European Parliament
2024-2029

Committee on Public Health
Committee on Industry, Research and Energy

2025/0406(COD)

14.7.2026

AMENDMENTS
391 - 602

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 391
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Citation 1

Text proposed by the Commission	*Amendment*
Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114, ***168(4) and*** 173(3) thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114, 173(3) ***and 191*** thereof,

Or. en

Amendment 392
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.	(1) Biotechnology is a strategic ***and cross-sectorial enabling*** technology central for the Union's competitiveness, strategic autonomy***, public and industrial value,*** and innovation leadership. It has applications across several sectors, with prominence in the health area***. The health dimension of biotechnology is of central importance for patients in the Union***. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.

However, the Union does not yet operate as a fully integrated Single Market for pharmaceutical and biotechnology products, and faces increasing dependencies in critical supply chains, as reflected in the decline of the Union's share of global pharmaceutical production from around 53 % to less than 25 % over recent decades. This Regulation should overall strengthen the Union's biotechnology and biomanufacturing capacity across sectors, while reinforcing in particular the Union's capacity in innovation, medicines, clinical trials, advanced therapies, health data,, resilient biomanufacturing, novel food and feed, sustainable food systems and environmental applications, and upholding principles of competitiveness, equality, safety, sustainability and timely access for patients and citizens in the Union.

Or. en

Amendment 393
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically	(1) ***Biotechnology and biomanufacturing, while offering major opportunities for innovation and strategic autonomy, may also raise significant ethical, environmental, labour and public health concerns. Innovation in biotechnology and biomanufacturing must serve societal needs and contribute to public welfare. Union action in this field should ensure that technological progress is directed toward public benefit rather than the exclusive maximisation of private profit. In that context, the***

contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.

precautionary principle, as enshrined in Article 191 TFEU, must be fully respected in the development, deployment and regulation of biotechnology products and services. Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.

Or. en

Amendment 394
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically	(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership***, it must therefore go hand in hand with improving patient access, supporting resilient health systems, reducing inequalities in access to innovation and reinforcing the European Health Union***. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008

contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.	and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.

Or. en

Amendment 395
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.	(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology ***including Plasma Derived Medicinal Products (PDMPs) and the global pioneering follow-on biologic medicines sector (i.e. biosimilar medicines),*** specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.

Or. en

Amendment 396
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.	(1) Biotechnology is a strategic technology central for the Union's competitiveness, strategic autonomy and innovation leadership. It has applications across several sectors, with prominence in the health area. In 2021, the Union was the second largest contributor to the global value of biotechnologies. Between 2008 and 2018, the biotechnology industry in the Union grew more than twice as fast as the overall economy, making it one of the fastest growing innovative industries in the Union. Health biotechnology ***including Plasma Derived Medicinal Products (PDMPs) and the global pioneering follow-on biologic medicines sector (i.e. biosimilar medicines)*** specifically contributes over 80% to the value of the overall biotechnology market and it is a key driver of today's innovative medical industry. Biological medicines, including biosimilars count for 40% of overall pharmaceutical sales in the Union.

Or. en

Justification

Plasma Derived Medicinal Products - represent 3-5% of the European biotech market and should be considered within the scope of the Regulation.

Amendment 397
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Biotechnology and biomanufacturing should be developed and deployed within a Union framework that combines competitiveness and scientific leadership with human dignity, fundamental human and patient rights, bioethics, data protection, non-discrimination, gender equality, public health, environmental protection and the right to benefit from scientific progress. This Regulation should therefore support responsible innovation in line with the principles reflected in relevant European and international frameworks on human rights and biomedicine, cross-border healthcare, clinical trials, substances of human origin, health technology assessment, the European Health Data Space and fair access to and use of data. It should also contribute to Union priorities on antimicrobial resistance in a One Health approach, preparedness, competitiveness, start-ups, scale-ups and spin-offs, research excellence. Measures under this Regulation should ensure that faster and more predictable pathways for biotechnology innovation are accompanied by robust scientific scrutiny, transparency, informed consent where required, protection of vulnerable groups, cybersecurity, accountability, and timely and equitable access to the benefits of biotechnology across the Union.

Or. en

Amendment 398
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*

(1a) Any European regulation and regulatory initiative in the field of health, including its implications in terms of biotechnology and biomanufacturing, must be approached first and foremost through the lens of One Health and of public health policy, accessibility and affordability before any consideration related to the competitiveness of industry players in the sector. Is of the opinion that reducing social inequality and unequal access to healthcare and a greater commitment to prevention and healthy environments are much more important for improving public health than biotechnology and deserve much more structural investments and commitments.

Or. en

Amendment 399
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Biotechnology and biomanufacturing can contribute to public health, resilience, sustainability and strategic autonomy. At the same time, certain biotechnology applications may pose risks to human health, animal health, biodiversity, ecosystems and the environment, including through accidental release, persistence, cross-border spread, contamination, antimicrobial resistance and dual-use misuse. This Regulation should therefore be implemented in accordance with the precautionary principle and ensure a high level of protection of human health and the environment, in line with Articles 11, 168 and 191 TFEU.

Or. en

Amendment 400
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Biotechnology and biomanufacturing should be developed and deployed within a Union framework that combines competitiveness and scientific leadership with human dignity, fundamental rights, bioethics, patients' rights, data protection, public health, and the right to benefit from scientific progress. Measures under this Regulation should ensure that faster and more predictable pathways for biotechnology innovation are accompanied by robust scientific scrutiny, cybersecurity,and timely access to the benefits of biotechnology across the Union.

Or. en

Amendment 401
Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Certain biological medicinal products were first authorised in one or more Member States under national marketing authorisations before the categories to which they belong became subject to mandatory Union authorisation. Some of those products have been used in clinical practice in the Union for decades, have a recognised

efficacy and an acceptable level of safety, and are of critical importance for continuity of care and security of supply in the Union.

Or. en

Amendment 402
Margarita de la Pisa Carrión, András Gyürk, Viktória Ferenc, Paolo Borchia, Laurent Castillo, Ondřej Knotek, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Strengthening the Union's biotechnology sector should contribute to reducing critical dependencies on third countries, reinforcing resilient supply chains for medicinal products and active substances, and strengthening the sustainability and long-term capacity of healthcare systems across the Union.

Or. en

Amendment 403
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) In order to strengthen the Union's strategic autonomy in biotechnology and biomanufacturing in a manner that serves the public interest, it is essential to establish a long-term industrial policy framework under the future EU Biotech Act that is guided by social, environmental and public health objectives rather than by market considerations alone. Such a framework

should support the development of resilient and sustainable biotechnology and biomanufacturing capacities within the Union, while ensuring that innovation delivers tangible benefits for patients, society and workers and respects the planetary boundaries and the common nature of genetic resources. In particular, the Union should prioritise public investment in strategic biotechnology and biomanufacturing infrastructure, with a view to securing the supply of critical biological inputs, raw materials and essential biotechnology products, while reducing dependencies on third countries and limiting vulnerabilities in strategic value chains.

Public support should be linked to clear public-interest conditions, including affordability, security of supply, environmental sustainability, transparency in the use of public funds, and guarantees that the benefits of innovation are shared fairly across society. The EU Biotech Act should also promote the development of high-quality employment, strong labour protections, workers' rights, and investment in skills, while supporting sustainable and circular production models that minimise environmental impact and contribute to the Union's climate and biodiversity objectives. In this context, industrial development in biotechnology and biomanufacturing must be aligned with the principles of social justice and ecological transition, ensuring that economic resilience does not come at the expense of workers, communities or the environment. By reinforcing public oversight, supporting strategic industrial capacity, and reducing structural dependencies, the Union can enhance its preparedness for future health, environmental and economic crises, while ensuring equitable access to critical biotechnology products and technologies, especially in relation to medicines

production, and strengthening Europe's capacity to innovate in line with the objectives of solidarity, sustainability and the common good.

Or. en

Amendment 404
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) The Union already has important building blocks for a strong biotechnology ecosystem, particularly in the area of health, including the European Health Data Space, interconnected and interoperable European Reference Networks and other cross-border health networks, biobanks, genomic initiatives, hospitals, universities, biotechnology clusters, research infrastructures, innovative SMCs, SMEs, start-ups, scale-ups and spin-offs. However, those assets remain insufficiently connected across the Union. This Regulation should therefore contribute to more coherent European health innovation ecosystems by reducing fragmentation, promoting interoperable rules and cross-border infrastructures, improving data sharing, accelerating coordinated multinational clinical trials and strengthening the translational research continuum from discovery to clinical validation, market access, manufacturing and patient access. It should also contribute to a more coherent Union biotechnology ecosystem by improving the conditions for research, development, validation, manufacturing and timely access to biotechnology innovations and products, in particular in the area of health, while also taking into account other relevant biotechnology

applications.

Or. en

Amendment 405
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) This Regulation should contribute to a stronger European Health Union and a more coherent Union biotechnology ecosystem by improving the conditions for research, development, validation, manufacturing and timely access to biotechnology innovations and products, in particular in the area of health, while also taking into account other relevant biotechnology applications, including novel food and environmental biotechnology. In line with the One Health approach, this Regulation should also support integrated research, surveillance, preparedness and innovation capacities to address antimicrobial resistance (AMR), zoonotic diseases and biological threats, and promote the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs), where scientifically appropriate, while ensuring high standards of safety, ethics, transparency, data protection, environmental protection, animal welfare and scientific scrutiny.

Or. en

Amendment 406
Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) For a narrowly defined category of such critical biological medicinal products, it is appropriate to provide for a proportionate centralised regulatory pathway allowing applicants, under strict conditions, to rely on bibliographic data and, where relevant, real-world data generated from use in the Union, provided that a scientific bridge to the medicinal product concerned is established and that all applicable quality requirements continue to be met. Such a pathway should not constitute a general derogation from the regulatory requirements applicable to biological medicinal products.

Or. en

Amendment 407
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) This Regulation should not be interpreted as permitting a lowering of requirements laid down in Union legislation on environmental protection, genetically modified organisms, chemical safety, waste management, occupational safety, animal welfare, veterinary public health, food and feed safety, substances of human origin, medicinal products, clinical trials, data protection or biosecurity. Compliance with such Union legislation should remain a precondition for authorisation, funding, accelerated procedures or access to regulatory support

under this Regulation.

Or. en

Amendment 408
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 1 c (new)

Text proposed by the Commission	*Amendment*
	(1c) This Regulation should function as a horizontal integrator across Union law on biotechnology, medicinal products, medical devices, in vitro diagnostics, clinical trials, orphan medicinal products, substances of human origin, health data and artificial intelligence. To that end, and in full respect of the principle of conferral and of the division of competences laid down in Articles 4, 6 and 168 of the Treaty on the Functioning of the European Union, Member States, the Commission, the European Medicines Agency and the relevant Union bodies should make full use of the coordination instruments provided for under the Treaties. In particular, the Open Method of Coordination should be actively employed in areas of Union supporting competence. Enhanced Cooperation under Article 20 of the Treaty on European Union and Articles 326 to 334 TFEU should be available to groups of Member States that wish to advance faster towards integrated procedures, provided that such cooperation remains open to all Member States and respects the acquis. The principle of mutual recognition should be used for scientific assessments, inspections and authorisation decisions issued by competent authorities of Member States or by Union bodies, save where a Member State raises a duly substantiated objection on grounds of

public health, public order, ethics, or national constitutional principals.

Or. en

Amendment 409
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 1 c (new)

Text proposed by the Commission	*Amendment*
	(1c) Ensuring democratic, transparent and inclusive governance must be a core pillar of the EU Biotech Act in order to guarantee the legitimacy, accountability and social effectiveness of the Union's industrial policy in biotechnology and biomanufacturing. A genuinely participatory governance framework should be established, ensuring the meaningful involvement of trade unions as well as public interest stakeholders, at all stages of decision-making, from the identification and implementation of strategic projects to the monitoring, evaluation and oversight of public support measures. Such participation is essential to ensure that patients and workers' voices, skills and expertise are fully recognised and taken into account, and that social, labour and environmental objectives are embedded throughout the biotechnology and biomanufacturing value chains.

Or. en

Amendment 410
Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Recital 1 c (new)

Text proposed by the Commission	*Amendment*
	(1c) In order to safeguard public health, that pathway should be limited to products whose active substances have been in well-established medicinal use within the Union for the same therapeutic use and route of administration for at least ten years, which are included in the Union List of Critical Medicinal Products, and which are linked to manufacturing capacity in the Union, including strategic projects contributing to the security of supply of critical medicinal products.

Or. en

Amendment 411
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 1 d (new)

Text proposed by the Commission	*Amendment*
	(1d) Public investment under the EU Biotech Act should therefore be subject to strong social and environmental conditionalities, ensuring that public funding contributes to the creation of quality jobs, the strengthening of regional cohesion and the advancement of the Union's sustainability objectives. In particular, the governance framework should guarantee the protection and promotion of workers' rights, including the right to safe and healthy working conditions, effective occupational health and safety standards, and robust prevention measures against occupational diseases and workplace accidents. It should also support skills development, workers' participation, and social dialogue as key components of a resilient and socially just biotechnology industrial strategy.

Or. en

Amendment 412
Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 1 d (new)

Text proposed by the Commission	*Amendment*
	(1d) Pursuant to Article 4(2)(k) and Article 168 TFEU, the Union shares competence with the Member States on common safety concerns in public health matters and must ensure a high level of human health protection in all its policies. Biotechnological innovation falling within this scope engages Articles 1, 3, 21 and 35 of the Charter of Fundamental Rights, namely human dignity, bodily integrity, non-discrimination and access to health care. Governance under this Regulation should accordingly be understood as an exercise of this public health and fundamental rights responsibility, and not merely as a matter of industrial competitiveness or internal market functioning.

Or. en

Amendment 413
Borys Budka, Kamila Gasiuk-Pihowicz

Proposal for a regulation
Recital 1 d (new)

Text proposed by the Commission	*Amendment*
	(1d) The Agency should develop guidance on the use of bibliographic data and real-world evidence for such legacy critical biological medicinal products, including principles for scientific bridging, quality comparability and

immunogenicity assessment, necessary to confirm the positive benefit-risk balance of the medicinal product.

Or. en

Amendment 414
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 1 e (new)

Text proposed by the Commission	*Amendment*
	(1e) In order to build a resilient and sustainable biotechnology and biomanufacturing sector in the Union, the EU Biotech Act should establish clear and binding conditions for companies benefiting from public support or participating in strategic projects, including commitments to maintain production capacity and quality employment within the Union. Such support should be made conditional on compliance with high social and environmental standards, including the effective involvement of workers and trade union representatives in planning and implementation processes. By linking public funding to the Union's social, environmental and climate objectives, the EU can ensure that industrial development strengthens strategic resilience without undermining public health, labour rights or environmental protection. This approach would support secure and localised value chains while promoting a fairer, greener and more socially responsible biotechnology industry.

Or. en

Amendment 415

Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) While recognised globally for its scientific excellence, the Union continues to face structural challenges in translating cutting-edge research and innovation into large-scale development, testing, manufacturing and deployment of biotechnology. As a result, the significant potential of biotechnology applications across several sectors to contribute to major societal challenges, modernise the Union economy and strengthen Union strategic autonomy and security remains largely underexploited.	(2) While recognised globally for its scientific excellence, the Union continues to face structural challenges in translating cutting-edge research and innovation into large-scale development, testing, manufacturing and deployment of biotechnology ***and biomanufacturing***. As a result, the significant potential of biotechnology ***and biomanufacturing*** applications across several sectors to contribute to major societal challenges, modernise the Union economy and strengthen Union strategic autonomy and security remains largely underexploited. ***In line with the objective of deepening the Single Market, this Regulation contributes to the development of a "fifth freedom", encompassing research, innovation, knowledge, data and education, as a driver for biotechnology and biomanufacturing in the Union.***

Or. en

Amendment 416
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) While recognised globally for its scientific excellence, the Union continues to face structural challenges in translating cutting-edge research and innovation into large-scale development, testing, manufacturing and deployment of biotechnology. As a result, the significant potential of biotechnology applications	(2) While recognised globally for its scientific excellence, the Union continues to face structural challenges in translating ***scientific advances, including*** cutting-edge research and innovation into large-scale development, testing, manufacturing and deployment of biotechnology ***along the life-cycle of products and technologies,***

across several sectors to contribute to major societal challenges, modernise the Union economy and strengthen Union strategic autonomy and security remains largely underexploited.

including follow-on biosimilar and biohybrid medicinal products. As a result, the significant potential of biotechnology applications across several sectors to contribute to major societal challenges ***such as access to affordable biologic therapies***, modernise the Union economy and strengthen Union strategic autonomy and security remains largely underexploited.

Or. en

Amendment 417
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) While recognised globally for its scientific excellence, the Union continues to face structural challenges in translating cutting-edge research and innovation into large-scale development, testing, manufacturing and deployment of biotechnology. As a result, the significant potential of biotechnology applications across several sectors to contribute to major societal challenges, modernise the Union economy and strengthen Union strategic autonomy and security remains largely underexploited.	(2) While recognised globally for its scientific excellence, the Union continues to face structural challenges in translating cutting-edge research and innovation into large-scale development, testing, manufacturing and deployment of biotechnology. As a result, the significant potential of biotechnology applications across several sectors to contribute to major societal challenges, ***including ensuring timely and affordable access to biological therapies, notably through the development and uptake of biosimilar medicines,*** modernise the Union economy and strengthen Union strategic autonomy and security remains largely underexploited.

Or. en

Justification

Biosimilars deliver high value for health systems, supporting broader patient access while creating substantial savings.

