideration*** for financial support from Union led initiatives, including those that aim to leverage private capital, and from Union funding programmes and instruments, as projects in a strategic technology and, where appropriate, in a strategic deep tech area. Such initiatives, programmes and instruments include the cohesion policy programmes, the InvestEU programme, the EIBG's TechEU programme and the European Tech Champions Initiative, supported by InvestEU, and launched by the EIBG with several Member States, and the European Innovation Council established under the Horizon Europe Programme, as well instruments for the duration of the MFF 2028-2034.	falling within the scope of this Regulation ***shall*** be given ***priority*** for financial support from Union led initiatives, including those that aim to leverage private capital, and from Union funding programmes and instruments, as projects in a strategic technology and, where appropriate, in a strategic deep tech area. Such initiatives, programmes and instruments include the cohesion policy programmes, the InvestEU programme, the EIBG's TechEU programme and the European Tech Champions Initiative, supported by InvestEU, and launched by the EIBG with several Member States, and the European Innovation Council established under the Horizon Europe Programme, as well instruments for the duration of the MFF 2028-2034.

Or. en

Justification

An ambitious biotech act should go beyond potential consideration for strategic projects. Prioritisation will be more attractive and supportive to the ecosystem. For the implementation of this act, the Commission should then propose mechanisms for prioritisation

Amendment 692
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) Companies, projects and initiatives falling within the scope of this Regulation ***could*** be given ***particular consideration*** for financial support from Union led initiatives, including those that aim to leverage private capital, and from Union funding programmes and instruments, as projects in a strategic technology and, where appropriate, in a strategic deep tech area. Such initiatives, programmes and instruments include the cohesion policy	(51) Companies, projects and initiatives falling within the scope of this Regulation ***shall*** be given ***priority*** for financial support from Union led initiatives, including those that aim to leverage private capital, and from Union funding programmes and instruments, as projects in a strategic technology and, where appropriate, in a strategic deep tech area. Such initiatives, programmes and instruments include the cohesion policy programmes, the InvestEU

programmes, the InvestEU programme, the EIBG's TechEU programme and the European Tech Champions Initiative, supported by InvestEU, and launched by the EIBG with several Member States, and the European Innovation Council established under the Horizon Europe Programme, as well instruments for the duration of the MFF 2028-2034.

programme, the EIBG's TechEU programme and the European Tech Champions Initiative, supported by InvestEU, and launched by the EIBG with several Member States, and the European Innovation Council established under the Horizon Europe Programme, as well instruments for the duration of the MFF 2028-2034.

Or. en

Amendment 693
Kristoffer Storm

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) Companies, projects and initiatives falling within the scope of this Regulation ***could*** be given ***particular consideration*** for financial support from Union led initiatives, including those that aim to leverage private capital, and from Union funding programmes and instruments, as projects in a strategic technology and, where appropriate, in a strategic deep tech area. Such initiatives, programmes and instruments include the cohesion policy programmes, the InvestEU programme, the EIBG's TechEU programme and the European Tech Champions Initiative, supported by InvestEU, and launched by the EIBG with several Member States, and the European Innovation Council established under the Horizon Europe Programme, as well instruments for the duration of the MFF 2028-2034.	(51) Companies, projects and initiatives falling within the scope of this Regulation ***shall*** be given ***priority*** for financial support from Union led initiatives, including those that aim to leverage private capital, and from Union funding programmes and instruments, as projects in a strategic technology and, where appropriate, in a strategic deep tech area. Such initiatives, programmes and instruments include the cohesion policy programmes, the InvestEU programme, the EIBG's TechEU programme and the European Tech Champions Initiative, supported by InvestEU, and launched by the EIBG with several Member States, and the European Innovation Council established under the Horizon Europe Programme, as well instruments for the duration of the MFF 2028-2034.

Or. en

Amendment 694
Marie Toussaint, Ville Niinistö

on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 52

Text proposed by the Commission	*Amendment*
(52) Further, high-impact health biotechnology strategic projects are projects with a high European added value, including cross-border projects***,*** expected to ***bring structural economic transformation***, productivity, long-term growth and quality jobs in the biotechnology sector, and ***benefiting*** the Single Market. ***Considering the necessity to align Union, public and private spending with Union competitiveness priorities[29]*** , such projects ***could be given particular consideration*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments.	(52) Further, high-impact health biotechnology strategic projects are ***exceptional*** projects with a ***demonstrated Union-wide systemic impact and*** high European added value, including cross-border ***effects. Such*** projects ***are*** expected to ***generate transformative benefits for the Union's biotechnology ecosystem***, ***by strengthening innovation capacity, scaling research-to-market pathways and enhancing resilience. They should contribute to the Union's public interest objectives, including adressing public health needs, promoting environmental sustainability and ressource efficiency, reducing the environmental footprint of biotechnology and manufacturing and improving access to healthcare technologies alongside their contribution to*** productivity, long-term growth and quality jobs in the biotechnology sector, and ***the proper functioning of*** the Single Market. ***Given their exceptional nature and the requirement for a strict assessment***, such projects ***shall be limited in number and shall be subject to higher threshold of justification compared to health biotechnology strategic projects. In view of their systemic importance and conditional on compliance with the applicable eligibility criteria, such projects may be taken into account*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments.

[29] Commission Staff Working Document, Impact Assessment Report on the European Competitiveness Fund, SWD(2025) 555 final.

Or. en

Amendment 695
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 52

Text proposed by the Commission	*Amendment*
(52) Further, high-impact health biotechnology strategic projects are projects with a high European added value, including cross-border projects, expected to bring structural economic transformation, productivity, long-term growth and quality jobs in the biotechnology sector, and benefiting the Single Market. Considering the necessity to align Union, public and private spending with Union competitiveness priorities[29] , such projects ***could*** be given ***particular consideration*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments.	(52) Further, high-impact health biotechnology strategic projects are projects with a high European added value, including cross-border projects, expected to bring structural economic transformation, productivity, long-term growth and quality jobs in the biotechnology sector, and benefiting the Single Market. Considering the necessity to align Union, public and private spending with Union competitiveness priorities[29] , such projects ***shall*** be given ***priority*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments.
[29] Commission Staff Working Document, Impact Assessment Report on the European Competitiveness Fund, SWD(2025) 555 final.	[29] Commission Staff Working Document, Impact Assessment Report on the European Competitiveness Fund, SWD(2025) 555 final.

Or. en

Justification

For high impact projects recognised, it is essential to provide more visibility and certainty. Potential consideration is not sufficient as an incentive for stakeholders to engage into a high impact strategic project application.

Amendment 696
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 52

Text proposed by the Commission	*Amendment*
(52) Further, high-impact health biotechnology strategic projects are projects with a high European added value, including cross-border projects, expected to bring structural economic transformation, productivity, long-term growth and quality jobs in the biotechnology sector, and benefiting the Single Market. Considering the necessity to align Union, public and private spending with Union competitiveness priorities[29] , such projects ***could*** be given ***particular consideration*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments.	(52) Further, high-impact health biotechnology strategic projects are projects with a high European added value, including cross-border projects, expected to bring structural economic transformation, productivity, long-term growth and quality jobs in the biotechnology sector, and benefiting the Single Market. Considering the necessity to align Union, public and private spending with Union competitiveness priorities[29] , such projects ***shall*** be given ***priority*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments.
[29] Commission Staff Working Document, Impact Assessment Report on the European Competitiveness Fund, SWD(2025) 555 final.	[29] Commission Staff Working Document, Impact Assessment Report on the European Competitiveness Fund, SWD(2025) 555 final.

Or. en

Amendment 697
Kristoffer Storm

Proposal for a regulation
Recital 52

Text proposed by the Commission	*Amendment*
(52) Further, high-impact health biotechnology strategic projects are projects with a high European added value, including cross-border projects, expected to bring structural economic transformation, productivity, long-term growth and quality jobs in the biotechnology sector, and benefiting the Single Market. Considering the necessity to align Union, public and private spending with Union competitiveness priorities[29] ,	(52) Further, high-impact health biotechnology strategic projects are projects with a high European added value, including cross-border projects, expected to bring structural economic transformation, productivity, long-term growth and quality jobs in the biotechnology sector, and benefiting the Single Market. Considering the necessity to align Union, public and private spending with Union competitiveness priorities[29] ,

such projects ***could*** be given ***particular consideration*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments.	such projects ***shall*** be given ***priority*** for Union financial support including in the form of blended financing, under Union programmes, funds and financial instruments.
[29] Commission Staff Working Document, Impact Assessment Report on the European Competitiveness Fund, SWD(2025) 555 final.	[29] Commission Staff Working Document, Impact Assessment Report on the European Competitiveness Fund, SWD(2025) 555 final.

Or. en

Amendment 698
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 52 a (new)

Text proposed by the Commission	*Amendment*
	(52a) Union support for biotechnology, particularly in the area of health, should contribute to ensuring that scientific breakthroughs translate into medicines, treatments, diagnostics and health technologies that are affordable, available and accessible for all patients across the Union. Public support should therefore be accompanied, where appropriate and in compliance with Union law, by transparency, access-related conditions and measures that support geographically balanced manufacturing capacity, resilient supply chains, timely patient access, fair pricing and the availability of generics and biosimilars after the expiry of relevant intellectual property rights. The benefits of publicly supported biotechnology innovation should be shared equitably across Member States, including those with less developed biotechnology ecosystems.

Or. en

Amendment 699
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.	(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. ***When designing and implementing those instruments, the competent authorities should explore the full range of funding mechanisms at their disposal, including outcome-based approaches such as milestone-linked prizes, so as to better align public support with the achievement of concrete results. To ensure that public investment translates into genuine public benefit, recipients of Union financial support should commit to measures ensuring that the health technologies developed as a result are made available, accessible and affordable throughout the Union.*** Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation ***in particular those contributing to a more resilient Union production base and supply chain for biosimilars and other biological medicinal products***. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance

with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.

Or. en

Amendment 700
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their	(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation***, including health biotechnology strategic projects for biosimilar development and manufacturing recognised pursuant to Article 29***. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation***, including projects that strengthen Union development, manufacturing and supply chain capacity for biosimilars and other biological medicinal products.***. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic

respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.

projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.

Or. en

Amendment 701
András Tivadar Kulja

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in	(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation***, including health biotechnology strategic projects for biosimilar development and manufacturing recognised pursuant to Article 29***. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation***, including projects that strengthen Union development, manufacturing and supply chain capacity for biosimilars and other biological medicinal products***. Therefore, Regulation

biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.

(EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.

Or. en

Amendment 702
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of	(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation ***including health biotechnology strategic projects for biosimilar development and manufacturing recognized pursuant to Article 29***. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation***, including projects that strengthen Union development, manufacturing and supply chain capacity for biosimilars and other biological***

supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.

medicinal products. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.

Or. en

Amendment 703
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to	(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation***, including health biotechnology strategic projects for biosimilar development and manufacturing recognised pursuant to Article 29***. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation***, including projects that strengthen Union development,***

contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate**.**

manufacturing and supply chain capacity for biosimilars and other biological medicinal products. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate

Or. en

Justification

This makes the funding bridge with STEP/Union programmes operational for projects recognised under Article 29. It avoids creating a formal hierarchy in which biosimilar strategic projects are recognised but not sufficiently visible for Union funding implementation

Amendment 704
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and	(54) Union-level funding may be leveraged to facilitate investments in health biotechnology strategic projects and high impact health biotechnology strategic projects recognised in accordance with this Regulation. Such projects may benefit from access to existing Union funding instruments, where they fulfil the criteria established in those instruments. Authorities in charge of the Union programmes covered by Regulation (EU) 2024/795 should consider supporting biotechnology health strategic projects and

high impact health biotechnology strategic projects recognised in accordance with this Regulation. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of labour and skills critical to all kinds of quality jobs in support of that objective, as appropriate.	high impact health biotechnology strategic projects recognised in accordance with this Regulation. Therefore, Regulation (EU) 2024/795 should be amended to provide that health biotechnology strategic projects and high-impact health biotechnology strategic projects recognised in accordance with this Regulation should be deemed to contribute to the STEP objectives of supporting the development or manufacturing of critical technologies in biotechnologies throughout the Union, or safeguarding and strengthening their respective value chains and also in addressing shortages of ***specialised*** labour and skills critical to all kinds of quality jobs ***over the medium and long term*** in support of that objective, as appropriate.

Or. ro

Amendment 705
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 55 a (new)

Text proposed by the Commission	*Amendment*
	(55a) The Commission should encourage full use of existing State aid frameworks to facilitate biotechnology manufacturing investments, particularly in cohesion regions and regions undergoing industrial transition.

Or. en

Amendment 706
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 56

Text proposed by the Commission	*Amendment*
(56) Strategic projects in health biotechnology may require blended financing from private, national and Union sources. ***National funding should be in full compliance with*** State Aid rules. The Commission, including through the European Biotechnology Support Network, should support project promoters in liaising with potential investors. Similarly, the European Health Biotechnology Steering Group established by this Regulation should coordinate financing for biotechnology health strategic projects and high-impact health biotechnology strategic projects.	(56) Strategic projects in health biotechnology may require blended financing from private, national and Union sources***, which should be encouraged and developed***. ***Calls for*** State aid rules ***to be revised in order to allow national authorities to invest in high-risk biotechnology projects, in particular those developed by biotechnology start-ups and SMEs***. The Commission, including through the European Biotechnology Support Network, should support project promoters in liaising with potential investors. Similarly, the European Health Biotechnology Steering Group established by this Regulation should coordinate financing for biotechnology health strategic projects and high-impact health biotechnology strategic projects.

Or. fr

Amendment 707
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 56 a (new)

Text proposed by the Commission	*Amendment*
	(56a) The Commission should facilitate coordinated investment strategies bringing together Union programmes, the European Investment Bank Group, national promotional banks and private investors in order to maximise leverage, avoid unnecessary duplication and accelerate biotechnology scale-up.

Or. en

Amendment 708
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.	***deleted***

Or. en

Amendment 709
Dimitris Tsiodras

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.	***deleted***

Or. en

Justification

This should be deleted in line with the deletion of Article 27.

Amendment 710
Viktória Ferenc, András Gyürk

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) Medicinal products developed with innovative biotechnology technologies	***deleted***

which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.

Or. en

Amendment 711
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.	***deleted***

Or. en

Amendment 712
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.	(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection ***Certificate. However, such extension should remain an exceptional, proportionate and targeted incentive, reserved for products that provide clearly demonstrated Union added value and contribute to societal benefits, resilient supply chains and sustainable health systems. It should therefore apply only***

where strict cumulative conditions are met, including a genuine therapeutic, clinical or One Health advantage compared with existing authorised products, robust evidence generated across several Member States, a substantial contribution to research, development or manufacturing capacity in the Union and a credible contribution to timely and equitable availability, affordability and accessibility across the Union. For medicinal products for human use, including chemically synthesised small molecules, biotechnology medicinal products and advanced therapy medicinal products, such an extension should support genuinely best-in-class innovation while avoiding additional protection for mere line extensions or products without a clinically meaningful advantage. For veterinary medicinal products intended to diagnose, treat or prevent zoonotic diseases, the extension should support innovation that strengthens preparedness, prevention and control of zoonoses in line with a One Health approach. Off-patent innovation, including biosimilar-led innovation, should be supported as a means to improve affordability, availability and accessibility, while public support should be accompanied by transparency on public investment, fair pricing, access commitments and geographically balanced biomanufacturing opportunities

Or. en

Amendment 713
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) Medicinal products developed with	(57) Medicinal products developed with

innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.	innovative biotechnology technologies which will bring a ***demonstrable*** therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate***; such an extension shall be granted on an exceptional basis and shall not exceed six months, and shall be contingent on the cumulative fulfilment of clear scientific criteria and criteria relating to production, transparency and accessibility. These criteria shall be assessed transparently by the European Medicines Agency, which shall publish a non-confidential summary, with the option of an effective judicial review. The extension shall not prejudice the attainment of a high level of public health protection, the availability of medicines or the competitiveness of biosimilars.***
	Or. pl

Amendment 714
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) ***Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to*** patients ***should be incentivised with an extension of the Supplementary Protection Certificate***.	(57) ***Timely entry of biosimilars into the Union market is essential to foster effective competition in the pharmaceutical sector and to ensure that*** patients ***benefit without undue delay from the availability of high-quality, safe and effective alternative biological medicines. It contributes to improving access to affordable medecines, lowering medicine prices, improving the efficiency and resilience of healthcare systems, and supporting their long-term financial sustainability.***
	Or. en

Amendment 715
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.	(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate ***and should be accessible to all possible beneficiaries in all Member States, at affordable prices and without discrimination***.

Or. ro

Amendment 716
Ingeborg Ter Laak

Proposal for a regulation
Recital 57

Text proposed by the Commission	*Amendment*
(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.	(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients***, by addressing unmet medical needs or significantly improving existing therapeutic options, which*** should ***then*** be incentivised with an extension of the Supplementary Protection Certificate.

Or. en

Amendment 717
Jessica Polfjärd

Proposal for a regulation

Recital 57

Text proposed by the Commission	*Amendment*
(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be incentivised with an extension of the Supplementary Protection Certificate.	(57) Medicinal products developed with innovative biotechnology technologies which will bring a therapeutic advantage to patients should be ***effectively*** incentivised with an extension of the Supplementary Protection Certificate.

Or. en

Amendment 718
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) The European Parliament has called for the Union and its Member States not to grant patents on biological material and to safeguard the freedom to operate and the breeders' exemption for varieties. It should be ensured that breeders have full access to the genetic material of NGT plants, which by definition are not transgenic plants. Access to genetic materials can best be secured when the right of patent holders is exhausted in the hand of the breeder (breeder's exemption). As current provisions in patent law do not provide for a full breeder's exemption, it should be ensured that patents should not restrict the use of NGT plants by breeders and farmers. Hence, NGT plants should not be subject to patent legislation, but should for the protection of intellectual property solely be subject to the Community Plant Variety Rights (CPVR) system, as laid down in Council Regulation (EC) No 2100/94, which allows the use of the breeder's exemption. NGT plants, their derived seeds, their plant material,

associated genetic material such as genes and gene sequences, and plant traits should therefore be excluded from patentability. The exclusion from patentability should be applied in a consistent manner across legislation. Furthermore, in order to avoid patents being granted or patent applications being submitted between the date of the entry into force of this Regulation and the application of its provisions, it should be ensured that plant material is excluded from patentability from the day of entry into force of this Regulation. For patents already granted or pending patent applications covering plant material, the effects of patents should be further limited. In addition, the Commission should assess and address, in the forthcoming study, how the broader problem of patents being granted, directly or indirectly, on plant material despite previous efforts to close loopholes, should be further addressed. The assessment should address in particular the role and impact of patents on breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, as well as on innovation and in particular on opportunities for SMEs. The report of the Commission should be accompanied by the appropriate legislative proposals in order to ensure further necessary adjustments are made to the intellectual property rights framework.

