European Parliament
2024-2029

Committee on Public Health
Committee on Industry, Research and Energy

2025/0406(COD)

14.7.2026

AMENDMENTS
1076 - 1412

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 1076
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety ***and*** biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union ***with the objective of improving patient outcomes, addressing unmet medical needs, and reinforcing the robustness and resilience of healthcare systems across the Union and reflecting the diversity of products, technologies, and supply chains within the sector***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2)***, across the entire lifecycle***, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety***, food and feed security,*** biosecurity ***and promoting human-relevant and human-centred innovation***. ***It recognises that health biotechnology includes both novel and already established strategic sectors and supports their development across the entire life-cycle, including the collection of starting materials, manufacturing, logistics, storage, processing, market access, as well as through appropriate funding, investment and capital support.***

Or. en

Justification

This amendment recognises that health biotechnology includes both novel and already established strategic sectors and supports their development across the entire life-cycle, including the collection of starting materials, manufacturing, logistics, storage, processing, market access, as well as through appropriate funding, investment and capital support.

Limiting the framework to early-stage innovation would overlook existing sectors that already underpin the Union's competitiveness, resilience and security of supply.

This change also reflects the importance of considering the entire life-cycle of health biotechnology products, including the collection of starting materials, manufacturing, logistics, storage, processing, market access and access to funding and investment.

Amendment 1077
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union***, reflecting the diversity of products, technologies, and supply chains within the sector***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2)***, across the entire life-cycle***, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity. ***It recognises that health biotechnology includes both novel and already established strategic sectors and supports their development across the entire life-cycle, including the collection of starting materials, manufacturing, logistics, storage, processing, market access, as well***

as through appropriate funding, investment and capital support.

Or. en

Amendment 1078
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
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union***, reflecting the diversity of products, technologies, and supply chains within the sector***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2)***, across the entire life-cycle***, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity. ***It recognises that health biotechnology includes both novel and already established strategic sectors and supports their development across the entire life-cycle, including the collection of starting materials, manufacturing, logistics, storage, processing, market access, as well as through appropriate funding, investment and capital support.***

Or. en

Amendment 1079
Ondřej Krutílek

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union***, reflecting the diversity of products, technologies, and supply chains within the sector***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2) ***across the entire life-cycle***, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity. ***It recognises that health biotechnology includes both novel and already established strategic sectors and supports their development across the entire life-cycle, including the collection of starting materials, manufacturing, logistics, storage, processing, market access, as well as through appropriate funding, investment and capital support.***

Or. en

Amendment 1080
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*

1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness***, resilience and sustainability*** of the health biotechnology sector in the Union***, while ensuring that biotechnology innovations contribute to timely, equitable and affordable access to biotechnology innovations and products for patients and citizens, and addressing unmet medical needs***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, ***where these innovations contribute to public health objectives and ensure meaningful benefits for patients and society,*** while ***implemented in accordance with the precautionary principle and*** safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. en

Amendment 1081
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high

standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

This Regulation shall also contribute, in line with the One Health approach, to addressing risks linked to zoonotic diseases, antimicrobial resistance, biological threats, food and feed safety, animal health, animal welfare and ecosystem health through integrated research, surveillance, preparedness and innovation capacities across sectors.

Or. en

Amendment 1082
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology ***innovations and*** products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union***, as well as reinforcing the sustainability and resilience of the Unions helathcare systems, with a view to improving patient outcomes and addressing unmet medcal needs***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology ***products, and processes including but not limited to biosimilar medicinal*** products***, biohybrids medicinal products*** , while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity***, including mitigating risks arisign from***

emerging biotechnological and technological appraoches.

Or. en

Amendment 1083
Christine Anderson

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union ***by reducing unnecessary regulatory and administrative burdens across the sector, in particular for SMEs, start-ups and scale-ups, and by improving legal certainty and predictability for all biotechnology innovators***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. en

Amendment 1084
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Victor Negrescu

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations ***and*** products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in ***the Union with the objective of improving patient outcomes, addressing unmet medical needs and reinforcing the sustainability and resilience of healthcare systems across*** the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations**,** products ***and innovative and follow-up processes***, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. en

Amendment 1085
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products,	1. This Regulation establishes a framework to ***enhance the sustainibility and safety and*** strengthen the competitiveness of the health biotechnology sector in the Union ***to the benefit of patients and public welfare systems***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection

food and feed safety and biosecurity.	of human health, patient safety***,*** ***affordability and accessibility of medicinal products*** and animal health ***and welfare,***, the environment, ethics, quality of products, food and feed safety and biosecurity ***anchored in the One Health principle***.

Or. en

Amendment 1086
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, ***including by promoting regulatory predictability, simplification, technology-neutral innovation incentives, protection of intellectual property and access to finance,*** while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. en

Amendment 1087
Ruggero Razza

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity ***and boosting the Union's strategic autonomy in the field of critical biotechnologies and the resilience of the related supply chains***.

Or. it

Amendment 1088
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products,	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union ***with the aim of making the Union more competitive in this field, achieving results for patients, and addressing unmet medical needs***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while

food and feed safety and biosecurity.	safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. fr

Amendment 1089
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations ***and*** products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations***,*** products ***and processes, whether innovative or follow-on (multi-source environment after expiry of intellectual property rights and exclusivities)***, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. en

Amendment 1090
Dimitris Tsiodras

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology ***innovations and*** products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology products ***and processes, whether innovative or follow-on (multi-source environment after expiry of intellectual property rights and exclusivities)***, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. en

Justification

For optimal impact, the Biotech Act I (health) needs to consider the full European biotech ecosystem and established synergies, both geographically (beyond in 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 1091
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union***, reflecting the diversity of products, technologies, and supply chains within the sector***. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1),

production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

point (2)***, across the entire life-cycle***, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. en

Justification

The full diversity of the health biotechnology sector, including both novel and established strategic activities, should explicitly be accounted for in the Biotech Act.Limiting the framework to early-stage innovation would overlook existing sectors that already underpin the Union's competitiveness, resilience and security of supply.This change also reflects the importance of considering the entire life-cycle of health biotechnology products, including the collection of starting materials, manufacturing, logistics, storage, processing, market access and access to funding and investment.

Amendment 1092
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union**.** It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union***, reflecting the diversity of products, technologies, and supply chains within the sector.***
	It creates and reinforces favourable conditions for health biotechnology as

	defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. en

Amendment 1093
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and ***security and*** biosecurity.

Or. en

Amendment 1094
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
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.	1. This Regulation establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union. It creates and reinforces favourable conditions for health biotechnology as defined in Article 2(1), point (2), from research and development to the timely placing on the Union market and production of biotechnology innovations***,*** ***processes*** and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity.

Or. en

Amendment 1095
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 1 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. This Regulation shall contribute to a stronger European Health Union by improving patient access to biotechnology innovations and products, in particular where they address unmet medical needs, improve patient outcomes or reduce inequalities in access to innovation, including through stronger links with interconnected and interoperable European Reference Networks, rare disease research and the Union's research and innovation ecosystem.

Or. en

Amendment 1096
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 1 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. This Regulation shall also contribute, in line with the One Health approach, to addressing risks linked to zoonotic diseases, antimicrobial resistance and biological threats through integrated research, surveillance, preparedness and innovation capacities across sectors.

Or. en

Amendment 1097
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 1 – paragraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) The promotion of scientific freedom, open and collaborative science, the development, validation, standardisation, regulatory acceptance and uptake of human-centred non-animal New Approach Methodologies (NAMs), in order to support human-relevant evidence generation, accelerate innovation and contribute to the phasing out of animal testing and use in research, development, manufacturing and regulatory safety assessment;

Or. en

Amendment 1098

Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 1 – paragraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) The development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies, where scientifically appropriate, in order to support human-relevant evidence generation and contribute to the replacement, reduction and refinement of animal testing and use in clinical trials;

Or. en

Amendment 1099
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) novel health biotechnology products ***and regulatory sandboxes*** to support innovation and take into account technological and scientific developments and progress;	(b) novel health biotechnology products to support innovation and take into account technological and scientific developments and progress;

Or. en

Amendment 1100
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 1 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) novel health biotechnology	(b) novel health biotechnology

products ***and regulatory sandboxes*** to support innovation and take into account technological and scientific developments and progress;	products to support innovation and take into account technological and scientific developments and progress;

Or. en

Amendment 1101
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 1 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the promotion of scientific freedom, open and collaborative science, and the development, validation, regulatory acceptance and uptake of human-centred non-animal New Approach Methodologies (NAMs), with the objective of accelerating innovation and progressively replacing animal testing in research, development, manufacturing and regulatory safety assessment;

Or. en

Amendment 1102
Ruggero Razza

Proposal for a regulation
Article 1 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) the support to promoters of biotechnology projects, SMEs, start-ups ***and*** scale-ups and non-profit developers of biotechnology products, by establishing an EU Health Biotechnology Support Network;	(c) the support to promoters of biotechnology projects, SMEs, start-ups***, university spin-offs, scientific healthcare and research institutes, public research organisations, public-private partnerships,*** scale-ups and non-profit developers of biotechnology products, by establishing an EU Health Biotechnology Support Network;

Or. it

Amendment 1103
Ruggero Razza

Proposal for a regulation
Article 1 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) the support for funding of, investments in, and access to capital for ***biotechnology*** companies and projects;	(d) the support for funding of, investments in, and access to capital for companies***, venture capital instruments, long-term financing and investment for the Union's industrial and productive development*** and ***biotechnology*** projects ***with a view to promoting a competitive European framework at international level, including by assessing the possibility of gradually bringing the effective duration of patent protection and supplementary protection mechanisms into line with the practice of economic competitors, and ultimately encouraging investment in the research, development and production of healthcare biotechnologies in the Union***;

Or. it

Amendment 1104
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 1 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) the support for funding of, investments in, and access to capital for biotechnology companies and projects;	(d) the support for funding of, investments in, and access to capital for biotechnology companies and projects ***as well as social, animal welfare and environnement conditions attached thereto***;

Or. en

Amendment 1105
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the conditions attached to Union or Member State financial support granted to biotechnology companies and projects, and the corrective measures and penalties applicable to beneficiaries in the event of non-compliance with those conditions;

Or. en

Amendment 1106
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 1 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) ***the enhancement of the*** manufacturing capacity ***of***, and expertise for biosimilars in the Union, including through international cooperation;	(e) ***facilitate, support and incentivise investments in new*** manufacturing capacity ***and strengthen existing manufacturing capacity***, and expertise for biosimilars in the Union, including through international cooperation;

Or. en

Amendment 1107
Dimitris Tsiodras

Proposal for a regulation
Article 1 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) the enhancement of the manufacturing capacity of, and expertise for biosimilars in the Union, including through international cooperation;	(e) the enhancement of the ***development and*** manufacturing capacity of, and expertise for biosimilars in the Union, including ***all current and future biotechnology platforms (e.g. ATMPs) and*** through ***European (EEA, CH, UK) and*** international cooperation;

Or. en

Justification

For optimal impact, the Biotech Act I (health) needs to consider the full European biotech ecosystem and established synergies, both geographically (beyond in 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 1108
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 1 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) the enhancement of the manufacturing capacity of, and expertise for biosimilars in the Union, including through international cooperation;	(e) the enhancement of the ***development and*** manufacturing capacity of, and expertise for biosimilars in the Union, including ***all current and future biotechnology platforms and*** through international cooperation;

Or. en

Amendment 1109
Ruggero Razza

Proposal for a regulation
Article 1 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) the enhancement of the	(e) the enhancement of the

manufacturing capacity of, and expertise for biosimilars in the Union, including through international cooperation;	manufacturing capacity of, and expertise for biosimilars ***and other strategic biotechnologies*** in the Union, including through international cooperation;

Or. it

Amendment 1110
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) the enhancement of the manufacturing capacity of, and expertise for biosimilars in the Union, including through international cooperation;	(e) the enhancement of the ***development and*** manufacturing capacity of, and expertise for biosimilars in the Union, including through international cooperation;

Or. en

Amendment 1111
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
Article 1 – paragraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) the enhancement of the manufacturing capacity of, and expertise for biosimilars in the Union, including through international cooperation;	(e) the enhancement of the manufacturing ***and development*** capacity of, and expertise for biosimilars in the Union, including through international cooperation;

Or. en

Amendment 1112

Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 1 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification, reducing dependencies, in particular on third countries, where these put the supply of biological medicinal products and biosimilar medicinal product at risk;

Or. en

Amendment 1113
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 1 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) the application in a facilitated manner of advanced technologies, including AI in biological applications***,*** ***into*** the Union's health biotechnology ecosystems, while monitoring and mitigating, in line with the Union harmonisation legislation on AI, biological risks arising from the use of such technologies;	(f) the application in a facilitated manner of advanced technologies, including ***but not limited to*** AI in biological applications ***and*** the Union's health biotechnology ecosystems, while monitoring and mitigating, in line with the Union harmonisation legislation on AI ***and***, biological risks ***such as risks arising from data-driven or automated approaches,*** arising from the use of such technologies;

Or. en

Amendment 1114
Ruggero Razza

Proposal for a regulation
Article 1 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) the application in a facilitated manner of advanced technologies, including AI in biological applications, into the Union's health biotechnology ecosystems, while monitoring and mitigating, in line with the Union harmonisation legislation on AI, biological risks arising from the use of such technologies;	(f) the application in a facilitated manner of advanced technologies, including AI in biological applications ***and research, development and biomanufacturing processes***, into the Union's health biotechnology ecosystems, while monitoring and mitigating, in line with the Union harmonisation legislation on AI, biological risks arising from the use of such technologies;

Or. it

Amendment 1115
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 1 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) the application in a facilitated manner of advanced technologies, including AI in biological applications, into the Union's health biotechnology ecosystems, while monitoring and mitigating, in line with the Union harmonisation legislation on AI, ***biological*** risks arising from the use of such technologies;	(f) the application in a facilitated manner of advanced technologies, including AI in biological applications, into the Union's health biotechnology ecosystems, while monitoring and mitigating, in line with the Union harmonisation legislation on AI, ***safety and data protection*** risks arising from the use of such technologies;

Or. en

Amendment 1116
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) the application in a facilitated	(f) the application in a facilitated

manner of advanced technologies, including AI in biological applications, into the Union's health biotechnology ecosystems, while monitoring and ***mitigating***, in line with the Union harmonisation legislation on AI, biological risks arising from the use of such technologies;	manner of advanced technologies, including ***ethical use of*** AI in biological applications, into the Union's health biotechnology ecosystems, while monitoring and ***preventing***, in line with the Union harmonisation legislation on AI, biological risks arising from the use of such technologies;

Or. en

Amendment 1117
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 1 – paragraph 2 – point g

Text proposed by the Commission	*Amendment*
(g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated and streamlined procedures;	(g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated and streamlined procedures***, with a priority where they address unmet medical needs, including in the area of mental health***;

Or. en

Amendment 1118
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 1 – paragraph 2 – point g

Text proposed by the Commission	*Amendment*
(g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated and streamlined procedures;	(g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated and streamlined procedures ***while respecting existing environmental, safety and social EU standards and regulations***;

Or. en

Amendment 1119
Ruggero Razza

Proposal for a regulation
Article 1 – paragraph 2 – point g

Text proposed by the Commission	*Amendment*
(g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated and streamlined procedures;	(g) the placing on the market in particular of health biotechnology products and biotechnology services in accelerated***,*** ***predictable*** and streamlined procedures;

Or. it

Amendment 1120
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 1 – paragraph 2 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) the reduction of fragmentation and the improvement of coordination across the Union market for biotechnology products, in particular in the area of health, and, where relevant, in relation to environmental biotechnology applications that contribute to public health, One Health, environmental protection or sustainable production;

Or. en

Amendment 1121
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 1 – paragraph 2 – point h

Text proposed by the Commission	*Amendment*

(h) the prevention of the misuse of biotechnologies ***and the strengthening of biodefence capabilities, without prejudice to, and in complementarity with, activities financed under any defence related Union funding programmes and instruments***.	(h) the prevention of the misuse of biotechnologies.

Or. en

Amendment 1122
Ruggero Razza

Proposal for a regulation
Article 1 – paragraph 2 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) the establishment of a European framework conducive to the protection, promotion and economic exploitation of the intellectual property rights associated with biotechnology research, including by facilitating the registration, certification and commercialisation of patents developed in the Union.

