Humane World for Animals

Formerly called
Humane Society International

# Recommended amendments on European Biotech Act (2025/0406 (COD))

Humane World for Animals welcomes the Commission's proposal for a Regulation establishing a European Biotech Act. We commend your office for contributing to the discussions on this important dossier at the Council Working Party.

We support the proposal's objective to strengthen initiatives to enhance EU competitiveness and sustainability by focusing on the medical and pharmaceutical sector. We believe this sector continues to be hampered by an overreliance on traditional models—such as animal testing and overly simplistic in vitro systems—as well as suboptimal clinical trial design. These factors have contributed significantly to the persistently high failure rate in drug development, which remains around 90%[1]. Directive 2010/63/EU has not sufficiently addressed the persistent overreliance on animal models, as the enforcement of the "last resort" principle remains weak and inconsistent across Member States. Non-animal technologies should be prioritised and used for human health product research and development wherever scientifically available and appropriate, including in disease modelling, drug discovery, efficacy testing and safety assessment. In particular, innovative human-relevant new approach methods (NAMs), such as complex in vitro models and advanced in silico tools, are already demonstrating improved predictive power and translational relevance[2,3], addressing genetic variability and susceptibility and enabling better representation of underserved populations (including women and elderlies). These approaches are accelerating the development of safer and more effective treatments and bringing us closer to truly patient-relevant drug design.

**We welcome and support the Commission's proposed definition of New Approach Methodologies (NAMs) and do not consider further amendments necessary.** The proposed definition is scientifically robust, technology-neutral and sufficiently broad to accommodate current and future innovations. Importantly, the definition clearly states that NAMs are methods that do not involve live animals. This provides legal certainty and reinforces the role of NAMs as innovative approaches that move biomedical research and safety assessment towards more human-relevant science. By focusing on non-animal methods, the definition supports the development and use of technologies that are increasingly capable of modelling human biology, disease mechanisms and treatment responses more accurately than traditional animal models.

The European Union's commitment to promote NAMs in research and safety assessment is also reflected in the ERA Strategic Agenda 2025–2027, the EU Life Sciences Strategy, and the EC Roadmap for Phasing Out Animal Testing in Chemical Safety Assessment. Nevertheless, implementation remains slow and fragmented.
We welcome the proposal's indication to "provide a flexible regulatory environment for a fast-growing innovative sector", including regulatory sandboxes and enabling increasing use of data and AI technologies. We believe such flexibility should be applied to the entire NAM toolbox to reduce

[1] Sun D, Gao W, Hu H, Zhou S. Why 90% of clinical drug development fails and how to improve it? Acta Pharm Sin B 2022;12:3049–62. https://doi.org/10.1016/j.apsb.2022.02.002.
[2] Ewart L, et al. Performance assessment and economic analysis of a human Liver-Chip for predictive toxicology. Commun Med (Lond). 2023 Feb 2;3(1):16. doi: 10.1038/s43856-023-00249-1.
[3] Sadybekov, A.V., Katritch, V. Computational approaches streamlining drug discovery. *Nature* **616**, 673–685 (2023). https://doi.org/10.1038/s41586-023-05905-z

procedural timelines, and foster a flexible and collaborative regulatory environment, ultimately increasing marketing and uptake.
In order to ensure that EC strong policy commitments to accelerate the development and deployment of human-relevant technologies in the medical and pharmaceutical sector, we respectfully propose a number of targeted amendments mainly focusing on emphasising the importance of (i) investing in non-animal new approach methodologies (NAMs), (ii) addressing skill and knowledge gaps in the field, (iii) increasing their marketing and regulatory uptake, and (iv) ultimately enhancing research impact.

These amendments have been proposed in relation to the following Recitals and Articles:

- Recitals 10, 12, 15, 17, 29, 39, 44, 149
- Articles 1, 3, 15, 22, 25

We thank you in advance for your consideration and support. We remain at your disposal for any meeting or exchange on the proposed amendments.

Yours sincerely,

*Humane World for Animals*

**Suggested amendments to the Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)**

**Recital 10**

| EC Proposal | Proposed amendment |
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| This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council[4] on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council. | This Regulation should not affect to the application of the Directive 2010/63/EU of the European Parliament and of the Council[4] on the protection of animals used for scientific purposes and of Regulation (EC) 2006/1907 of the European Parliament and of the Council. **In line with the objective of the Directive 2010/63/EU and taking into account the Commission Roadmap towards phasing out animal testing, this Regulation should support the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs). These methodologies can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D) cell culture models, organoids and human stem cells-based models; in silico tools, in chemico technologies and any combination thereof or read-across models. Ultimately, efforts should be made to fully replace procedures on live animals for scientific purposes.** |
| **Justification**<br>*This addition ensures coherence between the European Biotech Act, Directive 2010/63/EU on the protection of animals used for scientific purposes, the Regulation on the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, and the Commission Roadmap towards phasing out animal testing. Supporting the development, validation, standardisation, regulatory acceptance and uptake of New Approach Methodologies (NAMs) will strengthen the EU biotechnology sector by promoting more human-relevant, innovative and predictive approaches to research, testing and product development.* | |