Or. en

Amendment 719
Viktória Ferenc, András Gyürk

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*

(57a) In 2019, the Union introduced an exception in Regulation (EU) 2019/933 of the European Parliament and of the Council from the protection granted to holders of supplementary protection certificates for medicinal products. It noted the absence of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of generics and biosimilars established in the Union from making generics and biosimilars in the Union, even for the purpose of export to third country markets or for the purpose of storing with a view to day-one placement on the Union market entry. Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The reasons for the introduction for the waiver and the conditions for its application remain applicable at the present time.

However, the limitation to making a product or medicinal product containing that product no earlier than six months before the expiry of the certificate has resulted being an impediment to the development and manufacturing of biosimilar medicines in the Union as it does not match the actual timelines for biotechnological production cycles.

Therefore, in order to create an effective level playing field between makers established in the Union and third-country makers, it is appropriate to finetune the exception to the protection conferred by a certificate so as to allow the making of a product, or a medicinal product containing that product, for the purpose of (i) export to third countries, (ii) supplying and placing on the market of any Member State where the certificate does not exist or has expired, and/or (iii) storing, and any related acts necessary for that making or for the actual export, or

for the supplying and the placing on the market, or the actual storing where such acts would otherwise require the consent of the certificate holder.

Similarly, due to the need to establish an effective level playing field between makers established in the Union and third-country makers, the notification requirements provided for in the SPC manufacturing waiver regulation should be removed.

Or. en

Amendment 720
Dimitris Tsiodras

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) In 2019, the Union introduced an exception in Regulation (EU) 2019/933 of the European Parliament and of the Council from the protection granted to holders of supplementary protection certificates for medicinal products. It noted the absence of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of generics and biosimilars established in the Union from making generics and biosimilars in the Union, even for the purpose of export to third country markets or for the purpose of storing with a view to day-one placement on the Union market entry. Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The reasons for the introduction for the waiver and the conditions for its application remain

applicable at the present time. However, the limitation to making a product or medicinal product containing that product no earlier than six months before the expiry of the certificate has resulted being an impediment to the development and manufacturing of biosimilar medicines in the Union as it does not match the actual timelines for biotechnological production cycles. Therefore, in order to create an effective level playing field between makers established in the Union and third-country makers, it is appropriate to finetune the exception to the protection conferred by a certificate so as to allow the making of a product, or a medicinal product containing that product, for the purpose of (i) export to third countries, (ii) supplying and placing on the market of any Member State where the certificate does not exist or has expired, and/or (iii) storing, and any related acts necessary for that making or for the actual export, or for the supplying and the placing on the market, or the actual storing where such acts would otherwise require the consent of the certificate holder. Similarly, due to the need to establish an effective level playing field between makers established in the Union and third-country makers, the notification requirements provided for in the SPC manufacturing waiver regulation should be removed.

Or. en

Justification

Recital mirroring the recital proposed by the European Commission in the SPC Recast (in the context of the Unitary SPC proposal) but introducing the correction to the SPC manufacturing waiver by removing the artificial differentiation between the export waiver and the EU-day-1 launch waiver.

Amendment 721
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation

Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) In 2019, the Union introduced an exception in Regulation (EU) 2019/933 of the European Parliament and of the Council28 from the protection granted to holders of supplementary protection certificates for medicinal products. It noted the absence of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of generics and biosimilars established in the Union from making generics and biosimilars in the Union, even for the purpose of export to third country markets or for the purpose of storing with a view to day-one placement on the Union market entry. Those circumstances put makers of generics and biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The reasons for the introduction for the waiver and the conditions for its application remain applicable at the present time. However, the limitation to making a product or medicinal product containing that product no earlier than six months before the expiry of the certificate has resulted being an impediment to the development and manufacturing of biosimilar medicines in the Union as it does not match the actual timelines for biotechnological production cycles. Therefore, in order to create an effective level playing field between makers established in the Union and third-country makers, it is appropriate to finetune the exception to the protection conferred by a certificate so as to allow the making of a product, or a medicinal product containing that product, for the purpose of (i) export to third countries, (ii) supplying and placing on the market of any Member State where the certificate does not exist or has expired, and/or (iii)

storing, and any related acts necessary for that making or for the actual export, or for the supplying and the placing on the market, or the actual storing where such acts would otherwise require the consent of the certificate holder. Similarly, due to the need to establish an effective level playing field between makers established in the Union and third-country makers, the notification requirements provided for in the SPC manufacturing waiver regulation should be removed.

Or. en

Amendment 722
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) The aim of this Regulation is to also promote the competitiveness of the Union, thereby enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions, by allowing makers of biosimilars established in the Union to make in the Union products, or medicinal products containing those products, for the purpose of export to third-country markets in which protection does not exist or has expired, thereby also helping those makers to compete effectively in those third-country markets. This Regulation should also allow such makers to make and store products, or medicinal products containing those products, in a Member State for an unlimited period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the Union immediately after

protection has expired ('EU day-one entry') and thus supporting the Union's strategic autonomy and competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector

Or. en

Amendment 723
Tomislav Sokol, András Tivadar Kulja

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) In order to promote a more balanced geographical distribution of clinical trials across the Union and to strengthen the research and innovation capacity of Member States with a lower level of participation in clinical trials, the extension of the supplementary protection certificate should be conditional upon the conduct of the clinical trials supporting the marketing authorisation in more than three Member States, including at least one Member State with a comparatively low share of clinical trials authorised under Regulation (EU) No 536/2014. In order to ensure that such participation is meaningful and contributes to the development of clinical research capacity, a minimum proportion of subjects enrolled in those clinical trials should be recruited in that Member State. As this requirement applies only to the granting of an additional period of supplementary protection and does not affect the availability of the supplementary protection certificate under Regulation (EC) No 469/2009 itself, it constitutes a proportionate incentive to encourage a wider geographical distribution of clinical

research activities across the Union.

Or. en

Amendment 724
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) To promote timely competition following the expiry of supplementary protection certificates, manufacturers of biosimilar medicinal products established in the Union should be permitted to manufacture and, where necessary, stockpile products during the period of protection solely for the purposes of export to third-country markets where protection does not exist or has expired, and for placing those products on the Union market immediately upon expiry of the corresponding certificate. Such measures do not affect the duration or scope of the protection conferred by the certificate but facilitate effective day-one market entry of biosimilar products, thereby supporting the availability of affordable medecines, enhancing the sustainability and resilience of healthcare systems, strengthening the Union's pharmaceutical manufacturing base and supporting the competitiveness and strategic autonomy of the Union.

Or. en

Amendment 725
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) Since an extension of intellectual property rights cannot in and of itself guarantee that the Union will be chosen as the location for research, development or production, the option to utilise an extension of the supplementary protection certificate should be contingent on the implementation of genuine and verifiable measures in the Union. In particular, these measures should involve significant investments into research and development, the relevant manufacturing steps, the performance of clinical trials in more than one Member State, cooperation with scientific and clinical bodies and actions to ensure availability of the medicinal product. The Agency shall protect confidential information but publish a non-confidential summary which makes it possible to assess whether the conditions for an extension have been fulfilled.

Or. pl

Amendment 726
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) Any extension of supplementary protection certificate protection for biotechnology medicines should be assessed in light of its impact on patients, public health systems and biosimilar competition. The Commission's own analysis indicates that an additional year of protection may delay biosimilar entry, postpone the expansion of patient access and generate direct costs for public payers

of approximately EUR 70 million per medicine in the central estimate. Such incentives should therefore be strictly proportionate, evidence-based and designed so as not to undermine the availability, accessibility and affordability of medicines or the sustainability of health systems.

Or. en

Amendment 727
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) Supplementary Protection Certificates, established by Regulation (EC) No 469/2009, constitute the principal Union instrument for extending market exclusivity for medicinal and plant protection products in order to compensate for the loss of effective patent protection during regulatory approval procedures. Economic analysis has shown that market exclusivity alone does not adequately address commercial uncertainty linked to reimbursement, market access and adoption, which developers of biotechnology products frequently identify as being at least as significant as intellectual property protection in shaping investment decisions.

Or. en

Amendment 728
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) The implementation of the Investment Pilot should be regularly monitored, including the geographical distribution of investments, participation of SMEs and scale-ups, contribution to public health objectives, mobilisation of private capital and progress towards reducing strategic dependencies in health biotechnology.

Or. en

Amendment 729
Ingeborg Ter Laak

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) A targeted extension of supplementary protection should reward biotechnology medicinal products that contain a genuinely new active substance and mechanism of action and provide a meaningful therapeutic benefit whilsy addressing unmet medical needs or significantly improving existing treatment options for patients.

Or. en

Amendment 730
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57a) Genetic information contained in humans and all other living organisms is

a public good and should not be patented

Or. en

Amendment 731
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 57 b (new)

Text proposed by the Commission	*Amendment*
	(57b) The aim of this Regulation is to also promote the competitiveness of the Union, thereby enhancing growth and job creation in the internal market and contributing to a wider supply of products under uniform conditions, by allowing makers of biosimilars established in the Union to make in the Union products, or medicinal products containing those products, for the purpose of export to third-country markets in which protection does not exist or has expired, thereby also helping those makers to compete effectively in those third-country markets. This Regulation should also allow such makers to make and store products, or medicinal products containing those products, in a Member State for an unlimited period pending the expiry of the certificate, for the purpose of entering the market of any Member State upon expiry of the corresponding certificate, thereby helping those makers to compete effectively in the Union immediately after protection has expired ('EU day-one entry') and thus supporting the Union's strategic autonomy and competitiveness by fostering a more stable and predictable market environment, encouraging investment and supporting innovation in the pharmaceutical sector.

Or. en

Amendment 732
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 57 b (new)

Text proposed by the Commission	*Amendment*
	(57b) At the same time, it is important to ensure that biosimilars can enter the Union market immediately upon expiry of the Supplementary Protection Certificate, in order to drive down prices, safeguard the sustainability of national healthcare systems, and improve patients' access to affordable medicines across the Union.

Or. en

Justification

To build a truly strong and competitive EU biotech ecosystem, both the SPC and the biosimilars industry should be incentivised.The biosimilars industry brings productive capacity and creates jobs in the EU.

Amendment 733
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 57 c (new)

Text proposed by the Commission	*Amendment*
	(57c) Without intervention, the viability of makers of biosimilars established in the Union could be threatened, with consequences for the Union's pharmaceutical industrial base as a whole. That situation could affect the fully effective functioning of the internal market through the loss of potential new business opportunities for makers of biosimilars, thereby possibly diminishing related investments and hampering job creation within the Union.

Or. en

Amendment 734
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 c (new)

Text proposed by the Commission	*Amendment*
	(57c) It is therefore necessary to complement Supplementary Protection Certificates and other intellectual-property-based incentives with demand-side, or "pull", incentives that reduce commercial uncertainty by increasing the predictability of demand and accelerating the uptake of high-value biotechnology products, without extending periods of market exclusivity.

Or. en

Amendment 735
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 57 c (new)

Text proposed by the Commission	*Amendment*
	(57c)) Since the adoption in 1992 of the predecessor to Regulation (EC) No 469/2009, markets have evolved significantly and there has been huge growth in the making of especially of biosimilars, and in the making of their active ingredients, in particular in countries outside the Union ('third countries') in which protection does not exist or has expired.

Or. en

Amendment 736
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 57 d (new)

Text proposed by the Commission	*Amendment*
	(57d) The absence in Regulation (EC) No 469/2009 of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of biosimilars established in the Union from making biosimilars in the Union, even for the purpose of export to third-country markets in which protection does not exist or has expired. Likewise, makers are prevented from making biosimilars for the purpose of storing them for a limited period before the expiry of the certificate. Those circumstances make it more difficult for those makers, in contrast to makers located in third countries where protection does not exist or has expired, to enter the Union market immediately after expiry of the certificate, given that they are not in a position to build up production capacity for the purpose of export or for the purpose of entering the market of a Member State until the protection provided by that certificate has expired.

Or. en

Amendment 737
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 57 d (new)

Text proposed by the Commission	*Amendment*

(57d) The timely entry of biosimilars into the Union market is important, particularly in order to increase competition, to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines.

Or. en

Amendment 738
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 e (new)

Text proposed by the Commission	*Amendment*
	(57e) Directive 2014/24/EU already provides contracting authorities with procurement procedures specifically designed to support innovation, in particular the competitive procedure with negotiation, the competitive dialogue, and the innovation partnership. Those procedures should be used, where appropriate, as the operational basis for the innovative purchase of biotechnology products under this Regulation, rather than through the creation of parallel procedures.

Or. en

Amendment 739
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 57 e (new)

Text proposed by the Commission	*Amendment*
	(57e) Those circumstances put makers

of biosimilars established in the Union at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection. The Union should strike a balance between restoring a level playing field between those makers and ensuring that the essence of the exclusive rights of holders of certificates ('certificate holders') is guaranteed in relation to the Union market.

Or. en

Amendment 740
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 57 f (new)

Text proposed by the Commission	*Amendment*
	(57f) Without intervention, the viability of makers of biosimilars established in the Union could be threatened, with consequences for the Union's pharmaceutical industrial base as a whole. That situation could affect the fully effective functioning of the internal market through the loss of potential new business opportunities for makers of biosimilars, thereby possibly diminishing related investments and hampering job creation within the Union.

Or. en

Amendment 741
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 g (new)

Text proposed by the Commission	*Amendment*
	(57g) Regulation (EC) No 1394/2007 establishes the Union legal framework for advanced therapy medicinal products (ATMPs), namely gene therapy, somatic cell therapy and tissue-engineered medicinal products. The development, manufacturing and scale-up of ATMPs, and of other biotechnological products, frequently depend on a limited number of specialised enabling technologies, platforms and components — such as viral vector production systems, plasmid manufacturing platforms, gene-editing systems, and specialised cell-processing equipment — the availability of which is often concentrated among a small number of suppliers. This Chapter identifies such enabling technologies as strategic biotechnology tools and extends the demand-side incentives established herein to their development and supply, in addition to the finished products that rely on them.

Or. en

Amendment 742
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 57 g (new)

Text proposed by the Commission	*Amendment*
	(57g) The timely entry of biosimilars into the Union market is important, particularly in order to increase competition, to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines.

Or. en

Amendment 743
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 i (new)

Text proposed by the Commission	*Amendment*
	(57i) Regulation (EU) 2021/2282 on health technology assessment establishes a framework for joint clinical assessment of certain categories of medicinal products at Union level. Closer coordination between that framework, the European Medicines Agency and national reimbursement authorities can reduce the time elapsed between marketing authorisation and effective patient access, and constitutes a commercial incentive complementary to, and independent of, exclusivity-based incentives.

Or. en

Amendment 744
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 k (new)

Text proposed by the Commission	*Amendment*
	(57k) Experience with pre-commercial procurement and public procurement of innovative solutions, as facilitated under Directive 2014/24/EU, demonstrates that public purchasers acting as first buyers or early adopters can share development risk, support clinical validation, and facilitate the participation of small and medium-sized enterprises and start-ups in the biotechnology sector.

Or. en

Amendment 745
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 m (new)

Text proposed by the Commission	*Amendment*
	(57m) International experience, in particular Union and Member State initiatives concerning antimicrobial resistance, demonstrates that outcome-based purchasing agreements, risk-sharing arrangements and subscription or "delinked" payment models can stimulate investment in areas where conventional sales-volume-based remuneration does not adequately reflect the societal value of innovation, without relying exclusively on extended intellectual property protection. Any such mechanism established under this Regulation should be voluntary for Member States and should respect their competence for the organisation and financing of their healthcare systems, in accordance with Article 168(7) TFEU.

Or. en

Amendment 746
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 o (new)

Text proposed by the Commission	*Amendment*
	(57o) Coordination between the Commission and Member States on horizon scanning, joint forecasting of healthcare needs, and common demand signalling can provide innovators with predictability regarding future adoption within Union healthcare systems, constituting an incentive of value

comparable to additional exclusivity, while contributing to more rapid and equitable patient access.

Or. en

Amendment 747
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 q (new)

Text proposed by the Commission	*Amendment*
	(57q) The instruments established under this Regulation are without prejudice to Regulation (EC) No 469/2009 and to the competence of Member States under Article 168(7) TFEU for the definition of their health policy and for the organisation and delivery of health services and medical care, including the allocation of the resources assigned to them.

Or. en

Amendment 748
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 57 s (new)

Text proposed by the Commission	*Amendment*
	(57s) Since the objectives of this Regulation, namely to strengthen the predictability of demand for high-value biotechnology products across the internal market, cannot be sufficiently achieved by Member States acting alone, but can, by reason of the scale of coordinated demand aggregation, be better achieved at Union level, the Union may adopt measures in accordance with

the principle of subsidiarity as set out in Article 5 TEU. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve those objectives.

Or. en

Amendment 749
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(58) The significant advances in analytical methodologies and biocompatibility assessment tools enable more precise demonstration of comparability between biosimilar medicines ('biosimilars') and their reference biological medicinal products. Building on its ongoing work on a Reflection paper on a tailored clinical approach in biosimilar development[34] , the European Medicines Agency[35] ('the Agency') should develop non-binding guidance giving consideration to a potential reduction of the clinical data required for the development and marketing authorisation procedures for biosimilars, based on robust analytical and other non-clinical evidence.	(58) The significant advances in analytical methodologies and biocompatibility assessment tools enable more precise demonstration of comparability between biosimilar medicines ('biosimilars') and their reference biological medicinal products. Building on its ongoing work on a Reflection paper on a tailored clinical approach in biosimilar development[34] , the European Medicines Agency[35] ('the Agency') should develop non-binding guidance giving consideration to a potential reduction of the clinical data required for the development and marketing authorisation procedures for biosimilars, based on robust analytical and other non-clinical evidence. ***Furthermore, the Agency should revise its biosimilar guidelines to reflect scientific advances: (i) streamlining biosimilar development requirements in general, including clinical pharmacokinetic (PK) bridging studies or PK studies as scientifically justified; (ii) the acceptance of a global comparator (foreign sourced reference product) should be reconfirmed and reciprocally included in international regulatory cooperation frameworks. The***

	European Medicines Agency should organise early dialogue on follow-on multi-source biotechnologies including ATMPs.
[34] EMA Reflection paper on a tailored clinical approach in biosimilar development, 17 March 2025, draft accessible at: https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf	[34] EMA Reflection paper on a tailored clinical approach in biosimilar development, 17 March 2025, draft accessible at: https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf
[35] [Revised REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006]	[35] [Revised REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006]

Or. en

Justification

To support the sustainability of EU health systems, the European regulatory network should lead the global regulatory conversation ahead of new biotechnology platforms opening up to multi-source, follow-on biologic competition. Early dialogue and requirements considerations for biosimilar candidate applications for e.g. ATMPs, ADCs are key to de-risk investment by industry and to attract and retain capability and capacity in Europe.