Or. it

Amendment 1123
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 1 – paragraph 2 – point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) the promotion of fair and equitable sharing of benefits arising from genetic resources.

Or. en

Amendment 1124

Christine Anderson

Proposal for a regulation
Article 1 – paragraph 3

Text proposed by the Commission	*Amendment*
3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities.	3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities***, without prejudice to Member States' competences in the organisation and delivery of healthcare, medical ethics, reproductive medicine, genetic testing, embryo research, the use of human biological material and the protection of personal data, including genetic data and data concerning health***.

Or. en

Amendment 1125
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 3

Text proposed by the Commission	*Amendment*
3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities.	3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities***, as well as aspects related to equitable access to, and the affordance***.

Or. en

Amendment 1126
Ruggero Razza

Proposal for a regulation
Article 1 – paragraph 3

Text proposed by the Commission	*Amendment*
3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, ***and*** use activities.	3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, use activities ***and subsequent monitoring, where applicable***.

Or. it

Amendment 1127
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 1 – paragraph 3

Text proposed by the Commission	*Amendment*
3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market, and use activities.	3. This Regulation applies to health biotechnology innovations and products and their ecosystem during their entire lifecycle, including related research, funding, development, innovation, testing, validation, manufacturing, placing on the market***, patient access***, and use activities.

Or. fr

Amendment 1128
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. where a biotechnology activity supported or facilitated under this Regulation may reasonably be expected to pose significant risks to biodiversity, ecosystems, human health, animal health or public health, the competent authority shall ensure that a specific environmental, biosafety and biosecurity risk assessment is carried out before any fast-track procedure, coordinated support or market-related facilitation is granted.

Or. en

Amendment 1129
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. Operators benefiting from measures under this Regulation shall establish and maintain an internal compliance system covering environmental risk management, biosafety, biosecurity, ethical compliance, traceability, waste management and corrective actions, and shall make it available to competent authorities upon request.

Or. en

Amendment 1130
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 3 c (new)

Text proposed by the Commission	*Amendment*
	3c. The Commission shall lay down rules by an implementing act on penalties applicable to infringements of this Article and shall take all measures necessary to ensure that those penalties are effective, proportionate.

Or. en

Amendment 1131
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 1 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The amendments to the Union legislation laid down in Articles 56 to 61 are not limited to health biotechnology products and activities, but also relate to the other products, services and activities that fall in the scope of that legislation.	***deleted***

Or. en

Amendment 1132
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 1 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The amendments to the Union legislation laid down in Articles 56 to 61 are not limited to health biotechnology products and activities, but also relate to the other products, services and activities that fall in the scope of that legislation.	***deleted***

Or. en

Amendment 1133
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 1 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The implementation of this Regulation shall ensure coherence with future Union initiatives addressing emerging biotechnologies and industrial biotechnology, in particular where measures under this Regulation concern biomanufacturing, data, AI, regulatory simplification, funding and infrastructures.

Or. en

Justification

Biotech Act I should act as a first step and a bridge towards Biotech Act II, covering emerging and industrial biotechnologies, including food, agri-biotech, biomaterials and biomanufacturing.

Amendment 1134
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
Article 1 – paragraph 5

Text proposed by the Commission	*Amendment*
5. This Regulation does not affect the application of Directive 2010/63/EU on the protection of animals used for scientific purposes and of Regulation (EU) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction	5. This Regulation does not affect the application of Directive 2010/63/EU on the protection of animals used for scientific purposes and of Regulation (EU) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ***while supporting,***

of Chemicals (REACH).	***where scientifically appropriate, the development, validation, regulatory acceptance and uptake of New Approach Methodologies (NAMs) in biotechnology research, development, risk assessment and clinical trial processes, including organ on chip, microphysiological systems and digital twin methodologies***.

Or. en

Amendment 1135
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 1 – paragraph 5

Text proposed by the Commission	*Amendment*
5. This Regulation does not affect the application of Directive 2010/63/EU on the protection of animals used for scientific purposes and of Regulation (EU) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).	5. This Regulation does not affect the application of Directive 2010/63/EU on the protection of animals used for scientific purposes and of Regulation (EU) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)***, while supporting the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies in biotechnology research, development, risk assessment and clinical trial processes***.

Or. en

Amendment 1136
Peter Liese

Proposal for a regulation
Article 1 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Nothing in this Regulation shall be

construed as permitting or encouraging

(a) the creation of human embryos for research or industrial purposes;

(b) reproductive cloning of human beings; or

(c) germ-line genetic modification of the human embryo,

as prohibited under Directive 98/44/EC, Article 6, and relevant national legislation.

Or. en

Justification

An explicit cross-reference to the prohibitions in Directive 98/44/EC ensures legal certainty for developers and regulators and prevents misinterpretation that the Act could open doors to embryo or germ-line research.

Amendment 1137
Jérémy Decerle, Christophe Grudler

Proposal for a regulation
Article 1 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. Taking into account the specific situation of outermost regions, in accordance with Article 349 TFEU, will be essential, given the structural constraints that hinder their socio-economic development and limit their access to the single market. This is necessary to ensure that outermost regions can fully benefit from the measures proposed under the Biotech Act.

Or. en

Justification

Considering that 90% of EU biodiversity is located in ORs, these could play a key role in developing "living labs" focused on global health, emerging diseases, biodiversity, blue economy, and climate change. To support attractiveness and the retention of researchers,

start-ups, and tech companies, more flexible regulatory frameworks for biotechnology trials and public procurement, and/or to compensatory measures within EU programmes are necessary. These measures would aim to mitigate structural disadvantages related to logistics, mobility, and access to equipment).

Amendment 1138
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 1 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. This Regulation shall not apply to food products intended for human consumption falling within the scope of Regulation (EU) 2015/2283 on novel foods, including products derived from cell culture.

Or. en

Amendment 1139
François-Xavier Bellamy, Céline Imart

Proposal for a regulation
Article 1 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. This Regulation shall not apply to food products intended for human consumption falling within the scope of Regulation EU 2015/2283 on novel foods, including products derived from cell culture.

Or. en

Amendment 1140
Jérémy Decerle

Proposal for a regulation

Article 1 – paragraph 7 b (new)

Text proposed by the Commission	*Amendment*
	7b. This Regulation shall not apply to food products intended for human consumption falling within the scope of Regulation (EU) 2015/2283 on novel foods, including products derived from cell culture.

Or. en

Justification

Food products, in particular novel foods within the meaning of Regulation (EU) 2015/2283, are subject to a dedicated and harmonised regulatory framework ensuring a high level of consumer protection. This Regulation should not create alternative pathways for their development, assessment or placing on the market.

Amendment 1141
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 2 – paragraph 1 – point 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) The Commission may adopt implementing acts in accordance with Article 2.1 to amend this Regulation in order to update the definitions referred to in paragraph 1 regarding what constitutes biotechnology, health biotechnology and biomanufacturing in light of technical and scientific advancements in the field of biotechnology and taking into account definitions agreed at the Union and international level without extending the scope of this definition.

Or. en

Justification

This amendment supports a dynamic and future-proof definition of biotechnology products, aligned with evolving OECD definitions.

Amendment 1142
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 2 – paragraph 1 – point 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) 'One Health' means One Health as defined in Article 3, point (7), of Regulation (EU) 2022/2371 of the European Parliament and of the Council;

Or. en

Amendment 1143
Margarita de la Pisa Carrión, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain, Ondřej Knotek

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;	(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health***, including the research, development and manufacturing of medicinal products substantially dependent on biotechnological processes,*** and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;

Or. en

Amendment 1144

Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;	(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health***, including the development and manufacturing of medicinal products substantially dependent on biotechnological processes,*** and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;

Or. en

Amendment 1145
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;	(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union ***excluding food products intended for***

human consumption falling within the scope of Regulation (EU) 2015/2283;

Or. en

Amendment 1146
François-Xavier Bellamy, Céline Imart

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;	(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union***,*** ***excluding food products intended for human consumption falling within the scope of Regulation EU 2015/2283***;

Or. en

Amendment 1147
Jérémy Decerle

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and	(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and

food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;	food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union***, excluding products falling within the scope of Regulation (EU) 2015/2283*** ;

Or. en

Justification

Food products, in particular novel foods within the meaning of Regulation (EU) 2015/2283, are subject to a dedicated and harmonised regulatory framework ensuring a high level of consumer protection. This Regulation should not create alternative pathways for their development, assessment or placing on the market.

Amendment 1148
Christine Anderson

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly ***or indirectly*** to the protection of human health ***and align with the Union's public health objectives, as set out under Article 168*** of the ***Treaty*** on the ***Functioning of the European Union***;	(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly ***and demonstrably*** to the protection of human health ***within the limits*** of the ***competences conferred*** on the ***Union by the Treaties***;

Or. en

Amendment 1149
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;	(2) 'health biotechnology' means ***the research and*** the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;

Or. en

Amendment 1150
Paulo Cunha, Sérgio Humberto

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;	(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human ***and animal*** health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;

Or. en

Amendment 1151
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;	(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human ***and animal*** health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;

Or. en

Justification

This clarifies that health biotechnology products encompass applications relating to both human and animal health.

Amendment 1152
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 2 – paragraph 1 – point 2

Text proposed by the Commission	*Amendment*
(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;	(2) 'health biotechnology' means the application of biotechnology for the promotion, protection, or restoration of human ***and animal*** health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union;

Or. en

Amendment 1153
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
Article 2 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) 'biotechnology product' means any good, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;	(3) 'biotechnology product' means any good***, including medicinal products***, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;

Or. en

Amendment 1154
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 2 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) 'biotechnology product' means any ***good***, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;	(3) 'biotechnology product' means any ***goods including medicines***, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;

Or. en

Amendment 1155
Kristoffer Storm

Proposal for a regulation
Article 2 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) 'biotechnology product' means any ***good***, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;	(3) 'biotechnology product' means any ***goods including medicines***, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;

Or. en

Amendment 1156
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 2 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) 'biotechnology product' means any ***good***, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;	(3) 'biotechnology product' means any ***goods including medicines***, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;

Or. en

Justification

The addition is needed to ensure that pharmaceutical products are included.

Amendment 1157
Paulo Cunha, Sérgio Humberto

Proposal for a regulation
Article 2 – paragraph 1 – point 3

Text proposed by the Commission	*Amendment*
(3) 'biotechnology product' means any ***good***, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge involving biotechnology;	(3) 'biotechnology product' means any ***goods including medicines***, technology or activity resulting from the application of biotechnology, including any process, action, technique, tool or knowledge

involving biotechnology;

Or. en

Justification

This amendment intends to ensure that pharmaceutical products are included, as it is important not to disincentivize innovation in this sector

Amendment 1158
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) 'biosimilar medicinal product' means a biosimilar product as defined in Article 4(1), point (14a) of Directive .../... [Directive on medicinal products for human use, as proposed in COM(2023)192]

Or. en

Amendment 1159
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 3 c (new)

Text proposed by the Commission	*Amendment*
	(3c) 'open platform' means a platform technology master file where the owner of the underlying technology makes the relevant regulatory data, documentation and validated scientific components available, under transparent and non-discriminatory conditions, to any third party developing a product sharing the same common regulatory data and scientific components.

Or. en

Amendment 1160
Ruggero Razza

Proposal for a regulation
Article 2 – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
(4) 'advanced biotechnology innovation' means a biotechnology product, process, service or enabling technology that demonstrates, on the basis of preliminary scientific or technical evidence, the potential to achieve a substantial improvement over existing solutions in terms of efficacy, safety, sustainability, accessibility, and/or cost-effectiveness, and that, by reason of its novelty, technical complexity and/or market-creating potential, entails a high level of technological or commercial risk and it is likely to create new markets or significantly disrupt existing ones;	(4) 'advanced biotechnology innovation' means a biotechnology product, process, service or enabling technology that demonstrates, on the basis of preliminary scientific or technical evidence, the potential to achieve a substantial improvement over existing solutions***, including the ability to meet unresolved health needs, bolster the resilience of healthcare systems and improve the availability of essential biotechnology products in the Union as well as*** in terms of efficacy, safety, sustainability, accessibility, and/or cost-effectiveness, and that, by reason of its novelty, technical complexity and/or market-creating potential ***or potential to boost the Union's industrial resilience***, entails a high level of technological or commercial risk and it is likely to create new markets or significantly disrupt existing ones;

Or. it

Amendment 1161
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) 'Biohybrid advanced therapy medicinal product (biohybrid ATMP)'

means an advanced therapy medicinal product that relies, in whole or in part, on the regulatory dossier of an authorised reference ATMP but incorporates scientifically justified modifications—including manufacturing processes, cellular or genetic components, delivery technologies, platform technologies or other product characteristics—that prevent demonstration of biosimilarity, while permitting reliance on existing knowledge and data supplemented by evidence addressing the residual uncertainties arising from those modifications.

Or. en

Amendment 1162
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 2 – paragraph 1 – point 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) 'advanced biomanufacturing technology' means a manufacturing method, platform, process or system used in the development or production of biotechnology-based or bio-based products and materials, including health and biotechnology products and industrial applications, which by virtue of its novelty or novel application of an established technology has the potential to substantially improve manufacturing robustness, efficiency, scalability, sustainability, valorisation of biomass feedstocks or supply resilience within the Union;

Or. en

Amendment 1163
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale***;***	(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale ***or the use of biotechnology in manufacturing processes, including manufacturing activities carried out under a manufacturing authorisation pursuant to Directive 2001/83/EC and in accordance with the principles and guidelines of Good Manufacturing Practice referred to in Article 46(f) of that Directive.***

Or. en

Amendment 1164
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'biomanufacturing' means the ***production*** of biotechnology products ***at a commercial scale***;	(5) 'biomanufacturing' means the ***commercial-scale manufacture*** of biotechnology products***, encompassing manufacturing activities carried out under a manufacturing authorisation pursuant to Directive 2001/83/EC and in accordance with the principles and guidelines of Good Manufacturing Practice referred to in Article 46(f) of that Directive***;

Or. en

Amendment 1165
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale;	(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale***, as well as the industrial, technology-neutral production through for example biological, chemical, and mechanical processes to convert renewable resources into bio-based products at scale***;

Or. en

Justification

The concept of biomanufacturing should be technology-neutral and encompass, in addition to biological processes, also for example, chemical, mechanical, and thermal methods. An overly narrow biotechnological interpretation would, in practice, limit policy measures and the regulatory framework to synthetic biology, fermentation, and similar traditional biotechnology applications, thereby excluding, for instance, bio-based value chains of the forest industry and their significant economic and environmental benefits.

Amendment 1166
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale;	(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale ***in accordance with Annex II of the EU guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use***;***[1a]***
	[1a] https://www.gmp-compliance.org/files/guidemgr/2018_annex2_en.pdf

Or. en

Amendment 1167
Paulo Cunha, Sérgio Humberto

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale;	(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale ***and the use of biotechnology in manufacturing processes***;

Or. en

Justification

The definition of 'biomanufacturing' should encompass other uses of biotechnology in order to completely encompass the reality of all biotech uses across the involved industries. This definition shall not be excessively restrictive

Amendment 1168
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale;	(5) 'biomanufacturing' means the production of biotechnology products ***and the use of biotechnology in manufacturing processes*** at a commercial scale;

Or. en

Justification

Taking account of the use of biotechnology processing in biomanufacturing such as biocatalysts for enzyme production, in the manufacture of small-molecule medicinal products, which constitutes an established and evolving manufacturing approach in the health biotech sector.

Amendment 1169
Margarita de la Pisa Carrión, András Gyürk, Viktória Ferenc, Laurent Castillo, Ondřej Knotek, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale;	(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale ***or the use of biotechnology in manufacturing processes***;

Or. en

Amendment 1170
Kristoffer Storm

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale;	(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale ***or the use of biotechnology in manufacturing processes***;

Or. en

Amendment 1171
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 2 – paragraph 1 – point 5

Text proposed by the Commission	*Amendment*
(5) 'biomanufacturing' means the production of biotechnology products at a	(5) 'biomanufacturing' means the production of biotechnology products at a commercial scale ***or the use of***

commercial scale***;***	***biotechnology in manufacturing processes.***

Or. en

Justification

Biotechnology is increasingly used in many areas, eg. to engineer biocatalysts such as enzymes for manufacture of small molecule drugs, and all these applications should be in scope.