Amendment 418
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) While recognised globally for its scientific excellence, the Union continues to face structural challenges in translating cutting-edge research and innovation into large-scale development, testing, manufacturing and deployment of biotechnology. As a result, the significant potential of biotechnology applications across several sectors to contribute to major societal challenges, modernise the Union economy and strengthen Union strategic autonomy and security remains largely underexploited.	(2) While recognised globally for its scientific excellence, the Union continues to face structural challenges in translating ***scientific advances, including*** cutting-edge research and innovation***,*** into large-scale development, testing, manufacturing and deployment of biotechnology ***along the life-cycle of products and technologies***. As a result, the significant potential of biotechnology applications across several sectors to contribute to major societal challenges, ***such as access to affordable biologic therapies,*** modernise the Union economy and strengthen Union strategic autonomy and security remains largely underexploited.

Or. en

Justification

Science and regulation need to continuously progress hand in hand, along the full spectrum of the life-cycle of products and technologies for scientific excellence to materialise as competitiveness and societal improvement engine.

Amendment 419
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) This is due in particular to limited access to risk capital and other sources of funding, skills shortages within the internal market, slow permitting processes that	(3) This is due in particular to limited access to risk capital and other sources of funding, skills shortages within the internal market, slow permitting processes that

hinder the timely deployment of projects and initiatives aiming to bring biotechnology innovations to the market, as well as fragmented and at times complex regulatory frameworks.	hinder the timely deployment of projects and initiatives aiming to bring biotechnology innovations to the market, as well as fragmented and at times complex regulatory frameworks. ***Reducing time-to-patient should encompass the entire innovation pathway, from research and clinical development to the translation of innovation into clinical practice and timely patient access, while maintaining the Union's high standards of quality, safety, ethics and public health protection.***

Or. en

Amendment 420
Christine Anderson

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) This is due in particular to limited access to risk capital and other sources of funding, skills shortages within the internal market, slow permitting processes that hinder the timely deployment of projects and initiatives aiming to bring biotechnology innovations to the market, as well as fragmented and at times complex regulatory frameworks.	(3) This is due in particular to limited access to risk capital and other sources of funding, skills shortages within the internal market, slow permitting processes that hinder the timely deployment of projects and initiatives aiming to bring biotechnology innovations to the market, as well as fragmented and at times complex regulatory frameworks. ***Those challenges are compounded by excessive administrative burdens, high labour, energy and compliance costs, taxation, fragmented capital markets, legal uncertainty and a regulatory culture that too often distrusts entrepreneurs, private capital and market-driven innovation.***

Or. en

Amendment 421
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) This is due in particular to limited access to risk capital and other sources of funding, skills shortages within the internal market, slow permitting processes that hinder the timely deployment of projects and initiatives aiming to bring biotechnology innovations to the market, as well as fragmented and at times complex regulatory frameworks.	(3) This is due in particular to limited access to risk capital and other sources of funding, skills shortages within the internal market, slow permitting processes that hinder the timely deployment of projects and initiatives aiming to bring biotechnology innovations to the market, as well as fragmented and at times complex regulatory frameworks. ***These situations give rise to legal uncertainty, increase administrative burdens, and make investment and research, development and innovation activities in this sector less attractive.***

Or. ro

Amendment 422
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) This is due in particular to limited access to risk capital and other sources of funding, skills shortages within the internal market, slow permitting processes that hinder the timely deployment of projects and initiatives aiming to bring biotechnology innovations to the market, as well as fragmented and at times complex regulatory frameworks.	(3) This is due in particular to limited access to risk capital and other sources of funding***, lack of a European skills strategy, skills mobility constraints***, skills shortages within the internal market, slow permitting processes that hinder the timely deployment of projects and initiatives aiming to bring biotechnology ***products and technologies*** innovations to the market, as well as fragmented and at times complex regulatory frameworks.

Or. en

Justification

The Commission's explanatory memorandum accompanying the Act identifies a broader set of structural barriers to biotechnology innovation in the Union, and it is appropriate these to also be reflected in the Recitals for consistency and interpretative clarity. Among these, access to capital and funding remains a critical bottleneck. Adequate financing is essential not only to support investment in biotechnology products and technologies generally, but also to enable state-of-the-art advances, modernisation, and innovation throughout the full product life-cycle — including second-wave innovation carried out by the follow-on industry, covering both novel processes and products. Without addressing this financing gap explicitly in the Recitals, the Regulation risks understating a structural constraint that the Commission itself has already recognised as central to the Union's innovation capacity in this sector.

Amendment 423
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) This is due in particular to limited access to risk capital and other sources of funding, skills shortages within the internal market, ***slow permitting processes that hinder the timely deployment of projects and initiatives aiming to bring biotechnology innovations to the market,*** as well as fragmented and at times complex regulatory frameworks.	(3) This is due in particular to ***a lack of a a publicly-driven long-term industrial policy framework,*** limited access to risk capital and other sources of funding, skills shortages within the internal market, as well as fragmented and at times complex regulatory frameworks.

Or. en

Amendment 424
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) The Union should strengthen its biotechnology and pharmaceutical sovereignty, industrial resilience and global competitiveness by increasing

Union-based manufacturing capacity, raw material value chains, research and development infrastructure, quality jobs and skills, while reducing strategic dependencies on third countries. Such growth should be consistent with decent work, workers' rights, gender equality, sustainability, social dialogue and the need to address workforce shortages in health, research, biotechnology and biomanufacturing. Where projects benefit from Union or national public support, proportionate social, environmental, access-related and transparency conditions should be considered, including conditions linked to affordability, availability, accessibility, security of supply and public return on public investment.

Or. en

Amendment 425
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3b) Patent protection across the Union remains fragmented. Regulation (EU) No 1257/2012, Council Regulation (EU) No 1260/2012 and the Agreement on a Unified Patent Court established a unitary patent and a single specialised jurisdiction, but not all Member States participate, obliging patent holders to seek and enforce protection separately in national jurisdictions. Supplementary Protection Certificates are granted and enforced at national level. This persisting fragmentation weakens the Union's attractiveness for biotechnology investment. Member States should therefore complete a fully functioning

unitary patent area with the broadest possible participation, and the Union should establish unitary Supplementary Protection Certificates granted and enforced at Union level.

Or. en

Amendment 426
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety***, food and feed security*** and biosecurity. ***Procurement reform mandating multiple award and criteria beyond price (MEAT) alongside efficient re-assessment of reimbursement restrictions after biosimilar launch would go a long way in enhancing market predictability and de-risking investments in biosimilar medicines development and manufacturing. Predictable market uptake and competition are essential to support investment decisions by***

companies.

Or. en

Justification

As regards biosecurity, the draft ENVI opinion report from MEP Casares lists biosecurity among the standards safeguarded by the Regulation but, like the Commission text, omits food and feed security. Now that Amendments 1 and 12 extend the Act beyond health to biomanufacturing and to fermentation-derived inputs, recognizing food and feed security among the safeguarded standards completes the scope the rapporteurs have themselves opened, and reflects the contribution of biomanufacturing to the resilience and strategic autonomy of the Union's food and feed supply.

As regards procurement reform, mandating multiple award and criteria beyond price (MEAT) alongside efficient re-assessment of reimbursement restrictions after biosimilar launch would go a long way in enhancing market predictability and de-risking investments in biosimilar medicines development and manufacturing. Predictable market uptake and competition are essential to support investment decisions by companies.

Amendment 427
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality***,*** ***food and feed safety and biosecurity***.	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality ***and ensuring that resulting biotechnology medicinal products are accessible, affordable and can effectively answer to***

patients' needs across the Union.Specific reforms of the pharmaceutical market and market competition policies, including pricing, reimbursement and procurement should also be considered as a pre-requisite to Europe's industrial competitiveness ambition and sustainability.

Or. en

Justification

Biotechnology medicinal products can represent essential innovations for the treatment of many diseases and have the potential to significantly improve patient outcomes while addressing current unmet medical needs, in particular in the field of rare diseases and rare cancers. Therefore, while we acknowledge that biotechnology and biomanufacturing have been identified as strategic areas for Europe's competitiveness and leadership in the development of innovative treatments and diagnostic tools, it is essential to ensure that improving public health and addressing patients' needs remain at the core of the Act's objectives and ensuring that resulting innovations are accessible, affordable and can effectively answer to patients' needs across the Union.

Amendment 428
Ingeborg Ter Laak

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality,	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality,

food and feed safety and biosecurity.	food and feed safety and biosecurity. ***In pursuing those objectives, this Regulation should also contribute to ensuring timely, equitable and sustainable access for patients throughout the Union to innovative biotechnology medicinal products, while maintaining the Union's high standards of quality, safety and efficacy.***

Or. en

Amendment 429
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, ***by reducing unnecessary administrative burdens, improving regulatory predictability and supporting investment, intellectual property protection, scale-up and manufacturing in the Union, in particular for SMEs, start-ups and scale-ups,*** while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.

Or. en

Amendment 430
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity ***and ensuring that resulting biotechnology medicinal products are accessible, affordable and can effectively answer to patients' needs across the Union***.

Or. en

Amendment 431
Christine Anderson

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and

innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.

innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks ***horizontally and in a generally applicable manner for all biotechnology innovators, in particular SMEs, start-ups, scale-ups and research actors***, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.

Or. en

Amendment 432
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, ***lightening administrative burdens on economic operators and encouraging private investment and public-private partnerships,*** while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and

biosecurity.

Or. ro

Amendment 433
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the ***health*** biotechnology ***sector*** from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of ***health*** biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the biotechnology ***and biomanufacturing sectors in the Union, particularly in the area of health,*** from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety***, food and feed security*** and biosecurity.

Or. en

Amendment 434
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by

establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.	establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human ***health, including sexual and reproductive health,*** and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.

Or. en

Justification

Amendment drafted by the Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 435
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality,	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and ***timely patient access, and*** production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment,

food and feed safety and biosecurity.	ethics, quality, food and feed safety and biosecurity.

Or. en

Amendment 436
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.	(4) To address this competitiveness gap, this Regulation should aim to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector from research and innovation to production, to create the conditions for research, development, timely placing on the Union market and production of health biotechnology innovations, products and services, including by simplifying and streamlining the Union legislative frameworks, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety***, food and feed security*** and biosecurity.

Or. en

Amendment 437
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) In order to ensure that the Union framework for health biotechnology

remains fit for purpose and capable of accommodating emerging biological innovations, this Regulation should take into account the specific characteristics of adaptive biological products and therapies. It should therefore establish conditions that enable a tailored regulatory approach to such innovations, including, where scientifically justified, an appropriate degree of adaptability in their composition, selection and deployment in response to evolving bacterial resistance patterns, patient-specific factors or real-time microbiological data. Such an approach should support research, development, clinical validation and timely market access for those products and therapies, including through the use of regulatory sandboxes and adapted clinical development pathways, while safeguarding high standards for the protection of human and animal health, patients, the environment, ethics, quality, food and feed safety and biosecurity.

Or. en

Amendment 438
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) To make sure that the European Union's biotechnology framework can respond effectively to emerging biological products, this Regulation should reflect the particular characteristics of a new category of adaptive biological innovation. For that reason, it is appropriate for this Regulation to contain provisions that permit a certain level of flexibility in the composition, selection, and use of products and therapies,

including where this flexibility is shaped by changing bacterial resistance patterns, individual patient factors, and up-to-date microbiological information. Such flexibility is particularly relevant in the context of regulatory sandboxes and the rules governing clinical trials.

Or. en

Amendment 439
Stine Bosse, Katri Kulmuni, Billy Kelleher, Sigrid Friis

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) The Union's food and feed supply depends in part on biotechnology-derived inputs, including precision fermentation-derived ingredients, feed additives and processing aids. Strategic dependencies on third-country suppliers for such inputs represent a vulnerability to the resilience of the Union food and feed value chain. In line with the Food and Agriculture Organization (FAO) of the United Nations' definition of biosecurity, strengthening Union biotechnology and biomanufacturing capacity for those inputs contributes to the food and feed security of the Union and to the reduction of strategic dependencies, in accordance with the objectives of this Regulation.

Or. en

Justification

This recital provides the policy rationale for recognizing food and feed security among the safeguarded standards. It connects the broadened biomanufacturing scope to the resilience of the food and feed supply and to the reduction of strategic dependencies, anchoring the concept in the internationally recognized FAO definition rather than creating a new Union-specific one.

Amendment 440
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sigrid Friis, Sophie Wilmès

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) The Union's food and feed supply depends in part on biotechnology-derived inputs, including precision fermentation-derived ingredients, feed additives and processing aids. Strategic dependencies on third-country suppliers for such inputs represent a vulnerability to the resilience of the food and feed value chain. In line with the Food and Agriculture Organization of the United Nations' definition of biosecurity, strengthening Union biotechnology and biomanufacturing capacity for those inputs contributes to the food and feed security of the Union and to the reduction of strategic dependencies, in accordance with the objectives of this Regulation.

Or. en

Justification

This recital provides the policy rationale for recognising food and feed security among the safeguarded standards. It connects the broadened biomanufacturing scope to the resilience of the food and feed supply and to the reduction of strategic dependencies, anchoring the concept in the internationally recognised FAO definition rather than creating a new Union-specific one.

Amendment 441
Aurelijus Veryga

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) While this Regulation establishes a key framework to support the

competitiveness of Union's biotechnology and biomanufacturing sectors, it should be understood as part of a broader and evolving policy approach. Structural challenges such as regulatory fragmentation, access to capital, scale-up barriers and uneven conditions for uptake are influenced by multiple policy areas and instruments. The effectiveness of this Regulation will therefore depend on coherence with related Union legislation, complementary non-legislative measures and consistent implementation at Member State level.

Or. en

Amendment 442
Margarita de la Pisa Carrión, András Gyürk, Viktória Ferenc, Laurent Castillo, Ondřej Knotek, Marie-Luce Brasier-Clain, Aleksandar Nikolic

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) The Union biotechnology framework should be capable of accommodating emerging adaptive biological innovations, such as technologies addressing antimicrobial resistance, whose development and deployment may require a degree of adaptability based on evolving biological characteristics, patient-specific factors or microbiological evidence, while ensuring compliance with quality, safety, traceability and monitoring requirements.

Or. en

Amendment 443
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation

Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4b) The Union's biotechnology sector competes in increasingly integrated global value chains, while EU patients increasingly depend on complex supply chains for biopharmaceuticals, their intermediate products, and combination products. Regulatory duplication, including redundant inspections of manufacturing facilities operating to equivalent standards and duplicative import testing, can increase costs, delay market access, divert regulatory resources and contribute to unnecessary waste of critical biotechnology products. To this end, greater use of international regulatory cooperation and Mutual Recognition Agreements (MRAs) with trusted partners, particularly jurisdictions participating in the Pharmaceutical Inspection Co-operation Scheme (PIC/S), can support robust patient access and faster availability for patients, strengthen supply chain resilience, support Union exporters, facilitate investment and scale-up within the Union, and allow regulatory authorities to focus resources on higher-risk activities, while maintaining the Union's high standards of quality, safety and public health protection.

Or. en

(See wording in the proposed Article 21a on "Establishing the Single European Regulatory Space: International Regulatory Cooperation and Mutual Recognition for Biotechnology Supply Chains")

Justification

The EU has in part relied on the US FDA for GMP inspections which is not sustainable going forward. To strengthen EU patient access to medicines and ensure the robustness of Union supply chains, it is essential for the EU medicines regulator to work more closely with partners such as the UK and Switzerland.

Amendment 444
Aurelijus Veryga

Proposal for a regulation
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4b) It is essential to strengthen the Union's capacity to innovate in biotechnology and support investment, research and development. Such efforts should enable the discovery, development and timely availability of safe and effective new therapies. In particular, Union measures under this Act should facilitate innovation, including that which addresses unmet needs, so that scientific and industrial progress translates into meaningful improvements for patients.

Or. en

Amendment 445
Aurelijus Veryga

Proposal for a regulation
Recital 4 c (new)

Text proposed by the Commission	*Amendment*
	(4c) Technologies, platforms, and manufacturing know-how developed to deliver orphan medicinal products often have broader applicability and can, in relatively short timeframes, be leveraged to discover therapies for more prevalent conditions. By de-risking novel modalities and building regulatory, clinical and production capabilities in smaller patient populations, such innovation can create transferable tools and evidence that accelerate subsequent development for major diseases. Supporting orphan medicine innovation should therefore be recognised not only for its direct benefit to people with rare conditions, including the

94% without a dedicated treatment, but also for its wider contribution to the Union's capacity to deliver new therapies across public health priorities.

Or. en

Amendment 446
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation focusses on, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should extend to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 TFEU on the protection of public health.	(5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation focusses on, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should extend to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 TFEU on the protection of public health***, as well as Article 191 TFEU aiming at a high level of protection of the environment and human health in line with the one health approach and precautionary principle***.

Or. en

Amendment 447
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Given the importance of health biotechnology amongst the other	(5) Given the importance of health biotechnology amongst the other

applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation ***focusses on***, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should ***extend*** to health biotechnology ***in a comprehensive manner and*** cover health within the wide meaning of Article 168 TFEU on the protection of public health.	applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation ***establishes a broad framework for biotechnology and biomanufacturing in the Union***, and sets out***, as a particular priority within that framework,*** specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should ***not be limited*** to health biotechnology ***and should in particular*** cover health within the wide meaning of Article 168 TFEU on the protection of public health.

Or. en

Amendment 448
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation focusses on, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should extend to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 TFEU on the protection of public health.	(5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation focusses on, and sets out specific measures for, the health dimension of biotechnology. To ensure the effectiveness of this Regulation, its scope of application should extend to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 TFEU on the protection of public health***, in line with the One Health Approach***.