**Recital 12**

| EC Proposal | Proposed amendment |
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| Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other | Health biotechnology strategic projects should serve as targeted instruments to mobilise public and private investments through coordinated action among the Union, the Member States, the industry, the research community and other |

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| relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as New Approach Methodologies (NAMs), or advanced data and digital platforms. Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria. Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making. | relevant actors. They should contribute to the Union's biotechnology objectives, by strengthening industrial capacity and value chains, scaling up critical research and technology infrastructures, accelerating innovation and technology deployment such as new approach methodologies (NAMs), or advanced data and digital platforms.<br>***In particular, projects advancing NAMs should be prioritised, given their potential to improve the human relevance, addressing genetic diversity and enabling better representation of underserved populations, including women, elderlies and different ethnicities, improving efficiency and translational value of biomedical research and safety assessment.***<br>Accordingly, this Regulation should lay down provisions for the recognition and support of such projects by the Member States and should establish criteria for such recognition. ***Those criteria should include, where relevant, the contribution to the development, validation, standardisation and regulatory acceptance of NAMs.*** With a view to facilitate the implementation and ensure a consistent approach across the Union, the Commission could issue guidance on the application of those criteria.<br>Recognition of health biotechnology strategic projects would deliver clear benefits for the most innovative businesses by accelerating permitting, reducing administrative burden, improving legal certainty and facilitating access to financial support. ***For NAM-based innovations, such support should also facilitate early engagement with regulatory authorities and promote pathways for their integration into regulatory frameworks.*** It would thus strengthen their capacity to scale biotechnology innovations faster. For authorities, the framework streamlines coordination, avoids duplication of assessments, and supports consistent, efficient decision-making. |
| **Justification**<br>*While NAMs are mentioned, their strategic importance for innovation and regulatory transformation is not sufficiently reflected. Strengthening their prioritisation and explicitly linking them to validation and regulatory uptake would help ensure that EU support mechanisms effectively enable their development, acceptance and integration into biomedical and safety assessment pipelines.* | |

**Recital 15**

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

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| | safer and more efficient development of innovative therapies.<br>***These centres should, where relevant, integrate NAMs into preclinical and translational workflows and support their regulatory acceptance through collaboration with competent authorities.***<br>When connected to digital and data infrastructures, they should have the potential to accelerate clinical translation, improve quality control and facilitate patient access across the Union.<br>***In addition, strategic projects contributing to the generation, sharing and interoperability of high-quality data derived from NAMs should be encouraged, as such data are essential to support their validation, reproducibility and regulatory uptake.*** |
| **Justification**<br>*NAMs are not yet sufficiently embedded in large-scale infrastructures and centres of excellence, limiting their translation and regulatory uptake. Strengthening their integration within strategic projects and data ecosystems would help bridge the gap between innovation and application, enhance Europe's leadership in human-relevant technologies, and maximise the impact of investments under the MFF.* | |

**Recital 17**

| EC Proposal | Proposed amendment |
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| Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners. Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation. | Effective implementation of objectives pursued in this Regulation relies on good governance and partnership between all actors at the relevant territorial levels and socio-economic actors. In particular, biotechnology strategic projects aimed at targeting talent and skills shortages vital to supporting biotechnology and biomanufacturing industries and to ensuring a workforce capable to supporting innovation, industrial scale-up and long-term competitiveness should be designed and developed with the full involvement of the relevant social partners.<br>***This should include the development of skills and training programmes related to NAMs, including advanced in vitro, microphysiological and in silico approaches, as well as their application in regulatory science and safety assessment*.**<br>Such active engagement is essential to ensure that social implications are addressed from the outset and to foster responsible innovation. |

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| | ***Addressing skills gaps in NAMs is critical to enable their uptake across research, industry and regulatory contexts, and to support the transition towards more human-relevant and innovative biotechnology ecosystems in the Union.*** |
| **Justification**<br>*Skills gaps are a key barrier to the uptake of NAMs. Explicitly supporting training and capacity-building in this area would facilitate their implementation across sectors and ensure the availability of a workforce equipped to support innovative and human-relevant approaches.* | |