Amendment 1172
Ruggero Razza

Proposal for a regulation
Article 2 – paragraph 1 – point 6

Text proposed by the Commission	*Amendment*
(6) 'biotechnology cluster' means a geographic concentration of interconnected companies, research institutions and organisations focused on biotechnology and life sciences, fostering collaboration and innovation;	(6) 'biotechnology cluster' means a geographic concentration of interconnected companies, research institutions and organisations focused on biotechnology and life sciences, fostering collaboration and innovation ***between research, industry and healthcare services***;

Or. it

Amendment 1173
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 6

Text proposed by the Commission	*Amendment*
(6) 'biotechnology cluster' means a geographic concentration of interconnected companies, research institutions and organisations focused on biotechnology and life sciences, fostering collaboration and innovation;	(6) 'biotechnology cluster' means a geographic concentration of interconnected companies, ***medical, veterinary and*** research institutions and organisations focused on biotechnology and life sciences, fostering collaboration and innovation;

Or. en

Amendment 1174
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 6

Text proposed by the Commission	*Amendment*
(6) 'biotechnology cluster' means a geographic concentration of interconnected companies, research institutions and organisations focused on biotechnology and life sciences, fostering collaboration and innovation;	(6) 'biotechnology cluster' means a geographic concentration of interconnected companies, ***medical, veterinary and*** research institutions and organisations focused on biotechnology and life sciences, fostering collaboration and innovation;

Or. en

Amendment 1175
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) 'innovation hub' means centralized environment of people, resources, and organizations to collaborate, share knowledge, accelerate innovation, foster the creation, development, and commercialization of new ideas, technologies, and businesses;

Or. en

Amendment 1176
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 7 b (new)

Text proposed by the Commission	*Amendment*
	(7b) 'translational research' means research activities that convert scientific knowledge, discoveries, or findings into practical applications for human health, and the study of how such applications are adopted and implemented in clinical practice and public health settings.

Or. en

Amendment 1177
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 7 c (new)

Text proposed by the Commission	*Amendment*
	(7c) 'spin-off' means a legal entity that has been established for the purpose of commercially exploiting intellectual property, know-how, research results, or other technology originating from a research or academic institution or an existing undertaking

Or. en

Amendment 1178
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 7 d (new)

Text proposed by the Commission	*Amendment*
	(7d) 'cross-border health network' means a structured collaboration involving healthcare providers, research institutions, biotechnology undertakings,

or competent authorities from at least two Member States

Or. en

Amendment 1179
Anja Hazekamp, Anthony Smith, Sebastian Everding

Proposal for a regulation
Article 2 – paragraph 1 – point 8

Text proposed by the Commission	*Amendment*
(8) 'permit-granting process' means a process that covers all relevant permits to build, expand, convert and operate health biotechnology strategic projects and high impact health biotechnology strategic projects, including building permits and environmental assessments and authorisations where required, and encompassing all applications and procedures from the acknowledgement that the application for such permits is complete to the notification of the decision on the outcome of the procedure by the single point of contact concerned;	***deleted***

Or. en

Amendment 1180
Ruggero Razza

Proposal for a regulation
Article 2 – paragraph 1 – point 8

Text proposed by the Commission	*Amendment*
(8) 'permit-granting process' means a process that covers all relevant permits to build, expand, convert and operate health biotechnology strategic projects and high impact health biotechnology strategic projects, including building permits and environmental assessments and	(8) 'permit-granting process' means a process that covers all relevant permits to build, expand, convert and operate health biotechnology strategic projects and high impact health biotechnology strategic projects, including building permits and environmental assessments and

authorisations where required, and encompassing all applications and procedures from the acknowledgement that the application for such permits is complete to the notification of the decision on the outcome of the procedure by the single point of contact concerned;	authorisations where required, and encompassing all applications and procedures from the acknowledgement that the application for such permits is complete ***and the coordinated execution of the relevant assessments*** to the notification of the decision on the outcome of the procedure by the single point of contact concerned;

Or. it

Amendment 1181
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) 'Innovative technology' means any emerging or rapidly evolving biotechnological, biomedical, digital, computational, manufacturing or delivery modality intended for the prevention, diagnosis, monitoring, treatment or cure of human disease, recognised by the Agency, after consultation with the Clinical Trials Advisory Group, the relevant European Reference Networks and the Steering Group established under the European Biotech Act;

Or. en

Amendment 1182
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 9 b (new)

Text proposed by the Commission	*Amendment*

(9b) 'Therapeutic combination product' means a therapeutic intervention composed of two or more components intended to function together as a single treatment, where those components fall under distinct Union regulatory frameworks.. Therapeutic combination products shall be assessed through a single integrated regulatory pathway coordinated by the Agency in accordance with Article 27f.

Or. en

Amendment 1183
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) 'strategic biotechnology tools' means key devices, technologies, platforms or components that are necessary or enabling for the development, manufacturing or scale-up of advanced therapy medicinal products within the meaning of Regulation (EC) No 1394/2007, or of other biotechnological products, and that are identified in accordance with Article 27c(2) as contributing to the Union's strategic autonomy in health technologies, addressing a critical dependency or supply risk;

Or. en

Amendment 1184
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 10 a (new)

Text proposed by the Commission	*Amendment*
	(10a) 'innovation partnership' means the procedure referred to in Article 31 of Directive 2014/24/EU;

Or. en

Amendment 1185
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 10 c (new)

Text proposed by the Commission	*Amendment*
	(10c) 'pre-commercial procurement' means the procurement of research and development services referred to in recital 4 of Directive 2014/24/EU, not falling within the scope of that Directive;

Or. en

Amendment 1186
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 10 d (new)

Text proposed by the Commission	*Amendment*
	(10d) 'delinked payment model' means a financing arrangement under which remuneration to the developer is wholly or partly disconnected from the volume of the product sold or supplied.

Or. en

Amendment 1187
Ruggero Razza

Proposal for a regulation
Article 2 – paragraph 1 – point 13

Text proposed by the Commission	*Amendment*
(13) 'implementing partner' means an entity implementing, in indirect management, support under the EU health biotechnology investment pilot;	(13) 'implementing partner' means an entity implementing, in indirect management, support under the EU health biotechnology investment pilot ***and providing the requisite technical expertise to that end***;

Or. it

Amendment 1188
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 2 – paragraph 1 – point 13

Text proposed by the Commission	*Amendment*
(13) 'implementing partner' means an entity implementing, in indirect management, support under the EU ***health*** biotechnology investment ***pilot***;	(13) 'implementing partner' means an entity implementing, in indirect management, support under the EU biotechnology investment ***facility***;

Or. en

Amendment 1189
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 2 – paragraph 1 – point 19

Text proposed by the Commission	*Amendment*
(19) 'New Approach Methodologies (NAMs)' means innovative methods that do not involve live animals, such as in vitro (cell or tissue-based), in chemico (chemical-based), or in silico (computer-based) approaches, as well as combinations of these;	(19) 'New Approach Methodologies (NAMs)' means innovative ***3R methods, including but not limited to those that do not involve live animals,*** methods that do not involve live animals, such as in vitro (cell or tissue-based), in chemico (chemical-based), or in silico (computer-based) approaches, as well as combinations

of these;

Or. en

Amendment 1190
Kristoffer Storm

Proposal for a regulation
Article 2 – paragraph 1 – point 19

Text proposed by the Commission	*Amendment*
(19) 'New Approach Methodologies (NAMs)' means innovative methods that do not involve live animals, such as in vitro (cell or tissue-based), in chemico (chemical-based), or in silico (computer-based) approaches, as well as combinations of these;	(19) 'New Approach Methodologies (NAMs)' means innovative ***3R*** methods***, including but not limited to those*** that do not involve live animals, such as in vitro (cell or tissue-based), in chemico (chemical-based), or in silico (computer-based) approaches, as well as combinations of these;

Or. en

Amendment 1191
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 2 – paragraph 1 – point 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) 'synthetic cell' means an engineered, cell-like system, built from biological components, non-living components or a combination thereof, which mimics one or more functions of a natural cell and is designed to perform specific, programmable tasks for technological applications such as biosensing, drug delivery and biochemical production;

Or. en

Justification

The Regulation acts only on the categories it defines. Synthetic cells sit between existing definitions, so a dedicated definition is needed for developers and authorities to know what the term covers. This definition is used by the research field.

Amendment 1192
Aurelijus Veryga

Proposal for a regulation
Article 2 – paragraph 1 – point 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) Advanced diagnostics means next-generation molecular and genomic testing and imaging approaches used in clinical practice to generate clinically actionable information on the biological and genetic drivers of disease, with the aim of supporting more accurate diagnosis, prognosis, patient stratification and therapy selection.

Or. en

Amendment 1193
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) (19 a) 'One Health' means One Health as defined in Article 3, point (7), of Regulation (EU) 2022/2371 of the European Parliament and of the Council

Or. en

Amendment 1194
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 2 – paragraph 1 – point 21

Text proposed by the Commission	*Amendment*
(21) 'biodefence' means actions, policies**,** and measures that are designed, in particular by state actors, for preventive, protective or peaceful purposes, to counter biological threats, reduce risks, and prepare for, detect, assess, respond to, and recover from biological threats;	(21) 'biodefence' means ***preparing through stockpiling, establishing ever-warm manufacturing capacities and other*** actions, policies and measures that are designed, in particular by state actors, for preventive, protective or peaceful purposes, to counter biological threats, ***whether such threats represent natural outbreaks, accidental releases, or deliberate malicious use; and*** reduce risks, and prepare for, detect, assess, ***and*** respond to, and recover from biological threats ***with known pathogens***;

Or. en

Amendment 1195
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 2 – paragraph 1 – point 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) 'pandemic preparedness' means preparing through stockpiling, ever-warm manufacturing capacities and other measures that are designed, in particular by state actors, to reduce the risks for and respond to infectious disease outbreaks emerging naturally from known and unknown pathogens of animal or human origins;

Or. en

Justification

A clearer definition of pandemic preparedness is necessary because there is confusion with the related notions of biosecurity, health security, health preparedness, and biodefence. Pandemic preparedness focuses on protecting public health from naturally emerging

infectious diseases through surveillance, healthcare capacity, vaccination, and outbreak response.

Amendment 1196
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 2 – paragraph 1 – point 22

Text proposed by the Commission	*Amendment*
(22) 'biosecurity' means the protection, control and accountability of high-consequence biological agents, technologies, materials and toxins of concern, as well as of critical relevant information against unauthorised access, loss, theft, misuse, diversion or intentional release by those who intend to misuse them;	(22) 'biosecurity' means the protection, control and accountability of high-consequence biological agents, technologies, materials and toxins of concern, as well as of critical relevant information against unauthorised access, loss, theft, misuse, diversion or intentional release by those who intend to misuse them; ***in the context of provisions relating to food and feed security and the resilience of biotechnology-derived value chains, 'biosecurity' is understood in addition to encompass, in line with the Food and Agriculture Organization (FAO) of the United Nations' definition of biosecurity, a strategic and integrated approach to analysing and managing risks to human, animal and plant life and health and to the environment, including risks arising from strategic dependencies on third-country suppliers of biotechnology-derived food and feed inputs;***

Or. en

Justification

The draft report from the rapporteurs does not touch upon the Commission definition, which covers only the prevention of misuse of high-consequence agents. The term is also used in the context of food and feed security and supply-chain resilience, where it carries a broader meaning. This amendment extends the definition to cover both meanings without changing the original enforcement-focused definition, which continues to govern the relevant chapters.

Amendment 1197
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 2 – paragraph 1 – point 22

Text proposed by the Commission	*Amendment*
(22) 'biosecurity' means the protection, control and accountability of high-consequence biological agents, technologies, materials and toxins of concern, as well as of critical relevant information against unauthorised access, loss, theft, misuse, diversion or intentional release by those who intend to misuse them;	(22) 'biosecurity' means the protection, control and accountability of high-consequence biological agents, technologies, materials and toxins of concern, as well as of critical relevant information against unauthorised access, loss, theft, misuse, diversion or intentional release by those who intend to misuse them***, in the context of provisions relating to food and feed security and the resilience of biotechnology-derived value chains, 'biosecurity' is understood in addition to encompass, in line with the Food and Agriculture Organization of the United Nations' definition of biosecurity, a strategic and integrated approach to analysing and managing risks to human, animal and plant life and health and to the environment, including risks arising from strategic dependencies on third-country suppliers of biotechnology-derived food and feed inputs***;

Or. en

Amendment 1198
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 2 – paragraph 1 – point 24

Text proposed by the Commission	*Amendment*
(24) 'benchtop nucleic acid synthesis equipment' means any equipment that allows a user to synthesise nucleic acids individually or in a core research facility.	(24) 'benchtop nucleic acid synthesis equipment' means any equipment that allows a user to synthesise nucleic acids individually or in a core research facility ***where such equipment is capable of***

producing or assembling double-stranded nucleic acid fragments of at least 200 base pairs with high sequence fidelity.

Or. en

Justification

Traditional phosphoramidite oligosynthesizers produce only short, single stranded DNA (up to 200 nucleotides) and have no automated capability to generate or assemble longer, functional sequences. Their risk profile has remained unchanged for more than three decades, and misuse would still require substantial expertise, manual assembly steps, and controlled laboratory conditions.

Applying Article 45 to these low risk instruments would impose redesign and compliance burdens without improving biosecurity, while limiting access to a core tool relied on by early stage European biotech companies. A proportionate, capability based approach therefore supports focusing regulation on newer benchtop DNA printers, which are the devices capable of producing long, structured DNA and are more relevant to the Act's objectives.

Amendment 1199
Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 2 – paragraph 1 – point 24

Text proposed by the Commission	*Amendment*
(24) 'benchtop nucleic acid synthesis equipment' means any equipment that allows a user to synthesise nucleic acids individually or in a core research facility.	(24) 'benchtop nucleic acid synthesis equipment' means any equipment that allows a user to synthesise nucleic acids individually or in a core research facility**,** ***and that is capable of producing, or assembling, custom short or long nucleic acid sequences with high sequence fidelity***.

Or. en

Amendment 1200
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 1 – point 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) 'Combination advanced therapy' ('ATMP combo') means a therapeutic strategy involving the concomitant or sequential administration of two or more products, at least one of which is an advanced therapy medicinal product within the meaning of Article 2(1)(a) of Regulation (EC) No 1394/2007, where each component is manufactured, authorised or investigated under its own distinct regulatory status and is not physically or structurally integrated into a single product. An ATMP combo shall be distinguished from a combined ATMP within the meaning of Article 2(1)(d) of Regulation (EC) No 1394/2007, which incorporates one or more medical devices as an integral part of the product. For the purposes of this Regulation, ATMP combos include, without limitation:
	(a) 'multi-cellular ATMP combination': the co-administration or sequential administration of two or more distinct cellular or gene-therapy medicinal products falling within the same regulatory class (for example, two chimeric antigen receptor T-cell products directed at different antigenic targets), excluding any single genetically modified product engineered to express multiple receptors or targeting moieties (a bispecific or multi-specific product), which shall be treated as one product and not as a combination;
	(b) 'cross-class ATMP combination': the co-administration of two or more advanced therapy medicinal products belonging to different regulatory sub-categories (for example, a CAR-T cell product administered together with a genetically modified dendritic cell product);
	(c) 'ATMP-medicinal product combination': the administration of an advanced therapy medicinal product together with, or in sequence with, a

chemical or biological medicinal product that is not itself an advanced therapy medicinal product, where the non-ATMP component is intended to modulate, potentiate, or sustain the therapeutic effect of the ATMP.