Or. en

Amendment 449
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation ***focusses on, and sets out specific measures for,*** the health dimension of biotechnology***. To ensure the effectiveness of this Regulation, its scope of application should extend to health biotechnology in a comprehensive manner and cover health within the wide meaning of Article 168 TFEU on*** the protection of public health.	(5) Given the importance of health biotechnology amongst the other applications of biotechnology as referred to in recital (1), it is appropriate that this Regulation ***focuses exclusively on*** the health dimension of biotechnology***, in view of its contribution to*** the protection of public health ***pursuant to Article 168 TFUE. Accordingly, biotechnology intended for food and feed purposes should not fall within the scope of this regulation.***

Or. en

Amendment 450
Kateřina Konečná

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Biotechnology-derived medicinal products and advanced therapy medicinal products constitute the primary means of treatment for a substantial and growing proportion of persons living with chronic and long-term conditions in the Union. Diabetes, which affects approximately 34 million persons in the Union, illustrates this dependence: all modern insulin is produced using recombinant DNA technology; biosimilar insulins are among the most widely used biological medicines in Europe; and next-generation treatments for type 1 diabetes (including cell-based therapies that fall within the scope of Regulation (EC) No 1394/2007) are at advanced stages of clinical

development. Consistent with Article 168(1) of the Treaty on the Functioning of the European Union and Article 35 of the Charter of Fundamental Rights of the European Union, the substantive and procedural provisions of this Regulation should be implemented, monitored and evaluated having regard to their effects on the access, affordability and continuity of supply of biotechnology-derived medicinal products and advanced therapy medicinal products for persons living with chronic and long-term conditions across all Member States.

Or. en

Amendment 451
Margarita de la Pisa Carrión, András Gyürk, Viktória Ferenc, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Whereas this Regulation should be implemented in full respect of human dignity, fundamental rights and the ethical principles recognised by the Member States in accordance with their constitutional traditions and legal frameworks, as reflected in the Universal Declaration of Human Rights and the Universal Declaration on the Human Genome and Human Rights, adopted by UNESCO on 11 November 1997. Accordingly, the implementation of this Regulation should promote biotechnology exclusively for diagnostic and therapeutic purposes and should not promote or facilitate interventions intended for genetic enhancement, the selection of persons on the basis of their genetic characteristics or any modification of the human germline.

Or. en

Amendment 452
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Mental health conditions represent a major public health and socioeconomic burden in the Union and remain structurally underserved by innovation, investment and clinical development. Particular attention should therefore be paid, in the implementation of this Regulation, to health biotechnology innovations addressing mental health conditions, including where market failures, scientific complexity, fragmented delivery pathways or regulatory uncertainty have slowed the development and scale-up of new solutions.

Or. en

Amendment 453
Aurelijus Veryga

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Mental health conditions represent a major public health and socioeconomic burden in the Union and remain structurally underserved by innovation, investment and clinical development. Particular attention should therefore be paid, in the implementation of this Regulation, to health biotechnology innovations addressing mental health conditions, including where market

failures, scientific complexity, fragmented delivery pathways or regulatory uncertainty have slowed the development and scale-up of new solutions.

Or. en

Amendment 454
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Regulatory frameworks, including this Regulation, should maintain a technology-neutral approach to medical technologies and foster synergies across the entire pharmaceutical sector. Innovation should be incentivized based on its scientific complexity and therapeutic potential, irrespective of whether it is derived from biotechnological or chemical processes.

Or. en

Amendment 455
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 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Regulatory frameworks, including this Regulation, should maintain a technology-neutral approach to medical technologies and foster synergies across the entire pharmaceutical sector. Innovation should be incentivized based on its scientific complexity and

therapeutic potential, irrespective of whether it is derived from biotechnological or chemical processes.

Or. en

Amendment 456
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) Synthetic cells are an emerging technology with significant potential for medicine, diagnostics and industry. This Regulation should therefore ensure that synthetic cells can benefit from financial support, regulatory sandboxes and strategic-project status.

Or. en

Justification

Synthetic cells are engineered, cell-like systems programmed to perform a defined task, such as targeted drug delivery, biosensing or biochemical production. They are a fast-advancing field of health biotechnology in which the United States and China are investing heavily, yet the Regulation does not mention them. To develop them, the Union needs to provide financial support, regulatory sandboxes and strategic-project status with faster permitting.

Amendment 457
Margarita de la Pisa Carrión, Aleksandar Nikolic, Laurent Castillo, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 5 b (new)

Text proposed by the Commission	*Amendment*
	(5b) The rapid pace of scientific and technological progress in biotechnology may lead to the emergence of novel

applications with ethical implications that require continuous oversight and periodic assessment throughout their lifecycle. Such assessment should be conducted in full respect to the competence of Member States to ensure compliance with their national legal and ethical requirements.

Or. en

Amendment 458
Margarita de la Pisa Carrión, Paolo Borchia, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 5 c (new)

Text proposed by the Commission	*Amendment*
	(5c) Regulatory frameworks, including this Regulation, should maintain a technology-neutral approach to medical technologies and foster synergies across the entire pharmaceutical sector. Innovation should be incentivized based on its scientific complexity and therapeutic potential, irrespective of whether it is derived from biotechnological or chemical processes.

Or. en

Amendment 459
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) Article 168(1) TFEU emphasises that a high level of human health protection is to be ensured when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies	(6) Article 168(1) TFEU emphasises that a high level of human health protection is to be ensured when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies

that this objective is, amongst others, to be pursued through measures setting high standards of quality and safety for medicinal products and devices for medical use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health.

that this objective is, amongst others, to be pursued through measures setting high standards of quality and safety for medicinal products and devices for medical use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health. ***In this context, the respect of precautionary principle, enshrined in Article 191(2) TFEU is of paramount importance, as it requires that where scientific uncertainty exists regarding potential risks to human health, preventive measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent. This principle empowers Union institutions and Member States to act proactively to avoid or minimise threats to public health, even in the absence of conclusive scientific evidence, provided that the measures adopted are proportionate, non-discriminatory, and subject to review in light of new scientific developments.***

Or. en

Amendment 460
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) Article 168(1) TFEU emphasises that a high level of human health protection is to be ensured when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies that this objective is, amongst others, to be pursued through measures setting high standards of quality and safety for medicinal products and devices for medical	(6) Article 168(1) TFEU emphasises that a high level of human health protection is to be ensured when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies that this objective is, amongst others, to be pursued through measures setting high standards of quality and safety for medicinal products and devices for medical

use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health.

use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health. ***Furthermore, mental health conditions remain structurally underserved by innovation, investment and clinical development. Particular attention should therefore be paid where relevant, in the implementation of this Regulation, to biotechnology innovations addressing mental health conditions, where market failures, scientific complexity, fragmented delivery pathways or regulatory uncertainty have slowed the development and scale-up of safe, effective and accessible solutions.***

Or. en

Amendment 461
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(6) Article 168(1) TFEU emphasises that a high level of human health protection is to be ensured when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies that this objective is, amongst others, to be pursued through measures setting high standards of quality and safety for medicinal products and devices for medical use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health.	(6) Article 168(1) TFEU emphasises that a high level of human health protection***, to be understood as part of One Health,*** is to be ensured when defining and implementing all Union policies and activities. Article 168(4) TFEU clarifies that this objective is, amongst others, to be pursued through measures setting high standards of quality and safety for medicinal products and devices for medical use and of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health. ***This may include, where duly justified, novel pharmacological***

approaches requiring structured therapeutic support, appropriate patient monitoring, long-term follow-up and high standards of safety, ethics and professional supervision.

Or. en

Amendment 462
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] , this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.	(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems***[1]***, this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. ***Significant proportion of emerging health threats originates from animal sources, including a large proportion of pathogens with potential bioterrorist use, underlining the need to strengthen integrated research, surveillance, early-warning and preparedness capacities across the Union.*** This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities. ***In the context of biotechnology, particularly in the area of health, the Union should strengthen structured cooperation between relevant Union bodies established under Union law, including EMA, ECDC, EFSA, ECHA, EEA, EDA, EU-OSHA and***

EURL ECVAM, notably through a Cross-Agency One Health Task Force. Such cooperation should include collaboration in the context of the One Health approach and the human exposome approach, better connect human health, animal health, food safety, the environment, biosecurity and biodefence, support coherent scientific advice, data and information exchange, interoperable formats, early warning and preparedness, and promote relevant scientific methodologies, including non-animal approaches, while ensuring that biotechnology innovation is assessed in light of its health, environmental, security and societal impacts

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[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/8697309.

Or. en

Amendment 463
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ***ecosystems[1]*** , this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the	(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ***ecosystems1***, this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the

development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.

development of biotechnology products and services. ***The One Health approach is particularly relevant for biotechnology, as human health is closely interconnected with animal health, plant health, food systems and the environment, whereas antimicrobial resistance is a major One Health threat and is responsible for more than 35 000 deaths every year in the EU/EEA. Resistant bacteria can emerge, circulate and spread across humans, animals, food-production systems, soil, water and ecosystems. Supporting biotechnology companies and manufacturing capacities with expertise across human and animal health can strengthen Union resilience, improve preparedness, support responsible innovation and enhance the Union's capacity to respond to cross-species biological threats.*** This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.

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[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/869730 9 .

Or. en

Amendment 464
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*

(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] , this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.	(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1], this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products***,*** ***technological platforms*** and services. This Regulation should apply to their entire lifecycle ***(during patent monopolies, exclusivity periods and in a multi-source competitive setting)*** , including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities. ***Particular attention shall also be given to ensuring equitable access to such health technologies across Europe, with a view to reducing disparities between Member States and among patients in general.***
[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/869730 9 .	***[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/869730 9 .***

Or. en

Justification

Biotechnology medicinal products can represent essential innovations for the treatment of many diseases and have the potential to significantly improve patient outcomes while addressing current unmet medical needs, in particular in the field of rare diseases and rare cancers. Therefore, while we acknowledge that biotechnology and biomanufacturing have been identified as strategic areas for Europe's competitiveness and leadership in the development of innovative treatments and diagnostic tools, it is essential to ensure that improving public health and addressing patients' needs remain at the core of the Act's objectives and ensuring that resulting innovations are accessible, affordable and can effectively answer to patients' needs across the Union.

Amendment 465
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] , this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.	(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] , this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities. ***Particular attention shall also be given to ensuring equitable access to such health technologies across the European Union, with a view to reducing disparities between Member States and among patients in general.***
[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/8697309 .	[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/8697309 .

Or. en

Amendment 466

Margarita de la Pisa Carrión, Paolo Borchia, Ondřej Knotek, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) ***Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] ,*** this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.	(7) This Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.

[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/869730 9 .

Or. en

Amendment 467
Ingeborg Ter Laak

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Accordingly, and in line with the	(7) Accordingly, and in line with the

One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] ***, this Regulation should apply to health biotechnology,*** understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.	One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities. ***In its application to health biotechnology, it should thereby contribute to tangible benefits for patients throughout the Union.***
[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/8697309 .	[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/8697309 .

Or. en

Amendment 468
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] , this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the	(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] , this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the

development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.

development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market***, clinical implementation, patient access*** and use activities.

[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/8697309 .

[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/8697309 .

Or. en

Amendment 469
András Tivadar Kulja

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] , this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.	(7) Accordingly, and in line with the One Health approach, that aims to comprehensively and sustainably balance and optimise the health of people, animals, and ecosystems[1] , this Regulation should apply to health biotechnology, understood as the application of biotechnology in the human medical, veterinary, pharmaceutical and phytosanitary areas for the development of biotechnology products***, technological platforms*** and services. This Regulation should apply to their entire lifecycle, including the related research, access to funding, development, innovation, testing, validation, manufacturing, placing on the market and use activities.

[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/8697309 .

[1] European Commission: Group of Chief Scientific Advisors and Directorate-General for Research and Innovation, One Health governance in the European Union, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/8697309 .

Or. en

Amendment 470
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) This Regulation should contribute to a fifth freedom and support the development, where appropriate, of an optional 28th regime for innovative biotechnology actors, particularly in health, in order to reduce fragmentation, accelerate responsible innovation and ensure that patients and health systems across the Union can benefit from scientific progress, as a stronger European Health Union requires that scientific knowledge, health data, clinical expertise and biotechnology innovation can circulate more effectively across the Union.

Or. en

Amendment 471
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) Union leadership in clinical research and biotechnology competitiveness requires clinical trial frameworks that work for academic, hospital and non-profit sponsors, recognise innovative trial designs and rely on a fully functional Union digital infrastructure. In parallel, the Clinical Trials Information System should be made fully interoperable with national regulatory and ethics systems, the European Health Data Space and ERN-associated registries,

Or. en

Amendment 472
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 7 b (new)

Text proposed by the Commission	*Amendment*
	(7b) Advanced therapy medicinal products prepared under the hospital exemption play an important role in enabling access for patients with high unmet medical needs, in particular, but not only, in rare, ultra-rare and paediatric conditions where centrally authorised therapies are not available or where commercial development is limited. The implementation of the hospital exemption should continue to ensure a high level of quality, safety, pharmacovigilance and patient protection, while preserving its patient-specific nature as a national derogation from the marketing authorisation framework. Without prejudice to the hospital exemption regime laid down in Union pharmaceutical law, to the competences of Member States under Article 168(7)

TFEU, and to the institutional balance agreed in the pharmaceutical reform, Union action in the field of biotechnology may support cooperation between Member States, exchange of best practices, evidence generation and transparency, with a view to strengthening patient safety, supporting academic and hospital-based innovation, and improving equitable access to advanced therapies.

Or. en

Amendment 473
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 7 b (new)

Text proposed by the Commission	*Amendment*
	(7b) This is particularly important for rare diseases, defined as affecting not more than five persons per 10,000 in Regulation (EC) No 141/2000, and ultra-rare diseases, defined as debilitating and often life-threatening diseases affecting no more than one person in 50,000 in Regulation (EU) No 536/2014. In this context, the implementation of this Regulation should, where appropriate and necessary, involve European Reference Networks (ERNs) and other specialised cross-border clinical and research infrastructures in activities related to research coordination, patient identification, evidence generation, registry governance, and long-term follow-up.

Or. en

Amendment 474
Marie Toussaint, Ville Niinistö

on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) With a view to ensuring the effectiveness, consistence and unity of some of the legal acts that this Regulation should amend to foster the Union's competitiveness in biotechnology, this Regulation should in certain cases also apply to products and activities other than biotechnology products and activities, so as to avoid the creation of different sets of rules for biotechnology and non-biotechnology products and activities. This is in particular the case in the area of health for Union legislation regarding clinical trials, and in the food and feed safety area, for Regulation (EC) No 178/2002 of the European Parliament and of the Council[2] .	***deleted***

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1. ELI: http://data.europa.eu/eli/reg/2002/178/oj.

Or. en

Amendment 475
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*

(8a) Environmental biotechnology and biomanufacturing can contribute to the Union's environmental, climate and circular economy objectives by supporting pollution prevention and remediation, biodiversity protection, resource efficiency, sustainable bio-based production, climate adaptation and the reduction of greenhouse gas emissions, including methane. Such applications should be supported where they are evidence-based, safe and consistent with Union environmental law, the precautionary principle, the do no significant harm principle and the Union's 2030, 2040 and 2050 climate objectives. Support for environmental biotechnology under this Regulation should not be understood as replacing the need for direct emission reductions, nature restoration, pollution prevention or compliance with existing Union environmental and climate obligations, but as complementing them through responsible innovation.

Or. en

Amendment 476
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) In order to ensure coherence with Union pharmaceutical legislation and the Critical Medicines Act, the implementation of this Regulation should take into account the specific characteristics of pharmaceutical and health biotechnology supply chains. Such supply chains may differ depending on the product, technology, process and starting materials involved, including as regards biological substances, critical

intermediates and key inputs, manufacturing processes, quality and batch controls, storage, logistics and regulatory requirements. These specificities should be reflected, where relevant, when assessing capacities, dependencies and systemic challenges across the Union's biotechnology and biomanufacturing value chains.

Or. en

Amendment 477
Ondřej Knotek, Viktória Ferenc, Marie-Luce Brasier-Clain, Valérie Deloge, Laurent Castillo, Aleksandar Nikolic, András Gyürk, Margarita de la Pisa Carrión

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) In order to ensure coherence with Union pharmaceutical legislation and the Critical Medicines Act, the implementation of this Regulation should take into account the specific characteristics of pharmaceutical and health biotechnology supply chains. Such supply chains may differ depending on the product, technology, process and starting materials involved, including as regards biological substances, critical intermediates and key inputs, manufacturing processes, quality and batch controls, storage, logistics and regulatory requirements. These specificities should be reflected, where relevant, when assessing capacities, dependencies and systemic challenges across the Union's biotechnology and biomanufacturing value chains

Or. en

Amendment 478

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

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) In order to ensure coherence with Union pharmaceutical legislation and the Critical Medicines Act, the implementation of this Regulation should take into account the specific characteristics of pharmaceutical and health biotechnology supply chains. Such supply chains may differ depending on the product, technology, process and starting materials involved, including as regards biological substances, critical intermediates and key inputs, manufacturing processes, quality and batch controls, storage, logistics and regulatory requirements. These specificities should be reflected, where relevant, when assessing capacities, dependencies and systemic challenges across the Union's biotechnology and biomanufacturing value chains.

Or. en

Justification

Pharmaceutical and health biotechnology supply chains are not uniform and may differ significantly depending on the nature of the product, technology, process and starting materials involved. Recognising these specificities is necessary to ensure that future mapping, policy support and resilience measures accurately reflect the operational and regulatory realities of biotechnology and pharmaceutical value chains.