Amendment 750
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(58) The significant advances in analytical methodologies and	(58) The significant advances in analytical methodologies and

biocompatibility assessment tools enable more precise demonstration of comparability between biosimilar medicines (‘biosimilars’) and their reference biological medicinal products. Building on its ongoing work on a Reflection paper on a tailored clinical approach in biosimilar development[34] , the European Medicines Agency[35] (‘the Agency’) should develop ***non-binding*** guidance giving consideration to a potential reduction of the clinical data required for the development and marketing authorisation procedures for biosimilars, based on robust analytical and other non-clinical evidence.

biocompatibility assessment tools enable more precise demonstration of comparability between biosimilar medicines (‘biosimilars’) and their reference biological medicinal products. Building on its ongoing work on a Reflection paper on a tailored clinical approach in biosimilar development, the European Medicines Agency (‘the Agency’) should develop ***nonbinding*** guidance giving consideration to a potential reduction of the clinical data required for the development and marketing authorisation procedures for biosimilars, based on robust analytical and other non-clinical evidence. ***Furthermore, EMA should revise its biosimilar guidelines to reflect scientific advances: (i) streamlining biosimilar development requirements in general, including clinical PK bridging studies or PK studies as scientifically justified; (ii) the acceptance of a global comparator (foreign sourced reference product) should be reconfirmed and reciprocally included in international regulatory cooperation frameworks. The European Medicines Agency should organise early dialogue on follow-on multi-source biotechnologies including ATMPs.***

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[34] EMA Reflection paper on a tailored clinical approach in biosimilar development, 17 March 2025, draft accessible at: https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf

[35] [Revised REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No

536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006]

Or. en

Justification

While EMA and the international regulators community are moving to implementation of Comparative Efficacy Studies (CES) waivers for most biosimilar medicine developments, following several years of regulatory-science discussions; it is important that the Biotech Act encourages further streamlining of regulatory requirements to ensure those are fit-for-purpose and as such supportive of Europe's competitiveness and attractivity for biotech R&D.

Amendment 751
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 59

Text proposed by the Commission	*Amendment*
(59) The manufacturing capacity and expertise for biosimilars in the Union can greatly contribute to ensure Union competitiveness, strategic autonomy and resilience, ***both from a health and sustainability perspective***. Therefore, Member States should recognise, and support projects that fulfil the conditions laid down in this Regulation for strategic projects for biosimilars manufacturing.	(59) The ***research, development and*** manufacturing capacity and expertise for biosimilars in the Union can greatly contribute to ensure Union competitiveness, strategic autonomy and resilience, ***while improving the availability and affordability of medicinal products and supporting sustainable healthcare systems***. Therefore, Member States should recognise, and support projects that fulfil the conditions laid down in this Regulation for strategic projects for biosimilars ***research, development and*** manufacturing.

Or. en

Amendment 752
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 59

Text proposed by the Commission	*Amendment*
(59) The manufacturing capacity and expertise for biosimilars in the Union can greatly contribute to ensure Union competitiveness, strategic autonomy and resilience, both from a health and ***sustainability*** perspective. Therefore, Member States should recognise**,** and support projects that fulfil the conditions laid down in this Regulation for strategic projects for biosimilars manufacturing.	(59) The ***development and*** manufacturing capacity and expertise for biosimilars in the Union ***and strategic partners, including those involving the EEA States and international cooperation,*** can greatly contribute to ensure Union competitiveness, strategic autonomy and resilience, both from a health and ***economic*** perspective. Therefore, Member States should recognise and support projects that fulfil the conditions laid down in this Regulation for strategic projects for biosimilars ***development and*** manufacturing.

Or. en

Amendment 753
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 59 a (new)

Text proposed by the Commission	*Amendment*
	(59a) The development and manufacturing capacity and expertise for biosimilars in the Union and strategic partners, including those involving European (EEA, CH, UK) cooperation, can greatly contribute to ensure Union competitiveness, strategic autonomy and resilience, and trade balance (exports), both from a health and economic sustainability perspective. Therefore, Member States should recognise, and support projects that fulfil the conditions laid down in this Regulation for strategic projects for biosimilars development and manufacturing.

Or. en

Justification

Since the early 2000s, Europe has developed into a leading global hub for biosimilar research, development, and manufacturing, alongside South Korea, India, China, and the United States.The biosimilar sector contributed €25.6 billion to European GDP in 2024, representing some 6% of the total pharmaceutical industry contribution. It is the leading global biosimilar market and a key export driver; a third of European-made biosimilar medicines areexported to a growing number of third-countries, with lead exports to North America and middle-eastern countries

Amendment 754
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) Biosimilars can play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly, the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters.	(60) Biosimilars can play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly, the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters***, under clear terms of partnership that do not disadvantage European organisations***.

Or. ro

Amendment 755
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) Biosimilars ***can*** play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly,	(60) Biosimilars play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly,

the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters.	the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters.

Or. en

Justification

The European biosimilar footprint is integral to the biotech ecosystem and involves a network of 100 companies ranging from fully integrated developers and manufacturers to CDMO, CRO and service providers (e.g. bioanalytical). These companies are part of the biotech ecosystem and serve biotech development and manufacturing needs regardless of the life-cycle stage of the biotech medicines (on- or off-patent medicines) and contribute to diversify capability (e.g. different technology platforms and expertise) as well as capacity buffer and export engine.

Amendment 756
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) Biosimilars ***can*** play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly, the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters.	(60) Biosimilars play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly, the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters.

Or. en

Amendment 757
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) Biosimilars ***can*** play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly, the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters.	(60) Biosimilars play an important role in diversifying and strengthening supply chains, promoting competition and fostering economic growth in the Union and for its global partners. Accordingly, the promoters of strategic projects for biosimilars and the companies active in this area should be encouraged to establish or strengthen cooperation with international biotechnology clusters.

Or. en

Amendment 758
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 60 a (new)

Text proposed by the Commission	*Amendment*
	(60a) Health technology assessments (HTAs) carried out by Member States play a key role in determining the relative and cost-effectiveness of medicinal products, and consequently influence decisions on pricing and reimbursement. Where a prior HTA of a reference medicinal product resulted in a negative recommendation, in particular due to insufficient cost-effectiveness at the price requested, the subsequent entry of a biosimilar or generic medicine corresponding to the same or a similar active substance, offered at a lower price, may alter the outcome of that cost-effectiveness analysis. Whereas the original submission of documentation to the HTA bodies are made by the originator companies, developers of generic and biosimilar medicinal products do not have access to that documentation. In such cases, biosimilar and generic

medicine developers should be able to request a recalculation or re-assessment of the relevant HTA on the basis of the new price, without submitting the aforementioned documentation, and Member States should give due consideration to such requests, including by reassessing whether a previously negative outcome would, on the basis of the lower price, result in a positive evaluation. This process should take place after the granting of the marketing authorisation irrespective of any remaining IP protection at that time. This would support patient access to effective treatments at a sustainable cost and reinforce market uptake of biosimilars and generics, without prejudice to the competence of Member States to organise their health technology assessment, pricing and reimbursement systems.

Or. en

Amendment 759
Christine Anderson

Proposal for a regulation
Recital 60 a (new)

Text proposed by the Commission	*Amendment*
	(60a) Strengthening the Union's biotechnology sector should not be pursued by extending market exclusivities, delaying competition or granting additional monopoly rents. Timely entry of generic and biosimilar alternatives contributes to competition, affordability, patient access and the sustainability of healthcare systems. Competitiveness is better served by reducing unnecessary regulatory barriers, improving legal certainty, facilitating timely market entry and strengthening Union-based manufacturing under competitive

conditions.

Or. en

Amendment 760
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Recital 61

Text proposed by the Commission	*Amendment*
(61) AI can enhance the development, safety, efficiency and scale-up of biotechnology and biomanufacturing, provided that its use is responsible and aligned with Union legislation. To pursue this, the Commission and the Member States should promote an AI-first policy approach as introduced in the Apply AI Strategy when implementing this Regulation and the exchange of knowledge, standards and best practices relevant to the responsible application of the AI-First Policy Approach[36] . The responsible and effective integration of AI can enhance research, development and regulatory processes and thereby support the competitiveness of Union innovators in biotechnology. The Commission and the Member States should therefore encourage the uptake of such approaches and facilitate the exchange of knowledge, standards and best practices relevant to their application. That cooperation should remain fully compliant with Union competition rules.	(61) AI can enhance the development, safety, efficiency and scale-up of biotechnology and biomanufacturing, provided that its use is responsible and aligned with Union legislation***. However, AI-usage in biotechnology and biomanufacturing might ultimately be limited not by compute, but by the availability of large, high-quality experimental datasets. While AI foundational models can identify patterns and generate hypotheses, biological systems remain vastly more complex than human language, and still suffer from sparse, biased, or poorly standardized data. Therefore, investment in biotechnological platforms is essential to create the next generation of high-throughput, automated, and scalable experimental infrastructures—combining DNA synthesis, cell engineering, organoid models, high-content screening, omics, and advanced sensing technologies. These platforms dramatically reduce the cost per datapoint and enable millions of reproducible biological measurements, generating the diverse datasets needed to train, validate, and continuously improve robust AI models. By closing the design–build–test–learn loop and connecting experiments directly to AI pipelines, biofoundries will form the backbone of***

tomorrow's biotech AI infrastructure enabling more predictive, generative, and trustworthy AI systems for drug discovery, biotechnology, and precision medicine. To pursue this, the Commission and the Member States should promote an AI-first policy approach as introduced in the Apply AI Strategy when implementing this Regulation and the exchange of knowledge, standards and best practices relevant to the responsible application of the AI-First Policy Approach[36] . The responsible and effective integration of AI can enhance research, development and regulatory processes and thereby support the competitiveness of Union innovators in biotechnology. The Commission and the Member States should therefore encourage the uptake of such approaches and facilitate the exchange of knowledge, standards and best practices relevant to their application. That cooperation should remain fully compliant with Union competition rules.

[36] Communication from the Commission to the European Parliament and the Council, Apply AI Strategy, COM/2025/723 final.

[36] Communication from the Commission to the European Parliament and the Council, Apply AI Strategy, COM/2025/723 final.

Or. en

Amendment 761
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 61

Text proposed by the Commission	*Amendment*
(61) AI can enhance the development, safety, efficiency and scale-up of biotechnology and biomanufacturing, provided that its use is responsible and aligned with Union legislation. To pursue this, the Commission and the Member	(61) AI can enhance the development, safety, efficiency and scale-up of biotechnology and biomanufacturing, provided that its use is responsible and aligned with Union legislation ***with a focus on human-centric approach and the***

States should promote an AI-first policy approach as introduced in the Apply AI Strategy when implementing this Regulation and the exchange of knowledge, standards and best practices relevant to the responsible application of the AI-First Policy Approach[36] . The responsible and effective integration of AI can enhance research, development and regulatory processes and thereby support the competitiveness of Union innovators in biotechnology. The Commission and the Member States should therefore encourage the uptake of such approaches and facilitate the exchange of knowledge, standards and best practices relevant to their application. That cooperation should remain fully compliant with Union competition rules.

development of secure, trustworthy and ethical AI. To pursue this, the Commission and the Member States should promote an AI-first policy approach as introduced in the Apply AI Strategy when implementing this Regulation and the exchange of knowledge, standards and best practices relevant to the responsible application of the AI-First Policy Approach[36]. The responsible and effective integration of AI can enhance research, development and regulatory processes and thereby support the competitiveness of Union innovators in biotechnology. The Commission and the Member States should therefore encourage the uptake of such approaches and facilitate the exchange of knowledge, standards and best practices relevant to their application. That cooperation should remain fully compliant with Union competition rules. ***At the same time ethical and professional standards for scientific research need to be ensured so that AI is used trustworthy and ethically sound.***

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[36] Communication from the Commission to the European Parliament and the Council, Apply AI Strategy, COM/2025/723 final.

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[36] Communication from the Commission to the European Parliament and the Council, Apply AI Strategy, COM/2025/723 final.

Or. en

Amendment 762
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 61

Text proposed by the Commission	*Amendment*
(61) AI can enhance the development, safety, efficiency and scale-up of biotechnology and biomanufacturing, provided that its use is responsible and aligned with Union legislation. To pursue	(61) AI can enhance the development, safety, efficiency and scale-up of biotechnology and biomanufacturing, provided that its use is responsible and aligned with Union legislation***, with a***

this, the Commission and the Member States should promote an AI-first policy approach as introduced in the Apply AI Strategy when implementing this Regulation and the exchange of knowledge, standards and best practices relevant to the responsible application of the AI-First Policy Approach[36] . The responsible and effective integration of AI can enhance research, development and regulatory processes and thereby support the competitiveness of Union innovators in biotechnology. The Commission and the Member States should therefore encourage the uptake of such approaches and facilitate the exchange of knowledge, standards and best practices relevant to their application. That cooperation should remain fully compliant with Union competition rules.

[36] Communication from the Commission to the European Parliament and the Council, Apply AI Strategy, COM/2025/723 final.

focus on human-centric approach and the development of secure, trustworthy and ethical AI. To pursue this, the Commission and the Member States should promote an AI-first policy approach as introduced in the Apply AI Strategy when implementing this Regulation and the exchange of knowledge, standards and best practices relevant to the responsible application of the AI-First Policy Approach[36] . The responsible and effective integration of AI can enhance research, development and regulatory processes and thereby support the competitiveness of Union innovators in biotechnology. The Commission and the Member States should therefore encourage the uptake of such approaches and facilitate the exchange of knowledge, standards and best practices relevant to their application. That cooperation should remain fully compliant with Union competition rules.

[36] Communication from the Commission to the European Parliament and the Council, Apply AI Strategy, COM/2025/723 final.

Or. en

Amendment 763
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 61

Text proposed by the Commission	*Amendment*
(61) AI can enhance the development, safety, efficiency and scale-up of biotechnology and biomanufacturing, provided that its use is responsible and aligned with Union legislation. To pursue this, the Commission and the Member States should promote an AI-first policy approach as introduced in the Apply AI Strategy when implementing this	(61) AI can enhance the development, safety, efficiency and scale-up of biotechnology and biomanufacturing, provided that its use is responsible and aligned with Union legislation***, with a focus on human-centric approach and the development of secure and ethical AI***. To pursue this, the Commission and the Member States should promote an AI-first

Regulation and the exchange of knowledge, standards and best practices relevant to the responsible application of the AI-First Policy Approach[36] . The responsible and effective integration of AI can enhance research, development and regulatory processes and thereby support the competitiveness of Union innovators in biotechnology. The Commission and the Member States should therefore encourage the uptake of such approaches and facilitate the exchange of knowledge, standards and best practices relevant to their application. That cooperation should remain fully compliant with Union competition rules.

[36] Communication from the Commission to the European Parliament and the Council, Apply AI Strategy, COM/2025/723 final.

policy approach as introduced in the Apply AI Strategy when implementing this Regulation and the exchange of knowledge, standards and best practices relevant to the responsible application of the AI-First Policy Approach[36] . The responsible and effective integration of AI can enhance research, development and regulatory processes and thereby support the competitiveness of Union innovators in biotechnology. The Commission and the Member States should therefore encourage the uptake of such approaches and facilitate the exchange of knowledge, standards and best practices relevant to their application. That cooperation should remain fully compliant with Union competition rules.

[36] Communication from the Commission to the European Parliament and the Council, Apply AI Strategy, COM/2025/723 final.

Or. en

Amendment 764
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 61 a (new)

Text proposed by the Commission	*Amendment*
	(61a) The deployment of artificial intelligence in connection with health biotechnology, including in clinical and care settings, can support health professionals, improve accuracy and broaden access to care. Artificial intelligence should nevertheless remain a tool that serves people and that functions under meaningful human control at all times, in line with the principle of human oversight laid down in Regulation (EU) 2024/1689 and with respect for human

dignity, personal autonomy and patients' rights as enshrined in the Charter of Fundamental Rights of the European Union. A human should at all times be able to understand, supervise, intervene in and override the functioning of such systems. In particular, where artificial intelligence is used in health and care settings, decisions concerning the prioritisation of patients, the allocation of care and treatment and the triage of patients, including in emergency or resource-constrained situations, should remain the responsibility of qualified health professionals and should not be determined by an artificial intelligence system. This Regulation applies without prejudice to Regulation (EU) 2024/1689 and to the responsibility of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, in accordance with Article 168(7) of the Treaty on the Functioning of the European Union.

Or. en

Amendment 765
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 61 a (new)

Text proposed by the Commission	*Amendment*
	(61a) The use of artificial intelligence in biotechnology may accelerate research and the development of new treatments, the inherent limitations of such systems must be acknowledged. AI systems operate by statistical inference and may therefore fail to capture the full complexity of biological effects. Furthermore, training data often reflect structural biases, in particular the overrepresentation of certain populations

in genomic databases, which may undermine the universality and equity of resulting therapeutic solutions. Biological validation through clinical trials therefore remains irreplaceable and mandatory in accordance with applicable Union law and no algorithmic prediction may substitute for it. In any case, the processing of personal data, in particular health and genetic data, must comply strictly with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725, ensuring in particular the principles of data minimisation, purpose limitation and security of processing.