Or. en

Amendment 1201
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 1 – point 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) (25 new) 'unmet medical need' has the meaning given to it in Article 83 of [the revised Directive on the Community code relating to medicinal products for human use], and shall apply, for the purposes of this Regulation, to a condition for which:
	(a) no satisfactory method of diagnosis, prevention, treatment or cure is authorised in the Union; or
	(b) where such methods exist, the medicinal product concerned will, in comparison with existing medicinal products or other methods of diagnosis, prevention, treatment or cure authorised in the Union, bring a clinically relevant improvement in efficacy, or in safety with at least comparable efficacy,
	having regard, in each case, to the remaining high morbidity or mortality of the condition, to the impact on health-related quality of life, and to the relevant patient population. The conditions and criteria referred to in this point shall be applied in accordance with the scientific guidelines developed by the European Medicines Agency and the implementing acts adopted by the Commission pursuant to Article 83 of [the revised Regulation

(EU) 726/2004];

(26 new) 'patient-relevant clinical benefit' means a measurable and clinically meaningful improvement in survival, symptoms, health-related quality of life, treatment burden or other patient-reported outcomes, assessed in accordance with the methodology developed under Regulation (EU) 2021/2282;

(27 new) 'access' means the availability of an authorised medicinal product to patients in the Member States concerned, taking into account effective placing on the market, inclusion in pricing and reimbursement systems, and the absence of unreasonable barriers to dispensing or prescribing.

Or. en

Amendment 1202
Peter Agius

Proposal for a regulation
Article 2 – paragraph 1 – point 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) 'unmet medical need' has the meaning given to it in Article 83 of [the revised Directive on the Community code relating to medicinal products for human use], and shall apply, for the purposes of this Regulation, to a condition for which:
	(a) no satisfactory method of diagnosis, prevention, treatment or cure is authorised in the Union; or
	(b) where such methods exist, the medicinal product concerned will, in comparison with existing medicinal products or other methods of diagnosis, prevention, treatment or cure authorised in the Union, bring a clinically relevant improvement in efficacy, or in safety with

at least comparable efficacy, having regard, in each case, to the remaining high morbidity or morality of the condition to the impact on health-related quality of life, and to the relevant patient population. The conditions an criteria referred to in this point shall be applied in accordance with the scientific guidelines developed by the European Medicines Agency and the implementing acts adopted by the Commission pursuant to Article 83 of [the revised Regulation (EU) 726/2004];

Or. en

Amendment 1203
Sirpa Pietikäinen

Proposal for a regulation
Article 2 – paragraph 1 – point 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) 'sex- and gender-disaggregated data' means data that is collected, recorded, analysed and reported in a manner that distinguishes outcomes, including safety and efficacy outcomes, by sex and, where collected, by gender, so as to permit the identification of differences between the groups. While sex and gender interact, they are to be differentiated: sex is a biological variable that includes hormones, genetics and anatomy. Gender refers to a social and structural variable which includes identity, relations and power dynamics. Both can influence health via distinct and intersecting pathways, and are prerequisites to the development of safe and effective health biotechnologies.

Or. en

Amendment 1204
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel

Proposal for a regulation
Article 2 – paragraph 1 – point 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) 'Strategic Biotechnology of Common European Interest' means a biopharmaceutical platform technology or biomanufacturing technology included in the list established and maintained by the Commission under Article 37, in respect of which developers established in the Union have the potential to compete internationally, in respect of which there is a scientific assessment as to a significant potential to address areas of high unmet medical need in the EU, and which is capable of resulting in development and manufacturing taking place in the Union.

Or. en

Justification

This list of technologies is instrumental in order to give EU-level industrial policy and public health policy steer to the application of the SPC extension in Article 27. The list that is mentioned in this amendment itself is proposed to be established under Article 37.

Amendment 1205
Monika Beňová

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	'biological foundation model' means an AI model, including where applicable a general-purpose AI model within the meaning of Article 3, point (63), of Regulation (EU) 2024/1689, trained on large scale biological, chemical, genomic, omic, biomedical, clinical or

biomanufacturing data, and capable of being adapted to a range of downstream health biotechnology tasks, including discovery, development, testing, validation, clinical-trial optimisation or biomanufacturing.

Or. en

Justification

The AI Act provides a horizontal framework for AI systems and general-purpose AI models. For the purposes of this Regulation, it is necessary to identify the specific category of AI models trained on biological, chemical, genomic, omic, biomedical, clinical or biomanufacturing data and adapted to health biotechnology tasks. Therefore they are directly relevant to the Union's biotechnology competitiveness, data strategy and regulatory preparedness.

Amendment 1206
Christine Anderson

Proposal for a regulation
Article 2 – paragraph 1 – point 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) 'individual data sovereignty' means the effective ability of a data subject to exercise the rights and safeguards provided for in Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 in relation to personal data concerning that data subject, in particular genetic data, biometric data and data concerning health.

Or. en

Amendment 1207
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) 'exposome' means the totality of environmental, occupational, dietary, social, biological and lifestyle-related exposures that may influence human health across the life course, including their interaction with genetic, biological and socioeconomic factors.

Or. en

Amendment 1208
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 24 b (new)

Text proposed by the Commission	*Amendment*
	(24b) 'Personalised nutrition' means biotechnology enabled, non medicinal nutritional approaches that use scientific and digital tools to tailor dietary guidance or nutritional support to individual needs and health status, supporting health promotion, prevention and wellbeing, while complementing Union public health strategies.

Or. en

Amendment 1209
Peter Agius

Proposal for a regulation
Article 2 – paragraph 1 – point 24 b (new)

Text proposed by the Commission	*Amendment*
	(24b) [26a] 'patient-relevant clinical benefit' means a measurable and clinically meaningful improvement in survival, symptoms, health-related quality

of life, treatment burden or other patient-reported outcomes, assessed in accordance with the methodology developed under Regulation (EU) 2021/2282;

[26a] To be added as new number 26

Or. en

Amendment 1210
Peter Agius

Proposal for a regulation
Article 2 – paragraph 1 – point 24 c (new)

Text proposed by the Commission	*Amendment*
	(24c) [27a] 'access' means the availability of an authorised medicinal product to patients in the Member States concerned, taking into account effective placing on the market, inclusion in pricing and reimbursement systems, and the absence of unreasonable barriers to dispensing or prescribing

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[27a] To be added as new number 27

Or. en

Amendment 1211
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 1 – point 24 c (new)

Text proposed by the Commission	*Amendment*
	(24c) 'Innovative technology' means any emerging or rapidly evolving biotechnological, biomedical, digital,

computational, manufacturing or delivery modality intended for the prevention, diagnosis, monitoring, treatment or cure of human disease,

Or. en

Amendment 1212
Paulo Cunha, Sérgio Humberto

Proposal for a regulation
Article 2 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission may adopt implementing acts in accordance with Article 2.1 to amend this Regulation in order to update the definitions referred to in paragraph 1 regarding what constitutes biotechnology, health biotechnology and biomanufacturing in light of technical and scientific advancements in the field of biotechnology and taking into account definitions agreed at the Union and international level without extending the scope of this definition.

Or. en

Justification

Health biotechnology and biomanufacturing are rapidly evolving fields, shaped by continuous scientific and technological advances. The legislation in force must have clear definitions and a clear scope of application, but always safeguarding that it does not fall behind on scientific discoveries and especially that it does not hinder innovation in the biotechnology field. It is important that there is a mechanism that allows the Commission to swiftly update this Regulation so it accompanies technological and scientific developments

Amendment 1213
Peter Liese

Proposal for a regulation
Article 2 – paragraph 1 a (new)
Article 2

Point (25) (new)

Text proposed by the Commission	*Amendment*
	1a. 'human embryo' means a human organism at any stage of development, in line with the interpretation of the Court of Justice in case C-34/10 (Brüstle)

Or. en

Justification

Ensures a harmonised interpretation across this regulation

Amendment 1214
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 2 – paragraph 2 – point d

Text proposed by the Commission	*Amendment*
(d) 'suspicious transaction' means any transaction concerning biotechnology products of concern for which there are reasonable grounds, taking into account all relevant factors, to doubt the legitimacy of the prospective customer's intentions.	(d) 'suspicious transaction' means any transaction concerning biotechnology products of concern for which there are reasonable grounds, taking into account all relevant factors, to doubt the legitimacy of the prospective customer's intentions***, institutional affiliation or destination, including, where relevant, indicators set out in Article 46(1)***.

Or. en

Amendment 1215
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 2 – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) 'sequence screening' means the process by which an economic operator or

a benchtop nucleic acid synthesis device assesses a requested or synthesised nucleic acid sequence, in accordance with standards or guidance pursuant to Article 54, to determine whether the sequence presents a biosecurity risk;

Or. en

Amendment 1216
Christine Anderson

Proposal for a regulation
Chapter II – title

Text proposed by the Commission	*Amendment*
II UNION HEALTH BIOTECHNOLOGY AND BIOMANUFACTURING	II ***HORIZONTAL SIMPLIFICATION FOR*** UNION HEALTH BIOTECHNOLOGY AND BIOMANUFACTURING

Or. en

Amendment 1217
Christine Anderson

Proposal for a regulation
Chapter II – Section 1 – title

Text proposed by the Commission	*Amendment*
1 ***recognition of*** health biotechnology ***strategic projects in the Union***	1 ***General simplification framework for the*** health biotechnology ***sector***

Or. en

Amendment 1218
Christine Anderson

Proposal for a regulation
Article 3

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. en

Amendment 1219
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 1

Text proposed by the Commission	*Amendment*
[...]	***deleted***

Or. en

Amendment 1220
Jérémy Decerle, Christophe Grudler

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:	1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to ***establishing, maintaining or developing critical capacities and technologies within the Union's health biotechnology value chain and to*** at least one of the following specific objectives:

Or. en

Amendment 1221
Dimitris Tsiodras

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:	1. To enable access to the support measures laid down in Section 2 of Chapter II***, including financial and technical support referred to in Article 14 and access to funding referred to in Chapter III***, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:

Or. en

Justification

Biosimilar strategic project, which is referred to in chapter V, should be explicitly included in Chapter II to facilitate common understanding and interpretation. International partners are a key element of the functioning and competitiveness of the European Biotech Hub.

Amendment 1222
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:	1. To enable access to the support measures laid down in Section 2 of Chapter II***, including financial and technical support referred to in Article 14 and access to funding referred to in Chapter III***, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:

Or. en

Amendment 1223
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:	1. To enable access to the support measures laid down in Section 2 of Chapter II***, including financial and technical support referred to in Article 14 and access to funding referred to in Chapter III***, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:

Or. en

Amendment 1224
Laurent Castillo, Aleksandar Nikolic, Valérie Deloge, Julie Rechagneux, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:	1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects***, whether private, public or carried out in partnership, and*** if they make a substantial contribution to at least one of the following specific objectives:

Or. fr

Amendment 1225
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:	1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives***, including where relevant in support of disease prevention***:

Or. en

Amendment 1226
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:	1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, by means of a reasoned decision, as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives ***including where relevant in support of disease prevention***:

Or. en

Amendment 1227
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, ***by means of a reasoned decision,*** as health biotechnology strategic projects if they make a substantial contribution to at least one of the following specific objectives:	1. To enable access to the support measures laid down in Section 2 of Chapter II, Member States shall recognise projects located in the Union, as health biotechnology strategic projects if they ***meet the criteria set in paragraph 2a and*** make a substantial ***and demonstrable*** contribution to at least one of the following specific objectives:

Or. en

Amendment 1228
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point a – introductory part

Text proposed by the Commission	*Amendment*
(a) strengthening the industrial capacity ***and value chains in the*** health biotechnology sector, through one or more of the following activities:	(a) strengthening the ***Union's*** industrial capacity ***in*** health biotechnology sector***, including medical technologies and advanced diagnostics and by addressing identified capacity gaps, strategic dependencies and vulnerabilities in production capacity and key biotechnology inputs, intermediates or critical starting materials***, through one or more of the following activities:

Or. en

Amendment 1229
Ondřej Krutílek

Proposal for a regulation
Article 3 – paragraph 1 – point a – introductory part

Text proposed by the Commission	*Amendment*
(a) strengthening the industrial capacity and value chains in the health biotechnology sector, through one or more of the following activities:	(a) strengthening the industrial capacity and value chains in the health biotechnology sector, ***including by addressing identified capacity gaps, strategic dependencies and vulnerabilities in production capacity and key biotechnology inputs, intermediates or critical starting materials,*** through one or more of the following activities:

Or. en

Amendment 1230
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 3 – paragraph 1 – point a – introductory part

Text proposed by the Commission	*Amendment*
(a) strengthening the industrial capacity and value chains in the health biotechnology sector, through one or more of the following activities:	(a) strengthening the industrial capacity and value chains in the health biotechnology sector ***in the Union***, through one or more of the following activities:

Or. en

Amendment 1231
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point a – point i

Text proposed by the Commission	*Amendment*
(i) pooling resources and expertise among research organisations, biotechnology industry actors and/or public authorities within the Union;	(i) pooling resources and expertise among research organisations, biotechnology industry actors and/or public authorities within the Union ***including university hospitals, academic medical centres, cross-border university hospital alliances and European clinical research infrastructures***;

Or. en

Justification

Iniversity hospitals and networks of university hospitals are not merelyusers of innovation but important innovation developers. Thestatus of "innovation developer" should explicitly include cross-borderconsortia of university hospitals, not only individual institutions. The targetpopulations for ATMP treatments are often small or rare patient groups, and asingle hospital or Member State rarely has the critical mass necessary tosupport development activities on its own.

Amendment 1232
Diana Iovanovici Şoşoacă

Proposal for a regulation
Article 3 – paragraph 1 – point a – point i

Text proposed by the Commission	*Amendment*
(i) pooling resources and expertise among research organisations, biotechnology industry actors and/or public authorities within the Union;	(i) pooling resources and expertise among research organisations, biotechnology industry actors and/or public authorities within the Union***, on the basis of protocols and partnerships appropriate to the field which comply with the laws in force in the Member States***;

Or. ro

Amendment 1233
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point a – point i

Text proposed by the Commission	*Amendment*
(i) pooling resources ***and*** expertise among research organisations, biotechnology industry actors and/or public authorities within the Union;	(i) pooling resources**,** expertise ***and research facilities*** among research organisations, biotechnology industry actors and/or public authorities within the Union;

Or. it

Amendment 1234
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 1 – point a – point i

Text proposed by the Commission	*Amendment*
(i) pooling resources and expertise among research organisations, biotechnology industry actors and/or public authorities within the Union;	(i) pooling resources and expertise***, including through technology transfer,*** among research organisations, biotechnology industry actors and/or public authorities within the Union;

Or. en

Amendment 1235
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;	(ii) creating new, ***significantly improving*** or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars***, priority antimicrobials and other medical countermeasures relevant to the Union's preparedness and health security, including those listed in the Union list of critical medicines***;

Or. en

Amendment 1236
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 3 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;	(ii) creating new, or significantly expanding, production facilities for biotechnology products***, including through automation, new technologies and innovative manufacturing processes***, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;

Or. en

Amendment 1237
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) creating new, ***or significantly*** expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;	(ii) creating new, expanding, ***modernising, and technologically upgrading or extending*** production facilities for biotechnology products ***at any stage of manufacturing***, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;

Or. en

Amendment 1238
András Tivadar Kulja

Proposal for a regulation
Article 3 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited,	(ii) creating new, or significantly expanding, ***modernising, and technologically upgrading or extending*** production facilities for biotechnology products, in particular in biotechnology

including for biosimilars;	sectors where such facilities do not exist or where they are limited, including for biosimilars;

Or. en

Amendment 1239
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 3 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) creating new, or significantly expanding***,*** production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars***;***	(ii) creating new, or significantly ***improving or*** expanding production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars***, in order to address identified capacity gaps.***

Or. en

Amendment 1240
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 3 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;	(ii) creating new, or significantly expanding, production facilities ***located in the Union*** for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;

Or. en

Amendment 1241

Angelika Winzig

Proposal for a regulation
Article 3 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;	(ii) creating new, or significantly expanding, production facilities for ***innovative health*** biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;

Or. en

Justification

The regulatory framework should prioritise the promotion of innovation and the strengthening of the Union's competitiveness.