Amendment 479
Ondřej Krutílek

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) In order to ensure coherence with

Union pharmaceutical legislation and the Critical Medicines Act, the implementation of this Regulation should take into account the specific characteristics of pharmaceutical and health biotechnology supply chains. Such supply chains may differ depending on the product, technology, process and starting materials involved, including as regards biological substances, critical intermediates and key inputs, manufacturing processes, quality and batch controls, storage, logistics and regulatory requirements. These specificities should be reflected, where relevant, when assessing capacities, dependencies and systemic challenges across the Union's biotechnology and biomanufacturing value chains.

Or. en

Amendment 480
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 8 b (new)

Text proposed by the Commission	*Amendment*
	(8b) In order to strengthen prevention-oriented biotechnology and health innovation, this Regulation should take into account the exposome, understood as the totality of environmental, occupational, dietary, social, biological and lifestyle-related exposures that may influence human health across the life course. Exposome-informed research and innovation can improve understanding of disease pathways, health inequalities, antimicrobial resistance, toxic exposures, climate-sensitive disease risks and the interaction between genetic, environmental and social determinants of health. Biotechnology, health data,

biomonitoring, advanced analytics and NAMs may support more precise, human-relevant and prevention-oriented evidence generation, provided that such approaches comply with Union law on data protection, non-discrimination, ethics and environmental protection.

Or. en

Amendment 481
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 8 c (new)

Text proposed by the Commission	*Amendment*
	(8c) Biotechnology, particularly in the area of health, should support the transition towards the 4P paradigm of healthcare: predictive, preventive, personalised and participatory medicine. This paradigm aims to anticipate disease risk through genomic, molecular and biomarker-based data; intervene before the onset or progression of disease; tailor diagnosis, prevention and therapy to the individual biology and needs of patients; and empower patients as active partners in their own care and in the responsible use of their health data. In line with this approach, biotechnology should not only advance scientific innovation, but also contribute to affordable, available and accessible medicines and treatments across the Union, ensuring that innovation translates into concrete and equitable health benefits for patients and health systems.

Or. en

Amendment 482

Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council[4] on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council[5] .	(10) This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council[4] on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council[5] . ***Directive 2010/63/EU sets the goal of full replacement of procedures on live animals for scientific and educational purposes as soon as scientifically possible, while applying the principles of replacement, reduction and refinement. In line with that objective, and taking into account the Commission roadmap towards phasing out animal testing, this Regulation should support the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs), where scientifically appropriate. Such methodologies, including human-based in vitro systems, organoids, organ-on-chip technologies, computational modelling and other advanced non-animal methods, can contribute to more predictive, human-relevant and efficient evidence generation in biotechnology, particularly in the area of health. Their use should not lower applicable standards of safety, quality, efficacy, ethics, environmental protection or scientific scrutiny.***
[4] Consolidated text: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). ELI: http://data.europa.eu/eli/dir/2010/63/2019-06-26	[4] Consolidated text: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). ELI: http://data.europa.eu/eli/dir/2010/63/2019-06-26
[5] Consolidated text: Regulation (EC) No	[5] Consolidated text: Regulation (EC) No

1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI: http://data.europa.eu/eli/reg/2006/1907/2025-09-01.	1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI: http://data.europa.eu/eli/reg/2006/1907/2025-09-01.

Or. en

Amendment 483
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council[4] on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council[5] .	(10) This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council***[4]*** on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council***[5]***. ***This Regulation should therefore support pilot projects and demonstration projects that test NAMs regulatory, scientific and industrial applicability in biotechnology, particularly in the area of health. Such support should cover human-relevant in vitro, in silico, organoid, microphysiological, computational and integrated testing approaches, as well as training, data infrastructures, reference datasets, standardisation activities and cooperation with regulators. Their use***

can also support faster research and development timelines and provide a deeper mechanistic understanding of biological processes, disease pathways, toxicity, immunogenicity and pharmacodynamics. This is particularly relevant where traditional animal models have limited predictive value for human outcomes, as 90 % of drugs that appear safe and effective in animals do not proceed to approval in humans, predominantly due to safety or efficacy issues

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[4] Consolidated text: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). ELI: http://data.europa.eu/eli/dir/2010/63/2019-06-26

[5] Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI: http://data.europa.eu/eli/reg/2006/1907/2025-09-01.

Or. en

Amendment 484
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) This Regulation should not affect ***to*** the application of the Directive 2010/63/EU of the European Parliament and of the ***Council***[4] on the protection of animals used for scientific purposes and of Regulation (EC) ***2006/1907*** of the European Parliament and of the ***Council***[5] .	(10) This Regulation should not affect the application of the Directive 2010/63/EU of the European Parliament and of the ***Council4*** on the protection of animals used for scientific purposes and of Regulation (EC) ***No 1907/2006*** of the European Parliament and of the ***Council5. Directive 2010/63/EU sets the long-term goal of fully replacing procedures on live animals for scientific and educational purposes as soon as scientifically possible, while applying the principles of replacement, reduction and refinement. In line with that objective measures under this Regulation should ensure that biotechnology innovation actively contributes to the implementation of those Union objectives and principles. This Regulation should therefore support the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs), where scientifically appropriate.***

[4] Consolidated text: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). ELI: http://data.europa.eu/eli/dir/2010/63/2019-06-26

[5] Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI:

http://data.europa.eu/eli/reg/2006/1907/2025-09-01.

Or. en

Amendment 485
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(10) This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council[4] on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council[5] .	(10) This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council[4] on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council[5] . ***In line with the objective of the Directive 2010/63/EU and taking into account the Commission Roadmap towards phasing out animal testing, this Regulation should support the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs). These methodologies can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D) cell culture models, organoids and human stem cells-based models; in silico tools, in chemico technologies and any combination thereof or read-across models. Ultimately, efforts should be made to fully replace procedures on live animals for scientific purposes.***
[4] Consolidated text: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). ELI:	[4] Consolidated text: Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance). ELI:

http://data.europa.eu/eli/dir/2010/63/2019-06-26	http://data.europa.eu/eli/dir/2010/63/2019-06-26
[5] Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI: http://data.europa.eu/eli/reg/2006/1907/2025-09-01.	[5] Consolidated text: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance). ELI: http://data.europa.eu/eli/reg/2006/1907/2025-09-01.

Or. en

(See Directive 2010/63/EU on the protection of animals used for scientific purposes)

Justification

This amendment ensures coherence between the European Biotech Act, Directive 2010/63/EU on the protection of animals used for scientific purposes, the Regulation on the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, and the Commission Roadmap towards phasing out animal testing. Supporting the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs) will strengthen the EU biotechnology sector by promoting more human-relevant, innovative and predictive approaches to research, testing and product development.

Amendment 486
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Recital 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) The competitiveness of the Union's pharmaceutical sector, including biotechnology and biomanufacturing sectors, and more broadly the security of supply of medicinal products, depend on a

predictable and coherent regulatory environment across Union policies and on the principle of technological neutrality. Measures adopted under Regulation (EC) No 1907/2006 may affect substances, materials, container and delivery systems, single-use systems and manufacturing equipment that are essential to the research, development, manufacture, packaging or supply of medicinal products, including, but not limited to, those derived from biotechnology. Any such measures should take due account of the specificities of the pharmaceutical sector, such as the complexity and length of substitution processes, the long development and supply timelines, the potential impact on patients and the continuity of treatment, and the benefit-risk assessment carried out by the European Medicines Agency. With a view to reducing administrative burden and to simplifying and streamlining the relevant procedures, concerning pharmaceutical sector, including biotechnology and biomanufacturing sectors, the Commission should explore solutions for the better and proper implementation of Regulation (EC) No 1907/2006. To that end, the Commission should assess the most appropriate modalities or instruments, of introducing, in the authorisation and restriction titles of that Regulation, a derogation for substances used in the development, manufacture and supply of medicinal products, irrespective of the technology or production process employed, covering also product and process orientated research and development (PPORD) activities so as to support the Union innovation ecosystem.

Or. en

Amendment 487
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) The Union has adopted other initiatives to strengthen the competitiveness of particular sectors of the Union economy. In this regard, Regulation (EU) 2024/1735 of the European Parliament and of the Council[6] focuses on clean and resource-efficient technologies which include, in particular, net-zero technologies. That Regulation establishes a framework to ensure the Union's access to a secure and sustainable supply of net-zero technologies listed in Article 4 thereof. Such technologies include sustainable biogas and biomethane technologies and biotechnology climate and energy solutions. However, as acknowledged by Regulation (EU) 2024/795 of the European Parliament and of the Council[7] , biotechnologies have applications beyond the clean and resource-efficient technologies. It is therefore appropriate that this Regulation applies without prejudice to the provisions of Regulation (EU) 2024/1735 regarding sustainable biogas and biomethane technologies and biotechnology climate and energy solutions.	(11) The Union has adopted other initiatives to strengthen the competitiveness of particular sectors of the Union economy. In this regard, Regulation (EU) 2024/1735 of the European Parliament and of the Council[6] focuses on clean and resource-efficient technologies which include, in particular, net-zero technologies. That Regulation establishes a framework to ensure the Union's access to a secure and sustainable supply of net-zero technologies listed in Article 4 thereof. Such technologies include sustainable biogas and biomethane technologies and biotechnology climate and energy solutions. However, as acknowledged by Regulation (EU) 2024/795 of the European Parliament and of the Council[7] , biotechnologies have applications beyond the clean and resource-efficient technologies. It is therefore appropriate that this Regulation applies without prejudice to the provisions of Regulation (EU) 2024/1735 regarding sustainable biogas and biomethane technologies and biotechnology climate and energy solutions. ***The Union already demonstrates a strong research base in life sciences, accounting for around 52 % of European Research Council funding and 40 % of European Innovation Council investment; however, this strength is not sufficiently translated into industrial competitiveness, scale-up capacity and market uptake in the Union, pointing to a persistent gap between research excellence and economic impact.***
[6] Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe's	[6] Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe's

net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724 (Text with EEA relevance), OJ L 1735 28.6.2024, p. 1. ELI: http://data.europa.eu/eli/reg/2024/1735/oj.

[7] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241 (OJ L, 2024/795, 29.2.2024. ELI: http://data.europa.eu/eli/reg/2024/795/oj).

net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724 (Text with EEA relevance), OJ L 1735 28.6.2024, p. 1. ELI: http://data.europa.eu/eli/reg/2024/1735/oj.

[7] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241 (OJ L, 2024/795, 29.2.2024. ELI: http://data.europa.eu/eli/reg/2024/795/oj).

Or. en

Amendment 488
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Martin Hojsík

Proposal for a regulation
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) Antimicrobial resistance constitutes one of the most serious cross-border threats to the Union's health security and represents a structural market failure that has been recognised in the European One Health Action Plan against Antimicrobial Resistance (2017), the Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (2023/C 220/01), and successive Council conclusions. The Union's strategy to address antimicrobial resistance combines targeted incentives at the pharmaceutical level, including the transferable data exclusivity voucher introduced under Union legislation on medicinal products for human use, with industrial and

manufacturing measures necessary to ensure that priority antimicrobials can be discovered, developed, scaled up and manufactured within the Union. This Regulation contributes to that integrated approach by ensuring that antimicrobial technologies, processes and products are fully eligible under its definitions, strategic project framework, financial instruments, intellectual property provisions and biodefence provisions, thereby strengthening the Union's public health, preparedness, strategic resilience and competitiveness via investment in biotechnology innovation and biomanufacturing.

Or. en

Justification

The introduction of a dedicated recital recognising antimicrobial resistance as a structural market failure within the scope of this Regulation ensures that the operational provisions (in particular the definitions in Article 2, the strategic project framework in Articles 3 and 4, the financial instruments in Chapter III, the intellectual-property mechanism in Chapter IV and the biodefence provisions in Chapter VIII) are interpreted in coherence with the integrated AMR strategy at Union level. This recital is designed to remain operative across successive Council recommendations and to anchor the Regulation to the broader Union policy framework on health security and preparedness.

Amendment 489
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) Biotechnology strategic projects should pursue the general objectives of reducing fragmentation within the Union, in particular regulatory fragmentation, increasing manufacturing capacity, stimulating innovation and facilitating cross-border collaboration and the circulation of research, innovation, knowledge and data within the Union.

While such projects should cover biotechnology and biomanufacturing more broadly, particular attention should be given to the area of health, in line with the objectives of this Regulation.

Or. en

Amendment 490
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Martin Hojsík

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. ***With*** a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission ***could*** issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital ***platforms. In particular, projects advancing NAMs should be prioritised, given their potential to improve the human relevance, addressing genetic diversity and enabling better representation of underserved populations, including women, elderlies and different ethnicities, improving efficiency and translational value of biomedical research and safety assessment.*** Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. ***Those criteria should include, where relevant, the contribution to the development,***

authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.	***validation, standardisation and regulatory acceptance of NAMs. With*** a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission ***shall*** issue guidance on the application of those criteria***, including on what constitutes a substantial contribution for the purposes of Article 3***. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. ***For NAM-based innovations, such support should also facilitate early engagement with regulatory authorities and promote pathways for their integration into regulatory frameworks.*** It would thus strengthen their capacity to scale biotechnology innovations faster. For ***public authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.***

Or. en

Justification

While NAMs are mentioned here, their strategic importance for innovation and regulatory transformation is not sufficiently reflected. Strengthening their prioritisation and explicitly linking them to validation and regulatory uptake would help ensure that EU support mechanisms effectively enable their development, acceptance and integration into biomedical and safety assessment pipelines.

Amendment 491
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted	(12) Health biotechnology strategic projects should serve as targeted

instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects ***would*** deliver ***clear*** benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, ***supporting sustainable and affordable access to biological medicinal products,*** scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms***, while delivering clear European added value and contributing to the public interest***. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition ***ensuring that only projects demonstrating sufficient strategic relevance and public value are recognised. Recognition of health biotechnology strategic projects should be based on a balanced assessment of their contribution to the Union's competitiveness, resilience, strategic autonomy and societal objectives, including public health needs, sustainability and access considerations***. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects ***should*** deliver ***targeted*** benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support***, where justified by their strategic contribution and public value***. It would thus strengthen their capacity to scale biotechnology innovations ***that deliver European added value and address critical needs*** faster. For authorities, the framework streamlines coordination, avoids duplication of

assessments, and supports consistent, efficient decision-making. ***Recognition and support of such projects should be conditional on compliance with Union requirements relating to environmental protection, biosafety, biosecurity, animal welfare, occupational safety, data protection and ethical standards, and should not entail any lowering of those standards.***

Or. en

Justification

While strengthening Europe's industrial biotech sector is a key priority, it should not come at the expense of the long-term sustainability of public healthcare financing or timely and affordable patient access. Competitiveness and innovation should therefore be pursued alongside explicit objectives on access and affordability.

Amendment 492
Christine Anderson

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) ***Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to*** the Union's biotechnology ***objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation*** should ***lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for***	(12) ***The competitiveness of*** the Union's biotechnology ***sector*** should ***be strengthened by*** reducing ***unnecessary*** administrative ***burdens, simplifying procedures***, improving legal certainty and ***ensuring predictable regulatory pathways for all*** biotechnology ***innovators. Simplification measures should not be limited to a small number of administratively selected lighthouse projects***, ***but should benefit the whole biotechnology ecosystem, in particular SMEs, start-ups and scale-ups***.

such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative ***burden***, improving legal certainty and ***facilitating access to financial support. It would thus strengthen their capacity to scale*** biotechnology ***innovations faster. For authorities***, ***the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making***.

Or. en

Amendment 493
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology ***and public health*** objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms ***across the entire life-cycle and by effectively addressing patients' unmet needs, by promoting the research and development of products that truly bring added value to***

to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support**.** It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.	***patients' care and ultimately improve equitable access across Member States***. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria ***shall adopt guidance setting out transparent and measurable criteria for such recognition and support, with a view to ensuring added value for the Union's competitiveness, healthcare systems, and the patient community. Prior to the adoption of such acts, the Commission shall ensure that patient representatives are consulted***. Recognition of health biotechnology strategic projects **,**would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

Or. en

Justification

For optimal impact, the Biotech Act I (health) needs to recognise the different stages of the lifecycle of products and technologies (from monopoly to multi-source, after expiry of intellectual property rights - IPRs) and the fact that at each stage, value can be added through innovation or other health benefits.

Amendment 494
Ingeborg Ter Laak

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making. ***Effective implementation of this Regulation should further be supported through structured coordination between the Commission, the Member States and relevant Union agencies, expert groups and advisory bodies. Such coordination should facilitate the exchange of information and best practices, promote coherent implementation across the Union and support the timely translation and uptake of biotechnology innovation. In the area***

of health biotechnology, it should thereby contribute to earlier and more equitable access for patients to innovative medicinal products.

Or. en

Amendment 495
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects ***based on clearly defined European criteria that facilitate the fastest possible market launch of innovative products and technologies*** would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial

coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

support. It would thus strengthen their capacity to scale biotechnology innovations faster ***and put research and innovation results to use for the benefit of the economy and society***. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

Or. ro

Amendment 496
Viktória Ferenc, András Gyürk

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden,	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms ***across the entire lifecycle (during patent monopolies, exclusivity periods and in a multi-source competitive setting)***. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects***,***

improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.	***including those involving European (EEA, CH, UK) and international cooperation,*** would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

Or. en

Amendment 497
Dimitris Tsiodras

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms ***across the entire lifecycle (during patent monopolies, exclusivity periods and in a multi-source competitive setting)***. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view

application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects***, including those involving European (EEA, CH, UK) and international cooperation,*** would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

Or. en

Justification

For optimal impact, the Biotech Act I (health) needs to recognise the different stages of the life-cycle of products and technologies (from monopoly to multi-source, after expiry of intellectual property rights - IPRs) and the fact that at each stage, value can be added through innovation or other health benefits. It also needs to consider the full European biotech ecosystem and established synergies, both geographically (beyond the EU Member States) and across the value chain (research, development, manufacturing, commercialisation) and the life-cycle of products and technologies (during monopolies and multi-source markets).