Or. en

Amendment 766
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(62) The rapid expansion and increasing complexity of AI applications throughout the medicinal-product lifecycle requires structured and coherent guidance to ensure their safe, effective and trustworthy use. The Agency is developing expertise in this area through initiatives such as the Good Manufacturing Practice (GMP) Annex 22 – Artificial Intelligence, Q&A in AI in Pharmacovigilance, the GCP Annex to the Guideline on computerised systems and electronic data in clinical trials and AI in Clinical Development. It is therefore appropriate for the Agency to develop non-binding guidance on the deployment and use of systems based on advanced technologies, including of AI systems and of general-purpose AI models across development, manufacturing, clinical trials, and post-authorisation activities for	(62) The rapid expansion and increasing complexity of AI applications throughout the medicinal-product lifecycle requires structured and coherent guidance to ensure their safe, effective***, ethical*** and trustworthy use. The Agency is developing expertise in this area through initiatives such as the Good Manufacturing Practice (GMP) Annex 22 – Artificial Intelligence, Q&A in AI in Pharmacovigilance, the GCP Annex to the Guideline on computerised systems and electronic data in clinical trials and AI in Clinical Development. It is therefore appropriate for the Agency to develop non-binding guidance on the deployment and use of systems based on advanced technologies, including of AI systems and of general-purpose AI models across development, manufacturing, clinical trials, and post-authorisation

compliance with applicable Union legislation in the health area. To ensure consistency across the health and digital domains, when developing or updating such guidance, the Agency should cooperate with the Commission, including the AI office and should consult relevant national competent authorities and stakeholders, and relevant expert coordination groups established under Union legislation in the health and digital areas, as appropriate**.**

activities for compliance with applicable Union legislation in the health area. To ensure consistency across the health and digital domains, when developing or updating such guidance, the Agency should cooperate with the Commission, including the AI office and should consult relevant national competent authorities and stakeholders, and relevant expert coordination groups established under Union legislation in the health and digital areas, as appropriate

Or. en

Amendment 767
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(62) The rapid expansion and increasing complexity of AI applications throughout the medicinal-product lifecycle requires structured and coherent guidance to ensure their safe, effective and trustworthy use. The Agency is developing expertise in this area through initiatives such as the Good Manufacturing Practice (GMP) Annex 22 – Artificial Intelligence, Q&A in AI in Pharmacovigilance, the GCP Annex to the Guideline on computerised systems and electronic data in clinical trials and AI in Clinical Development. It is therefore appropriate for the Agency to develop non-binding guidance on the deployment and use of systems based on advanced technologies, including of AI systems and of general-purpose AI models across development, manufacturing, clinical trials, and post-authorisation activities for compliance with applicable Union legislation in the health area. To ensure consistency across the health and digital domains, when developing or updating	(62) The rapid expansion and increasing complexity of AI applications throughout the medicinal-product lifecycle requires structured and coherent guidance to ensure their safe, effective***, ethical*** and trustworthy use. The Agency is developing expertise in this area through initiatives such as the Good Manufacturing Practice (GMP) Annex 22 – Artificial Intelligence, Q&A in AI in Pharmacovigilance, the GCP Annex to the Guideline on computerised systems and electronic data in clinical trials and AI in Clinical Development. It is therefore appropriate for the Agency to develop non-binding guidance on the deployment and use of systems based on advanced technologies, including of AI systems and of general-purpose AI models across development, manufacturing, clinical trials, and post-authorisation activities for compliance with applicable Union legislation in the health area. To ensure consistency across the health and digital domains, when developing or

such guidance, the Agency should cooperate with the Commission, including the AI office and should consult relevant national competent authorities and stakeholders, and relevant expert coordination groups established under Union legislation in the health and digital areas, as appropriate.

updating such guidance, the Agency should cooperate with the Commission, including the AI office and should consult relevant national competent authorities and stakeholders, and relevant expert coordination groups established under Union legislation in the health and digital areas, as appropriate.

Or. en

Amendment 768
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 62

Text proposed by the Commission	*Amendment*
(62) The rapid expansion and increasing complexity of AI applications throughout the medicinal-product lifecycle requires structured and coherent guidance to ensure their safe, effective and trustworthy use. The Agency is developing expertise in this area through initiatives such as the Good Manufacturing Practice (GMP) Annex 22 – Artificial Intelligence, Q&A in AI in Pharmacovigilance, the GCP Annex to the Guideline on computerised systems and electronic data in clinical trials and AI in Clinical Development. It is therefore appropriate for the Agency to develop non-binding guidance on the deployment and use of systems based on advanced technologies, including of AI systems and of general-purpose AI models across development, manufacturing, clinical trials, and post-authorisation activities for compliance with applicable Union legislation in the health area. To ensure consistency across the health and digital domains, when developing or updating such guidance, the Agency should cooperate with the Commission, including the AI office and should consult relevant	(62) The rapid expansion and increasing complexity of AI applications throughout the medicinal-product lifecycle requires structured and coherent guidance to ensure their safe, effective***, ethical*** and trustworthy use. The Agency is developing expertise in this area through initiatives such as the Good Manufacturing Practice (GMP) Annex 22 – Artificial Intelligence, Q&A in AI in Pharmacovigilance, the GCP Annex to the Guideline on computerised systems and electronic data in clinical trials and AI in Clinical Development. It is therefore appropriate for the Agency to develop non-binding guidance on the deployment and use of systems based on advanced technologies, including of AI systems and of general-purpose AI models across development, manufacturing, clinical trials, and post-authorisation activities for compliance with applicable Union legislation in the health area. To ensure consistency across the health and digital domains, when developing or updating such guidance, the Agency should cooperate with the Commission, including the AI office and should consult relevant

national competent authorities and stakeholders, and relevant expert coordination groups established under Union legislation in the health and digital areas, as appropriate.

national competent authorities and stakeholders, and relevant expert coordination groups established under Union legislation in the health and digital areas, as appropriate.

Or. en

Amendment 769
Viktória Ferenc, András Gyürk

Proposal for a regulation
Recital 62 a (new)

Text proposed by the Commission	*Amendment*
	(62a) Clinical trials conducted in more than two Member States play an important role in strengthening the Union's research and innovation ecosystem. While the selection of clinical trial sites should remain based on scientific, medical and operational considerations, the participation of Member States in such clinical trials remains uneven across the Union. Measures encouraging the inclusion of Member States that are persistently underrepresented in clinical trials conducted in more than two Member States can contribute to a more balanced geographical distribution of clinical research, improve patients' access to innovative medicinal products, strengthen research capacity across the Union and enhance the representativeness of clinical evidence.

Or. en

Amendment 770
Angelika Winzig

Proposal for a regulation
Recital 63

Text proposed by the Commission	*Amendment*
(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities.	(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities ***while preserving the quality, integrity and independence of regulatory decision-making, and ensuring appropriate safeguards for the protection of confidential information relating to patients and other stakeholders***. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities ***and in consultation with stakeholders***.

Or. en

Amendment 771
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 63

Text proposed by the Commission	*Amendment*
(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities.	(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities. ***Such guidance should furthermore support a***

homogenous application of common ethical principles enshrined in law when developing, deploying and using artificial intelligence, especially high-risk AI as well as robotics and related technologies.

Or. en

Amendment 772
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 63

Text proposed by the Commission	*Amendment*
(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities.	(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities ***whilst preserving the quality and integrity of regulatory decision making and creating appropriate safeguards to protect patient and stakeholders' confidential information***. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities ***and in consultaton with stakeholders***.

Or. en

Amendment 773
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Sophie Wilmès

Proposal for a regulation
Recital 63

Text proposed by the Commission	*Amendment*
(63) Moreover, the Agency should	(63) Moreover, the Agency should

develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities.	develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities ***while preserving the integrity, independence and quality of regulatory decision-making and ensuring appropriate safeguards to protect confidential information concerning patients and other stakeholders***. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities.

Or. en

Justification

The Agency's use of AI tools should not affect the quality of regulatory decision-making. Stakeholders whose documentation may be assessed using AI tools should be consulted on the rules governing their use to ensure transparency in the decision-making process.

Amendment 774
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 63

Text proposed by the Commission	*Amendment*
(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities.	(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities ***whilst preserving the quality and integrity of regulatory decision making and creating appropriate safeguards to protect patient and stakeholders' confidential information***. Such guidance should be developed and published in agreement with

the Commission, the AI Board and the competent authorities ***and in consultation with stakeholders***.

Or. en

Justification

The Agency use of AI tools should not affect the quality and integrity of regulatory decision-making. In addition, stakeholders whose documentation could be assessed by means of AI tools should be consulted on the guidance governing the use of those tools and their use in order to maintain trust and transparency in the decision-making process.

Amendment 775
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 63

Text proposed by the Commission	*Amendment*
(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities.	(63) Moreover, the Agency should develop non-binding guidance on the deployment and use of AI systems and of general-purpose AI models also in the procedures for the authorisation of medicinal products, with a view to optimising processes and increasing efficiency of regulatory activities***, without allowing decisions to be taken solely by AI systems***. Such guidance should be developed and published in agreement with the Commission, the AI Board and the competent authorities.

Or. ro

Amendment 776
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Recital 63 a (new)

Text proposed by the Commission	*Amendment*

(63a) The Agency has a central role in developing regulatory guidance on artificial intelligence in view of its scientific expertise and the need to ensure coherent and harmonised approaches across the Union.

Or. en

Justification

The Biotech Act should recognise the expertise of the Agency as one of the key players in the international and European development of guidelines on the use of AI in regulatory practice.

Amendment 777
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 64

Text proposed by the Commission	*Amendment*
(64) In order to accelerate the development and scale-up of biotechnology innovations that are enabled, enhanced or significantly supported by AI and advanced computational methods, the Union requires dedicated testing environments that combine experimental, computational and data-driven capabilities. Given their essential role for supporting AI-enabled biotechnology innovations, it is appropriate to establish requirements in this Regulation for the recognition by the Commission and the support for high-impact health biotechnology strategic projects in the form of biotechnology testing environments, under certain conditions.	(64) In order to accelerate the development and scale-up of biotechnology innovations that are enabled, enhanced or significantly supported by AI and advanced computational methods, the Union requires dedicated testing environments that combine experimental, computational and data-driven capabilities***, while upholding high safety and ethical standards***. Given their essential role for supporting AI-enabled biotechnology innovations, it is appropriate to establish requirements in this Regulation for the recognition by the Commission and the support for high-impact health biotechnology strategic projects in the form of biotechnology testing environments, under certain conditions. ***The Commission should put in place sufficient, effective and specific technical and organisational measures to safeguard the fundamental rights, ethical standards and interests of data subjects in line with Union Law.***

Or. en

Amendment 778
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 64

Text proposed by the Commission	*Amendment*
(64) In order to accelerate the development and scale-up of biotechnology innovations that are enabled, enhanced or significantly supported by AI and advanced computational methods, the Union requires dedicated testing environments that combine experimental, computational and data-driven capabilities. Given their essential role for supporting AI-enabled biotechnology innovations, it is appropriate to establish requirements in this Regulation for the recognition by the Commission and the support for high-impact health biotechnology strategic projects in the form of biotechnology testing environments, under certain conditions.	(64) In order to accelerate the development and scale-up of biotechnology innovations that are enabled, enhanced or significantly supported by AI and advanced computational methods, the Union requires dedicated testing environments that combine experimental, computational and data-driven capabilities. Given their essential role for supporting AI-enabled biotechnology innovations, it is appropriate to establish requirements in this Regulation for the recognition by the Commission and the support for high-impact health biotechnology strategic projects in the form of biotechnology testing environments, under certain conditions. ***Such requirements shall be aimed at upholding high safety and ethical standards and at safeguarding the fundamental rights of data subjects.***

Or. en

Amendment 779
Anja Hazekamp, Anthony Smith, Sebastian Everding, Lynn Boylan

Proposal for a regulation
Recital 64

Text proposed by the Commission	*Amendment*
(64) In order to accelerate the development and scale-up of biotechnology innovations that are enabled, enhanced or significantly supported by AI	(64) In order to accelerate the development and scale-up of biotechnology innovations ***including NAMs and those*** that are enabled,

and advanced computational methods, the Union requires dedicated testing environments that combine experimental, computational and data-driven capabilities. Given their essential role for supporting AI-enabled biotechnology innovations, it is appropriate to establish requirements in this Regulation for the recognition by the Commission and the support for high-impact health biotechnology strategic projects in the form of biotechnology testing environments, under certain conditions.	enhanced or significantly supported by AI and advanced computational methods, the Union requires dedicated testing environments that combine experimental, computational and data-driven capabilities. Given their essential role for supporting ***NAMs and*** AI-enabled biotechnology innovations, it is appropriate to establish requirements in this Regulation for the recognition by the Commission and the support for high-impact health biotechnology strategic projects in the form of biotechnology testing environments, under certain conditions.

Or. en

Amendment 780
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the functions of regulatory sandboxes established under Union or national law as well as the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union legislation. These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimised CRISPR site prediction, tumour antigen identification,	(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the functions of regulatory sandboxes established under Union or national law as well as the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union legislation. These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimised CRISPR site prediction, tumour antigen identification,

sequence engineering, delivery-vehicle design, or the matching of diverse patient cancer-cell variants with CAR-T cell types.	sequence engineering, delivery-vehicle design, or the matching of diverse patient cancer-cell variants with CAR-T cell types***, provided that these AI predictions are subsequently checked and confirmed by medical specialists to avoid possible errors***. ***These specialists must adjust the way they check and confirm data obtained through AI systems by adapting to the rapid changes in this field and updating their methods.***

Or. ro

Amendment 781
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the functions of regulatory sandboxes established under Union or national law as well as the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union legislation. These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimised CRISPR site prediction, tumour antigen identification, sequence engineering, delivery-vehicle design, or the matching of diverse patient	(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the functions of regulatory sandboxes established under Union or national law as well as the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union legislation. These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimised CRISPR site prediction, tumour antigen identification, sequence engineering, delivery-vehicle design, or the matching of diverse patient

cancer-cell variants with CAR-T cell types.	cancer-cell variants with CAR-T cell types. ***Given the sensitivity of personal electronic health data, this Regulation should provide sufficient safeguards at both Union and national level to ensure a high degree of data protection, security, confidentiality and ethical use.***

Or. en

Amendment 782
Sirpa Pietikäinen

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the functions of regulatory sandboxes established under Union or national law as well as the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union legislation. These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimised CRISPR site prediction, tumour antigen identification, sequence engineering, delivery-vehicle design, or the matching of diverse patient cancer-cell variants with CAR-T cell types.	(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the functions of regulatory sandboxes established under Union or national law as well as the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union legislation. These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as ***women's health, through the development of AI-assisted clinical development tools like virtual twins, and*** advanced therapies, where AI can improve efficacy and safety — for example through optimised CRISPR site prediction, tumour antigen identification, sequence engineering, delivery-vehicle design, or the matching of diverse patient cancer-cell variants with CAR-T cell types.

Or. en

Amendment 783
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, ***the functions of regulatory sandboxes established under Union or national law as well as*** the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union legislation. These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimised CRISPR site prediction, tumour antigen identification, sequence engineering, delivery-vehicle design, or the matching of diverse patient cancer-cell variants with CAR-T cell types.	(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union legislation. These infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through optimised CRISPR site prediction, tumour antigen identification, sequence engineering, delivery-vehicle design, or the matching of diverse patient cancer-cell variants with CAR-T cell types.

Or. en

Amendment 784
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the functions of regulatory sandboxes established under Union or national law as well as the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union ***legislation. These*** infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through ***optimised*** CRISPR site prediction, tumour antigen identification, sequence engineering, delivery-vehicle design, or the matching of diverse patient cancer-cell variants with CAR-T cell types.	(65) Such environments could provide the wet-lab, bioprocess, pilot-line and translational validation capacities necessary for AI-enabled biotechnology development, and should complement, without duplicating, the functions of regulatory sandboxes established under Union or national law as well as the testing and experimentation facilities established in accordance with Regulation (EU) 2024/1689. Where relevant, they should also leverage health data and the European Health Data Space in accordance with Union ***legislationThese*** infrastructures should support the development of biotechnology applications where the use of AI has the potential to accelerate progress, in particular in health-related areas such as advanced therapies, where AI can improve efficacy and safety — for example through ***optimized*** CRISPR site prediction, tumour antigen identification, sequence engineering, delivery-vehicle design, ***quantitative imaging, modelling and treatment optimization,*** or the matching of diverse patient cancer-cell variants with CAR-T cell types.

Or. en

Justification

The amendment does three things. First, it anchors the recital in an area where AI-enabled biotechnology is already demonstrating measurable gains in efficacy and safety, which strengthens the proportionality and evidence base for creating dedicated infrastructure support. Second, it signals to Member States and the Commission which capacities should be prioritised when these environments are built out in practice, rather than leaving "AI-enabled biotechnology development" undefined and open to divergent national interpretations. Third, it reinforces the broader regulation's logic of linking infrastructure investment to therapeutic outcomes (efficacy and safety) rather than treating AI adoption as a goal in itself.

Amendment 785
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 65 a (new)

Text proposed by the Commission	*Amendment*
	(65a) High-quality, comparable and interoperable data are a strategic asset for the Union's biotechnology ecosystem, particularly in the area of health. Building on existing Union data infrastructures and governance frameworks, including the European Health Data Space established by Regulation (EU) 2025/327 and the European statistical system and drawing on the approach used for the Eurostat dashboard on environmental economic accounts pursuant to Article 9a of Regulation (EU) 2024/3024, a Union health biotechnology data dashboard should provide comparable aggregated statistical information relevant to the implementation of this Regulation and support research, regulatory science, artificial intelligence, clinical trials, post-authorisation evidence generation, public health preparedness and patient access. The availability of more robust Union-level data should also be recognised as a missing innovation enabler for the biotechnology economy, as it can improve market intelligence, identify unmet needs, support investment decisions and help companies scale innovative products and services across the Single Market. Such coordination should avoid duplication of existing reporting obligations and should fully respect Union law on statistics, data protection, health data governance, cybersecurity, patients' rights and the protection of commercially confidential information.

Or. en

Amendment 786
Monika Beňová

Proposal for a regulation
Recital 66

Text proposed by the Commission	*Amendment*
(66) Having high-quality, interoperable, provenance-verified and well-annotated datasets is essential for the development, testing and validation of trustworthy and competitive AI systems and models used in biotechnology applications. For example, datasets generated in the course of provision of healthcare are usually recorded in a way that supports their initial purpose, such as diagnosis or treatment. Often, they are technically not easily usable and fit for training, testing and validation of AI systems, for example due to the use of different data standards or lacking annotations. Given the potential of AI systems and models to support research and innovation in biotechnology applications, it is important to ensure that high-quality data are available for training, testing ***and*** validating AI systems and models used in health biotechnology applications. To make such data more easily usable for those purposes, it is appropriate to facilitate the enhancement of the quality of that data. Therefore, this Regulation should lay down provisions for the recognition by the Commission of high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, to provide assistance to entities that lawfully hold relevant data to improve data quality, ***standardize*** such data and make further improvements.	(66) Having high-quality, interoperable, provenance-verified and well-annotated datasets is essential for the development, testing and validation of trustworthy and competitive AI systems and models used in biotechnology applications***, including biological foundation models and other biotechnology specific AI models. Such models may support protein structure and function prediction, molecule and biologic design, multi-omic sequence analysis, toxicity prediction, clinical-trial optimisation and biomanufacturing process optimisation among other things***. For example, datasets generated in the course of ***the*** provision of healthcare are usually recorded in a way that supports their initial purpose, such as diagnosis or treatment. Often, they are technically not easily usable and fit for training, testing and validation of AI systems ***and models, including biological foundation models***, for example due to the use of different data standards***, insufficient interoperability, incomplete metadata*** or lacking annotations. Given the potential of ***such*** AI systems and models to support research and innovation in biotechnology applications, it is important to ensure that high-quality***, representative and appropriately documented*** data are available for training, testing***,*** validating ***and benchmarking*** AI systems and models used in health biotechnology applications. To make such data more easily usable for those purposes, it is appropriate to facilitate the enhancement of the quality of that data. Therefore, this Regulation should lay down provisions for the recognition by the Commission of high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, to provide assistance to entities that

lawfully hold relevant data to improve data quality, ***standardise*** such data***, annotate such data, document provenance*** and make further improvements***, in accordance with applicable Union law, including Regulation (EU) 2025/327***.