Amendment 1242
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;	(ii) creating new, or significantly expanding, production facilities for ***innovative health*** biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited, including for biosimilars;

Or. en

Amendment 1243
Kristoffer Storm

Proposal for a regulation
Article 3 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*

(ii) creating new, or significantly expanding, production facilities for biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited***, including for biosimilars***;	(ii) creating new, or significantly expanding, production facilities for ***innovative health*** biotechnology products, in particular in biotechnology sectors where such facilities do not exist or where they are limited;

Or. en

Amendment 1244
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;	(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies***, including process innovation, modernisation, digitalisation or greening of production and manufacturing processes***;

Or. en

Justification

The strategic projects should explicitly cover critical aspects of the modernisation of production and manufacturing in Europe

Amendment 1245
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally	(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally

enabled processes and technologies;	enabled processes and technologies***,*** ***including process innovation, modernisation, or digitalisation of production and manufacturing processes***;

Or. en

Amendment 1246
Margarita de la Pisa Carrión, Laurent Castillo, Ondřej Knotek, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;	(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies***,*** ***including process innovation, modernisation or digitalisation of production and manufacturing processes***;

Or. en

Amendment 1247
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;	(iii) creating***, expanding*** or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies***,*** ***including innovation, modernisation, digitalisation and manufacturing processes***;

Or. en

Amendment 1248
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;	(iii) creating***, expanding*** or upgrading industrial scale biomanufacturing sites***, including associated quality control, packaging and supporting infrastructure*** with innovative, sustainable, safe and digitally enabled processes and technologies;

Or. en

Amendment 1249
Kristoffer Storm

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;	(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies***, including innovation, modernisation, digitalisation and manufacturing processes***;

Or. en

Amendment 1250
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) creating or upgrading industrial	(iii) creating or upgrading industrial

scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;	scale biomanufacturing sites ***located in the Union*** with innovative, sustainable, safe and digitally enabled processes and technologies;

Or. en

Amendment 1251
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;	(iii) creating or upgrading industrial scale biomanufacturing sites with innovative, ***resilient,*** sustainable, safe and digitally enabled processes and technologies;

Or. it

Amendment 1252
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) creating or ***upgrading*** industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;	(iii) creating or ***modernising*** industrial scale biomanufacturing sites with innovative, sustainable, safe and digitally enabled processes and technologies;

Or. en

Amendment 1253
Manuela Ripa

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) supporting the development of interdisciplinary curricula and training programmes linking biotechnology, biomanufacturing, clinical research, regulatory science, data science, artificial intelligence, ethics, non-animal science, intellectual property, technology transfer and entrepreneurship;

Or. en

Amendment 1254
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) promoting the development, validation or qualification, standardisation, regulatory acceptance and uptake of NAMs, with a view to replacing animal use in biotechnology research, development and safety Assessment;

Or. en

Amendment 1255
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iv

Text proposed by the Commission	*Amendment*
(iv) reducing dependencies on third-country suppliers for key biotechnology inputs and intermediates;	(iv) ***optimising supply chains, including by*** reducing ***excessive*** dependencies on ***high-risk*** third-country suppliers for key biotechnology inputs and

	intermediates***, such as, where relevant, active substances, drug substances, drug products, fill-finish capacity, critical raw materials, media, reagents, consumables and analytical testing capacity necessary for the development, manufacturing or supply of biological medicinal products, including biosimilars***;

Or. en

Amendment 1256
Dimitris Tsiodras

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iv

Text proposed by the Commission	*Amendment*
(iv) reducing dependencies on third-country suppliers for key biotechnology inputs and intermediates;	(iv) reducing dependencies on third-country suppliers for key biotechnology inputs and intermediates***, including where relevant active substances, drug substances, drug products, fill-finish capacity, critical raw materials, media, reagents, consumables and analytical testing capacity necessary for the development, manufacturing or supply of biological medicinal products, including biosimilars***;

Or. en

Justification

Biosimilar strategic project, which is referred to in chapter V, should be explicitly included in Chapter II to facilitate common understanding and interpretation. International partners are a key element of the functioning and competitiveness of the European Biotech Hub.

Amendment 1257
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iv

Text proposed by the Commission	*Amendment*
(iv) reducing dependencies on third-country suppliers for key biotechnology inputs ***and*** intermediates***;***	(iv) reducing dependencies on third-country suppliers ***and support the supply-chain resilience*** for key biotechnology inputs***,*** intermediates ***and critical starting materials***

Or. en

Amendment 1258
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iv

Text proposed by the Commission	*Amendment*
(iv) reducing dependencies on third-country suppliers for key biotechnology inputs and intermediates;	(iv) ***optimising supply chains, including*** reducing ***excessive*** dependencies on ***high risk*** third-country suppliers for key biotechnology inputs and intermediates;

Or. en

Amendment 1259
Kristoffer Storm

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iv

Text proposed by the Commission	*Amendment*
(iv) ***reducing dependencies on third-country suppliers*** for key biotechnology inputs and intermediates;	(iv) ***contributing to supply chain resilience*** for key biotechnology inputs and intermediates;

Or. en

Amendment 1260
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iva) addressing mental health conditions, where biotechnology innovations can respond to unmet medical needs, including through evidence-based diagnostics, personalised medicine, digital and data-supported care pathways, or, 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 1261
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point a – point iv b (new)

Text proposed by the Commission	*Amendment*
	(ivb) establish demonstrable and structured long-term cooperation between academia, research institutions, large industrial actors and small and medium-sized enterprises, start-ups, scale-ups and spin-offs, which may include systematic spin-out or spin-in programmes, early-stage licensing frameworks, or co-development activities that anchor innovation within the Union's industrial base.

Or. en

Amendment 1262
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v

Text proposed by the Commission	*Amendment*
(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains;	(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains ***and supporting advanced digital, artificial intelligence-enabled and environmentally sustainable biotechnology manufacturing capabilities***;

Or. en

Amendment 1263
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
Article 3 – paragraph 1 – point a – point v

Text proposed by the Commission	*Amendment*
(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains;	(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains ***and life-cycle***;

Or. en

Amendment 1264
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v

Text proposed by the Commission	*Amendment*
(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains;	(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains ***and life-cycle***;

Or. en

Amendment 1265
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v

Text proposed by the Commission	*Amendment*
(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains;	(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains ***and life-cycle***;

Or. en

Amendment 1266
Dimitris Tsiodras

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v

Text proposed by the Commission	*Amendment*
(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains;	(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains ***and life-cycle***;

Or. en

Justification

Biosimilar strategic project, which is referred to in chapter V, should be explicitly included in Chapter II to facilitate common understanding and interpretation. International partners are a key element of the functioning and competitiveness of the European Biotech Hub.

Amendment 1267
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v

Text proposed by the Commission	*Amendment*
(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability and sustainability across biotechnology value chains;	(v) integrating advanced digital and AI-driven manufacturing and supply-chain management systems to enhance productivity, traceability***, safety*** and sustainability across biotechnology value chains;

Or. it

Amendment 1268
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v a (new)

Text proposed by the Commission	*Amendment*
	(va) establish demonstrable and structured long-term cooperation between large industrial actors and small and medium-sized enterprises, start-ups or scale-ups, which may include systematic spin-out or spin-in programmes, early-stage licensing frameworks, or co-development activities that anchor innovation within the Union's industrial base.

Or. en

Amendment 1269
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v a (new)

Text proposed by the Commission	*Amendment*
	(va) establishing, maintaining or materially contributing to reserved ("ever-warm") manufacturing capacity for vaccines or other medical countermeasures that is available to supply both the Union and third countries, including low- and middle-income countries, whether operated by a marketing authorisation holder or by a contract manufacturing scheme.

Or. en

Amendment 1270
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v a (new)

Text proposed by the Commission	*Amendment*
	(va) diversifying production sites, sourcing and supply routes within the Union, with a view to reducing vulnerabilities and the risk of disruption in production capacity for health biotechnology products.

Or. en

Justification

The amendments to Article 3 clarify that strategic projects should be able to address not only the creation of new capacity, but also existing capacity gaps, strategic dependencies and vulnerabilities across health biotechnology value chains. This is necessary to ensure that the Regulation reflects the operational realities of biotechnology production, including reliance on key inputs, intermediates and critical starting materials. It also ensures that projects strengthening existing production capacity and supply-chain resilience can be recognised where they contribute to the Union's industrial capacity and security of supply. In the case of

bacteriophage technologies, particularly where treatment is personalized, susceptibility-guided or adaptative, the central challenge is not only to produce phages, but to identify, qualify and deploy the appropriate phage or phage combination for a given pathogen within clinically meaningful timelines and under appropriate quality assurance. This requires infrastructures, that are collective and cumulative by nature, including curated phage libraries, bacterial host collections, susceptibility-testing networks, interoperable data systems and computational tools. Their establishment should therefore be recognized as eligible under Strategic Health Biotechnology Projects foreseen in the European Biotech Act.

Amendment 1271
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v a (new)

Text proposed by the Commission	*Amendment*
	(va) helping to bring previously offshored production capacities back to the Union and to reduce strategic dependencies on third countries for critical biotechnology products.

Or. it

Amendment 1272
Kristoffer Storm, Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v a (new)

Text proposed by the Commission	*Amendment*
	(va) maintaining, creating or upgrading manufacturing capacity in the Union for active pharmaceutical ingredients (APIs) and medicines listed in the Union list of critical medicines.

Or. en

Amendment 1273
Waldemar Buda, Kosma Złotowski

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v b (new)

Text proposed by the Commission	*Amendment*
	(vb) maintaining, modernising, diversifying or expanding Union biomanufacturing capacities for biological medicinal products, including biosimilar medicinal products, across all stages of their lifecycle, where such activities contribute to the security and continuity of supply;

Or. en

Amendment 1274
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point a – point v c (new)

Text proposed by the Commission	*Amendment*
	(vc) initiatives aimed at establishing, maintaining or reserving spare development or manufacturing capacity that can be rapidly mobilised in response to priority public health threats;

Or. en

Amendment 1275
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 3 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) Establish demonstrable and structured long-term cooperation between large industrial actors and small and

medium-sized enterprises, start-ups or scale-ups, which may include co-development activities, early-stage licensing frameworks, or spin-out or spin-in programmes, anchoring innovation within the Union's industrial base.

Or. en

Amendment 1276
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point b – introductory part

Text proposed by the Commission	*Amendment*
(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:	(b) scaling-up or upgrading critical research***, clinical*** and technology infrastructures underpinning the development, testing***, clinical evaluation*** and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:

Or. en

Amendment 1277
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point b – introductory part

Text proposed by the Commission	*Amendment*
(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital	(b) scaling-up or upgrading critical research***, clinical*** and technology infrastructures underpinning the development, testing***, clinical evaluation*** and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for

platforms, through one or more of the following activities:	biomanufacturing, data and digital platforms, through one or more of the following activities:

Or. en

Amendment 1278
András Tivadar Kulja

Proposal for a regulation
Article 3 – paragraph 1 – point b – introductory part

Text proposed by the Commission	*Amendment*
(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:	(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing***,*** ***clinical evaluation*** and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:

Or. en

Amendment 1279
Dimitris Tsiodras

Proposal for a regulation
Article 3 – paragraph 1 – point b – introductory part

Text proposed by the Commission	*Amendment*
(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing ***and*** validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:	(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing***,*** validation ***and manufacturing*** of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:

Or. en

Justification

Biosimilar strategic project, which is referred to in chapter V, should be explicitly included in Chapter II to facilitate common understanding and interpretation.International partners are a key element of the functioning and competitiveness of the European Biotech Hub.

Amendment 1280
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point b – introductory part

Text proposed by the Commission	*Amendment*
(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing ***and*** validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:	(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing**,** validation ***and manufacturing*** of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:

Or. en

Amendment 1281
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
Article 3 – paragraph 1 – point b – introductory part

Text proposed by the Commission	*Amendment*
(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the	(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing**,** ***manufacturing*** and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the

following activities:	following activities:

Or. en

Amendment 1282
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 3 – paragraph 1 – point b – introductory part

Text proposed by the Commission	*Amendment*
(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing ***and*** validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:	(b) scaling-up or upgrading critical research and technology infrastructures underpinning the development, testing validation ***and manufacturing*** of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:

Or. en

Amendment 1283
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 3 – paragraph 1 – point b – introductory part

Text proposed by the Commission	*Amendment*
(b) scaling-up or ***upgrading*** critical research and technology infrastructures underpinning the development, testing and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:	(b) scaling-up or ***modernising*** critical research and technology infrastructures underpinning the development, testing and validation of health biotechnology products, including but not limited to pilot or testing infrastructures for biomanufacturing, data and digital platforms, through one or more of the following activities:

Or. en

Amendment 1284
Dimitris Tsiodras

Proposal for a regulation
Article 3 – paragraph 1 – point b – point i

Text proposed by the Commission	*Amendment*
(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes; or	(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation***, quality-control, analytical testing*** and industrial deployment capacities for biotechnology products and processes***, including for biosimilar comparability***; or

Or. en

Justification

Biosimilar strategic project, which is referred to in chapter V, should be explicitly included in Chapter II to facilitate common understanding and interpretation. International partners are a key element of the functioning and competitiveness of the European Biotech Hub.

Amendment 1285
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point b – point i

Text proposed by the Commission	*Amendment*
(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes; or	(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation ***quality-control, analytical testing*** and industrial deployment capacities for biotechnology products and processes***, including for biosimilar comparability***; or

Or. en

Amendment 1286
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point b – point i

Text proposed by the Commission	*Amendment*
(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes; or	(i) establishing, expanding or upgrading pilot, testing***, clinical research*** and demonstration infrastructures linking research, development***, clinical evaluation***, validation and industrial deployment capacities for biotechnology products and processes; or

Or. en

Amendment 1287
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point b – point i

Text proposed by the Commission	*Amendment*
(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes; or	(i) establishing, expanding or upgrading pilot, testing***, clinical research*** and demonstration infrastructures linking research, development***, clinical evaluation***, validation and industrial deployment capacities for biotechnology products and processes; or

Or. en

Amendment 1288
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
Article 3 – paragraph 1 – point b – point i

Text proposed by the Commission	*Amendment*
(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes; or	(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation***, quality-control, analytical testing,*** and industrial deployment capacities for biotechnology products and processes; or

Or. en

Amendment 1289
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 1 – point b – point i

Text proposed by the Commission	*Amendment*
(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes; or	(i) establishing, expanding or upgrading pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes ***including through technology transfer***; or

Or. en

Amendment 1290
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 3 – paragraph 1 – point b – point i

Text proposed by the Commission	*Amendment*
(i) establishing, expanding or ***upgrading*** pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes; or	(i) establishing, expanding or ***modernising*** pilot, testing and demonstration infrastructures linking research, development, validation and industrial deployment capacities for biotechnology products and processes; or

Or. en

Amendment 1291
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 3 – paragraph 1 – point b – point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) establishing, expanding or upgrading pilot, testing and demonstration infrastructures which, while contributing to the objectives of this Regulation, may also support cross-sectoral learning, regulatory preparedness and scale-up capabilities relevant to emerging biotechnology and biomanufacturing applications.

Or. en

Justification

Biotech Act I should remain focused on health biotechnology, while also creating practical bridges to the wider biotechnology and biomanufacturing agenda expected under Biotech Act II. This addition would ensure that the investments also generate learning and scale-up capacity for emerging and industrial biotechnology applications, including food, agri-biotechnology, biomaterials and biomanufacturing.