Amendment 498
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other

relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms***, and by supporting resilient European manufacturing capacity in areas of high strategic value, including advanced therapies, biosimilars, radiopharmaceuticals and medical countermeasures***. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

Or. en

Amendment 499
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic	(12) Health biotechnology strategic

projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

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Or. en

Amendment 500

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 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors***, including university hospitals, academic medical centres, cross-border university hospital alliances and European clinical research infrastructures***. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

Or. en

Amendment 501
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms ***across the entire lifecycle (during patent monopolies, exclusivity periods and in a multi-source competitive setting).***. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

Or. en

Amendment 502
András Tivadar Kulja

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms ***across the entire lifecycle***. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

Or. en

Amendment 503
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by ***accelerating permitting,*** reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.	(12) Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions ***and conditions*** for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by reducing administrative burden ***where appropriate***, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making.

Or. en

Amendment 504
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) Advanced therapy medicinal products for rare diseases are often administered at a limited number of highly specialised centres, meaning that access for many patients may depend on treatment in a Member State other than that of affiliation. Where Member States so choose, voluntary joint procurement of orphan medicinal products under relevant Union instruments may improve availability for participating Member States and facilitate access to recognised centres of excellence for advanced therapies. Such access should take place in accordance with Directive 2011/24/EU and Regulation (EC) No 883/2004.

Or. en

Amendment 505
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) Health biotechnology strategic projects recognised under this Regulation should be considered in the context of the broader Union policy framework for competitiveness and capital markets, including the proposed Savings and Investments Union (SIU) and the forthcoming European Innovation Act. The recognition and support of such projects should be consistent with and

complementary to Union initiatives aimed at deepening capital markets, mobilising long-term institutional investment, and strengthening the innovation capacity of the Union's industrial base.

Or. en

Amendment 506
Christine Anderson

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) The Union should not repeat in biotechnology the errors made in other strategic technology sectors, where high ambitions were combined with over-regulation, excessive central planning and insufficient trust in entrepreneurs. Biotechnology competitiveness depends primarily on legal certainty, proportionate regulation, affordable energy, competitive taxation, private investment, strong property rights, open capital markets and entrepreneurial freedom.

Or. en

Amendment 507
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) In order to ensure that biotechnology strategic projects, high-impact biotechnology strategic projects and pan-European high-impact biotechnology strategic projects generate genuine Union added value, their

recognition should be based on transparent criteria.

Or. en

Amendment 508
Christine Anderson

Proposal for a regulation
Recital 12 b (new)

Text proposed by the Commission	*Amendment*
	(12b) The internal market requires competent authorities to avoid unnecessary duplication of studies, inspections, assessments and authorisations. Studies, assessments, inspections, permits, authorisations, certificates and opinions issued by a competent authority in one Member State should, as a rule, be recognised or relied upon by competent authorities in other Member States, unless a refusal is justified by material differences, site-specific conditions, new scientific evidence or substantiated concerns relating to safety, biosecurity, ethics, environmental protection or data protection.

Or. en

Amendment 509
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Recital 12 c (new)

Text proposed by the Commission	*Amendment*
	(12c) The deployment of health biotechnology should facilitate the development and uptake of personalised medicine through the appropriate

integration of biomarkers, companion diagnostics and advanced genomic technologies, while ensuring full compliance with Union legislation on data protection, artificial intelligence and, where applicable, the European Health Data Space.

Or. en

Amendment 510
Christine Anderson

Proposal for a regulation
Recital 12 c (new)

Text proposed by the Commission	*Amendment*
	(12c) Innovation cannot be planned ex ante by public authorities. The role of Union and national regulation should be to create a simple, predictable and non-discriminatory framework within which entrepreneurs, scientists, investors and patients can discover which technologies and business models succeed.

Or. en

Amendment 511
Christine Anderson

Proposal for a regulation
Recital 12 e (new)

Text proposed by the Commission	*Amendment*
	(12e) The use of health data, genetic data and other personal data in biotechnology may support research and innovation, but it must remain subject to Regulation (EU) 2016/679 and Regulation (EU) 2018/1725. Individual data sovereignty should be understood as the effective exercise by data subjects of

their rights under Regulation (EU) 2016/679, including transparency, purpose limitation, data minimisation, access, rectification, restriction, objection and, where processing is based on consent, the right to withdraw consent. Public-interest objectives in biotechnology shall not be interpreted as permitting generalised or open-ended processing of genetic data or data concerning health.

Or. en

Amendment 512
Christine Anderson

Proposal for a regulation
Recital 12 g (new)

Text proposed by the Commission	*Amendment*
	(12g) Nothing in this Regulation should be interpreted as authorising a weakening of informed consent, individual bodily autonomy, medical ethics, data protection, genetic privacy, the right to refuse participation in research or the right of Member States to maintain higher ethical safeguards in areas such as reproductive medicine, embryo research, human germline interventions and genetic testing.

Or. en

Amendment 513
Christine Anderson

Proposal for a regulation
Recital 12 i (new)

Text proposed by the Commission	*Amendment*
	(12i) Biotechnology is not an ordinary industrial sector. Where technologies

involve the human body, genetic identity, human biological material, reproductive medicine, embryo research, germline interventions or clinical trials, simplification of administrative procedures must not lead to deregulation of the human person.

Or. en

Amendment 514
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) NAMs applied in biological research, early discovery, preclinical development, and the regulatory and quality testing of medicinal products and medical technologies, have the potential to generate scientific and technological data that are comparable to, or in some cases more informative and generated ***more rapidly than***, those obtained through current standard methods. The resulting ***advantage*** will contribute to strengthen the innovation ecosystem and enhanced European competitiveness in biotechnology.	(13) NAMs applied in biological research, early discovery, preclinical development, and the regulatory and quality testing of medicinal products and medical technologies, have the potential to generate scientific and technological data that are comparable to, or in some cases more informative and generated ***faster than***, those obtained through current standard methods. ***Using these methods can help to cut costs, shorten research and development processes, make results easier to reproduce and more reliable, and launch innovative products on the market sooner. NAMs also support the transition to more sustainable and ethical research models by reducing reliance on animal testing and promoting approaches based on advanced technologies.*** The resulting ***advantages*** will contribute to strengthen the ***European*** innovation ecosystem***, to stimulate collaboration between academia, industry and regulatory authorities,*** and enhanced European ***Union*** competitiveness in biotechnology ***and life sciences***.

Or. ro

Amendment 515
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) NAMs applied in biological research, early discovery, preclinical development, and the regulatory and quality testing of medicinal products and medical technologies, have the potential to generate scientific and technological data that are comparable to, or in some cases more informative and generated more rapidly than, those obtained through current standard methods. The resulting advantage will contribute to strengthen the innovation ecosystem and enhanced European competitiveness in biotechnology.	(13) NAMs applied in biological research, early discovery, preclinical development, and the regulatory and quality testing of medicinal products and medical technologies***, such as advanced in vitro systems, microphysiological systems, and in silico approaches, where they are validated and can provide an equivalent predictive capacity as human and animal data***, have the potential to generate scientific and technological data that are comparable to, or in some cases more informative and generated more rapidly than, those obtained through current standard methods. The resulting advantage will contribute to strengthen the innovation ecosystem and enhanced European competitiveness in biotechnology. ***A close coordination with the Commission Roadmap towards phasing out animal testing, in order to ensure that the Union regulatory framework remains forward-looking and science-driven will be needed.***

Or. en

Amendment 516
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Martin Hojsík

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) NAMs applied in biological research, early discovery, preclinical	(13) NAMs applied in biological research, early discovery, preclinical

development, and the regulatory and quality testing of medicinal products and medical technologies, have the potential to generate scientific and technological data that are comparable to, or in some cases more informative and generated more rapidly than**,** those obtained through current standard methods. The resulting advantage will contribute to ***strengthen*** the innovation ecosystem and enhanced European competitiveness in biotechnology.	development, and the regulatory and quality testing of medicinal products and medical technologies, ***such as advanced in vitro systems, microphysiological systems, and in silico approaches,*** have the potential to generate scientific and technological data that are comparable to, or in some cases more informative***, robust, reproducible*** and generated more rapidly than those obtained through current standard methods. The resulting advantage will contribute to ***strengthening*** the innovation ecosystem and enhanced European competitiveness in biotechnology. ***Close coordination with the Commission Roadmap towards phasing out animal testing, in order to ensure that the Union regulatory framework remains forward-looking and science-driven, will be needed.***

Or. en

(See C(2026)3497 - Communication from the Commission - Roadmap towards phasing out animal testing for chemical safety assessments.)

Justification

This amendment provides examples of NAMs. In addition, reference to the European Commission Roadmap is provided to ensure consistency and coherent coordination.

Amendment 517
Aurelijus Veryga

Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission	*Amendment*
	(13a) Advanced diagnostics are next-generation molecular, cellular, multi-omic, and advanced imaging testing approaches used in clinical practice to generate clinically actionable information on the biological, genetic, epigenetic, and structural drivers of disease, with the aim of supporting more accurate

diagnosis, prognosis, patient stratification, therapy selection, and continuous longitudinal monitoring. They include, but are not limited to, high-throughput sequencing, comprehensive genomic and epigenomic profiling (such as DNA methylation), transcriptomics, proteomics, metabolomics, single-cell analysis, multi-marker liquid biopsies (including circulating cell-free nucleic acids and analytes), mass spectrometry, multiplex modalities, and advanced functional or molecular imaging technologies. This definition encompasses all current, evolving, and future analytical, imaging, and computational/artificial intelligence tools integrated into routine diagnostics, surveillance, disease tracking, and personalized medicine pathways to optimize patient care and long-term clinical monitoring.

Or. en

Amendment 518
Aurelijus Veryga

Proposal for a regulation
Recital 13 b (new)

Text proposed by the Commission	*Amendment*
	(13b) Significant innovation is also taking place in in vivo diagnostic modalities, including molecular imaging techniques such as positron emission tomography (PET) and single-photon emission computed tomography (SPECT) radiopharmaceuticals, as well as the development of novel structured contrast agents. These technologies can generate clinically actionable information and contribute to earlier diagnosis, improved treatment selection and more efficient healthcare delivery. In this context, radiopharmaceuticals, including

emerging therapeutic applications such as radioligand therapies (RLTs), illustrate the evolving continuum between diagnostics and treatment. In order to reflect scientific progress and ensure a comprehensive and future-proof approach, the development and use of such diagnostics, including molecular imaging, should be recognised as an integral part of the health biotechnology ecosystem.

Or. en

Amendment 519
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for regional biotechnology clusters and innovation ecosystems across Member States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment ***and*** strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular consideration for Union funding, priority access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8] provides measures for the support of	(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for regional biotechnology clusters and innovation ecosystems across Member States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment***,*** strengthen the Union's position in global value chains***, speed up the transfer of research results to clinical and commercial applications, facilitate the development and adoption of innovative technologies, and help to make healthcare systems more resilient by strengthening the Union's research, production and supply capacities***. ***They can also promote the development of skills in key fields and encourage cross-border collaboration, thereby helping to reduce innovation***

critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9], (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

disparities between Member States. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular consideration for Union funding, priority access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8] provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9], (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

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[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just

[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just

Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

Or. ro

Amendment 520
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for regional biotechnology clusters and innovation ecosystems across Member States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment and strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular	(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for regional biotechnology clusters and innovation ecosystems across Member States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment and strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular

consideration for Union funding, priority access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8] provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9] , (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

consideration for Union funding, priority access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8] provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9] , (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives. ***For projects with exceptional cross-border relevance and systemic Union added value, a further category of pan-European high-impact biotechnology strategic projects are established.***

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of

29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

Or. en

Amendment 521
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for regional biotechnology clusters and innovation ecosystems across Member States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment and strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular consideration for Union funding, priority	(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia***, civil society, patients' organisations, social partners***, industry and public authorities, and can serve as anchors for regional biotechnology clusters and innovation ecosystems across Member States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment and strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular

access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8] provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9] , (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

consideration for Union funding, priority access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8] provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9] , (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

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[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of

[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of

24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

Or. en

Justification

Amendment draft by Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 522
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for ***regional*** biotechnology clusters and innovation ecosystems ***across Member*** States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment and strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular consideration for Union funding, priority access to administrative support and fast-	(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for biotechnology ***and biomanufacturing*** clusters and innovation ecosystems***,*** ***including the EEA*** States ***and international cooperation***. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment and strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular consideration for Union funding, priority

tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8] provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9] , (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8] provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9] , (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

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[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European

[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European

Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

Or. en

Amendment 523
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for regional biotechnology clusters and innovation ecosystems across Member States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment and strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular consideration for Union funding, priority access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8]	(14) Certain health biotechnology strategic projects have the potential to contribute to the Union's objectives in biotechnology in a manner that is systemic and can produce a multiplier effect ***across the entire lifecycle***. Such projects act as catalysts for cooperation between academia, industry and public authorities, and can serve as anchors for regional biotechnology clusters and innovation ecosystems across Member States. Experience in several Member States has shown that such projects can quickly raise industrial capability, attract investment and strengthen the Union's position in global value chains. Accordingly, such projects should be recognised as high impact health biotechnology strategic projects by the Commission and could be given particular consideration for Union funding, priority access to administrative support and fast-tracked procedures at Member State level. As regards national funding of such projects, Regulation (EU) 2024/795[8]

provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9] , (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

provides measures for the support of critical and emerging strategic technologies and their respective value chains within programmes implemented under shared management. That Regulation amends the basic acts of several shared-management funds, namely Regulations (EU) 2021/1056[9] , (EU) 2021/1057[10] and (EU) 2021/1058 of the European Parliament and of the Council[11] , in order to enable Member States to steer their national and regional programmes towards investments in critical technologies, including biotechnologies. Without prejudice to the applicable rules governing each such funding instrument, and in line with applicable State aid rules, this approach may therefore be applied to high-impact health biotechnology strategic projects, which are deemed in accordance with this Regulation as to contribute to the STEP objectives.

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[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[8] Regulation (EU) 2024/795 of the European Parliament and of the Council of 29 February 2024 establishing the Strategic Technologies for Europe Platform (STEP), and amending Directive 2003/87/EC and Regulations (EU) 2021/1058, (EU) 2021/1056, (EU) 2021/1057, (EU) No 1303/2013, (EU) No 223/2014, (EU) 2021/1060, (EU) 2021/523, (EU) 2021/695, (EU) 2021/697 and (EU) 2021/241, ELI: .

[9] Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/1056/oj).

[10] Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21, ELI: http://data.europa.eu/eli/reg/2021/1057/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

[11] Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231, 30.6.2021, p. 60, ELI: http://data.europa.eu/eli/reg/2021/1058/oj).

Or. en

Justification

For optimal impact, the Biotech Act I (health) needs to recognise the different stages of the lifecycle of product and technologies (from monopoly to multi-source, after expiry of intellectual property rights - IPRs) within the scope of both strategic projects and high-impact strategic projects - and the fact that at each stage, value can be added through innovation or other health benefits.. It also needs to consider the full European biotech ecosystem and established synergies across the value chain (research, development, manufacturing, commercialisation) and the lifecycle of products and technologies (during monopolies and multi-source markets).

Amendment 524
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 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Rare diseases constitute a strategic area of biotechnology innovation, where public and private investment generates significant scientific, medical and societal benefits. The development of therapies for rare diseases relies on dedicated research infrastructures, patient registries and cross-border collaboration, which require sustained and coordinated support. When assessing applications for recognition as strategic projects or high-impact strategic projects, Member States and the Commission shall give due consideration to projects addressing rare diseases, including those supporting patient registries, diagnostic infrastructures, referral networks and cross-border data-

sharing infrastructures linked to the European Reference Networks. Such projects should be recognised for their strategic importance in strengthening the European biotechnology ecosystem and addressing the unmet medical needs of patients with rare diseases.

Or. en

Amendment 525
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) In order to strengthen the global competitiveness of the Union's biotechnology sector, it is necessary to complement network-based cooperation with targeted concentration of excellence. The designation of a limited number of EU Biotech Flagship Zones should allow the Union to build globally recognisable centres of biotechnology excellence, based on existing regional ecosystems, without undermining cohesion or fair competition within the internal market.

Or. en

Amendment 526
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) In order to strengthen the global competitiveness of the Union's biotechnology sector, it is necessary to complement network-based cooperation

with targeted concentration of excellence. The designation of a limited number of EU Biotech Flagship Zones should allow the Union to build globally recognisable centres of biotechnology excellence, based on existing regional ecosystems, without undermining cohesion or fair competition within the internal market.

Or. en

Justification

Recognising geographically concentrated strategic projects as EU Biotech Flagship Zones will signal to global investors that specific clusters of excellence are strategic hubs, accelerating the informal connections, collaboration and talent circulation that cross-border networks alone cannot replicate.

Amendment 527
Angelika Winzig

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) The achievement of excellence and the maximisation of impact in Union-led projects frequently require active collaboration at the international level. Accordingly, health biotechnology strategic projects and high-impact strategic projects shall be open to the participation of entities established in third countries.