Or. en

Amendment 787
Ingeborg Ter Laak

Proposal for a regulation
Recital 66

Text proposed by the Commission	*Amendment*
(66) Having high-quality, interoperable, provenance-verified and well-annotated datasets is essential for the development, testing and validation of trustworthy and competitive AI systems and models used in biotechnology applications. For example, datasets generated in the course of provision of healthcare are usually recorded in a way that supports their initial purpose, such as diagnosis or treatment. Often, they are technically not easily usable and fit for training, testing and validation of AI systems, for example due to the use of different data standards or lacking annotations. Given the potential of AI systems and models to support research and innovation in biotechnology applications, it is important to ensure that high-quality data are available for training, testing and validating AI systems and models used in health biotechnology applications. To make such data more easily usable for those purposes, it is appropriate to facilitate the enhancement of the quality of that data. Therefore, this Regulation should lay down provisions for the recognition by the Commission of high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, to provide assistance	(66) Having high-quality, interoperable, provenance-verified and well-annotated datasets is essential for the development, testing and validation of trustworthy and competitive AI systems and models used in biotechnology applications. For example, datasets generated in the course of provision of healthcare are usually recorded in a way that supports their initial purpose, such as diagnosis or treatment. Often, they are technically not easily usable and fit for training, testing and validation of AI systems, for example due to the use of different data standards or lacking annotations. Given the potential of AI systems and models to support research and innovation in biotechnology applications, it is important to ensure that high-quality data are available for training, testing and validating AI systems and models used in health biotechnology applications. ***Responsible access to and use of such high-quality data should facilitate evidence generation throughout the lifecycle of medicinal products, support regulatory decision-making, improve the design and conduct of multinational clinical trials and ultimately contribute to earlier and more equitable patient access to innovative medicinal***

to entities that lawfully hold relevant data to improve data quality, standardize such data and make further improvements.

products. To make such data more easily usable for those purposes, it is appropriate to facilitate the enhancement of the quality of that data. Therefore, this Regulation should lay down provisions for the recognition by the Commission of high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, to provide assistance to entities that lawfully hold relevant data to improve data quality, standardize such data and make further improvements.

Or. en

Amendment 788
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 66

Text proposed by the Commission	*Amendment*
(66) Having high-quality, interoperable, provenance-verified and well-annotated datasets is essential for the development, testing and validation of trustworthy and competitive AI systems and models used in biotechnology applications. For example, datasets generated in the course of provision of healthcare are usually recorded in a way that supports their initial purpose, such as diagnosis or treatment. Often, they are technically not easily usable and fit for training, testing and validation of AI systems, for example due to the use of different data standards or lacking annotations. Given the potential of AI systems and models to support research and innovation in biotechnology applications, it is important to ensure that high-quality data are available for training, testing and validating AI systems and models used in health biotechnology applications. To make such data more easily usable for those purposes, it is	(66) Having high-quality, interoperable, provenance-verified and well-annotated datasets is essential for the development, testing and validation of trustworthy and competitive AI systems and models used in biotechnology applications. For example, datasets generated in the course of provision of healthcare are usually recorded in a way that supports their initial purpose, such as diagnosis or treatment. Often, they are technically not easily usable and fit for training, testing and validation of AI systems, for example due to the use of different data standards or lacking annotations. Given the potential of AI systems and models to support research and innovation in biotechnology applications, it is important to ensure that high-quality data are available for training, testing and validating AI systems and models used in health biotechnology applications. To make such data more easily usable for those purposes, it is

appropriate to facilitate the enhancement of the quality of that data. Therefore, this Regulation should lay down provisions for the recognition by the Commission of high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, to provide assistance to entities that lawfully hold relevant data to improve data quality, standardize such data and make further improvements.	appropriate to facilitate the enhancement of the quality of that data. Therefore, this Regulation should lay down provisions for the recognition by the Commission of high impact health biotechnology strategic projects in the form of biotechnology data quality accelerators, to provide assistance to entities that lawfully hold relevant data to improve data quality, standardize such data and make further improvements***, while ensuring that ethical standards of AI use are adhered to***. ***In order to support compliance with fundamental rights and the principle of non-discrimination, efforts to improve data quality should, where appropriate, include measures to minimise bias and enhance the representativeness of datasets.***

Or. en

Amendment 789
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 66 a (new)

Text proposed by the Commission	*Amendment*
	(66a) In areas where datasets remain fragmented or patient populations are small, no single Member State may have sufficient data scale, diversity or representativeness to support high-quality research, innovation, regulatory evidence generation or the development and validation of trustworthy AI systems in health biotechnology. Union-level coordination, interoperability and secure data sharing are therefore particularly important for rare diseases, rare cancers, paediatric conditions, complex diseases and other areas of unmet medical need, where cross-border cooperation may be necessary to generate meaningful evidence and avoid unnecessary

duplication. Biotechnology data quality accelerators should, where appropriate, support the linking of relevant registries, biobanks, genomic initiatives, clinical research infrastructures and European Reference Networks, in full respect of Union law on the protection of personal data, health data governance, cybersecurity and patients' rights.

Or. en

Amendment 790
Sirpa Pietikäinen

Proposal for a regulation
Recital 66 a (new)

Text proposed by the Commission	*Amendment*
	(66a) The availability of high quality, representative data depends on the accurate and systematic collection of sex- and gender-disaggregated data throughout all stages of the research cycle. Data, wherever relevant, should further be disaggregated through an intersectional approach taking into account variables such as age, race, disability etc. The Commission should specify that EU-funded health biotechnology projects, including the high impact health biotechnology strategic projects and biotechnology data quality accelerators, mandate these requirements for data collection, and particularly in view of AI usage, recalling the provisions laid out in the 2026 EU Gender Equality Strategy regarding the risk that AI poses in intensifying gender inequalities and gender biases.

Or. en

Amendment 791

Aura Salla

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) Such biotechnology data quality accelerator projects should complement Union initiatives such as data labs[37] and by addressing the specific data-quality requirements of biotechnology, ensuring that biological and health datasets are reliable, interoperable and usable for the development of advanced AI models.	(67) Such biotechnology data quality accelerator projects should complement Union initiatives such as ***European*** data labs[37] and by addressing the specific data-quality requirements of biotechnology, ensuring that biological and health datasets are reliable, interoperable and usable for the development of advanced AI models. ***Those projects should contribute to reducing strategic dependencies in data infrastructures while strengthening the development of AI models.***
[37] Proposed in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE), COM(2025) 724 final of 8 October 2025.	[37] Proposed in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE), COM(2025) 724 final of 8 October 2025.

Or. en

Amendment 792
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) Such biotechnology data quality accelerator projects should complement Union initiatives such as data labs[37] and by addressing the specific data-quality requirements of biotechnology, ensuring that biological and health datasets are	(67) Such biotechnology data quality accelerator projects should complement Union initiatives such as data labs[37] and by addressing the specific data-quality requirements of biotechnology, ensuring that biological and health datasets are

reliable, interoperable and usable for the development of advanced AI models.

reliable, interoperable and usable for the development of advanced AI models ***and also regularly updated in line with changes in the field***.

[37] Proposed in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE), COM(2025) 724 final of 8 October 2025.

[37] Proposed in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE), COM(2025) 724 final of 8 October 2025.

Or. ro

Amendment 793
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) Such biotechnology data quality accelerator projects should complement Union initiatives such as data labs[37] and by addressing the specific data-quality requirements of biotechnology, ensuring that biological and health datasets are reliable, interoperable and usable for the development of advanced AI models.	(67) Such biotechnology data quality accelerator projects should complement Union initiatives such as data labs[37] and by addressing the specific data-quality requirements of biotechnology, ensuring that biological and health datasets are reliable, interoperable***, without any discriminatory impacts and unfair biases*** and usable for the development of advanced AI models.
[37] Proposed in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE),	[37] Proposed in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE),

COM(2025) 724 final of 8 October 2025.	COM(2025) 724 final of 8 October 2025.

Or. en

Amendment 794
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) Such biotechnology data quality accelerator projects should complement Union initiatives such as data labs[37] and by addressing the specific data-quality requirements of biotechnology, ensuring that biological and health datasets are reliable, interoperable and usable for the development of advanced AI models.	(67) Such biotechnology data quality accelerator projects should complement Union initiatives such as data labs[37] and by addressing the specific data-quality requirements of biotechnology, ensuring that biological and health datasets are reliable, interoperable and usable for the development of advanced AI models ***avoiding discriminatory impacts and unfair biases***.
[37] Proposed in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE), COM(2025) 724 final of 8 October 2025.	[37] Proposed in the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European Strategy for Artificial Intelligence in Science – Paving the way for the Resource for AI Science in Europe (RAISE), COM(2025) 724 final of 8 October 2025.

Or. en

Amendment 795
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 67 a (new)

Text proposed by the Commission	*Amendment*
	(67a) The availability of high quality,

representative data depends on the accurate and systematic collection of sex- and gender-disaggregated data throughout all stages of the research cycle. Data, wherever relevant, should further be disaggregated through an intersectional approach taking into account variables such as age, race, disability etc. The Commission should specify that EU-funded health biotechnology projects, including the high impact health biotechnology strategic projects and biotechnology data quality accelerators, mandate these requirements for data collection, and particularly in view of AI usage, recalling the provisions laid out in the 2026 EU Gender Equality Strategy regarding the risk that AI poses in intensifying gender inequalities and gender biases.

Or. en

Justification

Amendment drafted by the Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 796
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 68

Text proposed by the Commission	*Amendment*
(68) The processing of personal data by the entities that lawfully hold the relevant data and by the biotechnology data quality accelerators, in the context of biotechnology data quality accelerators projects, takes place in the public interest. The Commission should specify in the decision recognising the project as a high impact health biotechnology strategic project, the specific provisions concerning the processing of personal data necessary in order to achieve the objectives of the	(68) The processing of personal data by the entities that lawfully hold the relevant data and by the biotechnology data quality accelerators, in the context of biotechnology data quality accelerators projects, takes place in the public interest. The Commission should specify in the decision recognising the project as a high impact health biotechnology strategic project, the specific provisions concerning the processing of personal data necessary in order to achieve the objectives of the

project. Such provision may in particular include the categories of data, the specific roles of the parties engaged in the processing, and the entities to which the personal data may be disclosed. Where biotechnology data quality accelerators are recognised by the Commission through calls for proposals, the Commission should be empowered to adopt, by means of an implementing act, specific provisions concerning the processing of personal data, through a decision prior to the launch of the call and the beneficiaries of the call should be subject to the obligations laid down in that decision.

project***, the way in which the data will be protected, and, in particular, the terms of access to the data***. Such provision may in particular include the categories of data, the specific roles of the parties engaged in the processing, and the entities to which the personal data may be disclosed***, including the period of access and the number of persons who may have access***. Where biotechnology data quality accelerators are recognised by the Commission through calls for proposals, the Commission should be empowered to adopt, by means of an implementing act, specific provisions concerning the processing of personal data, through a decision prior to the launch of the call and the beneficiaries of the call should be subject to the obligations laid down in that decision.

Or. ro

Amendment 797
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 68

Text proposed by the Commission	*Amendment*
(68) The processing of personal data by the entities that lawfully hold the relevant data and by the biotechnology data quality accelerators, in the context of biotechnology data quality accelerators projects, takes place in the public interest. The Commission should specify in the decision recognising the project as a high impact health biotechnology strategic project, the specific provisions concerning the processing of personal data necessary in order to achieve the objectives of the project. Such provision may in particular include the categories of data, the specific roles of the parties engaged in the	(68) The processing of personal data by the entities that lawfully hold the relevant data and by the biotechnology data quality accelerators, in the context of biotechnology data quality accelerators projects, takes place in the public interest. The Commission should specify in the decision recognising the project as a high impact health biotechnology strategic project, the specific provisions concerning the processing of personal data necessary in order to achieve the objectives of the project ***in full compliance with the Union data protection rules***. Such provision may in particular include the categories of data,

processing, and the entities to which the personal data may be disclosed. Where biotechnology data quality accelerators are recognised by the Commission through calls for proposals, the Commission should be empowered to adopt, by means of an implementing act, specific provisions concerning the processing of personal data, through a decision prior to the launch of the call and the beneficiaries of the call should be subject to the obligations laid down in that decision.

the specific roles of the parties engaged in the processing, and the entities to which the personal data may be disclosed. Where biotechnology data quality accelerators are recognised by the Commission through calls for proposals, the Commission should be empowered to adopt, by means of an implementing act, specific provisions concerning the processing of personal data, through a decision prior to the launch of the call and the beneficiaries of the call should be subject to the obligations laid down in that decision.

Or. en

Amendment 798
Ingeborg Ter Laak

Proposal for a regulation
Recital 69

Text proposed by the Commission	*Amendment*
(69) Electronic health data referred to in Article 51 of Regulation (EU) 2025/327 of the European Parliament and of the Council[38] , enhanced by biotechnology data quality accelerators should be made available in accordance with that Regulation. The biotechnology data quality accelerators support the objectives of the European Health Data Space by contributing to improving the quality of data that is to be made available under that space.	(69) Electronic health data referred to in Article 51 of Regulation (EU) 2025/327 of the European Parliament and of the Council[38] , enhanced by biotechnology data quality accelerators should be made available in accordance with that Regulation. The biotechnology data quality accelerators support the objectives of the European Health Data Space by contributing to improving the quality of data that is to be made available under that space. ***By enabling the secure and interoperable secondary use of electronic health data in accordance with Regulation (EU) 2025/327, the European Health Data Space should facilitate scientific research, biotechnology innovation, regulatory evidence generation and cross-border clinical research, thereby contributing to faster development of innovative biotechnology products and earlier and more equitable patient access to innovative medicinal***

	products throughout the Union.
[38] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj .	[38] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj .
	Or. en

Amendment 799
Monika Beňová

Proposal for a regulation
Recital 69 a (new)

Text proposed by the Commission	*Amendment*
	(69a) The European Health Data Space established by Regulation (EU) 2025/327 provides a Union framework for the secure secondary use of electronic health data for research, innovation, regulatory activities and the training, testing and evaluation of AI systems. In order to strengthen the Union's biotechnology competitiveness, this Regulation should complement that framework by supporting the development of high-quality, interoperable, provenance-verified and AI-ready datasets for health biotechnology, while ensuring that personal data, trade secrets, intellectual property and biotechnology know-how are protected. Measures adopted under this Regulation should not create a parallel data-access regime to Regulation (EU) 2025/327, but should support the lawful, secure and effective use of electronic health data for biotechnology and AI-enabled biotechnology under the safeguards laid down in that Regulation;
	Or. en

Amendment 800
Monika Beňová

Proposal for a regulation
Recital 69 b (new)

Text proposed by the Commission	*Amendment*
	(69b) The use of AI systems, general-purpose AI models, general-purpose AI systems and biological foundation models in health biotechnology may accelerate discovery, development, testing, validation, clinical trials and biomanufacturing. At the same time, the use of third-party AI systems or models, including those provided by providers established in third countries or active in competing biotechnology or AI markets, may expose electronic health data, commercially sensitive biotechnology data, trade secrets, intellectual property, clinical insights, annotations, prompts, model outputs and industrial know-how to unauthorised use, including for model training, fine-tuning, improvement or competing product development. Union support for AI-enabled biotechnology, biotechnology data quality accelerators and trusted testing environments should therefore be accompanied by appropriate technical, contractual and organisational safeguards to ensure that such data and derived know-how remain under the effective control of the data holder or project promoter, unless further use is expressly authorised under applicable Union law, the relevant data permit or contractual arrangements.

Or. en

Amendment 801
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 70

Text proposed by the Commission	*Amendment*
(70) To enable innovation and competitiveness in biotechnology, it is necessary to ensure that SMEs, start-ups and scale-ups, and research organisations can access the high computing capacity and AI resources required for advanced research, development and biomanufacturing. Those actions may be supported through Union funding programmes, funds and financial instruments, in accordance with the regulations governing them. The Commission should ensure effective coordination with other Union initiatives offering computing capacities to maximise efficiency and avoid duplication. The Commission, including through the European Biotechnology Support Network, should provide information and support, in particular to SMEs, start-ups and scale-ups, for accessing high computing capacity and AI resources relevant to biotechnology and biomanufacturing activities.	(70) To enable innovation and competitiveness in biotechnology, it is necessary to ensure that SMEs, start-ups and scale-ups, and research organisations can access the high computing capacity and AI resources required for advanced research, development and biomanufacturing. Those actions may be supported through Union funding programmes, funds and financial instruments, in accordance with the regulations governing them. The Commission should ensure effective coordination with other Union initiatives offering computing capacities to maximise efficiency and avoid duplication. The Commission, including through the European Biotechnology Support Network, should provide information and support, in particular to SMEs, start-ups and scale-ups, for accessing high computing capacity and AI resources relevant to biotechnology and biomanufacturing activities.***To this end, the use of European high-performance computing infrastructures, common European data spaces and other relevant digital infrastructures should be encouraged, to facilitate access to high-quality datasets, advanced modelling and simulation tools, and machine learning technologies.***

Or. ro

Amendment 802
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 70

Text proposed by the Commission	*Amendment*
(70) To enable innovation and competitiveness in biotechnology, it is necessary to ensure that SMEs, start-ups and scale-ups, and research organisations can access the high computing capacity and AI resources required for advanced research, development and biomanufacturing. Those actions may be supported through Union funding programmes, funds and financial instruments, in accordance with the regulations governing them. The Commission should ensure effective coordination with other Union initiatives offering computing capacities to maximise efficiency and avoid duplication. The Commission, including through the European Biotechnology Support Network, should provide information and support, in particular to SMEs, start-ups and scale-ups, for accessing high computing capacity and AI resources relevant to biotechnology and biomanufacturing activities.	(70) To enable innovation and competitiveness in biotechnology, it is necessary to ensure that SMEs, start-ups and scale-ups, ***non-profits*** and research organisations can access the high computing capacity and AI resources required for advanced research, development and biomanufacturing. Those actions may be supported through Union funding programmes, funds and financial instruments, in accordance with the regulations governing them. The Commission should ensure effective coordination with other Union initiatives offering computing capacities to maximise efficiency and avoid duplication. The Commission, including through the European Biotechnology Support Network, should provide information and support, in particular to SMEs, start-ups and scale-ups, ***non-profits and research organisations*** for accessing high computing capacity and AI resources relevant to biotechnology and biomanufacturing activities.