Amendment 1292
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 3 – paragraph 1 – point b – point ii

Text proposed by the Commission	*Amendment*
(ii) ***integrating advanced digital, data and AI capabilities to enhance modelling, simulation and process optimisation; or***	(ii) ***establishing public-private partnerships between universities, vocational education and training providers, trade unions, businesses, in particular SMEs, start-ups and scale-ups, social partners and applied research institutes, both for human and animal***

health;

Or. en

Amendment 1293
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point b – point ii

Text proposed by the Commission	*Amendment*
(ii) integrating advanced digital, data and AI capabilities to enhance modelling, simulation and process optimisation; or	(ii) integrating advanced digital, data and AI capabilities to enhance modelling, simulation***, clinical trial design, regulatory science*** and process optimisation; or

Or. en

Amendment 1294
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point b – point ii

Text proposed by the Commission	*Amendment*
(ii) integrating advanced digital, data and AI capabilities to enhance modelling, simulation and process optimisation; or	(ii) integrating advanced digital, data and AI capabilities to enhance modelling, simulation***, clinical trial design, regulatory science*** and process optimisation; or

Or. en

Amendment 1295
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iii

Text proposed by the Commission	*Amendment*
(iii) establishing interoperable	(iii) establishing interoperable

infrastructures connecting research organisations, industry and public authorities across the Union; or	infrastructures connecting research organisations, industry and public authorities across the Union***, including cross-border university hospital alliances, clinical trial networks, health data infrastructures and advanced therapy development networks***; or

Or. en

Amendment 1296
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iii

Text proposed by the Commission	*Amendment*
(iii) establishing interoperable infrastructures connecting research organisations, industry and public authorities across the Union; or	(iii) establishing interoperable infrastructures connecting research organisations, industry***, clinical trial networks*** and public authorities across the Union; or

Or. en

Amendment 1297
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iii

Text proposed by the Commission	*Amendment*
(iii) establishing interoperable infrastructures connecting research organisations, industry and public authorities across the Union; or	(iii) establishing interoperable infrastructures connecting research organisations, industry***, clinical trial networks*** and public authorities across the Union; or

Or. en

Amendment 1298

Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv

Text proposed by the Commission	*Amendment*
(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies.	(iv) promoting and integrating the use of ***human relevant and non-animal*** NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies***, chemical and pharmaceutical safety and efficacy assessment, and toxicity testing***. ***NAMs enable the prediction of toxicological effects, as well as the modelling of human and species-specific physiology and disease mechanisms, thereby increasing research translatability while progressively replacing animal testing.***

Or. en

Justification

Human-relevant new approach methodologies can both help increase research translatability and reduce or avoid animal use, in line with Directive 2010/63. NAMs are also are increasingly used for safety and toxicity assessment, for modelling human and species-specific physiology, disease mechanisms, and for applications in drug discovery and efficacy testing. This clarification ensures legal coherence with ongoing scientific developments and supports the regulatory recognition and uptake of NAMs across the full biomedical innovation continuum.

Amendment 1299
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv

Text proposed by the Commission	*Amendment*
(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing	(iv) promoting and integrating the use of ***human relevant and non-animal*** NAMs in areas such as biological research, discovery and preclinical development,

and production of medicinal products and medical technologies.	regulatory and quality testing and production of medicinal products and medical technologies***, chemical and pharmaceutical safety and efficacy assessment, and toxicity testing***. ***NAMs enable the prediction of toxicological effects, as well as the modelling of human and species-specific physiology and disease mechanisms, thereby increasing research translatability while progressively replacing animal testing.***

Or. en

Amendment 1300
Kristoffer Storm

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv

Text proposed by the Commission	*Amendment*
(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies.	(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies***, irrespective of the regulatory classification or chemical or biological nature of the final product***.

Or. en

Amendment 1301
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv

Text proposed by the Commission	*Amendment*
(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing	(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing

and production of medicinal products and medical technologies.	and production of medicinal products and medical technologies***, irrespective of the regulatory classification or chemical or biological nature of the final product***.

Or. en

Amendment 1302
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv

Text proposed by the Commission	*Amendment*
(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies.	(iv) promoting and integrating the use of ***human relevant and non-animal*** NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies.

Or. en

Amendment 1303
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv

Text proposed by the Commission	*Amendment*
(iv) promoting and integrating the use of NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies.	(iv) promoting and integrating the use of ***scientifically validated*** NAMs in areas such as biological research, discovery and preclinical development, regulatory and quality testing and production of medicinal products and medical technologies.

Or. it

Amendment 1304
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iva) establishing collective systems capable of supporting the development, selection, characterization, validation and deployment of personalized treatments and adaptive biological innovations including curated libraries, representative bacterial host collections, standardized testing networks, interoperable data layers, and computational tools capable of addressing the complexity of such products.

Or. en

Amendment 1305
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iva) establishing collective systems capable of supporting the development, selection, characterization, validation and deployment of personalized treatments and adaptive biological innovations including curated libraries, representative bacterial host collections, standardized testing networks, interoperable data layers, and computational tools capable of addressing the complexity of such products.

Or. en

Amendment 1306
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iva) establishing collective systems capable of supporting the development, selection, characterization, validation and deployment of personalized treatments and adaptive biological innovations including curated libraries, representative bacterial host collections, standardized testing networks, interoperable data layers, and computational tools capable of addressing the complexity of such products.

Or. en

Justification

In the case of bacteriophage technologies, particularly where treatment is personalized, susceptibility-guided or adaptative, the central challenge is not only to produce phages, but to identify, qualify and deploy the appropriate phage or phage combination for a given pathogen within clinically meaningful timelines and under appropriate quality assurance. This requires infrastructures, that are collective and cumulative by nature, including curated phage libraries, bacterial host collections, susceptibility-testing networks, interoperable data systems and computational tools. Their establishment should therefore be recognized as eligible under Strategic Health Biotechnology Projects foreseen in the European Biotech Act.

Amendment 1307
Christophe Clergeau, Vytenis Povilas Andriukaitis, Marta Temido, Michalis Hadjipantela, Sirpa Pietikäinen, Ondřej Krutílek, Marcos Ros Sempere, Tilly Metz

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iva) establishing, expanding or connecting population and longitudinal cohorts, biobanks and exposome-characterisation infrastructures to support the development, safety

evaluation and validation of health biotechnology products;

Or. en

Justification

This amendment allows cohort and exposome infrastructure to be recognised by a Member State as a health biotechnology strategic project under Article 3, to be able to access the permit-granting priority (Article 14(2)(b)), the access principles (Article 16) or Network support (Article 19)

Amendment 1308
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iva) improving facilities dedicated to translational research and technology transfer between universities, scientific healthcare and research institutes, clinical centres and industry;

Or. it

Amendment 1309
Margarita de la Pisa Carrión, Paolo Borchia, Laurent Castillo, Ondřej Knotek, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point b – point iv a (new)

Text proposed by the Commission	*Amendment*
	(iva) establishing collective infrastructures supporting the research, development, validation and deployment of innovative technologies.

Or. en

Amendment 1310
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point c – introductory part

Text proposed by the Commission	*Amendment*
(c) accelerating innovation and technology deployment in health biotechnology through one or more of the following activities:	(c) accelerating innovation and technology deployment in health biotechnology ***from research to industrial and clinical application*** through one or more of the following activities:

Or. en

Amendment 1311
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point c – introductory part

Text proposed by the Commission	*Amendment*
(c) accelerating innovation and technology deployment in health biotechnology through one or more of the following activities:	(c) accelerating innovation and technology deployment in health biotechnology ***from research to industrial and clinical application*** through one or more of the following activities:

Or. en

Amendment 1312
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point c – point i

Text proposed by the Commission	*Amendment*
(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies and	(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies and

tools;	tools***, new approach methodologies, and innovations supporting the discovery, development or manufacturing of priority antimicrobials within the meaning of Union legislation on medicinal products for human use***;

Or. en

Justification

This amendment recognises three categories of breakthrough innovation that are not explicitly captured by the Commission's formulation: new approach methodologies, which reduce reliance on animal testing while accelerating early-stage development; and innovations supporting the discovery, development or manufacturing of priority antimicrobials. The cross-reference to "Union legislation on medicinal products for human use" is deliberately functional rather than tied to a specific Article number, ensuring that the provision remains operative regardless of the final numbering of the revised pharmaceutical Regulation following its publication in the Official Journal.

Amendment 1313
Wouter Beke, Ingeborg Ter Laak, Angelika Niebler, Adam Jarubas, Aura Salla, Jessica Polfjärd, Liesbet Sommen, Paulo Cunha, Sérgio Humberto, Sirpa Pietikäinen, Willemien Koning, Andrea Wechsler, Dolors Montserrat, Oliver Schenk, Elena Nevado del Campo, András Tivadar Kulja, Niels Flemming Hansen

Proposal for a regulation
Article 3 – paragraph 1 – point c – point i

Text proposed by the Commission	*Amendment*
(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies ***and*** tools;	(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies***,*** tools ***and AI enabled biofoundries for drug-, antibody- and cell- engineering and their use in drug discovery, clinical validation and manufacturing***;

Or. en

Amendment 1314
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point c – point i

Text proposed by the Commission	*Amendment*
(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies and tools;	(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies***, medical devices associated with the use, administration or monitoring of biotechnology products, and related*** and tools;

Or. en

Amendment 1315
Katri Kulmuni, Stine Bosse, Morten Løkkegaard, Billy Kelleher, Bart Groothuis, Sophie Wilmès

Proposal for a regulation
Article 3 – paragraph 1 – point c – point i

Text proposed by the Commission	*Amendment*
(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies and tools;	(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies and tools ***and synthetic cells***;

Or. en

Justification

Strategic-project recognition is the gateway to priority status, accelerated permits and facilitated funding. Synthetic cells can be reprogrammed for many applications, from targeted drug delivery to biosensing and biochemical production. This broad, market-creating potential is precisely the industrial competitiveness these projects should aim to do.

Amendment 1316
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point c – point i

Text proposed by the Commission	*Amendment*
(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies and tools;	(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial ***and technological*** competitiveness, including AI-enabled technologies and tools;

Or. it

Amendment 1317
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 3 – paragraph 1 – point c – point i

Text proposed by the Commission	*Amendment*
(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including AI-enabled technologies and tools;	(i) introducing or scaling up breakthrough innovations in biotechnology that have the potential to strengthen the Union's industrial competitiveness, including ***NAMs and*** AI-enabled technologies and tools;

Or. en

Justification

Amendment drafted with the Eurogroup for Animals

Amendment 1318
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) supporting SMEs, start-ups and scale-ups, universities and research centres	(ii) supporting SMEs***, not-for-profit product developers***, start-ups and scale-

in accessing advanced biomanufacturing and laboratory capacities;	ups, universities***, university hospitals, academic medical centres*** and research centres in accessing advanced biomanufacturing and laboratory capacities;

Or. en

Amendment 1319
Sirpa Pietikäinen

Proposal for a regulation
Article 3 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing and laboratory capacities;	(ii) supporting SMEs***, not-for-profit product developers***, start-ups and scale-ups***, social partners***, universities and research centres in accessing advanced biomanufacturing and laboratory capacities;

Or. en

Amendment 1320
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, Tomislav Sokol

Proposal for a regulation
Article 3 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing and laboratory capacities;	(ii) supporting SMEs, start-ups and scale-ups, universities***, university hospitals, academic medical centres*** and research centres in accessing advanced biomanufacturing and laboratory capacities;

Or. en

Amendment 1321
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing and laboratory capacities;	(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing and laboratory capacities ***including through technology transfer***;

Or. en

Amendment 1322
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing and laboratory capacities;	(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in ***developing,*** accessing ***or establishing*** advanced biomanufacturing and laboratory capacities;

Or. en

Amendment 1323
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing	(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in ***developing,*** accessing ***or establishing***

and laboratory capacities;	advanced biomanufacturing and laboratory capacities;

Or. en

Amendment 1324
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
Article 3 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing and laboratory capacities;	(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing***,*** ***analytical testing,*** and laboratory capacities;

Or. en

Amendment 1325
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing and laboratory capacities;	(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing***,*** ***analytical testing*** and laboratory capacities;

Or. en

Amendment 1326
Dimitris Tsiodras

Proposal for a regulation
Article 3 – paragraph 1 – point c – point ii

Text proposed by the Commission	*Amendment*
(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing and laboratory capacities;	(ii) supporting SMEs, start-ups and scale-ups, universities and research centres in accessing advanced biomanufacturing***,*** ***analytical testing*** and laboratory capacities;

Or. en

Justification

Biosimilar strategic project, which is referred to in chapter V, should be explicitly included in Chapter II to facilitate common understanding and interpretation. International partners are a key element of the functioning and competitiveness of the European Biotech Hub.

Amendment 1327
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 1 – point c – point iii

Text proposed by the Commission	*Amendment*
(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law**.**	(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law***, including, where the project has received public funding and the resulting products address significant public health needs, non-exclusive licensing arrangements or other measures to facilitate access to such products in low- and middle-income countries, including through development partners or voluntary licensing;***

Or. en

Amendment 1328

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

Proposal for a regulation
Article 3 – paragraph 1 – point c – point iii

Text proposed by the Commission	*Amendment*
(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law.	(iii) promoting technology transfer and collaboration with ***strategic partners and*** corresponding facilities in third countries, where Union-led partnerships are established under Union law***, and where such cooperation does not undermine the Union's supply resilience or strategic autonomy objectives.***

Or. en

Amendment 1329
Dimitris Tsiodras

Proposal for a regulation
Article 3 – paragraph 1 – point c – point iii

Text proposed by the Commission	*Amendment*
(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law.	(iii) promoting technology transfer and collaboration with ***strategic partners and*** corresponding facilities in third countries***, including European (EEA, CH, UK) and international partners***, where Union-led partnerships are established under Union law ***and where such cooperation does not undermine the Union's supply resilience or strategic autonomy objectives***.

Or. en

Justification

Biosimilar strategic project, which is referred to in chapter V, should be explicitly included in Chapter II to facilitate common understanding and interpretation.International partners are a key element of the functioning and competitiveness of the European Biotech Hub.

Amendment 1330
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 1 – point c – point iii

Text proposed by the Commission	*Amendment*
(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law.	(iii) promoting technology transfer and collaboration with ***strategic partners and*** corresponding facilities in third countries***, including European (EEA, CH, UK) and international partners***, where Union-led partnerships are established under Union law ***and where such cooperation does not undermine the Union's supply resilience or strategic autonomy objectives***.

Or. en

Amendment 1331
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
Article 3 – paragraph 1 – point c – point iii

Text proposed by the Commission	*Amendment*
(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law.	(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law ***and where such cooperation does not undermine Union's strategic autonomy***.

Or. en

Amendment 1332
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point c – point iii

Text proposed by the Commission	*Amendment*
(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established under Union law.	(iii) promoting technology transfer and collaboration with corresponding facilities in third countries, where Union-led partnerships are established ***on the basis of the principle of reciprocity and*** under Union law.

Or. it

Amendment 1333
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) reinforcing the readiness of healthcare providers, including hospitals, to receive, prepare and administer health biotechnologies, in particular through investments in dedicated infrastructure, so as to ensure timely patient access to the resulting treatments.

Or. en

Amendment 1334
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point c – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) exploiting the potential of intellectual property pertaining to the findings of Union- or nationally funded research;

Or. it

Amendment 1335
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 3 – paragraph 1 – point d – point i

Text proposed by the Commission	*Amendment*
(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;	(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, ***non-animal science,*** intellectual property and project management, and entrepreneurial skills, through activities including ***quality and paid*** apprenticeships, traineeships, ***cost-free*** continuing education and training ***during working time***, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners; ***in particular with regards to attracting and retaining women in the biotech workforce, acknowledging that the widening gender gap leads the EU to lose out on talent, ideas and innovation;***

Or. en

Justification

Amendment drafted with the Eurogroup for Animals and Deutesche Stiftung Weltbevölkerung (DSW)

Amendment 1336
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 1 – point d – point i

Text proposed by the Commission	*Amendment*
(i) attracting and retaining talent in the	(i) attracting and retaining talent in the

Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;	Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, ***as well as for healthcare professionals involved in the handling and administration of emerging biotechnologies, in order to ensure their safe and effective uptake in clinical practice,*** through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;

Or. en

Amendment 1337
Sirpa Pietikäinen

Proposal for a regulation
Article 3 – paragraph 1 – point d – point i

Text proposed by the Commission	*Amendment*
(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property ***and*** project management***,*** and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;	(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property***, immunology, including quantitative and computational immunology, molecular imaging, quality-system skills relevant to good manufacturing, clinical and laboratory practice,*** project management and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training

institutions, businesses and social partners;

Or. en

Justification

This addition would strengthen Europe's competitive edge in advanced health biotechnology, including biological medicines, immunotherapies, radiopharmaceuticals and personalised medicine.

Amendment 1338
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 3 – paragraph 1 – point d – point i

Text proposed by the Commission	*Amendment*
(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;	(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills***, disease prevention and immunisation expertise***, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners ***and with input on curriculum design from relevant public and private stakeholders***;

Or. en

Amendment 1339
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point d – point i

Text proposed by the Commission	*Amendment*
(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;	(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills***, disease prevention and immunisation expertise***, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners ***and with input on curriculum design from relevant public and private stakeholders***;

Or. en

Justification

Strengthening disease prevention and immunisation expertise is necessary to ensure the availability of a skilled workforce, support innovation and preparedness, and address evolving public health challenges across the Union.