Or. en

Amendment 528
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Health biotechnology innovation should be developed with meaningful involvement of patients and healthcare professionals throughout the innovation lifecycle, including the identification of unmet needs, clinical development, evidence generation and implementation into healthcare systems, where appropriate.

Or. en

Amendment 529
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Martin Hojsík

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact	(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology ***across the entire value chain and lifecycle of medicinal products***. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their

health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity.

Biotechnology testing environments recognised under this Regulation should include dedicated capacities for the testing, benchmarking and regulatory qualification of non-animal methodologies and integrated human-relevant testing strategies.

By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies.

These centres should, where relevant, integrate NAMs into preclinical and translational workflows and support their regulatory acceptance through collaboration with competent authorities.

When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

In addition, strategic projects contributing to the generation, sharing and interoperability of high-quality data derived from NAMs should be encouraged, as such data are essential to support their validation, reproducibility

	and regulatory uptake.
[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.	[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. en

Justification

NAMs are not yet sufficiently embedded in large-scale infrastructures and centres of excellence, limiting their translation and regulatory uptake. Strengthening their integration within strategic projects and data ecosystems would help bridge the gap between innovation and application, enhance Europe's leadership in human-relevant technologies, and maximise the impact of investments under the MFF.

Amendment 530
Sirpa Pietikäinen

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of	(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of

categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative***, sex- and gender-responsive*** therapies***, including to address areas of unmet health needs***. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate ***equitable*** patient access across the Union. ***Furthermore, high impact health biotechnology strategic projects, for instance in the form of centers of excellence for women's health research, should aim to close the gender health gap by improving early-stage research and the understanding of sex-based biological differences, contribute to advancing diagnostics and treatment plans for sex-specific conditions, and increase the share of biopharma innovation investments in women's health.***

[12] Draghi, Mario. The future of European

[12] Draghi, Mario. The future of European

competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. en

Amendment 531
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 15

Text proposed by the Commission	*Amendment*
(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities	(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology***. These centres of excellence may bring together public institutions, university hospitals, academic medical centres, their cross-border networks, including European Reference Networks where appropriate, joint ventures, public-private partnerships and other deeply integrated partnerships, while maintaining the core objective of reducing fragmentation, avoiding duplication and establishing globally competitive European centres for health biotechnology and advanced therapies***. High impact biotechnology health strategic projects have the potential to contribute to

replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. en

Amendment 532

Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in	(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in

the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.	the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies***, and should speed up the deployment of research results through clinical and commercial applications, so that innovative technologies can be developed and adopted and so that the Union's research, production and supply capacities can be strengthened***. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.
[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.	[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. ro

Amendment 533
Ingeborg Ter Laak

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited	(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited

number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

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[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. en

Amendment 534
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European ***Competitiveness[12]*** recommends that the Union should focus resources on a limited number of world-class ***centres*** of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence	(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European ***Competitiveness12*** recommends that the Union should focus resources on a limited number of world-class ***networks*** of excellence in life sciences and biotechnology***, across the entire value chain and lifecycle (during patent monopolies, exclusivity periods and in a multi-source competitive setting).***. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing

into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of ***centres*** of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced ***state-of-the-art*** equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of ***networks*** of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

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[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. en

Amendment 535
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF)	(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF)

for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated ‘Health, Biotech, Agriculture and Bioeconomy’ window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe’s scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

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facilitate patient access across the Union.

[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. en

Justification

Amendment drafted by the Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 536
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact	(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology ***across the entire value chain and lifecycle*** . High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their

health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

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[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. en

Amendment 537
András Tivadar Kulja

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*

(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated ‘Health, Biotech, Agriculture and Bioeconomy’ window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe’s scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to

(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated ‘Health, Biotech, Agriculture and Bioeconomy’ window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology ***across the entire value chain and lifecycle***. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe’s scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more

digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.

[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. en

Amendment 538
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology. High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of such high impact projects and specific criteria should be established for	(15) The strategic importance of biotechnology for European competitiveness has already been established, including through the proposed a European Competitiveness Fund (ECF) for the Multiannual Financial Framework (MFF) period 2028-2034, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' window. The Draghi Report on the Future of European Competitiveness[12] recommends that the Union should focus resources on a limited number of world-class centres of excellence in life sciences and biotechnology ***for advanced therapy medicinal products*** . High impact biotechnology health strategic projects have the potential to contribute to this focus of efforts and be a tool for an impactful use of resources in the MFF period 2028-2034, to help position the Union among the leading regions for biotechnology. Examples of categories of

their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.	such high impact projects and specific criteria should be established for their recognition by the Commission. Amongst those categories, high impact health biotechnology strategic projects in the form of biotechnology development accelerators providing, amongst others, trusted testing or demonstration facilities replicating real-world biomanufacturing processes, should play a key role in translating Europe's scientific excellence into productive industrial capacity. By pooling advanced equipment and expertise and offering criteria-based access, including for small and medium-sized enterprises, start-ups and scale-ups, such projects should reduce duplication of efforts, lower entry barriers, and foster the specialised skills required for advanced biomanufacturing. Similarly, high impact health biotechnology strategic projects in the form of centres of excellence for advanced therapies, including for advanced therapy medicinal products, should combine research, regulatory science and manufacturing capabilities, enabling faster, safer and more efficient development of innovative therapies. When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.
[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.	[12] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.

Or. en

Justification

The addition is the complete and correct sentence from the Draghi report (p 35).

Amendment 539
András Tivadar Kulja

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) The safe and effective administration of advanced therapy medicinal products requires highly specialised knowledge, technical expertise and multidisciplinary clinical skills that must be continuously developed and updated in line with scientific and technological advances.
	Centres of excellence for advanced therapies should play a central role in the provision of specialised education, continuous professional development and upskilling of healthcare professionals involved in the preparation, administration and follow-up of patients receiving such therapies. To that end, those centres, including the networks comprising hospitals and affiliated clinical sites administering advanced therapy medicinal products, should have access to funding and other incentives to strengthen their education and training capacity, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners. As those hospitals and affiliated clinical sites carry out the related clinical follow-up of patients, such centres should also maintain interoperable patient registries in order to support the generation of evidence relating to advanced therapy medicinal products.

Or. en

Amendment 540
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Martin Hojsík

Proposal for a regulation

Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) In view of the specialised infrastructures required for the administration of advanced therapy medicinal products (ATMPs), Centres of Excellence for Advanced Therapies should also include networks comprising hospitals, including university hospitals, and affiliated clinical sites administering such products. These treatment and diagnosis networks shall have access to EU and Member State funding and other incentives aimed at enhancing their capacity and capabilities, including through continuing education and training of their technical and clinical staff, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners. As those hospitals and affiliated clinical sites carry out the related clinical follow-up of patients, such centres should maintain interoperable patient registries in order to support the generation of evidence relating to advanced therapy medicinal products.

Or. en

Justification

The Commission's proposal focuses exclusively on the innovation-translation segment of the ATMP value chain (research, development, and manufacturing). This leaves out the critical post-authorisation phase where ATMPs are administered to patients and real-world evidence is generated. A new recital is needed to signal that the concept of centres of excellence must extend to clinical administration to ensure patient access across the EU.

Amendment 541
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) In view of the specialised infrastructures required for the administration of advanced therapy medicinal products, centres of excellence for advanced therapies should also include networks comprising hospitals and affiliated clinical sites administering such products. These treatment networks shall have access to funding and other incentives aimed at enhancing their capacity and capabilities, including through continuing education and training of their technical and clinical staff, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners. As those hospitals and affiliated clinical sites carry out the related clinical follow-up of patients, such centres should maintain interoperable patient registries in order to support the generation of evidence relating to advanced therapy medicinal products.

Or. en

Justification

The Commission's proposal focuses exclusively on the innovation-translation segment of the ATMP value chain (research, development, manufacturing). This leaves out the critical post-authorisation phase where ATMPs are administered to patients and real-world evidence is generated. A new recital is needed to signal that the concept of centres of excellence must extend to clinical administration to ensure patient access across the EU.

Amendment 542
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) Europe's long-term competitiveness depends not only on generating scientific discoveries but also

on creating the conditions for innovative biotechnology companies to scale, manufacture and remain within the Union throughout their development, thereby strengthening European industrial capacity, strategic resilience and access to innovation.

Or. en

Amendment 543
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) In order to strengthen the Union's competitiveness in biotechnology, support under this Regulation should be guided by scientific and technological excellence, industrial relevance and clear Union added value.

Or. en

Amendment 544
Stine Bosse, Katri Kulmuni, Billy Kelleher, Martin Hojsík

Proposal for a regulation
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(15b) Advanced therapy medicinal products (ATMPs) frequently require long-term follow-up in clinical practice to generate evidence and real-world data relating to their safety, efficacy, and effectiveness. Such evidence is important for the post-authorisation assessment of the benefit-risk balance or health technology assessments. The current landscape of patient registries relating to

advanced therapy medicinal products is fragmented, with national, regional and product-specific registries operating without harmonised technical specifications. In order to support the generation of evidence relating to advanced therapy medicinal products, a Union framework for the designation of patient registries should be established. That framework should provide for common technical requirements ensuring the syntactic and semantic interoperability of patient registries, as well as disease- and therapy-specific minimum data elements, such as patient baseline characteristics, treatment exposure data, outcome data and minimum monitoring requirements. Patient registries complying with those technical specifications should be eligible for designation by the competent authorities of the Member States and for support under this Regulation. Designated patient registries shall make their data available to relevant stakeholders under conditions set by the Commission. Access to these registries should be granted on transparent, proportionate and non-discriminatory terms.

Or. en

Justification

ATMPs are administered to patients with serious conditions who require extended clinical follow-up. The systematic generation of post-authorisation evidence is essential for regulatory and reimbursement purposes. The existing registry landscape is fragmented, operating under divergent national, regional, and product-specific arrangements without harmonised specifications. This recital justifies the new framework proposed in Article 6a, and signals the voluntary, incentive-based nature of the designation mechanism, which is legally necessary to respect Member States' competences under Article 168(7) TFEU.

Amendment 545
András Tivadar Kulja

Proposal for a regulation
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(15b) Advanced therapy medicinal products frequently require long-term clinical follow-up to generate evidence on their safety, efficacy and effectiveness, including for post-authorisation monitoring and health technology assessments. To contribute to the effective implementation of the European Health Data Space and improve the availability of high-quality real-world evidence, patient registries relating to advanced therapy medicinal products should comply with common technical and interoperability requirements, including disease- and therapy-specific minimum datasets. Patient registries designated by the competent authorities of the Member States should be eligible for support under this Regulation and make data available, in accordance with Union law, to relevant stakeholders under transparent, proportionate and non-discriminatory conditions.

Or. en

Amendment 546
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(15b) Limited biomanufacturing capacity remains a structural bottleneck for the Union's biotechnology ecosystem, particularly in the area of health. This is especially relevant for advanced therapies, including cell and gene therapies, viral vectors and other complex biological products, where the transition from academic research, including translational research and early clinical

development to GMP-compliant manufacturing and commercial scale-up remains highly demanding. A coordinated Union approach is therefore needed to map available biomanufacturing capacity, identify bottlenecks and supply chain dependencies, support investment priorities and connect manufacturing capacity more effectively with clinical expertise, including European Reference Networks and other cross-border health networks where relevant.

Or. en

Amendment 547
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 15 c (new)

Text proposed by the Commission	*Amendment*
	(15c) To incentivise the development and uptake of novel manufacturing methods, the Commission should be able to grant, upon application by a natural or legal person established in the Union, an Advanced Biomanufacturing Technology Designation to a manufacturing technology used in the development or production of biotechnology products, including biological medicinal products for human use, where that technology incorporates a novel technology or a novel application of an established technology, maintains or improves the quality, safety or robustness of the manufacturing process, including through the use or validation of New Approach Methodologies, and contributes to strengthening manufacturing capacity within the Union, enhancing the security or resilience of supply, improving development, scalability, efficiency or production lead times, or reducing environmental impact and improving

resource efficiency. Such a designation should be valid throughout the Union and should not affect or replace any authorisation, assessment or compliance requirement applicable under Union or national law.

Or. en

Amendment 548
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 15 d (new)

Text proposed by the Commission	*Amendment*
	(15d) Recent high-level Union reports have, from complementary perspectives, underlined the need for a stronger European framework for biotechnology and biomanufacturing.
	(i) The report of Enrico Letta[1a] in April 2024 highlighted the importance of deepening the Single Market through a fifth freedom for research, innovation, knowledge, data and education, identified biotechnology as a field that could particularly benefit from this approach, stressed the absence of a genuine Single Market for pharmaceuticals, and called for stronger production capacity, innovation-friendly regulatory frameworks and more integrated clinical research networks, while also proposing measures to reduce administrative burdens for SMEs, including through the development of a voluntary European legal framework, referred to as a "28th regime". It further underlined the growing importance of a "One Health" approach, recognising the strong interconnection between human, animal and environmental health, including the fact that a majority of emerging infectious diseases are of zoonotic origin, and called

for strengthened integrated research, surveillance and preparedness capacities, including through enhanced roles for Union agencies and medical countermeasure frameworks.

(ii) The report of Mario Draghi[2a] in September 2024 identified biotechnology as a strategic driver of European competitiveness and highlighted persistent Union weaknesses in translating scientific excellence into biologics, orphan medicines, advanced therapies, clinical trials, scale-up finance and industrial capacity, as well as the need for world-class innovation hubs and stronger links between European Reference Networks, disease registries and European health data infrastructures.

(iii) The report of Manuel Heitor[3a] in October 2024 emphasised life sciences as a major priority field for Union research and innovation and called for a prevention priority approach, enhancing patients quality of life, stronger research and technology infrastructures, innovation procurement, long-term sustainable funding, simplification, skills development and improved technology monitoring in order to better translate scientific excellence into European industrial leadership.

(iv) The report of Sauli Niinistö[4a] in October 2024 underlined the importance of biotechnology for preparedness, resilience, biosecurity, medical countermeasures and relevant dual-use capabilities, highlighted emerging risks linked to AI-enabled synthetic biology, and stressed the importance of resilient manufacturing capacity, stockpiling and public-private cooperation for crisis preparedness. Taken together, those reports support the establishment of a health-driven Union framework that reduces fragmentation, connects research centres, hospitals, regulators, manufacturers, data infrastructures and

patients more effectively, strengthens cross-border clinical and manufacturing capacity, including for rare diseases and advanced therapies, supports in particular SMEs, start-ups and scale-ups, and promotes innovation while ensuring safety, ethics, transparency, resilience, data protection and equitable access across the Union.

[1a] Letta, Enrico. Much More Than a Market: Speed, Security, Solidarity – Empowering the Single Market to deliver a sustainable future and prosperity for all EU Citizens, European Council, 18 April 2024. Link: https://www.consilium.europa.eu/media/ny3j24sm/much-more-than-a-market-report-by-enrico-letta.pdf

[2a] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024. Link: https://commission.europa.eu/document/download/97e481fd-2dc3-412d-be4c-f152a8232961_en

[3a] Heitor, Manuel. Align, Act, Accelerate: Research, Technology and Innovation to boost European competitiveness, European Commission, October 2024. Link: https://op.europa.eu/en/publication-detail/-/publication/2f9fc221-86bb-11ef-a67d-01aa75ed71a1

[4a] Niinistö, Sauli. Safer Together: Strengthening Europe's Civilian and Military Preparedness and Readiness, European Commission, 30 October 2024. Link: https://commission.europa.eu/publications/safer-together-strengthening-europes-civilian-and-military-preparedness-and-readiness_en

Or. en

Amendment 549
Wouter Beke

Proposal for a regulation
Recital 15 e (new)

Text proposed by the Commission	*Amendment*
	(15e) The recognition of biotechnology strategic projects, high-impact biotechnology strategic projects, and pan-European high-impact biotechnology strategic projects should be based solely on merit, quality and the fulfilment of the conditions and criteria laid down in this Regulation. Geographical location within the Union should not constitute a selection criterion, an eligibility condition, or an award criterion for the purposes of such recognition, nor for the prioritisation of projects under Union funds, programmes and financial instruments implemented in accordance with this Regulation.

Or. en

Amendment 550
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) To maximise the Union-wide benefits of investments made in projects or entities operating infrastructures, facilities and services supported and established or recognised in accordance with this Regulation, such projects or entities should provide open, non-discriminatory, transparent and criteria-based access to users from all Member States, including academic institutions, industrial undertakings, with particular attention to SMEs, start-ups and scale-ups, and public	(16) To maximise the Union-wide benefits of investments made in projects or entities operating infrastructures, facilities and services supported and established or recognised in accordance with this Regulation, such projects or entities should provide open, non-discriminatory, transparent and criteria-based access to users from all Member States, including academic institutions, industrial undertakings, with particular attention to SMEs, start-ups and scale-ups, and public

research bodies. Access conditions should be proportionate and ensure fair treatment among users, taking into account the objectives and capacity of each infrastructure, the need to guarantee equitable opportunities for SMEs, start-ups and scale-ups, and research actors, and appropriate safeguards to protect security, confidentiality, intellectual property and economic-security interests.

research bodies. Access conditions should be proportionate and ensure fair treatment among users, taking into account the objectives and capacity of each infrastructure, the need to guarantee equitable opportunities for SMEs, start-ups and scale-ups, and research actors, and appropriate safeguards to protect security, confidentiality, intellectual property and economic-security interests. ***Those access conditions should not impose disproportionate costs, reporting obligations or disclosure requirements on SMEs, start-ups, scale-ups or research organisations.***

Or. en

Amendment 551
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(16) To maximise the Union-wide benefits of investments made in projects or entities operating infrastructures, facilities and services supported and established or recognised in accordance with this Regulation, such projects or entities should provide open, non-discriminatory***,*** transparent ***and criteria-based*** access to users from all Member States, including academic institutions, industrial undertakings, with particular attention to SMEs, start-ups and scale-ups, and public research bodies. Access conditions should be proportionate and ensure fair treatment among users, taking into account the objectives and capacity of each infrastructure, the need to guarantee equitable opportunities for SMEs, start-ups and scale-ups, and research actors, and appropriate safeguards to protect security, confidentiality, intellectual property and	(16) To maximise the Union-wide benefits of investments made in projects or entities operating infrastructures, facilities and services supported and established or recognised in accordance with this Regulation, such projects or entities should provide open, non-discriminatory ***and*** transparent access ***based on common European criteria*** to users from all Member States, including academic institutions, industrial undertakings, with particular attention to SMEs, start-ups and scale-ups, and public research bodies. Access conditions should be proportionate and ensure fair treatment among users, taking into account the objectives and capacity of each infrastructure, the need to guarantee equitable opportunities for SMEs, start-ups and scale-ups ***in all Member States, without discrimination***, and research actors, and appropriate

economic-security interests.	safeguards to protect security, confidentiality, intellectual property and economic-security interests.