Or. en

Amendment 803
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 70 a (new)

Text proposed by the Commission	*Amendment*
	(70a) The Commission should, through the European Biotechnology Support Network and in cooperation with relevant Union initiatives, and building on existing Union programmes and resources, facilitate access for qualifying biotechnology small and medium-sized enterprises, start-ups and scale-ups to federated data infrastructures, data quality accelerators, high-performance

computing capacity, AI factories, testing environments and relevant advisory services. Such support may include, where appropriate, targeted assistance on data governance, interoperability, regulatory compliance, cybersecurity, artificial-intelligence implementation and ethics.

Or. en

Amendment 804
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 70 a (new)

Text proposed by the Commission	*Amendment*
	(70a) Fostering digital and AI skills among researchers and businesses in the biotechnology sector and using these technologies responsibly and safely, in accordance with Union law, will help to improve the process of innovation and competitiveness in the field of biotechnology for SMEs, start-ups and scale-ups.Such an approach may speed up the research and innovation process, reduce development costs, and make the European biotechnology ecosystem more competitive in global markets.

Or. ro

Amendment 805
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Very innovative health biotechnology products or services vary	(71) Very innovative health biotechnology products or services vary

significantly in the degree to which they align or can align with existing Union legislative frameworks and procedures. These products, despite their complexity, should however be efficiently and adequately assessed within a single regulatory pathway, possibly through a combination pathway. This is notwithstanding the fact that such health biotechnology products or services, in the form of preparations, devices, diagnostics, or other, for human use, exhibit characteristics that challenge the Union legislative frameworks in the area of health ('health biotechnology products'), for example because they are under development and could potentially fall under the scope of an Union legislative framework but there are questions related to the relevance of other Union legislative frameworks; and/or because they combine different products, technologies, processes, or components regulated under different Union legislative frameworks; ***and/or because they*** require ***targeted adaptations of certain requirements*** of the applicable Union legislative frameworks, ***ideally at an early stage of development***. These characteristics are not mutually exclusive and may overlap.	significantly in the degree to which they align or can align with existing Union legislative frameworks and procedures. These products, despite their complexity, should however be efficiently and adequately assessed within a single regulatory pathway, possibly through a combination pathway. This is notwithstanding the fact that such health biotechnology products or services, in the form of preparations, devices, diagnostics, or other, for human use, exhibit characteristics that challenge the Union legislative frameworks in the area of health ('health biotechnology products'), for example because they are under development and could potentially fall under the scope of an Union legislative framework but there are questions related to the relevance of other Union legislative frameworks; and/or because they combine different products, technologies, processes, or components regulated under different Union legislative frameworks; ***may*** require ***early regulatory engagement or coordinated application*** of the applicable Union legislative frameworks, ***without affecting the level of protection of human health or the applicable safety, quality and efficacy requirements***. These characteristics are not mutually exclusive and may overlap.
	Or. en

Amendment 806
Aurelijus Veryga

Proposal for a regulation
Recital 71

Text proposed by the Commission	*Amendment*
(71) Very innovative health biotechnology products or services vary significantly in the degree to which they align or can align with existing Union	(71) Very innovative health biotechnology products or services vary significantly in the degree to which they align or can align with existing Union

legislative frameworks and procedures. These products, despite their complexity, should however be efficiently and adequately assessed within a single regulatory pathway, possibly through a combination pathway. This is notwithstanding the fact that such health biotechnology products or services, in the form of preparations, devices, diagnostics, or other, for human use, exhibit characteristics that challenge the Union legislative frameworks in the area of health ('health biotechnology products'), for example because they are under development and could potentially fall under the scope of an Union legislative framework but there are questions related to the relevance of other Union legislative frameworks; and/or because they combine different products, technologies, processes, or components regulated under different Union legislative frameworks; and/or because they require targeted adaptations of certain requirements of the applicable Union legislative frameworks, ideally at an early stage of development. These characteristics are not mutually exclusive and may overlap.	legislative frameworks and procedures. These products, despite their complexity, should however be efficiently and adequately assessed within a single regulatory pathway, possibly through a combination pathway. This is notwithstanding the fact that such health biotechnology products or services, in the form of preparations, devices, diagnostics, ***including IVD and imaging*** or other, for human use, exhibit characteristics that challenge the Union legislative frameworks in the area of health ('health biotechnology products'), for example because they are under development and could potentially fall under the scope of an Union legislative framework but there are questions related to the relevance of other Union legislative frameworks; and/or because they combine different products, technologies, processes, or components regulated under different Union legislative frameworks; and/or because they require targeted adaptations of certain requirements of the applicable Union legislative frameworks, ideally at an early stage of development. These characteristics are not mutually exclusive and may overlap.

Or. en

Amendment 807
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Recital 72 a (new)

Text proposed by the Commission	*Amendment*
	(72a) Small and medium-sized enterprises (SMEs) play a pivotal role in driving disruptive innovation and in fostering the development of emerging technologies; it is therefore essential to ensure adequate support for disruptive innovators and to establish a clear and

efficient process enabling smooth coordination and interaction among all competent authorities involved in determining the appropriate regulatory pathway for innovative products;

Or. en

Justification

The continued support of SMEs is key to foster biotech innovation in Europe. It is important to establish a process that foresees a smooth interaction between the different authorities involved in the final decision.

Amendment 808
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Recital 72 a (new)

Text proposed by the Commission	*Amendment*
	(72a) Small and medium-sized enterprises are central to disruptive innovation and the advancement of emerging technologies; therefore, adequate support should be ensured for such innovators, together with a clear and efficient framework facilitating coordination and cooperation among the competent authorities responsible for determining the appropriate regulatory pathway for innovative products;

Or. en

Amendment 809
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Recital 73

Text proposed by the Commission	*Amendment*
(73) At the same time, the Union has the strong experience and expertise to handle regulatory complexity, and important measures to deal with health biotechnology products have already been proposed. Directive 2001/83/EC of the European Parliament and of the Council[39] clarifies which legislative frameworks apply to combinations of medicinal products and other products and establishes a single authorisation pathway for them. In addition, existing Union legislative frameworks in the area of health such as [revised Regulation (EU) 2017/745 of the European Parliament and of the Council, [revised Regulation (EU) 2017/746], [revised Regulation No (EC) 726/2004], Regulation (EU) 2024/1938 of the European Parliament and of the Council[40] contain specific mechanisms to manage the determination of the regulatory status of products that do not fall clearly within a Union legislative framework in the area of health. These mechanisms include the possibility of requesting a recommendation or opinion from the respective advisory bodies or the Agency, as applicable, at Union level, and eventually the possibility for binding decisions of the Commission on the regulatory status. These mechanisms should ensure predictability and conclusive opinions for products of which the status is being debated, avoiding cases where it remains unclear which framework applies, and the assessment of the product is consequently halted or delayed.	(73) At the same time, the Union has the strong experience and expertise to handle regulatory complexity, and important measures to deal with health biotechnology products have already been proposed. Directive 2001/83/EC of the European Parliament and of the Council[39] clarifies which legislative frameworks apply to combinations of medicinal products and other products and establishes a single authorisation pathway for them. In addition, existing Union legislative frameworks in the area of health such as [revised Regulation (EU) 2017/745 of the European Parliament and of the Council, [revised Regulation (EU) 2017/746], [revised Regulation No (EC) 726/2004], Regulation (EU) 2024/1938 of the European Parliament and of the Council[40] contain specific mechanisms to manage the determination of the regulatory status of products that do not fall clearly within a Union legislative framework in the area of health. These mechanisms include the possibility of requesting a recommendation or opinion from the respective advisory bodies or the Agency, as applicable, at Union level, and eventually the possibility for binding decisions of the Commission on the regulatory status. These mechanisms should ensure predictability and conclusive opinions for products of which the status is being debated, avoiding cases where it remains unclear which framework applies, and the assessment of the product is consequently halted or delayed. ***This is particularly relevant for synthetic cells and products incorporating them, as they may fall between existing frameworks such as medicinal products, medical devices, and genetically modified organisms.***
[39] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code	[39] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code

relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj.

[40] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.07.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj.

[40] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.07.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

Or. en

Justification

The main regulatory obstacle for synthetic cells is uncertainty over which framework applies to them. Many are not living organisms and cannot replicate, so their status is unsettled and assessment can stall. The Biotech Act's regulatory-status mechanisms are the appropriate route for resolving that uncertainty.

Amendment 810
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 74

Text proposed by the Commission	*Amendment*
(74) Developers of health biotechnology products, in particular SMEs, start-ups and scale-ups, often lack the regulatory expertise and capacity needed to identify, anticipate and plan their entry into the appropriate regulatory procedural pathways. In order to address this challenge, the EU Health Biotechnology Support Network, acting as a service provider, should provide preliminary support to such developers by facilitating information on, and access to, applicable legislative frameworks, and should point to relevant opinions, recommendations, guidance and decisions.	(74) Developers of health biotechnology products, in particular SMEs, start-ups and scale-ups, often lack the regulatory expertise and capacity needed to identify, anticipate and plan their entry into the appropriate regulatory procedural pathways. In order to address this challenge, the EU Health Biotechnology Support Network, acting as a service provider, should provide preliminary support to such developers by facilitating information on, and access to, applicable legislative frameworks, and should point to relevant opinions, recommendations, guidance and decisions***, the amount of time it takes to obtain these opinions and other necessary documents so that***

	activities can begin as soon as possible, and any costs of those procedures.

Or. ro

Amendment 811
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 74

Text proposed by the Commission	*Amendment*
(74) Developers of health biotechnology products, in particular SMEs, start-ups ***and*** scale-ups, often lack the regulatory expertise and capacity needed to identify, anticipate and plan their entry into the appropriate regulatory procedural pathways. In order to address this challenge, the EU Health Biotechnology Support Network, acting as a service provider, should provide preliminary support to such developers by facilitating information on, and access to, applicable legislative frameworks, and should point to relevant opinions, recommendations, guidance and decisions.	(74) Developers of health biotechnology products, in particular SMEs, start-ups**,** scale-ups ***and non-profits***, often lack the regulatory expertise and capacity needed to identify, anticipate and plan their entry into the appropriate regulatory procedural pathways. In order to address this challenge, the EU Health Biotechnology Support Network, acting as a service provider, should provide preliminary support to such developers by facilitating information on, and access to, applicable legislative frameworks, and should point to relevant opinions, recommendations, guidance and decisions.

Or. en

Amendment 812
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 75

Text proposed by the Commission	*Amendment*
(75) To allow developers to anticipate and navigate procedures to determine the regulatory status, a Union-wide and cross-framework Regulatory Status Repository should be established. That Repository	(75) To allow developers to anticipate and navigate procedures to determine the regulatory status, a Union-wide and cross-framework Regulatory Status Repository should be established. That Repository

should compile relevant opinions, recommendations, decisions and guidance developed under the mechanisms established in the Union legislative frameworks in the area of health with a view to determine the regulatory status of a product. That Repository should also include the recommendations on the classifications of products as advanced therapy medicinal products (ATMPs) issued by the Committee for Advanced Therapies, established in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council[41] prior to the date of application of Regulation (EC) No 726/2004. Such repository should be accessible for developers and authorities to enable them to understand how similar health biotechnology products are evaluated in terms of status, and what considerations are put forward. This will guide developers and authorities, to improve efficiency, foster transparency, and ensure consistency and mutual learning across Union and national authorities. This Regulatory Status Repository should not include opinions, recommendations, decisions and guidance on the regulatory status of AI systems and models within the scope of the Regulation (EU) 2024/1689.

[41] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 324, 10.12.2007, p. 121. ELI:

should compile ***both national and centralised*** relevant opinions, recommendations, decisions and guidance developed under the mechanisms established in the Union legislative frameworks in the area of health with a view to determine the regulatory status of a product. That Repository should also include the recommendations on the classifications of products as advanced therapy medicinal products (ATMPs) issued by the Committee for Advanced Therapies, established in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council[41] prior to the date of application of Regulation (EC) No 726/2004. Such repository should be accessible for developers and authorities to enable them to understand how similar health biotechnology products are evaluated in terms of status, and what considerations are put forward. This will guide developers and authorities, to improve efficiency, foster transparency, and ensure consistency and mutual learning across Union and national authorities. This Regulatory Status Repository should not include opinions, recommendations, decisions and guidance on the regulatory status of AI systems and models within the scope of the Regulation (EU) 2024/1689. ***All information included on the repository should respect confidentiality and protection of proprietary data and designs. In advance of the publication on the repository, the sponsor should be notified and given the opportunity to assess if the information is correct, prior to making the repository accessible for developers and authorities.***

[41] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 324, 10.12.2007, p. 121. ELI:

http://data.europa.eu/eli/reg/2007/1394/oj. http://data.europa.eu/eli/reg/2007/1394/oj.

Or. en

Amendment 813
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 75

Text proposed by the Commission	*Amendment*
(75) To allow developers to anticipate and navigate procedures to determine the regulatory status, a Union-wide and cross-framework Regulatory Status Repository should be established. That Repository should compile relevant opinions, recommendations, decisions and guidance developed under the mechanisms established in the Union legislative frameworks in the area of health with a view to determine the regulatory status of a product. That Repository should also include the recommendations on the classifications of products as advanced therapy medicinal products (ATMPs) issued by the Committee for Advanced Therapies, established in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council[41] prior to the date of application of Regulation (EC) No 726/2004. Such repository should be accessible for developers and authorities to enable them to understand how similar health biotechnology products are evaluated in terms of status, and what considerations are put forward. This will guide developers and authorities, to improve efficiency, foster transparency, and ensure consistency and mutual learning across Union and national authorities. This Regulatory Status Repository should not include opinions, recommendations, decisions and guidance on the regulatory status of AI systems and models within the scope of the Regulation	(75) To allow developers to anticipate and navigate procedures to determine the regulatory status, a Union-wide and cross-framework Regulatory Status Repository should be established. That Repository should compile relevant opinions, recommendations, decisions and guidance developed under the mechanisms established in the Union legislative frameworks in the area of health with a view to determine the regulatory status of a product. That Repository should also include the recommendations on the classifications of products as advanced therapy medicinal products (ATMPs) issued by the Committee for Advanced Therapies, established in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council[41] prior to the date of application of Regulation (EC) No 726/2004. Such repository should be accessible for developers and authorities to enable them to understand how similar health biotechnology products are evaluated in terms of status, and what considerations are put forward. This will guide developers and authorities, to improve efficiency, foster transparency, and ensure consistency and mutual learning across Union and national authorities. This Regulatory Status Repository should not include opinions, recommendations, decisions and guidance on the regulatory status of AI systems and models within the scope of the Regulation

(EU) 2024/1689.	(EU) 2024/1689. ***This Regulatory Status Repository should serve as horizon scanning tool for the European regulatory network and to timely initiate regulatory dialogue regarding guideline development, including for the development of follow-on biosimilar medicines.***
[41] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 324, 10.12.2007, p. 121. ELI: http://data.europa.eu/eli/reg/2007/1394/oj.	[41] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 324, 10.12.2007, p. 121. ELI: http://data.europa.eu/eli/reg/2007/1394/oj.

Or. en

Justification

The next generation of follow-on biosimilar medicines will include biosimilars of ATMPs.Cell and Gene Therapies (CGT) are advanced biologic therapies which provide for new and sometimes curative treatment options for patients, mainly in cancer (60%). The European pharmaceutical budget impact is expected to grow 6-fold (2023-2029) and reach nearly 14bio€. With the first CGT products approaching loss of exclusivity (e.g. Yescarta EPAR and Spinraza EPAR), Europe faces an immense opportunity to become an ATMP excellence centre both industrially (capability and capacity), while also enabling better access for all patients that need those life-changing therapies

Amendment 814
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 75

Text proposed by the Commission	*Amendment*
(75) To allow developers to anticipate and navigate procedures to determine the regulatory status, a Union-wide and cross-framework Regulatory Status Repository should be established. That Repository should compile relevant opinions, recommendations, decisions and guidance	(75) To allow developers to anticipate and navigate procedures to determine the regulatory status, a Union-wide and cross-framework Regulatory Status Repository should be established. That Repository should compile relevant opinions, recommendations, decisions and guidance

developed under the mechanisms established in the Union legislative frameworks in the area of health with a view to determine the regulatory status of a product. That Repository should also include the recommendations on the classifications of products as advanced therapy medicinal products (ATMPs) issued by the Committee for Advanced Therapies, established in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council[41] prior to the date of application of Regulation (EC) No 726/2004. Such repository should be accessible for developers and authorities to enable them to understand how similar health biotechnology products are evaluated in terms of status, and what considerations are put forward. This will guide developers and authorities, to improve efficiency, foster transparency, and ensure consistency and mutual learning across Union and national authorities. This Regulatory Status Repository should not include opinions, recommendations, decisions and guidance on the regulatory status of AI systems and models within the scope of the Regulation (EU) 2024/1689.

[41] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 324, 10.12.2007, p. 121. ELI: http://data.europa.eu/eli/reg/2007/1394/oj.

developed under the mechanisms established in the Union legislative frameworks in the area of health with a view to determine the regulatory status of a product***, including the amount of time that these steps take and any costs involved***. That Repository should also include the recommendations on the classifications of products as advanced therapy medicinal products (ATMPs) issued by the Committee for Advanced Therapies, established in accordance with Regulation (EC) No 1394/2007 of the European Parliament and of the Council[41] prior to the date of application of Regulation (EC) No 726/2004. Such repository should be accessible for developers and authorities to enable them to understand how similar health biotechnology products are evaluated in terms of status, and what considerations are put forward. This will guide developers and authorities, to improve efficiency, foster transparency, and ensure consistency and mutual learning across Union and national authorities. This Regulatory Status Repository should not include opinions, recommendations, decisions and guidance on the regulatory status of AI systems and models within the scope of the Regulation (EU) 2024/1689.

[41] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, OJ L 324, 10.12.2007, p. 121. ELI: http://data.europa.eu/eli/reg/2007/1394/oj.

Or. ro

Amendment 815
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation

Recital 75 a (new)

Text proposed by the Commission	*Amendment*
	(75a) Radiopharmaceuticals, radioligand therapies and other medicinal products involving ionising radiation are closely related to biotechnological products and might be considered as a hybrid derivatives thereof as set out in Article 3 (2). In that sense, they may offer significant benefits for patients, in particular in oncology and other areas of high unmet medical need. Their development and use is, however, not only being affected by this Regulation but also by the interaction between Union pharmaceutical law, clinical trial rules, radiation protection requirements and national authorisation procedures. Without prejudice to Council Directive 2013/59/Euratom and to the responsibility of Member States for radiation protection, this Regulation should support better coordination, predictability and timely assessment of such products, including in clinical trials, while fully maintaining high standards of patient safety, radiation protection, quality, efficacy and public health.