Amendment 1340
Nikos Papandreou, Romana Jerković, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 3 – paragraph 1 – point d – point i

Text proposed by the Commission	*Amendment*
(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property ***and*** project management***,*** and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close	(i) attracting***, training*** and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, ***regulatory science, clinical trial management, advanced diagnostics, genomic medicine, health technology assessment,*** data science, AI, intellectual property***,*** project management and

cooperation with regional and local authorities, education and training institutions, businesses and social partners;	entrepreneurial skills , through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;

Or. en

Amendment 1341
Giorgio Gori

Proposal for a regulation
Article 3 – paragraph 1 – point d – point i

Text proposed by the Commission	*Amendment*
(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;	(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills***, disease prevention and immunisation expertise***, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;

Or. en

Amendment 1342
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 3 – paragraph 1 – point d – point i

Text proposed by the Commission	*Amendment*
(i) attracting and retaining talent in the Union and aiming to provide adequate	(i) attracting and retaining talent in the Union and aiming to provide adequate

upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses ***and*** social partners;	upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses***,*** social partners ***and other relevant stakeholders***;

Or. en

Amendment 1343
Diana Iovanovici Şoşoacă

Proposal for a regulation
Article 3 – paragraph 1 – point d – point i

Text proposed by the Commission	*Amendment*
(i) attracting and retaining talent in the Union and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;	(i) attracting and retaining talent in the Union ***in the medium and long term*** and aiming to provide adequate upskilling or reskilling opportunities covering the broad range of skills required for biotechnology and biomanufacturing, including technical skills, data science, AI, intellectual property and project management, and entrepreneurial skills, through activities including apprenticeships, traineeships, continuing education and training, in close cooperation with regional and local authorities, education and training institutions, businesses and social partners;

Or. ro

Amendment 1344
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point d – point ii

Text proposed by the Commission	*Amendment*
(ii) establishing public-private partnerships between universities, vocational education and training providers, businesses, in particular SMEs, start-ups and scale-ups, social partners and applied research institutes;	(ii) establishing public-private partnerships between universities, vocational education and training providers, businesses, in particular SMEs, start-ups and scale-ups, social partners and applied research institutes ***both for human and animal health***;

Or. en

Amendment 1345
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point d – point ii

Text proposed by the Commission	*Amendment*
(ii) establishing public-private partnerships between universities, vocational education and training providers, businesses, in particular SMEs, start-ups and scale-ups, social partners and applied research institutes;	(ii) establishing public-private partnerships between universities, vocational education and training providers, businesses, in particular SMEs, start-ups and scale-ups, ***not-for-profit developers,*** social partners and applied research institutes;

Or. en

Amendment 1346
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point d – point iii

Text proposed by the Commission	*Amendment*
(iii) establishing university alliances, also in cooperation with employers, to improve their delivery on innovation and the development of skills and talent.	(iii) establishing university ***and university hospital*** alliances, ***including cross-border alliances integrating healthcare delivery, research, innovation,***

	clinical trials, advanced manufacturing and cross-border clinical training and workforce development also in cooperation with employers, to improve their delivery on innovation and the development of skills and talent.

Or. en

Amendment 1347
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 3 – paragraph 1 – point d – point iii

Text proposed by the Commission	*Amendment*
(iii) establishing university alliances, also in cooperation with employers, to improve their delivery on innovation and the development of skills and talent.	(iii) establishing university alliances, also in cooperation with employers, to improve their delivery on innovation***, including on NAMs development*** and the development of skills and talent.

Or. en

Amendment 1348
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, Tomislav Sokol

Proposal for a regulation
Article 3 – paragraph 1 – point d – point iii

Text proposed by the Commission	*Amendment*
(iii) establishing university alliances, also in cooperation with employers, to improve their delivery on innovation and the development of skills and talent.	(iii) establishing university ***and university hospital*** alliances, also in cooperation with employers, to improve their delivery on innovation and the development of skills and talent.

Or. en

Amendment 1349
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 3 – paragraph 1 – point d – point iii

Text proposed by the Commission	*Amendment*
(iii) establishing university alliances, also in cooperation with employers, to improve their delivery on innovation and the development of skills and talent.	(iii) establishing ***and improving*** university alliances, also in cooperation with employers, to improve their delivery on innovation and the development of skills and talent.

Or. en

Amendment 1350
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point d – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) supporting the development of interdisciplinary curricula and training programmes linking biotechnology, biomanufacturing, clinical research, regulatory science, data science, artificial intelligence, ethics, intellectual property, technology transfer and entrepreneurship;

Or. en

Amendment 1351
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point d – point iii a (new)

Text proposed by the Commission	*Amendment*

(iiia) strengthening expertise in the fields of intellectual property, patents, licensing and technology transfer;

Or. it

Amendment 1352
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point d – point iii b (new)

Text proposed by the Commission	*Amendment*
	(iiib) supporting training models developed by European Reference Networks, centres of excellence, universities, vocational education and training providers and clinical research networks, in particular where they contribute to addressing skills shortages in rare diseases, advanced therapies and other areas of high unmet need.

Or. en

Amendment 1353
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point d – point iii b (new)

Text proposed by the Commission	*Amendment*
	(iiib) promoting mobility programmes for universities, research centres, healthcare facilities and businesses with a view to facilitating the exchange of expertise and disseminating best practices in the biotechnology sector.

Or. it

Amendment 1354
Stine Bosse, Katri Kulmuni, Billy Kelleher, Olivier Chastel, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures**.**	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the ***research,*** development, manufacturing and supply of medical countermeasures***, including for prevention of disease and by voluntarily setting aside a defined portion of manufacturing capacity for the development and production of specific pharmaceutical forms or active substances as marketing authorisation holder or contract manufacturer at the request of the European Commission in order to improve the Union's preparedness, as well as strengthening the EU's global health objectives as laid out in the 2022 EU Global Health Strategy, the 2025 Union Prevention, Preparedness, and Response Plan for Health Crises, the 2025 Medical Countermeasures Strategy and the 2026 Global Health Resilience Initiative, through these activities enhancing the EU's preparedness and response capacity to priority global health threats, including antimicrobial resistance (AMR), by supporting the development, manufacturing and equitable supply of innovative and sex-responsive medical countermeasures;***

Or. en

Justification

The voluntarily dedication of production capacity should be considered a strategic project because it contributes to the scale-up of production capacity for pharmaceutical forms and technologies and ensures flexibility to future crisis. By not only increasing output but also setting aside a defined portion of manufacturing capacity that can be mobilised within a fixed timeframe upon request of the European Commission, it strengthens the Union's preparedness and supports the timely availability of medicines in times of need.

It is important to include a reference to "research", alongside development, under Article 3(1)(e), in particular if strategic projects relating to surveillance data are to be covered. Strengthening disease prevention is necessary to support innovation and preparedness, and address evolving public health challenges across the Union.

Amendment 1355
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the ***research,*** development, manufacturing and supply of medical countermeasures***, including for prevention of disease and by voluntarily setting aside a defined portion of manufacturing capacity for the development and production of specific pharmaceutical forms or active substances as marketing authorisation holder or contract manufacturer at the request of the European Commission in order to improve the Union's preparedness***.

Or. en

Amendment 1356
Carlo Ciccioli, Michele Picaro, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the ***research,*** development, manufacturing and supply of medical countermeasures***, including for prevention of disease and by***

	voluntarily setting aside a defined portion of manufacturing capacity for the development and production of specific pharmaceutical forms or active substances as marketing authorisation holder or contract manufacturer at the request of the European Commission in order to improve the Union's preparedness.

Or. en

Amendment 1357
Giorgio Gori

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the ***research,*** development, manufacturing and supply of medical countermeasures***, including for prevention of disease and by voluntarily setting aside a defined portion of manufacturing capacity for the development and production of specific pharmaceutical forms or active substances as marketing authorisation holder or contract manufacturer at the request of the European Commission in order to improve the Union's preparedness***.

Or. en

Amendment 1358
Margarita de la Pisa Carrión, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures**.**	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures***, including by reserving a defined portion of its translational development infrastructure, specialized competences and manufacturing capacity for specific pharmaceutical forms or their active substances as marketing authorisation holder or contract manufacturer at the request of the European Commission in order to improve the Union's preparedness;***

Or. en

Amendment 1359
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures ***like human and veterinary vaccines against transboundary animal diseases and other animal diseases, including zoonotic diseases, where vaccination contributes to the prevention and control of disease and to the reduction of antimicrobial use in animal production.***

Or. en

Amendment 1360

Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the ***EU's*** preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the ***Member States'*** preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures***, including by reserving a defined portion of its translational development infrastructure, specialized competences and manufacturing capacity for specific pharmaceutical forms or their active substances as marketing authorisation holder or contract manufacturer in order to improve the preparedness***.

Or. en

Amendment 1361
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu, Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the ***research,*** development, manufacturing and supply of medical countermeasures ***like human and veterinary vaccines against transboundary animal diseases and other animal diseases, including zoonotic diseases, where vaccination contributes to the prevention and control of disease and to the reduction of antimicrobial use in animal production***.

Or. en

Amendment 1362
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures ***like human and veterinary vaccines against transboundary animal diseases and other animal diseases, including zoonotic diseases, where vaccination contributes to the prevention and control of disease and to the reduction of antimicrobial use in animal production***.

Or. en

Amendment 1363
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
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the ***EU's*** preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the ***Union's*** preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures***, including critical medicines, vulnerable to supply shocks***.

Or. en

Amendment 1364
Ondřej Krutílek

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures***, including critical medicines, vulnerable to supply shocks***.

Or. en

Amendment 1365
Dario Nardella, Georgia Tramacere, Sofie Eriksson, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures**.**	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures***, including critical medicines, vulnerable to supply shocks***

Or. en

Justification

Critical medicines vulnerable to supply shocks are central to health preparedness and should be reflected alongside medical countermeasures. This is necessary to ensure coherence with the Critical Medicines Act and to strengthen continuity of supply for medicines essential to public health.

Amendment 1366

Morten Løkkegaard, Katri Kulmuni, Stine Bosse, Sophie Wilmès

Proposal for a regulation
Article 3 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the development, manufacturing and supply of medical countermeasures.	(e) contributing to strengthening the EU's preparedness and response capacity to priority health threats by supporting the ***research,*** development, manufacturing and supply of medical countermeasures***, including for prevention***.

Or. en

Amendment 1367
Aurelijus Veryga

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) contributing to improving public health outcomes, healthcare quality and patient access within the Union, in particular where low return on investment is foreseen, through one or more of the following activities:
	(i) Improving accessibility, affordability, availability and equitable use of health biotechnology innovations, particularly for patients with unmet medical needs, rare diseases or limited commercial market potential;
	(ii) developing, validating, implementing, scaling up or maintaining noncommercial or social-profit health biotechnology innovations;
	(iii) supporting the translation of publicly funded research results into clinical practice, public health policies or healthcare services where no sufficient commercial incentive exists to ensure

implementation;

(iv) establishing, expanding or coordinating infrastructures, services or support structures that facilitate the societal uptake, dissemination, implementation and long-term maintenance of research-based innovations in healthcare systems;

(v) supporting the regulatory, methodological, clinical or organisational activities necessary to enable the further development and implementation of academically developed health biotechnology products, services or interventions that provide significant societal benefit.

Or. en

Amendment 1368
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) contributing to improving public health outcomes, healthcare quality and patient access within the Union, in particular where low return on investment is foreseen, through one or more of the following activities:
	(i) Improving accessibility, affordability, availability and equitable use of health biotechnology innovations, particularly for patients with unmet medical needs, rare diseases or limited commercial market potential;
	(ii) developing, validating, implementing, scaling up or maintaining noncommercial or social-profit health biotechnology innovations;
	(iii) supporting the translation of publicly funded research results into clinical

practice, public health policies or healthcare services where no sufficient commercial incentive exists to ensure implementation;

(iv) establishing, expanding or coordinating infrastructures, services or support structures that facilitate the societal uptake, dissemination, implementation and long-term maintenance of research-based innovations in healthcare systems;

(v) supporting the regulatory, methodological, clinical or organisational activities necessary to enable the further development and implementation of academically developed health biotechnology products, services or interventions that provide significant societal benefit.

Or. en

Amendment 1369
Nicolás González Casares, Tiemo Wölken

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) contributing to the coordinated development, regulatory navigation or repurposing of combination advanced therapies (ATMP combos), as defined in Article 2, including multi-cellular ATMP combinations, cross-class ATMP combinations, and ATMP-medicinal product combinations, in particular through projects that: (i) advance a rational combination regimen involving two or more advanced therapy medicinal products, or an advanced therapy medicinal product and another medicinal product, towards separate but coordinated authorisation; or (ii) generate the clinical, non-clinical or real-world evidence

required to establish the safety and efficacy of an existing, already-authorised medicinal product for combined use with an advanced therapy medicinal product, irrespective of the patent, data-protection, or generic/biosimilar-competition status of that medicinal product.

Or. en

Amendment 1370
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) addressing therapeutic areas characterised by a major public health and socioeconomic burden and persistent innovation gaps, including mental health conditions, through one or more of the following activities:
	(i) strengthening clinical development capacity for innovations addressing such conditions, including through multi-country clinical research and trial readiness;
	(ii) developing or expanding cross-border research and innovation infrastructures, including data and digital capabilities, relevant to such conditions;
	(iii) supporting implementation readiness and the translation of research into accessible care.

Or. en

Amendment 1371
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the project contributes to addressing the antimicrobial market failure recognised in the Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (2023/C 220/01), or in any successor instrument, by supporting the discovery, development, scale-up or manufacturing of priority antimicrobials within the meaning of the Directive and the Regulation constituting the Union legislation on medicinal products for human use, and demonstrates exceptional potential to strengthen the Union's public health, preparedness, strategic resilience or security of supply.

Or. en

Justification

This amendment recognises that certain biotechnology projects may warrant high impact strategic project status precisely because they generate exceptional value for the Union's public health, preparedness and strategic resilience objectives, while continuing to face structural market failures that limit the deployment of private capital at the scale required. The Council Recommendation 2023/C 220/01 explicitly calls on the Commission to address the antimicrobial market failure. The targeted market incentives introduced by the revised Union legislation on medicinal products for human use, in particular the transferable data exclusivity voucher, address one dimension of that failure. The proposed point (f) addresses the complementary industrial dimension by enabling priority antimicrobial projects to access the enhanced support available to high impact strategic projects under this Regulation. The reference to "or any successor instrument" ensures that the provision remains operative if the 2023 Council Recommendation is replaced or updated.

Amendment 1372
Anthony Smith, Anja Hazekamp, Marina Mesure, Emma Fourreau

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) supporting the development of

health biotechnologies that aim to strengthen public health through one or more of the following sectors: women's health, in particular to close the gender health gap by addressing and bringing to market solutions to, conditions that affect women exclusively, differently or disproportionately, including sexual and reproductive health technologies, such as novel contraceptive technologies for all genders.

Or. en

Justification

Amendment draft by the Deutsche Stiftung Weltbevölkerung (DSW)

Amendment 1373
Peter Agius

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) addressing an unmet medical need within the meaning of Article 2(1), point (25), or substantially improving patient-relevant clinical benefit within the meaning of Article 2(1), point (26), in particular for chronic and long-term conditions for which biotechnology-derived medicinal products represent the primary or essential means of treatment.

Or. en

Amendment 1374
Carlo Ciccioli, Michele Picaro, Ruggero Razza, Francesco Torselli, Lara Magoni

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) supporting essentials enabling technologies, including advanced synthetic chemistry and critical precursor manufacturing, where they are necessary to ensure the production and availability of innovation medicines;

Or. en

Amendment 1375
Paolo Borchia, Laurent Castillo, Raffaele Stancanelli, Isabella Tovaglieri, Julie Rechagneux, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) supporting essential enabling technologies, including advanced synthetic chemistry and critical precursor manufacturing, where they are necessary to ensure the production and availability of innovative medicines.

Or. en

Amendment 1376
Margarita de la Pisa Carrión, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) supporting essential enabling technologies, including advanced sythentic chemistry and critical precursor manufacturing, where they are necessary to ensure the production and availability of innovative medicines;

Or. en

Amendment 1377
Ruggero Razza

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) strengthening the Union's capacity to attract international investment in biotechnology research, development and production, while safeguarding the Union's strategic interests.