Or. ro

Amendment 552
Letizia Moratti, Fulvio Martusciello, Massimiliano Salini

Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) The Union's competitiveness and strategic autonomy in the area of medicines depend on its ability to attract the early development and the first launch of innovative medicinal products. In order to encourage marketing authorisation applicants to choose the Union as the first jurisdiction in which to seek authorisation, and to ensure the timely availability of such medicines to patients across the Union, applicants that submit their application to the Agency before submitting the corresponding application to the regulatory authorities of third countries, and that undertake to make the medicinal product available in a significant number of Member States, should benefit from enhanced incentives. Those incentives should consist of priority support during development and of the extended supplementary protection certificate referred to in Article 27. Such incentives are open, on a non-discriminatory basis, to all applicants irrespective of their place of establishment, and are proportionate to the contribution made to the Union's innovation base and to patient access.

Or. en

Amendment 553
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) Small mid-cap enterprises, as defined in Commission Recommendation (EU) 2025/1099, often face scale-up and financing challenges comparable to those of small and medium-sized enterprises, start-ups and scale-ups, while no longer qualifying as such. In order to support the growth and retention of promising biotechnology companies within the Union, the support measures, access conditions and facilitation provided for under this Regulation should, where appropriate, also benefit small mid-cap enterprises.

Or. en

Amendment 554
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Angelika Winzig, 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 16 b (new)

Text proposed by the Commission	*Amendment*
	(16b) The Union's competitiveness and strategic autonomy in the field of medicines depend on its ability to attract the early development and the first launch of innovative medicinal products. There right incentivises should be in place for market authorisation applicants to choose the Union as the first jurisdiction in which to seek authorisation, and to ensure the timely availability of such medicines to patients across the Union.

Or. en

Amendment 555
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Martin Hojsík

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.	(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. ***This should include the development of skills and training programmes related to NAMs, including advanced in vitro, microphysiological and in silico approaches, as well as their application in regulatory science and safety assessment.*** Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation. ***Addressing skills gaps in NAMs is critical to enable their uptake across research, industry and regulatory contexts, and to support the transition towards more human-relevant and innovative biotechnology ecosystems in the Union.***

Or. en

Justification

Skills gaps are a key barrier to the uptake of NAMs. Explicitly supporting training and capacity-building in this area would facilitate their implementation across sectors and ensure

the availability of a workforce equipped to support innovative and human-relevant approaches.

Amendment 556
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.	(17) ***The development of biotechnology and biomanufacturing must contribute to quality employment, safe working conditions and fair industrial transitions.*** Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation. ***Financial public support under this Regulation should be conditional upon respect for workers' rights, collective bargaining rights, European and international labour standards, including the International Labour Organisation Conventions No. 87, No. 98, No. 155 and No. 187.***

Or. en

Amendment 557
Marie Toussaint, Ville Niinistö

on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.	(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. ***This could include the development of skills and training programmes related to NAMs.*** Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation. ***Addressing skills gaps in NAMs is one of several relevant factors that may support their broader uptake across research, industry and regulatory contexts, and can contribute to the ongoing evolution of more human-relevant and innovative biotechnology ecosystems in the Union.***

Or. en

Amendment 558
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Effective implementation of objectives pursued in this Regulation relies	(17) Effective implementation of objectives pursued in this Regulation relies

on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.	on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a ***specialised*** workforce***, in the medium and long term, that is*** capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.

Or. ro

Amendment 559
Kristoffer Storm

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.	(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners ***and stakeholders***. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.

Or. en

Amendment 560
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.	(17) Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners ***and stakeholders***. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation.

Or. en

Amendment 561
Nikos Papandreou, Romana Jerković

Proposal for a regulation
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) The Commission should continue to assess whether the Union regulatory framework applicable to genetically modified organisms remains proportionate for the conduct of clinical trials involving advanced therapy

medicinal products, while ensuring a high level of protection for human health and the environment.

Or. en

Amendment 562
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) In order to safeguard the Union's security, public order and strategic interests, access to biotechnology infrastructures and datasets of health biotechnology strategic projects and of high impact health biotechnology strategic projects recognised in accordance with this Regulation and that receive funding in accordance with Union programmes, in relation to such infrastructures or datasets, should be governed by the rules established in those programmes. This addresses risks linked to unlawful technology transfer, hostile interference or strategic dependency.	(19) In order to safeguard the Union's security, public order and strategic interests, access to biotechnology infrastructures and datasets of health biotechnology strategic projects and of high impact health biotechnology strategic projects recognised in accordance with this Regulation and that receive funding in accordance with Union programmes, in relation to such infrastructures or datasets, should be governed by the rules established in those programmes***, including lists clearly specifying which persons can access all such information and, in particular, the duration of their access***. This addresses risks linked to unlawful technology transfer, hostile interference or strategic dependency.

Or. ro

Amendment 563
Christophe Clergeau, Tomislav Sokol, Vytenis Povilas Andriukaitis, Marta Temido, Michalis Hadjipantela, Sirpa Pietikäinen, Ondřej Krutílek, Marcos Ros Sempere, Tilly Metz

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*

(19a) 'exposome' refers to the totality of environmental exposures to which an individual is subjected across the lifespan, including chemical, biological, physical and lifestyle factors, together with the body's biological responses to them;

Or. en

Amendment 564
Christophe Clergeau, Vytenis Povilas Andriukaitis, Marta Temido, Michalis Hadjipantela, Sirpa Pietikäinen, Ondřej Krutílek, Marcos Ros Sempere, Tilly Metz

Proposal for a regulation
Recital 19 b (new)

Text proposed by the Commission	*Amendment*
	(19b) 'population and longitudinal cohort' means an organised group of individuals recruited and followed over time under a defined research protocol, for whom health, environmental exposure, lifestyle or biological data are collected repeatedly, with a view to studying the determinants of health outcomes;

Or. en

Amendment 565
Stine Bosse, Katri Kulmuni, Billy Kelleher, Martin Hojsík

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities,	(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities,

infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce.	infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce. ***The mapping should also assess the availability, maturity, uptake and regulatory integration of NAMs as well as identify gaps in validation, standardisation, data availability and infrastructure supporting their deployment. Furthermore, it should evaluate barriers and opportunities for the integration of NAMs into research, development and regulatory pathways, including skills needs and access to relevant facilities and data ecosystems.***

Or. en

Justification

Current ecosystem mapping risks overlooking key gaps related to NAMs. Including their assessment would provide a clearer evidence base to guide investments, address barriers to uptake, and support their integration into research and regulatory frameworks.

Amendment 566
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping	(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping

should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce.

should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing***, identify gaps and duplications***, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce. ***The Commission should, on the basis of that mapping, provide recommendations to the Member States on measures to further strengthen the biotechnology and biomanufacturing sectors. Where relevant, the Commission should also engage with relevant stakeholders, including patient and healthcare professionals, to gather the information necessary to identify the needs of the Union***

Or. en

Amendment 567
Angelika Winzig

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in	(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing***, identify duplications***, and assess factors affecting the Union's ability to attract and retain

biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce.	investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce***, and provide recommendations***.

Or. en

Amendment 568
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce.	(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing***, identify duplications***, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce***, and provide recommendations***.

Or. en

Amendment 569

Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce.	(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce ***in close cooperation with relevant social partners***.

Or. en

Amendment 570
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to	(20) To provide an evidence base for future Union action to further strengthen the biotechnology and biomanufacturing sectors, the Commission should carry out a strategic mapping of the Union's biotechnology ecosystem. That mapping should analyse industrial capacities, infrastructures and facilities relevant to

biotechnology research, development, testing and manufacturing, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce.	biotechnology research, development, testing and manufacturing***, identify duplications***, and assess factors affecting the Union's ability to attract and retain investment in biomanufacturing, including access to public and private risk-tolerant capital across all stages of the innovation cycle, the development and coordination of biotechnology clusters and biomanufacturing ecosystems across the Union, and assess challenges and needs in terms of the workforce***, and provide recommendations***.

Or. en

Justification

The mapping exercise should identify existing synergies, clusters and duplications across the ecosystem. It should not be used only for information but also provide recommendations.

Amendment 571
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(20a) The Union's biotechnology ecosystem remains unevenly distributed across Member States and regions. In order to strengthen the Union's competitiveness as a whole, this Regulation should not only reinforce already developed biotechnology hubs, but also support the activation of under-represented Member States and regions, including in Southern, Eastern and less developed regions of the Union. Geographic balance should therefore be pursued as a means of mobilising untapped excellence, strengthening cohesion and resilience, and ensuring that biotechnology capacities develop across the Union, without lowering the

criteria for quality, performance, safety or strategic relevance. Where Member States did not participate in the Commission's consultation process or show structurally low participation in Union biotechnology initiatives, the Commission should carry out targeted outreach, including through European Reference Network coordinators, national academies, universities, regional development agencies, patient organisations and SME organisations. Strategic mapping, the EU Health Biotechnology Support Network, Union funding instruments and capacity-building measures should therefore contribute to geographic balance, the development of emerging biotechnology ecosystems and the participation of relevant actors across all Member States.

Or. en

Amendment 572
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space***[14]*** , the Apply AI Strategy***[15]*** , the Data Union Strategy***[16]*** , the AI Continent Action Plan***[17]*** and the European Strategy for AI in Science***[18]*** . With a view to ensuring appropriate	(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, ***ensuring the ethical use of AI and*** building on analyses done in the context of existing Union initiatives such as the European Health Data Space***[14]*** , the Apply AI Strategy***[15]***, the Data Union Strategy***[16]***, the AI Continent Action Plan***[17]*** and the European Strategy for AI

cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects**.**

in Science***[18]. With respect to AI-enabled biotechnology innovation, specific attention should be given to the ethics standards applicable to AI applications in the field of biotechnology and health, and the potential need to adapt them in light of technological developments and of their potential systemic risks, as foreseen by Regulation (EU) 2024/1689***. With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects

[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

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https://ec.europa.eu/newsroom/dae/redirection/document/114523

18 ***Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.***

Or. en

Amendment 573
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established	(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector***, as well as relevant gaps in digital and AI literacy across the biotechnology workforce,*** and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks***, ensuring the ethical and fair use of AI***, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the

under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.

Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.

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[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

Or. en

Amendment 574
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group (‘the Steering Group’) established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.	(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector ***as well as relevant gaps in digital and AI literacy across the biotechnology workforce*** and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks***, ensuring the ethical and fair use of AI***, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group (‘the Steering Group’) established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.

[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

Or. en

Justification

The amendment broadens the mapping exercise from infrastructure alone (data, computing capacity, digital infrastructure) to include the human capital dimension, recognising that responsible AI-enabled innovation requires not only access to digital resources but also a workforce equipped to use them safely and effectively. This is consistent with the recital's stated aim of identifying measures to mitigate AI-related risks, since skills gaps are a precondition for — and a driver of — those risks.

Amendment 575
Aura Salla

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.	(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity***, including quantum computing,*** and digital infrastructure for the health biotechnology sector ***and biomanufacturing, including industrial data spaces,*** and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks ***and strategic dependencies***, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.
[14] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health	[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

Or. en

Justification

Biotechnology and biomanufacturing should be better integrated into the EU's digital and AI strategies. Strategic mapping should therefore assess not only general access to data and computing capacity, but also the availability of industrial data spaces, biological data standards and advanced computing capabilities, including quantum computing.

Amendment 576
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*

(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.

(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to ***and protection of personal*** data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks ***and biases, including biases related to sex and gender***, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.

[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee

[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee

and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

Or. en

Justification

Amendment drafted with the Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 577
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing	(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, ***ensuring the ethical use of AI and***

Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.

building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Health Biotechnology Steering Group ('the Steering Group') established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to health biotechnology strategic projects and high impact health biotechnology strategic projects.

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[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirect

[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirect

ion/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

ion/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

Or. en

Amendment 578
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European ***Health*** Biotechnology	(21) Recognising the transformative role of data and AI in the area of biotechnology and biomanufacturing, that mapping should also assess access to data, computing capacity and digital infrastructure for the health biotechnology sector and identify measures to foster responsible AI-enabled biotechnology innovation and possible measures to mitigate related risks, building on analyses done in the context of existing Union initiatives such as the European Health Data Space[14] , the Apply AI Strategy[15] , the Data Union Strategy[16] , the AI Continent Action Plan[17] and the European Strategy for AI in Science[18] . With a view to ensuring appropriate cooperation with the Member States and optimising the use of relevant knowledge and expertise available at Union level, such mapping should be conducted by the Commission in cooperation with relevant Union agencies and bodies, including, where relevant, the AI Board established under the Regulation (EU) 2024/1689, and with the European Biotechnology Steering

Steering Group (‘the Steering Group’) established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to ***health*** biotechnology strategic projects and high impact ***health*** biotechnology strategic projects.

Group (‘the Steering Group’) established in accordance with this Regulation, to facilitate its implementation, provide advice to the Commission and to the Member States, and ensure coordinated action in particular with regard to biotechnology strategic projects and high impact biotechnology strategic projects.

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[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

[14] 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).

[15] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Apply AI Strategy, COM(2025)723 final of 8 October 2025.

[16] Communication from the Commission to the European Parliament and the Council, Data Union Strategy, Unlocking Data For AI, COM(2025) 835 final, 19 November 2025.

[17] https://ec.europa.eu/newsroom/dae/redirection/document/114523

[18] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: European Strategy for Artificial Intelligence in Science – Harnessing AI for research, innovation and excellence in the Union, COM(2025)724 final of, 8 October 2025.

Or. en

Amendment 579

Christophe Clergeau, Vytenis Povilas Andriukaitis, Marta Temido, Michalis Hadjipantela, Sirpa Pietikäinen, Ondřej Krutílek, Marcos Ros Sempere, Tilly Metz

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) Human health outcomes are shaped not only by genetic factors but by the totality of environmental exposures across the lifespan, together with the body's response to them. Characterising this exposome is increasingly enabled by biotechnological and analytical tools, including omics technologies, biomarkers and digital measurement technologies. Well-characterised population and longitudinal cohorts, alongside biobanks, patient registries and the European Reference Networks, constitute a valuable research infrastructure for the Union, both for exposome research and as a basis from which interventional studies, including clinical (pharmaceutical and non-pharmaceutical) trials, may be designed and conducted. Consistent with the responsible use of real-world data and with the secure secondary use of electronic health data under Regulation (EU) 2025/327, the strategic mapping referred to in Article 17 should take account of such cohorts and data resources, with a view to strengthening the predictive value of safety evaluation and supporting more personalised and preventive approaches to health, while reinforcing the competitiveness of the Union's biotechnology ecosystem.

Or. en

Justification

This recital anchors the exposome and cohort infrastructure to recitals (20)–(21) (strategic mapping) and to the rapporteur's emphasis on real-world data, the EHDS, ERNs and biobanks.

Amendment 580
Diana Iovanovici Şoşoacă

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) In order to ensure a transparent, coherent and efficient process for the identification of health biotechnology strategic projects, each Member State should designate a competent authority responsible for assessing and verifying whether a project fulfils the conditions set out in this Regulation for its recognition as a health biotechnology strategic project. The designated authority should carry out the assessment through a fair, transparent and time-bound process. Where a project is found to fulfil the conditions for recognition as a biotechnology strategic project, the designated authority should issue a formal recognition decision.	(22) In order to ensure a transparent, coherent and efficient process for the identification of health biotechnology strategic projects, each Member State should designate a competent authority responsible for assessing and verifying whether a project fulfils the conditions set out in this Regulation for its recognition as a health biotechnology strategic project. ***In addition, clarifying how to cooperate with similar institutions in the Member States would benefit any common cross-border projects that may be developed jointly.*** The designated authority should carry out the assessment through a fair, transparent and time-bound process. Where a project is found to fulfil the conditions for recognition as a biotechnology strategic project, the designated authority should issue a formal recognition decision.

Or. ro

Amendment 581
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) In order to ensure a transparent, coherent and efficient process for the identification of health biotechnology strategic projects, each Member State should designate a competent authority responsible for assessing and verifying whether a project fulfils the conditions set out in this Regulation for its recognition as	(22) In order to ensure a transparent, coherent and efficient process for the identification of health biotechnology strategic projects, each Member State should designate a competent authority responsible for assessing and verifying***, in cooperation with relevant social, animal welfare and environmental partners,***

a health biotechnology strategic project. The designated authority should carry out the assessment through a fair, transparent and time-bound process. Where a project is found to fulfil the conditions for recognition as a biotechnology strategic project, the designated authority should issue a formal recognition decision.	whether a project fulfils the conditions set out in this Regulation for its recognition as a health biotechnology strategic project. The designated authority should carry out the assessment through a fair, transparent and time-bound process. Where a project is found to fulfil the conditions for recognition as a biotechnology strategic project, the designated authority should issue a formal recognition decision.