Or. en

Amendment 816
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(76) Existing mechanisms for addressing health biotechnology products, including those for determining their regulatory status as described above, provide for consultation among various advisory bodies and the Agency. However, such	(76) Existing mechanisms for addressing health biotechnology products, including those for determining their regulatory status as described above, provide for consultation among various advisory bodies and the Agency. However, such

procedures are typically focused on individual products on a case-by-case basis. There is, therefore, a need for more systematic coordination across Union legislative frameworks to better identify and prepare for emerging innovations driving the development of health biotechnology products that may challenge existing Union legislative frameworks in the area of health. With an expected increase in health biotechnology products entering the regulatory system, there is a growing need for horizontal foresight anticipating technological developments through structured horizon-scanning activities which will enable the regulators to adopt regulatory approaches proactively, rather than reactively addressing each new difficult case.

procedures are typically focused on individual products on a case-by-case basis. There is, therefore, a need for more systematic coordination across Union legislative frameworks to better identify and prepare for emerging innovations driving the development of health biotechnology products that may challenge existing Union legislative frameworks in the area of health. With an expected increase in health biotechnology products entering the regulatory system, there is a growing need for horizontal foresight anticipating technological developments through structured horizon-scanning activities which will enable the regulators to adopt regulatory approaches proactively, rather than reactively addressing each new difficult case. ***Such foresight should contribute to early identification of emerging technologies, scientific and regulatory challenges, and any gaps in the Union's regulatory framework.This may help to develop coherent and evidence-based regulatory guidelines, improve coordination between competent authorities, and make regulatory requirements more predictable for biotechnology product developers.***

Or. ro

Amendment 817
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 76

Text proposed by the Commission	*Amendment*
(76) Existing mechanisms for addressing health biotechnology products, including those for determining their regulatory status as described above, provide for consultation among various advisory bodies and the Agency. However, such procedures are typically focused on	(76) Existing mechanisms for addressing health biotechnology products, including those for determining their regulatory status as described above, provide for consultation among various advisory bodies and the Agency. However, such procedures are typically focused on

individual products on a case-by-case basis. There is, therefore, a need for more systematic coordination across Union legislative frameworks to better identify and prepare for emerging innovations driving the development of health biotechnology products that may challenge existing Union legislative frameworks in the area of health. With an expected increase in health biotechnology products entering the regulatory system, there is a growing need for horizontal foresight anticipating technological developments through structured horizon-scanning activities which will enable the regulators to adopt regulatory approaches proactively, rather than reactively addressing each new difficult case.	individual products on a case-by-case basis. There is, therefore, a need for more systematic coordination across Union legislative frameworks to better identify and prepare for emerging innovations driving the development of health biotechnology products that may challenge existing Union legislative frameworks in the area of health. With an expected increase in health biotechnology products entering the regulatory system, there is a growing need for horizontal foresight anticipating technological developments through structured horizon-scanning activities which will enable the regulators to adopt regulatory approaches proactively, rather than reactively addressing each new difficult case. ***Biotechnology increasingly presents dual-use characteristics, requiring a coordinated approach to maximise innovation benefits while preventing misuse and strengthening resilience.***

Or. en

Amendment 818
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(77) To that end, this Regulation should establish a Foresight Panel for Emerging Health Innovation to complement existing mechanisms by providing a platform for horizontal coordination and forward-looking analysis. The Panel should conduct horizon scanning to identify emerging technologies at an early stage and discuss cross-cutting regulatory issues, thereby informing and anticipating discussions on health biotechnology products that may subsequently arise within individual frameworks. It should provide expertise on	(77) To that end, this Regulation should establish a Foresight Panel for Emerging Health Innovation to complement existing mechanisms by providing a platform for horizontal coordination and forward-looking analysis. The Panel should conduct horizon scanning to identify emerging technologies at an early stage and discuss cross-cutting regulatory issues, thereby informing and anticipating discussions on health biotechnology products that may subsequently arise within individual frameworks. It should provide expertise on

emerging science and technology in the field of health underpinning the development of health biotechnology products to the Commission, the Agency and to relevant Union-level advisory bodies and competent authorities and other entities in the Member States in the area of health.

emerging science and technology in the field of health underpinning the development of health biotechnology products to the Commission, the Agency and to relevant Union-level advisory bodies and competent authorities and other entities in the Member States in the area of health. ***This horizon scanning by the Panel may make it easier to adapt the regulatory framework to scientific and technological advances, thereby helping to maintain high standards of safety, efficacy and quality without hindering innovation.***

Or. ro

Amendment 819
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(77) To that end, this Regulation should establish a Foresight Panel for Emerging Health Innovation to complement existing mechanisms by providing a platform for horizontal coordination and forward-looking analysis. The Panel should conduct horizon scanning to identify emerging technologies at an early stage and discuss cross-cutting regulatory issues, thereby informing and anticipating discussions on health biotechnology products that may subsequently arise within individual frameworks. It should provide expertise on emerging science and technology in the field of health underpinning the development of health biotechnology products to the Commission, the Agency and to relevant Union-level advisory bodies and competent authorities and other entities in the Member States in the area of health.	(77) To that end, this Regulation should establish a Foresight Panel for Emerging Health Innovation to complement existing mechanisms by providing a platform for horizontal coordination and forward-looking analysis. The Panel should conduct horizon scanning to identify emerging technologies at an early stage and discuss cross-cutting regulatory issues, thereby informing and anticipating discussions on health biotechnology products that may subsequently arise within individual frameworks. It should provide expertise on emerging science and technology in the field of health underpinning the development of health biotechnology products to the Commission, the Agency and to relevant Union-level advisory bodies and competent authorities and other entities in the Member States in the area of health. ***Industry stakeholders and patient representatives shall be invited to***

participate in these discussions.

Or. en

Amendment 820
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 77 a (new)

Text proposed by the Commission	*Amendment*
	(77a) In conducting horizon scanning and forward-looking analysis, the Foresight Panel for Emerging Health Innovation should pay due attention to areas characterised by a major public health and socioeconomic burden and persistent innovation gaps, including mental health. In such areas, scientific complexity, fragmented care pathways, and the interaction of pharmacological and non-pharmacological elements may raise cross-cutting regulatory questions that benefit from early, coordinated discussion at Union level.

Or. en

Amendment 821
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 79

Text proposed by the Commission	*Amendment*
(79) Health biotechnology products increasingly challenge Union legislation in the area of health and necessitate further flexibility of that legislation, in particular regarding health biotechnology products that could be candidates for regulatory sandboxes under such	***deleted***

frameworks. The development and implementation of those sandboxes can clearly benefit from effective consultation across the authorities responsible for regulatory sandboxes falling within the scope of Union legislative acts other than this Regulation. By facilitating the exchange of information and experiences between sandboxes, including on regulatory approaches, technological challenges, and emerging scientific understanding, the Union can develop more coherent and responsive regulatory responses to health biotechnology products. The activities of sandboxes should be carried out in full compliance of antitrust information exchanges provisions under Union competition law. The Foresight Panel for Emerging Health Innovation could play a role in promoting such coherence and knowledge sharing.

Or. en

Amendment 822
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Recital 79

Text proposed by the Commission	*Amendment*
(79) Health biotechnology products increasingly challenge Union legislation in the area of health ***and necessitate further flexibility of that legislation, in particular regarding health biotechnology products that could be candidates for*** regulatory ***sandboxes under such frameworks. The development and implementation of those sandboxes can clearly benefit from effective consultation across the authorities responsible for regulatory sandboxes falling within the scope of Union legislative acts other than this Regulation. By facilitating the exchange of information and experiences between***	(79) Health biotechnology products increasingly challenge Union legislation in the area of health***. Hence, it is of the upmost importance to encourage the use of thorough risk assessments and high*** regulatory ***standards to test*** emerging ***human centered biotechnologies in a controlled, adaptable framework that ensures safety, animal welfare and respect for bioethics;***

sandboxes, including on regulatory approaches, technological challenges, and emerging ***scientific understanding, the Union can develop more coherent and responsive regulatory responses to health biotechnology products. The activities of sandboxes should be carried out in full compliance of antitrust information exchanges provisions under Union competition law. The Foresight Panel for Emerging Health Innovation could play a role in promoting such coherence and knowledge sharing.***

Or. en

Amendment 823
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 79 a (new)

Text proposed by the Commission	*Amendment*
	(79a) Cooperation between the Member States and academia should promote the exchange of best practices, harmonisation of regulatory approaches and the development of common assessment methodologies, while avoiding duplication and unnecessary administrative requirements. Regulatory sandboxes should enable developers to test innovative biotechnology products and technologies in a controlled environment and under the supervision of the competent authorities while ensuring a high level of protection of public health, patient safety and fundamental rights. The experience gained through these mechanisms should help to identify any regulatory obstacles and to adapt and modernise the Union's legal framework, where necessary, in order to facilitate the market launch of the innovation without lowering safety and quality standards. This addition is in keeping with the style

of recitals in EU regulations and explains the role of regulatory sandboxes more clearly.

Or. ro

Amendment 824
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(80) The Commission should be able to establish regulatory sandboxes for health biotechnology products which are at a very early stage of development and do not fall within the scope of existing Union legislative acts in the area of health, thus not being in a position to benefit from the regulatory sandboxes established in accordance with those other acts. Those sandboxes should provide a controlled environment in which to explore and assess innovative technologies. The sandboxes should operate according to a specific sandbox plan that specifies the duration of the sandbox, risk mitigation measures and supervision arrangements. For the development and implementation of the sandbox plan for such products, the Commission may consult advisory bodies and Agencies established under the Union legislative acts in the area of health for example to determine which requirements or rules laid down in those acts could, or could not, be applied to the products concerned. The outcome of the sandbox would be a recommendation by the Commission on an existing appropriate regulatory procedural pathway for authorising the product in question. The lessons learned from those sandboxes should lead to reflections on possible regulatory actions to be taken at Union level for the products or categories of	***deleted***

products concerned. Accordingly, this approach would provide a flexible Union response to emerging innovations while building an evidence base for potential future legislative developments.

Or. en

Amendment 825
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(80) The Commission should be able to establish regulatory sandboxes for health biotechnology products which are at a very early stage of development and do not fall within the scope of existing Union legislative acts in the area of health, thus not being in a position to benefit from the regulatory sandboxes established in accordance with those other acts. Those sandboxes should provide a controlled environment in which to explore and assess innovative technologies. The sandboxes should operate according to a specific sandbox plan that specifies the duration of the sandbox, risk mitigation measures and supervision arrangements. For the development and implementation of the sandbox plan for such products, the Commission may consult advisory bodies and Agencies established under the Union legislative acts in the area of health for example to determine which requirements or rules laid down in those acts could, or could not, be applied to the products concerned. The outcome of the sandbox would be a recommendation by the Commission on an existing appropriate regulatory procedural pathway for authorising the product in question. The lessons learned from those sandboxes	***deleted***

should lead to reflections on possible regulatory actions to be taken at Union level for the products or categories of products concerned. Accordingly, this approach would provide a flexible Union response to emerging innovations while building an evidence base for potential future legislative developments.

Or. en

Amendment 826
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(80) The Commission should be able to establish regulatory sandboxes for health biotechnology products which are at a very early stage of development and do not fall within the scope of existing Union legislative acts in the area of health, thus not being in a position to benefit from the regulatory sandboxes established in accordance with those other acts. Those sandboxes should provide a controlled environment ***in which to explore and assess*** innovative technologies. The sandboxes should operate according to a specific sandbox plan that specifies the duration of the sandbox, risk mitigation measures and supervision arrangements. For the development and implementation of the sandbox plan for such products, the Commission may consult advisory bodies and Agencies established under the Union legislative acts in the area of health for example to determine which requirements or rules laid down in those acts could, or could not, be applied to the products concerned. The outcome of the sandbox would be a recommendation by the Commission on an existing appropriate regulatory procedural pathway for	(80) The Commission should be able to establish regulatory sandboxes for health biotechnology products which are at a very early stage of development and do not fall within the scope of existing Union legislative acts in the area of health, thus not being in a position to benefit from the regulatory sandboxes established in accordance with those other acts. Those sandboxes should provide a ***structured context for experimentation under a controlled framework, to enable where appropriate in a real-world a*** controlled environment ***the testing of*** innovative technologies. The sandboxes should operate according to a specific sandbox plan that specifies the duration of the sandbox, risk mitigation measures and supervision arrangements. For the development and implementation of the sandbox plan for such products, the Commission may consult advisory bodies and Agencies established under the Union legislative acts in the area of health for example to determine which requirements or rules laid down in those acts could, or could not, be applied to the products concerned. The outcome of the sandbox

authorising the product in question. The lessons learned from those sandboxes should lead to reflections on possible regulatory actions to be taken at Union level for the products or categories of products concerned. Accordingly, this approach would provide a flexible Union response to emerging innovations while building an evidence base for potential future legislative developments.	would be a recommendation by the Commission on an existing appropriate regulatory procedural pathway for authorising the product in question. The lessons learned from those sandboxes should lead to reflections on possible regulatory actions to be taken at Union level for the products or categories of products concerned. Accordingly, this approach would provide a flexible Union response to emerging innovations while building an evidence base for potential future legislative developments.

Or. en

Amendment 827
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 80 a (new)

Text proposed by the Commission	*Amendment*
	(80a) Certain health biotechnology innovations may present particular regulatory challenges because their development and use depend not only on the characteristics of the product itself but also on the conditions of administration, patient selection, structured therapeutic support, long-term follow-up, or the interaction between pharmacological and non-pharmacological elements. This may be particularly relevant for innovations addressing mental health conditions, including lawful and clinically supervised treatments under development that involve controlled psychoactive substances in combination with structured therapeutic support, where conventional regulatory pathways may not adequately capture the full evidence needs, delivery conditions, or risk-mitigation requirements. Union regulatory sandboxes should therefore be available, where appropriate, to support the

development of such innovations in a controlled environment while maintaining a high level of public health protection.

Or. en

Amendment 828
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 80 a (new)

Text proposed by the Commission	*Amendment*
	(80a) Certain health biotechnology innovations may present particular regulatory challenges because their development and use depend not only on the characteristics of the product itself but also on the conditions of administration, patient selection, structured therapeutic support, long-term follow-up, or the interaction between pharmacological and non-pharmacological elements. This may be particularly relevant for innovations addressing mental health conditions, including lawful and clinically supervised treatments under development that involve controlled psychoactive substances in combination with structured therapeutic support, where conventional regulatory pathways may not adequately capture the full evidence needs, delivery conditions, or risk-mitigation requirements. Union regulatory sandboxes should therefore be available, where appropriate, to support the development of such innovations in a controlled environment while maintaining a high level of public health protection.

Or. en

Justification

Clarifies that regulatory sandboxes should also apply to complex mental health innovations, including experience-mediated treatment models, where outcomes depend not only on the

product itself but also on the conditions of administration, therapeutic support and follow-up, and which may not fit standard development pathways.

Amendment 829
Aurelijus Veryga

Proposal for a regulation
Recital 80 a (new)

Text proposed by the Commission	*Amendment*
	(80a) Certain health biotechnology innovations may present particular regulatory challenges because their development and use depend not only on the characteristics of the product itself but also on the conditions of administration, patient selection, structured therapeutic support, long-term follow-up, or the interaction between pharmacological and non-pharmacological elements. This may be particularly relevant for innovations addressing mental health conditions, including lawful and clinically supervised treatments under development that involve controlled psychoactive substances in combination with structured therapeutic support, where conventional regulatory pathways may not adequately capture the full evidence needs, delivery conditions, or risk-mitigation requirements. Union regulatory sandboxes should therefore be available, where appropriate, to support the development of such innovations in a controlled environment while maintaining a high level of public health protection.

Or. en

Amendment 830
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 80 a (new)

Text proposed by the Commission	*Amendment*
	(80a) In developing regulatory sandboxes, the Commission, together with other relevant Union and national regulatory authorities involved in their design, implementation and supervision, should take account of practical experience and lessons learned from relevant Union-level initiatives and projects, including multi-stakeholder projects such as Innovative Health Initiative (IHI)-supported initiatives, which aim to further the effective use of regulatory sandboxes for the development and placing on the market of innovative products.

Or. en

Justification

EU regulatory sandboxes should build on existing experience such as that developed by public-private partnerships including i.a. the IHI.

Amendment 831
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Recital 80 a (new)

Text proposed by the Commission	*Amendment*
	(80a) In designing, implementing and supervising regulatory sandboxes, the Commission and the relevant Union and national regulatory authorities should draw on practical experience and lessons learned from Union-level initiatives and projects, including multi-stakeholder initiatives such as those supported by IHI, in order to improve the effective use of regulatory sandboxes for enabling the development and market introduction of innovative products.

Or. en

Justification

EU regulatory sandboxes should draw on existing experience, including that gained through public–private partnerships such as IHI.

Amendment 832
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.	(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. ***Such coordination may also help to make the Union better able to prevent, detect and address biological threats, including natural, accidental or deliberate ones, and to make the relevant critical infrastructures and supply chains more resilient. In addition, harnessing synergies between civilian and dual-use applications may speed up the development of innovative technologies, while maintaining a high level of biosecurity, biosafety and public health protection.*** Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar as high impact health biotechnology strategic projects, subject to conditions established in this Regulation. ***Such projects should, where appropriate, facilitate cooperation between competent authorities, research institutions, the relevant industry and other entities involved in managing biological risks, thereby contributing to the development of European integrated capacities for early warning, monitoring and response to biological threats.***

Or. ro

Amendment 833
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.	(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar***, where appropriate in collaboration with the Health Emergency Response Authority (HERA) and European Center for Disease Control (ECDC) each acting within their respective competences,*** as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.

Or. en

Amendment 834
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation	(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation

should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.	should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar ***where appropriate in collaboration with the Health Emergency Response Authority (HERA) and European Center for Disease Control (ECDC) each acting within their respective competences*** as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.

Or. en

Amendment 835
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar as high impact ***health*** biotechnology strategic projects, subject to conditions established in this Regulation.	(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar***, where appropriate in collaboration with the Health Emergency Response Authority (HERA) and European Center for Disease Control (ECDC) each acting within their respective competences,*** as high impact biotechnology strategic projects, subject to conditions established in this Regulation.

Or. en

Amendment 836
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.	(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects contributing to an EU Biothreat Radar***, where appropriate in collaboration with the Health Emergency Response Authority (HERA) and European Center for Disease Control (ECDC) each acting within their respective competences*** as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.

Or. en

Justification

Highlight the specific roles of HERA and ECDC in the EU Biothreat radar and the detection and assessment of biological threats.

Amendment 837
Sirpa Pietikäinen

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) Biotechnologies are critical for the Union's defence and security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition by the Commission and support of projects	(81) Biotechnologies are critical for the Union's defence and ***security, including health*** security. Closer coordination between civil and defence research, development and manufacturing can accelerate safe innovation and reduce fragmentation. Therefore, this Regulation should make provisions for the recognition

contributing to an EU Biothreat Radar as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.

by the Commission and support of projects contributing to an EU Biothreat Radar as high impact health biotechnology strategic projects, subject to conditions established in this Regulation.