Or. it

Amendment 1378
Peter Liese, Sirpa Pietikäinen, Tiemo Wölken, Tilly Metz, Stine Bosse

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) supporting the development of breakthrough health biotechnologies that offer transformative public health, including novel contraceptive technologies for all genders, including male contraceptives,

Or. en

Justification

Novel contraceptive technologies, including male contraceptives, have the potential to address an important unmet public health need and are increasingly being developed through innovative biotechnological approaches. They should therefore benefit from the same support and regulatory framework as other innovative health biotechnologies.

Amendment 1379
Marie Toussaint, Ville Niinistö

on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) contributing to the Union's public interest objectives by improving the accessibility, affordability, sustainability, resilience or societal value of health biotechnology products and services.

Or. en

Amendment 1380
Margarita de la Pisa Carrión, Paolo Borchia, Laurent Castillo, Ondřej Knotek, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) contributing to reducing critical dependencies on third countries, reinforcing resilient supply chains for medicinal products and active substances;

Or. en

Amendment 1381
Peter Liese

Proposal for a regulation
Article 3 – paragraph 1 – point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) demonstrate compliance with the ethical constraints of Union and national law on human embryonic and germ-line research.

Or. en

Justification

Strategic project status provides access to significant public support and administrative facilitation. Compliance with Union ethical standards should therefore be a prerequisite for eligibility.

Amendment 1382
Peter Liese, Sirpa Pietikäinen, Tiemo Wölken, Tilly Metz, Stine Bosse

Proposal for a regulation
Article 3 – paragraph 1 – point e c (new)
Article 3
Paragraph 1, Point e a (new)

Text proposed by the Commission	*Amendment*
	(ec) (ea) supporting the development of breakthrough health biotechnologies that offer transformative public health, including novel contraceptive technologies for all genders, including male contraceptives,

Or. en

Justification

Novel contraceptive technologies, including male contraceptives, have the potential to address an important unmet public health need and are increasingly being developed through innovative biotechnological approaches. They should therefore benefit from the same support and regulatory framework as other innovative health biotechnologies.

Amendment 1383
Margarita de la Pisa Carrión, Laurent Castillo, Ondřej Knotek, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point e c (new)

Text proposed by the Commission	*Amendment*
	(ec) contributing to the prevention, monitoring or treatment of antimicrobial resistance, as well as the research, development and manufacture of novel

antimicrobial drugs and treatments;

Or. en

Amendment 1384
Margarita de la Pisa Carrión, Paolo Borchia, Laurent Castillo, Aleksandar Nikolic, Marie-Luce Brasier-Clain

Proposal for a regulation
Article 3 – paragraph 1 – point e d (new)

Text proposed by the Commission	*Amendment*
	(ed) contributing to improving public health outcomes, healthcare quality and patient access within the Union, including:
	(i) innovation in cancer prevention, population screening programmes and early detection;
	(ii) AI-based diagnostic tools for cancer and other oncological applications;
	(iii) epidemiological research and surveillance systems for cancer;
	(iv) support for the translation of publicly funded research results into clinical practice or public health policies.

Or. en

Amendment 1385
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. A project shall be recognised as a health biotechnology strategic project where it fulfils at least two of the following strategic criteria:
	(a) it provides significant European added value and cross-border impact;

(b) it addresses an unmet medical need within the meaning of Article 2(1), point (25), or substantially improves patient-relevant clinical benefit within the meaning of Article 2(1), point (26), in particular for chronic and long-term conditions for which biotechnology-derived medicinal products represent, or are expected to become, the primary or essential means of treatment;

(c) it addresses a critical strategic need, including market failures, external dependencies, capability gaps or health security priorities;

(d) it has a scale or transformational effect on the Union's biotechnology ecosystem, manufacturing capacity, innovation pipeline, or resilience;

(e) it contributes significantly to the Union's competitiveness, strategic autonomy, or capacity to attract investment and accelerate deployment.

(f) addressing an unmet medical need within the meaning of Article 2(1), point (25), or substantially improving patient-relevant clinical benefit within the meaning of Article 2(1), point (26), in particular for chronic and long-term conditions for which biotechnology-derived medicinal products represent the primary or essential means of treatment.

Or. en

Amendment 1386
Michalis Hadjipantela

Proposal for a regulation
Article 3 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. A project shall be recognised as a health biotechnology strategic project where it fulfils at least two of the

following strategic criteria:

(a) it provides significant European added value and cross-border impact;

(b) it addresses an unmet medical need within the meaning of Article 2(1), point (25), or substantially improves patient-relevant clinical benefit within the meaning of Article 2(1), point (26), in particular for chronic and long-term conditions for which biotechnology-derived medicinal products represent, or are expected to become, the primary or essential means of treatment;

(c) it addresses a critical strategic need, including market failures, external dependencies, capability gaps or health security priorities;

(d) it has a scale or transformational effect on the Union's biotechnology ecosystem, manufacturing capacity, innovation pipeline, or resilience; it contributes significantly to the Union's competitiveness, strategic autonomy, or capacity to attract investment and accelerate deployment.

Or. en

Amendment 1387
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. All biotechnology strategic projects shall be developed and implemented in compliance with applicable Union and national labour and social law and shall, where appropriate, contribute to quality employment, skills development, gender equality, decent working conditions and social dialogue. Member States and the

Commission shall ensure the involvement of social partners, where relevant, in the design and implementation of support measures for such projects.

Or. en

Amendment 1388
Tiemo Wölken, Nicolás González Casares

Proposal for a regulation
Article 3 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. For the purposes of paragraph 1, projects contributing to the research, development, scaling-up, manufacturing, analytical testing or marketing authorisation of biosimilar medicinal products, biohybrids medicinal products, according to article 11 and 12 of Directive 2023/0132, shall be eligible for recognition where they make a substantial contribution to the objectives set out in paragraph 1.

Or. en

Amendment 1389
Kristoffer Storm

Proposal for a regulation
Article 3 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. maintaining, creating or upgrading manufacturing capacity in the Union for active pharmaceutical ingredients (APIs) and medicines listed in the Union list of critical medicines.

Or. en

Amendment 1390
Angelika Winzig

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The projects referred to in paragraph 1 may be located on the territory of ***two*** or more Member States.	2. The projects referred to in paragraph 1 may be located on the territory of ***one*** or more Member States***, and may include participants established in third countries***.

Or. en

Justification

The participation of entities from third countries may be necessary to provide complementary expertise, resources and international cooperation that enhance the success and impact of strategic projects. Their participation should remain subject to the applicable programme rules governing the eligibility of third-country and associated-country entities for Union funding.

Amendment 1391
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The projects referred to in paragraph 1 may be located on the territory of two or more Member States.	2. The projects referred to in paragraph 1 ***and 2a*** may be located on the territory of two or more Member States.

Or. en

Amendment 1392
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The projects referred to in paragraph 1 may be located on the territory of two or more Member States.	2. The projects referred to in paragraph 1 ***and 2a*** may be located on the territory of two or more Member States.

Or. en

Amendment 1393
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The projects referred to in paragraph 1 may be located on the territory of two ***or more*** Member States.	2. The projects referred to in paragraph 1 may be located on the territory of ***at least*** two Member States.

Or. en

Amendment 1394
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. A project shall be recognised as a health biotechnology strategic project only where it fulfils at least two of the following strategic criteria:
	(a) provides significant European added value, including by generating benefits beyond the Member State in which it is established;
	(b) addresses a critical strategic need, including market failures, external dependencies, capability gaps, unmet medical needs, or health security

priorities;

(c) has the potential to generate a transformative impact on the Union's biotechnology ecosystem, manufacturing capacity, innovation pipeline, or resilience;

(d) contributes significantly to the Union's competitiveness, resilience, strategic autonomy, or capacity to attract investment and accelerate the deployment of innovative biotechnology;

(e) contributes to the public interest by delivering demonstrable societal value, including through improved patient outcomes, accessibility, affordability, sustainability or resilience.

Or. en

Justification

While flexibility is important, greater selectivity is needed to preserve the credibility of the Strategic Project label.

Amendment 1395
Jérémy Decerle, Christophe Grudler

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Projects referred to in paragraph 1 shall be assessed, where relevant and proportionate to their nature, with regard to their contribution to public health priorities and patient benefit, including their capacity to address an unmet medical need, in particular for rare or neglected diseases, antimicrobial resistance, paediatric conditions or age-related diseases; to strengthen the resilience of health systems, including the security and diversification of supply chains and production capacities or to improve care pathways, efficiency and

sustainability of health systems.

Or. en

Amendment 1396
Adam Jarubas, Krzysztof Hetman, Ewa Kopacz, Borys Budka

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Projects recognised as strategic projects under Regulation (EU) …/… [Critical Medicines Act; reference to be added after adoption, cf. COM(2025) 102 final], which concern critical biological medicinal products, their active substances, or key inputs necessary for their manufacture, shall benefit from a presumption that they contribute to the objectives of this Regulation, provided that the competent authority confirms that the project falls within the scope of health biotechnology.

Or. en

Amendment 1397
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis, Giorgio Gori

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Projects recognised as strategic projects under Regulation (EU) …/… [Critical Medicines Act; reference to be added after adoption, cf. COM(2025) 102 final], which concern critical biological medicinal products, their active substances, or key inputs necessary for their manufacture, shall benefit from a presumption that they contribute to the

objectives of this Regulation, provided that the competent authority confirms that the project falls within the scope of health biotechnology.

Or. en

Justification

The proposed amendment is intended to ensure effective coordination between the Critical Medicines Act and the European Biotech Act, while preserving the distinct scope and assessment criteria of both instruments. Strategic projects recognised under the Critical Medicines Act may be highly relevant for the objectives of the Biotech Act where they concern critical biological medicinal products, their active substances or key manufacturing inputs. A presumption of contribution, subject to confirmation by the competent authority that the project falls within the scope of health biotechnology, would ensure practical complementarity between the two instruments, avoid parallel or duplicative procedures, and maintain legal certainty in the application of both frameworks.

Amendment 1398
Waldemar Buda, Kosma Złotowski

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Projects recognised as strategic projects under Regulation (EU) …/… [Critical Medicines Act; reference to COM(2025) 102 final], which concern critical biological medicinal products, their active substances, or key inputs necessary for their manufacture, shall benefit from a presumption that they contribute to the objectives of this Regulation, provided that the competent authority confirms that the project falls within the scope of health biotechnology.

Or. en

Amendment 1399
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The objectives and activities set out in paragraph 1 establish the overarching criteria for the recognition of health biotechnology strategic projects.
	In order to ensure consistent and proportionate application of those criteria across Member States, the Commission, in cooperation with the European Health Biotechnology Steering Group referred to in Article 20, shall develop guidance on the interpretation and practical application of this Article.

Or. en

Amendment 1400
Stine Bosse, Katri Kulmuni, Billy Kelleher, Morten Løkkegaard

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Measures adopted under this Regulation shall avoid creating parallel or duplicative regulatory pathways for clinical research. In particular, any Union-level coordination mechanisms shall be designed to complement and streamline existing national systems, without introducing additional layers of administrative burden or increasing costs for sponsors, especially for academic and non-commercial research conducted by healthcare providers.

Or. en

Amendment 1401
Dimitris Tsiodras

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. For the purposes of paragraph 1, projects contributing to the research, development, scaling-up, manufacturing, analytical testing or marketing authorisation of biosimilars and other follow-on biological medicinal products, shall be eligible for recognition where they make a substantial contribution to the objectives set out in paragraph 1.

Or. en

Justification

Biosimilar strategic project, which is referred to in chapter V, should be explicitly included in Chapter II to facilitate common understanding and interpretation. International partners are a key element of the functioning and competitiveness of the European Biotech Hub.

Amendment 1402
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. For the purposes of paragraph 1, projects contributing to the research, development, scaling-up, manufacturing, analytical testing or marketing authorisation of biosimilars and other follow-on biological medicinal products, shall be eligible for recognition where they make a substantial contribution to the objectives set out in paragraph 1.

Or. en

Amendment 1403
François-Xavier Bellamy, Céline Imart

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Projects whose primary or ancillary objective is the development, production or placing on the market of food products falling within the scope of Regulation EU 2015/2283 shall not be recognised as health biotechnology strategic projects.

Or. en

Amendment 1404
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
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Projects related to biosimilars and other follow-on biological medicinal products may be eligible for recognition, provided that they make a substantial contribution to the objectives set out in paragraph 1.

Or. en

Amendment 1405
Marie Toussaint, Ville Niinistö
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 3 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The recognition and support of a health biotechnology strategic project pursuant to this Article shall be conditional upon compliance with Union requirements relating to environmental protection, biosafety, biosecurity, animal welfare, occupational safety, data protection and ethical standards. Such recognition and support shall not, under any circumstances, result in a lowering of those standards.

Or. en

Amendment 1406
Vytenis Povilas Andriukaitis, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. In the selection of these projects priority shall be given to:
	a) Projects addressing unmet medical needs, as referred to in Article 83(1) of [revised Directive 2001/83/EC] or
	b) Critical medicines as listed in the Union list of critical medicines, as referred in (revised Regulation (EC) no 726/2004].

Or. en

Amendment 1407
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Projects whose primary or ancillary objective is the development, production or placing on the market of food products falling within the scope of Regulation (EU) 2015/2283 shall not be recognised as health biotechnology strategic projects.

Or. en

Amendment 1408
Vytenis Povilas Andriukaitis, Nikos Papandreou, Marta Temido, Romana Jerković, Dario Nardella, Victor Negrescu

Proposal for a regulation
Article 3 – paragraph 2 c (new)

Text proposed by the Commission	*Amendment*
	2c. The Commission shall, in cooperation with Member States and relevant stakeholders, including patient organisations, publish guidance to support the consistent and transparent recognition of biotechnology strategic projects across the Union. That guidance shall set out criteria to assess their added value for public health, including their contribution to addressing unmet medical needs, improving patient-relevant outcomes, strengthening supply resilience and supporting equitable access to the products and services developed under such projects.

Or. en

Amendment 1409
Elena Nevado del Campo, Dolors Montserrat

Proposal for a regulation
Article 3 – paragraph 2 c (new)

Text proposed by the Commission	*Amendment*
	2c. For the purposes of paragraph 1, projects contributing to the research, development, scaling-up, manufacturing, analytical testing or marketing authorisation of biosimilars and other follow-on biological medicinal products, shall be eligible for recognition where they make a substantial contribution to the objectives set out in paragraph 1.

Or. en

Amendment 1410
Christine Anderson

Proposal for a regulation
Article 3 a (new)

Text proposed by the Commission	*Amendment*
	Article 3a
	General simplification principle
	1. Member States and the Commission shall ensure that administrative, regulatory and permitting procedures applicable to health biotechnology projects are clear, proportionate, predictable, time-bound and non-discriminatory.
	2. Simplification measures under this Chapter shall be available to all health biotechnology projects falling within the scope of this Regulation, with particular attention to SMEs, start-ups, scale-ups, non-commercial research organisations and university spin-offs.
	3. Access to simplified procedures shall not depend on prior designation as a strategic project, participation in a Union funding programme or recognition by the Commission or a Member State.
	4. Nothing in this Chapter shall affect requirements relating to patient safety,

informed consent, ethics, environmental protection, biosecurity, data protection, judicial remedies or Member States' competences in healthcare and bioethics.

Or. en

Amendment 1411
Viktória Ferenc, András Gyürk

Proposal for a regulation
Article 3 a (new)

Text proposed by the Commission	*Amendment*
	Article 3a
	Health biotechnology strategic projects
	For the purposes of paragraph 1, projects contributing to the research, development, scaling-up, manufacturing, analytical testing or marketing authorisation of biosimilars and other follow-on biological medicinal products, shall be eligible for recognition where they make a substantial contribution to the objectives set out in paragraph 1.

Or. en

Amendment 1412
Dario Nardella, Georgia Tramacere, Vytenis Povilas Andriukaitis

Proposal for a regulation
Article 3 a (new)

Text proposed by the Commission	*Amendment*
	Article3a
	The general objectives of the Health biotechnology strategic projects is to contribute to reducing regulatory fragmentation and stimulate innovation in the Union.

Or. en