Or. en

Amendment 582
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(22) In order to ensure a transparent, coherent and efficient process for the identification of ***health*** biotechnology strategic projects, each Member State should designate a competent authority responsible for assessing and verifying whether a project fulfils the conditions set out in this Regulation for its recognition as a health biotechnology strategic project. The designated authority should carry out the assessment through a fair, transparent and time-bound process. Where a project is found to fulfil the conditions for recognition as a biotechnology strategic project, the designated authority should issue a formal recognition decision.	(22) In order to ensure a transparent, coherent and efficient process for the identification of biotechnology strategic projects, each Member State should designate a competent authority responsible for assessing and verifying whether a project fulfils the conditions set out in this Regulation for its recognition as a health biotechnology strategic project. The designated authority should carry out the assessment through a fair, transparent and time-bound process. Where a project is found to fulfil the conditions for recognition as a biotechnology strategic project, the designated authority should issue a formal recognition decision.

Or. en

Amendment 583
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 22 a (new)

Text proposed by the Commission	*Amendment*
	(22a) In order to ensure a consistent and fair application of the recognition criteria across the Union, the Commission should be able to provide its opinion on the assessment of a biotechnology strategic project. Where a Member State rejects an application, the applicant should have the right to submit the application to the Commission for assessment. Such an assessment by the Commission should be carried out within a short time-limit and should be without prejudice to the decision of the Member State concerned.

Or. en

Amendment 584
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) In order to support the effective implementation of centres of excellence for advanced therapies, including for advanced therapy medicinal products, the Commission may issue operational guidance on the integration of clinical research, disease registries and innovation infrastructures across the Union, including through structured clinical cooperation with interconnected and interoperable European Reference Networks as referred to in Article 40a, in particular where such centres concern advanced therapies for rare diseases, rare cancers, paediatric conditions or other areas of high unmet medical need covered by those networks

Or. en

Amendment 585
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) To achieve critical mass and ensure that strategic investments deliver wider benefits, creating positive spill-over effects that reinforce the Union's competitiveness, networking and cooperation among ***health*** biotechnology strategic projects, high impact ***health*** biotechnology strategic projects, research organisations, industrial clusters and other relevant actors across borders, should be promoted and facilitated by the Commission and the Member States, with a view to help pooling national and Union resources and facilities, promote the development of interoperable infrastructures and digital platforms and facilitate knowledge transfer. This cooperation should be in compliance with Union competition law.	(25) To achieve critical mass and ensure that strategic investments deliver wider benefits, creating positive spill-over effects that reinforce the Union's competitiveness, networking and cooperation among biotechnology strategic projects, high impact ***biotechnology strategic projects, pan-European high impact*** biotechnology strategic projects, research organisations, industrial clusters and other relevant actors across borders, should be promoted and facilitated by the Commission and the Member States, with a view to help pooling national and Union resources and facilities, promote the development of interoperable infrastructures and digital platforms and facilitate knowledge transfer. This cooperation should be in compliance with Union competition law.

Or. en

Amendment 586
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 25

Text proposed by the Commission	*Amendment*
(25) To achieve critical mass and ensure that strategic investments deliver wider benefits, creating positive spill-over effects	(25) To achieve critical mass and ensure that strategic investments deliver wider benefits, creating positive spill-over effects

that reinforce the Union's competitiveness, networking and cooperation among health biotechnology strategic projects, high impact health biotechnology strategic projects, research organisations, industrial clusters and other relevant actors across borders, should be promoted and facilitated by the Commission and the Member States, with a view to help pooling national and Union resources and facilities, promote the development of interoperable infrastructures and digital platforms and facilitate knowledge transfer. This cooperation should be in compliance with Union competition law.	that reinforce the Union's competitiveness, networking and cooperation among health biotechnology strategic projects, high impact health biotechnology strategic projects, research organisations, industrial clusters and other relevant actors across borders, ***including university hospitals alliances*** should be promoted and facilitated by the Commission and the Member States, with a view to help pooling national and Union resources and facilities, promote the development of interoperable infrastructures and digital platforms and facilitate knowledge transfer. This cooperation should be in compliance with Union competition law.

Or. en

Amendment 587
Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance, networks supported under Horizon Europe, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should	(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance, networks supported under Horizon Europe ***including the European Partnership on Rare Diseases (ERDERA)***, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer

aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.

Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.

[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.

[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.

[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

Or. en

Amendment 588
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance,	(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance,

networks supported under Horizon Europe, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.

networks supported under Horizon Europe***, the Innovative Health Initiative***, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.

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[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.

[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.

[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

Or. en

Amendment 589
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance, networks supported under Horizon Europe, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.	(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance, networks supported under Horizon Europe***, the Innovative Health Initiative***, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.
[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.	[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.
[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.	[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

Or. en

Justification

EU-wide platforms or infrastructures established via public-private partnerships are also very relevant, as highlighted by the Draghi report for IHI (e.g. the EHDEN or c4c projects

Amendment 590
Angelika Winzig

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance, networks supported under Horizon Europe, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.	(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance, networks supported under Horizon Europe***, the Innovative Health Initiative***, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.

[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.

[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.

[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

Or. en

Amendment 591
Kristoffer Storm

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance, networks supported under Horizon Europe, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European Reference Networks as defined in	(26) Such networking and cooperation should integrate, collaborate with, or build upon, existing networks emerging from other Union initiatives relevant for biotechnology, including those operating under the European Cluster Collaboration Platform, the European Cluster Alliance, networks supported under Horizon Europe***, the Innovative Health Initiative***, the Smart Specialisation Partnerships, and the European Network of Centres of Excellence for Advanced Therapy Medicinal Products (ATMPs) announced by the Commission in the European Strategy for Life Sciences[19] , the European

Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.

Reference Networks as defined in Directive 2011/24/EU of the European Parliament and of the Council[20] and the EU Network of Comprehensive Cancer Centres announced by Europe's Beating Cancer Plan[21] . Such cooperation should aim to reinforce synergies, facilitate access to regional and Union level funding, and enhance the coordination of biotechnology-related innovation ecosystems across the Union.

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[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.

[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A strategy for European life sciences: Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030, COM(2025) 525 final of 2 July 2025.

[20] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, pp. 45–65. ELI: http://data.europa.eu/eli/dir/2011/24/oj.

[21] Communication from the Commission to the European Parliament and the Council, Europe's Beating Cancer Plan, COM/2021/44 final of 3 February 2021.

Or. en

Amendment 592
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26a) In areas of major public health and socioeconomic burden characterised by persistent innovation gaps, including

mental health, cross-border coordination structures or networks may be needed to overcome fragmentation and accelerate the translation of research into accessible care. Such cooperation may support the coordination of multi-country clinical research, the development of shared data and digital infrastructures, the dissemination of best practices, the provision of scientific and regulatory support to innovators, and the strengthening of workforce and implementation capacity across the Union.

Or. en

Amendment 593
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) In order to reduce complexity and increase efficiency, transparency and consistency in the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects, there should be a single point of contact at national level that is responsible for facilitating and coordinating the entire permit-granting process. The single point of contact should be the interface between the promoters of health biotechnology strategic projects or of high impact health biotechnology strategic projects and the relevant permitting authorities. To that end, Member States should establish or designate one or more authorities as single points of contact. With a view to ensure streamlined processes, that single point of contact should be the same as the single point of contact referred to in Regulation (EU) ../.. [Regulation on speeding-up	(27) In order to reduce complexity and increase efficiency, transparency and consistency in the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects, there should be a single point of contact at national level that is responsible for facilitating and coordinating the entire permit-granting process***., including the needed regulatory inspections (GxP), as needed to allow activity and/or supply from a given facility***. The single point of contact should be the interface between the promoters of health biotechnology strategic projects or of high impact health biotechnology strategic projects and the relevant permitting authorities. To that end, Member States should establish or designate one or more authorities as single points of contact. With a view to ensure streamlined processes, that single point of

environmental impact assessmentsc - permitting regulation], responsible for facilitating and coordinating all aspects of the environmental assessments. It should be for Member States to decide whether a single point of contact is also an authority that makes permitting decisions. To ensure the effective implementation of their responsibilities, Member States should provide their single points of contact, as well as any authority involved in the permit-granting process with sufficient personnel and resources.

contact should be the same as the single point of contact referred to in Regulation (EU) ../.. [Regulation on speeding-up environmental impact assessmentsc - permitting regulation], responsible for facilitating and coordinating all aspects of the environmental assessments. It should be for Member States to decide whether a single point of contact is also an authority that makes permitting decisions. To ensure the effective implementation of their responsibilities, Member States should provide their single points of contact, as well as any authority involved in the permit-granting ***or GxP inspection and certification*** process with sufficient personnel and resources.

Or. en

Amendment 594
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) In order to reduce complexity and increase efficiency, transparency and consistency in the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects, there should be a single point of contact at national level that is responsible for facilitating and coordinating the entire permit-granting process. The single point of contact should be the interface between the promoters of health biotechnology strategic projects or of high impact health biotechnology strategic projects and the relevant permitting authorities. To that end, Member States should establish or designate one or more authorities as single points of contact. With a view to ensure streamlined processes, that single point of	(27) In order to reduce complexity and increase efficiency, transparency and consistency in the permit-granting process for health biotechnology strategic projects and high impact health biotechnology strategic projects, there should be a single point of contact at national level that is responsible for facilitating and coordinating the entire permit-granting process***. including the needed regulatory inspections (GxP), as needed to allow activity and/or supply from a given facility***. The single point of contact should be the interface between the promoters of health biotechnology strategic projects or of high impact health biotechnology strategic projects and the relevant permitting authorities. To that end, Member States should establish or

contact should be the same as the single point of contact referred to in Regulation (EU) ../.. [Regulation on speeding-up environmental impact assessmentsc - permitting regulation], responsible for facilitating and coordinating all aspects of the environmental assessments. It should be for Member States to decide whether a single point of contact is also an authority that makes permitting decisions. To ensure the effective implementation of their responsibilities, Member States should provide their single points of contact, as well as any authority involved in the permit-granting process with sufficient personnel and resources.

designate one or more authorities as single points of contact. With a view to ensure streamlined processes, that single point of contact should be the same as the single point of contact referred to in Regulation (EU) ../.. [Regulation on speeding-up environmental impact assessmentsc - permitting regulation], responsible for facilitating and coordinating all aspects of the environmental assessments. It should be for Member States to decide whether a single point of contact is also an authority that makes permitting decisions. To ensure the effective implementation of their responsibilities, Member States should provide their single points of contact, as well as any authority involved in the permit-granting process ***or GxP inspection and certification*** with sufficient personnel and resources.

Or. en

Justification

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

Amendment 595
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) In order to reduce complexity and increase efficiency, transparency and consistency in the permit-granting process for ***health*** biotechnology strategic projects and high impact ***health*** biotechnology strategic projects, there should be a single point of contact at national level that is responsible for facilitating and coordinating the entire permit-granting process. The single point of contact should be the interface between the promoters of	(27) In order to reduce complexity and increase efficiency, transparency and consistency in the permit-granting process for ***biotechnology strategic projects, high impact*** biotechnology strategic projects and ***pan-European*** high impact biotechnology strategic projects, there should be a single point of contact at national level that is responsible for facilitating and coordinating the entire permit-granting process. The single point

health biotechnology strategic projects ***or of*** high impact ***health*** biotechnology strategic projects and the relevant permitting authorities. To that end, Member States should establish or designate one or more authorities as single points of contact. With a view to ensure streamlined processes, that single point of contact should be the same as the single point of contact referred to in Regulation (EU) ../.. [Regulation on speeding-up environmental impact assessmentsc - permitting regulation], responsible for facilitating and coordinating all aspects of the environmental assessments. It should be for Member States to decide whether a single point of contact is also an authority that makes permitting decisions. To ensure the effective implementation of their responsibilities, Member States should provide their single points of contact, as well as any authority involved in the permit-granting process with sufficient personnel and resources.

of contact should be the interface between the promoters of ***biotechnology strategic projects of high impact*** biotechnology strategic projects ***and pan-European*** high impact biotechnology strategic projects**,** and the relevant permitting authorities. To that end, Member States should establish or designate one or more authorities as single points of contact. With a view to ensure streamlined processes, that single point of contact should be the same as the single point of contact referred to in Regulation (EU) ../.. [Regulation on speeding-up environmental impact assessmentsc - permitting regulation], responsible for facilitating and coordinating all aspects of the environmental assessments. It should be for Member States to decide whether a single point of contact is also an authority that makes permitting decisions. To ensure the effective implementation of their responsibilities, Member States should provide their single points of contact, as well as any authority involved in the permit-granting process with sufficient personnel and resources.

Or. en

Amendment 596
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) The Union has progressively recognised health biotechnology as a strategic sector contributing to Union's overall resilience. Regulation (EU) 2024/795 identifies biotechnology among the strategic technologies essential for reducing the Union's strategic dependencies and strengthening its economic and industrial resilience. The Commission Communication Commission	***deleted***

Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' further identifies biotechnology and biomanufacturing as strategic technologies for Europe's competitiveness, resilience and autonomy, and furthermore explicitly recognises that health biotechnology is essential for health-system resilience. In view of this consistent Union framework confirming biotechnology's systemic contribution to resilience, health biotechnology strategic projects and high impact health biotechnology strategic projects should therefore be deemed to contribute to the objectives referred to in Article 14 of Regulation […] [Regulation on speeding-up environmental assessments – permitting regulation].

Or. en

Amendment 597
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) The Union has progressively recognised health biotechnology as a strategic sector contributing to Union's overall resilience. Regulation (EU) 2024/795 identifies biotechnology among the strategic technologies essential for reducing the Union's strategic dependencies and strengthening its economic and industrial resilience. The Commission Communication Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' further identifies biotechnology and biomanufacturing as strategic technologies for Europe's competitiveness, resilience	(28) The Union has progressively recognised health biotechnology as a strategic sector contributing to Union's overall resilience. Regulation (EU) 2024/795 identifies biotechnology among the strategic technologies essential for reducing the Union's strategic dependencies and strengthening its economic and industrial resilience. The Commission Communication Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' further identifies biotechnology and biomanufacturing as strategic technologies for Europe's competitiveness, resilience

and autonomy, and furthermore explicitly recognises that health biotechnology is essential for health-system resilience. In view of this consistent Union framework confirming biotechnology's systemic contribution to resilience, ***health*** biotechnology strategic projects and high impact ***health*** biotechnology strategic projects should therefore be deemed to contribute to the objectives referred to in Article 14 of Regulation […] [Regulation on speeding-up environmental assessments – permitting regulation].	and autonomy, and furthermore explicitly recognises that health biotechnology is essential for health-system resilience. In view of this consistent Union framework confirming biotechnology's systemic contribution to resilience, biotechnology strategic projects and high impact biotechnology strategic projects should therefore be deemed to contribute to the objectives referred to in Article 14 of Regulation […] [Regulation on speeding-up environmental assessments – permitting regulation].

Or. en

Amendment 598
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28a) In areas characterised by major public health and socioeconomic burden and persistent innovation gaps, including mental health, strategic projects may play an important role in strengthening the Union's innovation ecosystem, clinical development capacity, cross-border infrastructures, data capabilities and translation of research into accessible care.

Or. en

Amendment 599
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*

(29) In light of their contribution to the Union's competitiveness, resilience and preparedness, health biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest. Similarly, Member States should grant such projects the highest national significance available under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting, and adopt facilitation measures in compliance with Union law.	***deleted***

Or. en

Amendment 600
Stine Bosse, Katri Kulmuni, Billy Kelleher

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) In light of their contribution to the Union's competitiveness, resilience and preparedness, health biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest. Similarly, Member States should grant such projects the highest national significance available under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting, and adopt facilitation measures in compliance with Union law.	(29) In light of their contribution to the Union's competitiveness, resilience and preparedness, health biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest***. Projects that significantly contribute to the development, validation and regulatory uptake of NAMs, as human-relevant and innovative technologies, should be recognised as having particular public interest due to their potential to address genetic variability and susceptibility and to improve the effectiveness, safety and efficiency of biomedical research and health innovation***. Similarly, Member States should grant such projects the highest national significance available

	under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting, and adopt facilitation measures in compliance with Union law.

Or. en

Justification

Recognising the specific public interest value of NAMs would support their prioritisation within strategic projects and facilitate their faster development, uptake and regulatory integration.

Amendment 601
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) In light of their contribution to the Union's competitiveness, resilience and preparedness, health biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest. Similarly, Member States should grant such projects the highest national significance available under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting, and adopt facilitation measures in compliance with Union law.	(29) In light of their contribution to the Union's competitiveness, resilience and preparedness, health biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest. Similarly, Member States should grant such projects the highest national significance available under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting ***and GxP inspection and certification***, and adopt facilitation measures in compliance with Union law.

Or. en

Amendment 602
Wouter Beke, Vytenis Povilas Andriukaitis

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) In light of their contribution to the Union's competitiveness, resilience and preparedness, ***health*** biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest. Similarly, Member States should grant such projects the highest national significance available under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting, and adopt facilitation measures in compliance with Union law.	(29) In light of their contribution to the Union's competitiveness, resilience and preparedness, biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest. Similarly, Member States should grant such projects the highest national significance available under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting, and adopt facilitation measures in compliance with Union law.

Or. en