Or. en

Amendment 838
Michalis Hadjipantela

Proposal for a regulation
Recital 81 a (new)

Text proposed by the Commission	*Amendment*
	(81a) In order to ensure that health biotechnology innovations developed, financed or manufactured in the Union can reach patients in a timely and predictable manner, it is necessary to review the effectiveness of the application of the procedural timelines and transparency obligations laid down in Council Directive 89/105/EEC. Delays between Union marketing authorisation and national pricing and reimbursement decisions can undermine patient access, weaken incentives to launch innovative products in the Union, and reduce the competitiveness of the Union health biotechnology ecosystem.

Or. en

Amendment 839
Kristoffer Storm

Proposal for a regulation
Recital 82

Text proposed by the Commission	*Amendment*
(82) Furthermore, this Regulation should make provisions for the recognition	(82) Furthermore, this Regulation should make provisions for the recognition

by the Commission and support of high impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments, including from those budgets allocated to defence.

by the Commission and support of high impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies***, including by disease prevention particularly through vaccine development, manufacturing, and deployment***. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments, including from those budgets allocated to defence.

Or. en

Amendment 840
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 82

Text proposed by the Commission	*Amendment*
(82) Furthermore, this Regulation should make provisions for the recognition by the Commission and support of high impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes	(82) Furthermore, this Regulation should make provisions for the recognition by the Commission and support of high impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies***, including by disease prevention particularly through vaccine development, manufacturing, and deployment***. As such, those projects should benefit from priority status in administrative procedures in accordance

and instruments, including from those budgets allocated to defence.	with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments, including from those budgets allocated to defence.

Or. en

Amendment 841
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Recital 82

Text proposed by the Commission	*Amendment*
(82) Furthermore, this Regulation should make provisions for the recognition by the Commission and support of high impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments, including from those budgets allocated to defence.	(82) Furthermore, this Regulation should make provisions for the recognition by the Commission and support of high impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies***, including disease prevention particularly through vaccine development, manufacturing, and deployment***. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments, including from those budgets allocated to defence.

Or. en

Justification

The wording of Recital (82) is modified and expanded to reinforce the proposed update and justification to include prevention and vaccination in Article 42. It is essential to explicitly include disease prevention, particularly vaccination. Vaccines offer a unique capability to protect a large population rapidly against serious diseases. This swift and broad protection is vital for maintaining the sustainability of healthcare systems and the economy, especially

during times of existing strain or in response to a biothreat. Prioritising prevention ensures robust readiness and resilience against future health security challenges.

Amendment 842
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 82

Text proposed by the Commission	*Amendment*
(82) Furthermore, this Regulation should make provisions for the recognition by the Commission and support of high impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments, including from those budgets allocated to defence.	(82) Furthermore, this Regulation should make provisions for the recognition by the Commission and support of high impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies***, as well as rapid response measures, including through cross-border cooperation, where necessary***. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments, including from those budgets allocated to defence.

Or. ro

Amendment 843
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 82

Text proposed by the Commission	*Amendment*
(82) Furthermore, this Regulation should make provisions for the recognition by the Commission and support of high	(82) Furthermore, this Regulation should make provisions for the recognition by the Commission and support of high

impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments***, including from those budgets allocated to defence***.	impact biodefence capability projects, as part of the category of high impact health biotechnology strategic projects, subject to conditions laid down in this Regulation. Such projects should make a significant contribution to objectives such as the prevention or mitigation of the misuse of biotechnologies. As such, those projects should benefit from priority status in administrative procedures in accordance with this Regulation and could be given particular consideration for support under national and Union funding programmes and instruments.

Or. en

Amendment 844
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 83

Text proposed by the Commission	*Amendment*
(83) Without prejudice to Member States' competences and in accordance with the Union funding programmes and instruments, biotechnology activities relevant to defence, security, safety, preparedness, and resilience, including dual-use technologies could be given particular consideration, where appropriate, for support under the European Defence Fund, the Union Research Framework Programmes and other Union funding instruments.	***deleted***

Or. en

Amendment 845
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation

Recital 84

Text proposed by the Commission	*Amendment*
(84) Moreover, where national authorities so decide, expenditure on such dual-use infrastructures and related biodefence activities may be counted toward relevant defence spending targets.	***deleted***

Or. en

Amendment 846
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 85

Text proposed by the Commission	*Amendment*
(85) The biotechnology landscape is evolving at an unprecedented speed, driven by advances in synthetic biology and genome editing, which, coupled with AI, make biotechnology stand at the forefront of innovation, offering unprecedented opportunities for advancing health and protecting against biological threats. These advances also make biotechnological misuse faster, cheaper, and more accessible. Biotechnologies can pose serious and distinctive risks that call for continuous assessment and anticipatory safeguards. Therefore, a limited set of biotechnology products with significant potential for misuse ('biotechnology products of concern') require a specific framework to prevent and protect against their misuse.	(85) The biotechnology landscape is evolving at an unprecedented speed, driven by advances in synthetic biology and genome editing, which, coupled with AI, make biotechnology stand at the forefront of innovation, offering unprecedented opportunities for advancing health and protecting against biological threats. These advances also make biotechnological misuse faster, cheaper, and more accessible. Biotechnologies can pose serious and distinctive risks that call for continuous assessment and anticipatory safeguards. ***Some biotechnological capabilities, such as the creation of mirror bacteria, have the potential to pose serious, large scale and cross border risks to human health, the environment and public order, as noted by the UN Secretary-General's Scientific Advisory Board, the World Health Organization, the UNESCO International Bioethics Committee, and the UN Advisory Board on Disarmament Matters.*** Therefore, a limited set of biotechnology products with significant potential for misuse ('biotechnology products of concern')

require a specific framework to prevent and protect against their misuse.

Or. en

Amendment 847
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 85

Text proposed by the Commission	*Amendment*
(85) The biotechnology landscape is evolving at an unprecedented speed, driven by advances in synthetic biology and genome editing, which, coupled with AI, make biotechnology stand at the forefront of innovation, offering unprecedented opportunities for advancing health and protecting against biological threats. These advances also make biotechnological misuse faster, cheaper, and more accessible. Biotechnologies can pose serious and distinctive risks that call for continuous assessment and anticipatory safeguards. Therefore, a limited set of biotechnology products with significant potential for misuse ('biotechnology products of concern') require a specific framework to prevent and protect against their misuse.	(85) The biotechnology landscape is evolving at an unprecedented speed, driven by advances in synthetic biology and genome editing, which, coupled with AI, make biotechnology stand at the forefront of innovation, offering unprecedented opportunities for advancing health and protecting against biological threats. These advances also make biotechnological misuse faster, cheaper, and more accessible. Biotechnologies can pose serious and distinctive risks that call for continuous assessment and anticipatory safeguards. Therefore, a limited set of biotechnology products with significant potential for misuse ('biotechnology products of concern') require a specific framework to prevent and protect against their misuse. ***Where the risks related to health are particularly high, increasingly sophisticated diagnostics systems and systems supporting human decisions should be reliable and accurate, while avoiding discriminatory impacts and unfair biases in accordance with Union or national law.***

Or. en

Amendment 848
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 85

Text proposed by the Commission	*Amendment*
(85) The biotechnology landscape is evolving at an unprecedented speed, driven by advances in synthetic biology and genome editing, which, coupled with AI, make biotechnology stand at the forefront of innovation, offering unprecedented opportunities for advancing health and protecting against biological threats. These advances also make biotechnological misuse faster, cheaper, and more accessible. Biotechnologies can pose serious and distinctive risks that call for continuous assessment and anticipatory safeguards. Therefore, a limited set of biotechnology products with significant potential for misuse ('biotechnology products of concern') require a specific framework to prevent and protect against their misuse.	(85) The biotechnology landscape is evolving at an unprecedented speed, driven by advances in synthetic biology and genome editing, which, coupled with AI, make biotechnology stand at the forefront of innovation, offering unprecedented opportunities for advancing health and protecting against biological threats. These advances also make biotechnological misuse faster, cheaper, and more accessible. Biotechnologies can pose serious and distinctive risks that call for continuous assessment and anticipatory safeguards. Therefore, a limited set of biotechnology products with significant potential for misuse ('biotechnology products of concern') require a specific framework to prevent and protect against their misuse***, as well as appropriate measures for their medium- and long-term storage, monitoring of storage conditions and the security of storage facilities, and controlled destruction, where necessary***.

Or. ro

Amendment 849
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 85

Text proposed by the Commission	*Amendment*
(85) The biotechnology landscape is evolving at an unprecedented speed, driven by advances in synthetic biology and genome editing, which, coupled with AI, make biotechnology stand at the forefront of innovation, offering unprecedented	(85) The biotechnology landscape is evolving at an unprecedented speed, driven by advances in synthetic biology and genome editing, which, coupled with AI, make biotechnology stand at the forefront of innovation, offering unprecedented

opportunities for advancing health and protecting against biological threats. These advances also make biotechnological misuse faster, cheaper, and more accessible. Biotechnologies can pose serious and distinctive risks that call for continuous assessment and anticipatory safeguards. Therefore, a limited set of biotechnology products with significant potential for misuse ('biotechnology products of concern') require a specific framework to prevent and protect against their misuse.	opportunities for advancing health and protecting against biological threats. These advances also make biotechnological misuse faster, cheaper, and more accessible. Biotechnologies can pose serious and distinctive risks that call for continuous assessment and anticipatory safeguards. Therefore, a limited set of biotechnology products with significant potential for misuse ('biotechnology products of concern')***, or the cases where the stakes for life and health are particularly high,*** require a specific framework to prevent and protect against their misuse.

Or. en

Amendment 850
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 86

Text proposed by the Commission	*Amendment*
(86) Union and international rules address certain aspects related to biological threats, biological incidents or biological risks, in particular in relation to serious cross-border threats to health[42] , the control of exports, brokering, technical assistance, transit and transfer of dual-use items[43] , resilience in biosafety and biosecurity through the Biological and Toxin Weapons Convention (BTWC)[44] , the Chemical Weapons Convention (CWC), the contained use of genetically modified micro-organisms[45] , workers' protection from risks related to exposure to biological agents at work[46] , in relation to AI systems and models through Regulation (EU) 2024/1689. However, the approach remains fragmented and does not sufficiently address all aspects related to the misuse related to biotechnologies. A	(86) Union and international rules address certain aspects related to biological threats, biological incidents or biological risks, in particular in relation to serious cross-border threats to health[42], the control of exports, brokering, technical assistance, transit and transfer of dual-use items[43], resilience in biosafety and biosecurity through the Biological and Toxin Weapons Convention (BTWC)[44], the Chemical Weapons Convention (CWC), the contained use of genetically modified micro-organisms[45], workers' protection from risks related to exposure to biological agents at work[46], in relation to AI systems and models through Regulation (EU) 2024/1689. However, the approach remains fragmented and does not sufficiently address all aspects related to the misuse related to biotechnologies. A

consistent and high level of protection throughout the Union should therefore be ensured in order to guarantee biotechnology remains trustworthy and provides legal certainty for economic operators in the biotechnology sector.

consistent and high level of protection throughout the Union should therefore be ensured in order to guarantee biotechnology remains ***ethical,*** trustworthy and provides legal certainty for economic operators in the biotechnology sector.

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[42] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/, p. 26. ELI: http://data.europa.eu/eli/reg/2022/2371/oj.

[43] Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items , OJ L 206, 11.6.2021, pp. 1. ELI: http://data.europa.eu/eli/reg/2021/821/oj.

[44] Council Decision (CFSP) 2023/2636 of 20 November 2023 amending Decision (CFSP) 2021/2072 in support of building resilience in biosafety and biosecurity through the Biological and Toxin Weapons Convention, no longer in force. OJ L, 2023/2636, 22.11.2023, ELI: http://data.europa.eu/eli/dec/2023/2636/oj

[45] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance), OJ L 125, 21.5.2009, p. 75. ELI: http://data.europa.eu/eli/dir/2009/41/oj.

[46] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 262, 17.10.2000, p. 21. ELI: http://data.europa.eu/eli/dir/2000/54/oj.

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[42] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/, p. 26. ELI: http://data.europa.eu/eli/reg/2022/2371/oj.

[43] Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items , OJ L 206, 11.6.2021, pp. 1. ELI: http://data.europa.eu/eli/reg/2021/821/oj.

[44] Council Decision (CFSP) 2023/2636 of 20 November 2023 amending Decision (CFSP) 2021/2072 in support of building resilience in biosafety and biosecurity through the Biological and Toxin Weapons Convention, no longer in force. OJ L, 2023/2636, 22.11.2023, ELI: http://data.europa.eu/eli/dec/2023/2636/oj

[45] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (Recast) (Text with EEA relevance), OJ L 125, 21.5.2009, p. 75. ELI: http://data.europa.eu/eli/dir/2009/41/oj.

[46] Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 262, 17.10.2000, p. 21. ELI: http://data.europa.eu/eli/dir/2000/54/oj.

Or. en

Amendment 851
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 87

Text proposed by the Commission	*Amendment*
(87) There are divergent requirements in Member States for screening, verification, reporting and tracking of suspicious transactions for biotechnology products of concern, which includes benchtop equipment and sequences of concern. 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.	(87) There are divergent requirements in Member States for screening, verification, reporting and tracking of suspicious transactions for biotechnology products of concern, which includes benchtop equipment and sequences of concern. 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. ***Divergences between national rules may lead to differing levels of protection against misuse of biotechnology products and may lessen the effectiveness of measures to prevent, detect and respond to biological risks, including through cross-border cooperation, where applicable.***

Or. ro

Amendment 852
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 88

Text proposed by the Commission	*Amendment*
(88) A Union framework for strengthening monitoring of the potential misuse of biotechnology products of concern is therefore needed and requested by industry actors, including SMEs, to safeguard the free movement of goods and ensure a level playing field in the internal	(88) A Union framework for strengthening monitoring of the potential misuse of biotechnology products of concern is therefore needed and requested by industry actors, including SMEs, to safeguard the free movement of goods and ensure a level playing field in the internal

market. This framework needs to take into account recent international developments and good practices in other jurisdictions and relevant industry consortia and standard-setting fora, including to promote interoperability for Union operators active globally and providing for a level playing field in the internal market.

market. This framework needs to take into account recent international developments and good practices in other jurisdictions and relevant industry consortia and standard-setting fora, including to promote interoperability for Union operators active globally and providing for a level playing field in the internal market ***and maintaining competitiveness for EU-based biotechnology and biomanufacturing companies, by overall strengthening the competitiveness of Union-based biotechnology and biomanufacturing companies***. ***Harmonised nucleic acid synthesis screening, customer due diligence and reporting requirements should reduce fragmentation, support responsible operators, facilitate trusted trade and research cooperation and prevent companies applying high biosecurity standards from being undercut by providers operating under weaker screening practices.***

Or. en

Amendment 853
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 88

Text proposed by the Commission	*Amendment*
(88) A Union framework for strengthening monitoring of the potential misuse of biotechnology products of concern is therefore needed and requested by industry actors, including SMEs, to safeguard the free movement of goods and ensure a level playing field in the internal market. This framework needs to take into account recent international developments and good practices in other jurisdictions and relevant industry consortia and standard-setting fora, including to promote	(88) A Union framework ***establishing common requirements for identifying, verifying, reporting and tracking suspicious transactions, taking account of the principle of proportionality and the need to avoid unnecessary administrative burdens, and*** for strengthening monitoring of the potential misuse of biotechnology products of concern is therefore needed and requested by industry actors, including SMEs, to safeguard the free movement of goods and ensure a level playing field in

interoperability for Union operators active globally and providing for a level playing field in the internal market.	the internal market. This framework needs to take into account recent international developments and good practices in other jurisdictions and relevant industry consortia and standard-setting fora, including to promote interoperability for Union operators active globally and providing for a level playing field in the internal market. ***Such a framework should ensure a high level of biosecurity and traceability, facilitate the exchange of information between competent authorities and economic operators, and boost confidence in the internal market, without unduly affecting legitimate research, innovation and production activities.***

Or. ro

Amendment 854
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 93

Text proposed by the Commission	*Amendment*
(93) Benchtop nucleic acid synthesis equipment poses a particular challenge to the verification of legitimate need and the tracking and monitoring of sequences of concern. Such equipment should therefore contain an automatic mechanism to screen for sequences of concern.	(93) Benchtop nucleic acid synthesis equipment poses a particular challenge to the verification of legitimate need and the tracking and monitoring of sequences of concern. Such equipment should therefore contain an automatic mechanism to screen for sequences of concern. ***The current Regulation should ensure a high level of biosecurity and traceability, facilitate the exchange of information between competent authorities and economic operators, and boost confidence in the internal market, without unduly affecting legitimate research, innovation and production activities.***

Or. ro

Amendment 855
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 93 a (new)

Text proposed by the Commission	*Amendment*
	(93a) For the purposes of legal certainty, sequence screening should be understood as the process by which an economic operator or a benchtop nucleic acid synthesis device assesses a requested or synthesised nucleic acid sequence, in accordance with the relevant guidance, in order to determine whether the sequence presents a biosecurity risk. Harmonised sequence screening contributes to preventing the misuse of biotechnology products of concern while ensuring a level playing field for economic operators across the internal market.

Or. en

Amendment 856
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 95

Text proposed by the Commission	*Amendment*
(95) Suspicious transactions should be detected and reported rapidly through harmonised procedures, with Member States designating national contact points that provide clear reporting channels, as well as record data and ensure compliance, with a view to contributing to safeguarding national and Union's safety.	(95) Suspicious transactions should be detected and reported rapidly through harmonised procedures, with Member States designating national contact points that provide clear reporting channels, as well as record data and ensure compliance, ***as well as subsequent monitoring*** with a view to ***avoiding similar situations and*** contributing to safeguarding national and Union's safety.

Or. ro

Amendment 857
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 97

Text proposed by the Commission	*Amendment*
(97) Licensed biotechnology products containing nucleic acid sequences, including authorised medicinal products for human and veterinary use, should not be subject to verification of legitimate need, as they have undergone regulatory assessment and do not constitute independent biological threats. However, the stand-alone nucleic acid sequences in synthetic form should fall within the scope of legitimate-need screening, as they may be misused and be relevant to biosecurity oversight.	(97) Licensed biotechnology products containing nucleic acid sequences, including authorised medicinal products for human and veterinary use, should not be subject to verification of legitimate need, as they have undergone regulatory assessment and do not constitute independent biological threats. However, the stand-alone nucleic acid sequences in synthetic form should fall within the scope of legitimate-need screening, as they may be misused ***by non-specialists*** and be relevant to biosecurity oversight.

Or. ro