**Recital 29**

| EC Proposal | Proposed amendment |
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| In light of their contribution to the Union's competitiveness, resilience and preparedness, health biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest.<br>Similarly, Member States should grant such projects the highest national significance available under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting, and adopt facilitation measures in compliance with Union law. | In light of their contribution to the Union's competitiveness, resilience and preparedness, health biotechnology strategic projects recognised by the Member States in accordance with this Regulation should be considered to be in the public interest.<br>***Projects that significantly contribute to the development, validation and regulatory uptake of NAMs, as human-relevant and innovative technologies, should be recognised as having particular public interest due to their potential to address genetic variability and susceptibility and to improve the effectiveness, safety and efficiency of biomedical research and health innovation.***<br>Similarly, Member States should grant such projects the highest national significance available under their national law, meaning the strongest designation applicable to major strategic projects, and should apply the corresponding procedural advantages, including priority treatment and coordinated and accelerated permit-granting, and adopt facilitation measures in compliance with Union law. |
| **Justification**<br>*Recognising the specific public interest value of NAMs would support their prioritisation within strategic projects and facilitate their faster development, uptake and regulatory integration.* | |

**Recital 39**

| EC Proposal | Proposed amendment |
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| Member States should provide to the Steering Group, on an annual basis, an overview of the health biotechnology strategic projects and of the high impact health biotechnology strategic | Member States should provide to the Steering Group, on an annual basis, an overview of the health biotechnology strategic projects and of the high impact health biotechnology strategic |

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| projects that they recognise, as well as of the existing and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices. | projects that they recognise, as well as of the existing and emerging cooperation initiatives and networks among such projects. Such overview is aimed at informing monitoring of progress in the implementation of this Regulation, supporting coordination and proposals of measures to enhance the Union's biotechnology and biomanufacturing ecosystem and facilitate exchange of best practices. In such overview, Member States should identify progress, obstacles and best practices.<br>***In particular, Member States should report on obstacles affecting the development, validation, regulatory acceptance and uptake of NAMs, including scientific, technical, infrastructural, skills-related and regulatory barriers, as well as examples of enabling practices. In addition, Member States should report on emerging opportunities in NAM development that may require future financial, skills, and infrastructural investment.*** |
| **Justification**<br>*Including a specific reporting requirement on obstacles to NAM uptake and emerging opportunities would improve the evidence base for Union-level coordination and policy action. It would allow systematic identification of recurring barriers across Member States (particularly those related to validation, regulatory acceptance, infrastructure and skills) thereby supporting targeted measures to accelerate the integration of NAMs into research, innovation and regulatory frameworks.* | |

**Recital 44**

| EC Proposal | Proposed amendment |
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| Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles. | Complementing the European Innovation Council support for deep tech and disruptive innovators in the area of biotechnology, an EU Health Biotechnology Investment Pilot to mobilise public and private investment and strengthen the Union's competitiveness and resilience should be created in partnership with the European Investment Bank Group (EIBG) or other implementing partners, for implementation in indirect management, linking equity and guarantee instruments with venture debt tailored to biotech-specific risk profiles, ***including support for Moonshot programmes advancing non-animal new approach methodologies across the innovation and regulatory value chain.*** |
| **Justification**<br>*Aligning the Investment Pilot with Moonshot programmes would support coordinated, large-scale investments in strategic technologies such as NAMs, helping to accelerate their uptake. This is* | |

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| *consistent with the growing emphasis on Moonshot initiatives within the proposed Horizon Europe 2028–2034 framework..* |

**Recital 149**

| EC Proposal | Proposed amendment |
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| The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing EN 65 EN regulators to test ***new methods*** for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments. | The disruptive and innovative approaches to clinical trials may require adaptations to the rules governing clinical trial approvals and conduct. To harness the benefits of this innovation while providing necessary safeguards, it is essential to create a safe space for testing new regulatory approaches and technologies. This includes, where appropriate, the use of AI in trial design, data collection, analysis, and participant interaction. For that reason, it is necessary to provide for a possibility of setting up a controlled experimental environment in the form of a regulatory sandbox, allowing EN 65 EN regulators to test ***human-relevant and non-animal NAMs*** for authorising and conducting clinical trials, for example, when some requirements of the dossier cannot be fully complied with, while ensuring strong safeguards for participant protection and data robustness. Insights gained from sandbox activities should inform future guidance and, where appropriate, legislative amendments. |
| **Justification** | |
| *Replacing "new methods" with "human-relevant and non-animal NAMs" provides greater legal clarity and scientific precision by explicitly identifying the innovative approaches covered by the provision. This amendment aligns the text with the EU's objective of promoting human-relevant, non-animal methodologies in clinical research and regulatory science.* | |

**Article 1 – Subject matter and scope, paragraph 1**

| EC Proposal | Proposed amendment |
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| 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 | 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 |

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| of products, food and feed safety and biosecurity | biosecurity ***and promoting human-relevant and human-centred innovation.*** |
| **Justification**<br>*It is important to emphasise that the Regulation should support the promotion of human-relevant and human-centred innovative biotechnologies.* | |

**Article 1 – Subject matter and scope, paragraph 2 (new)**

| EC Proposal | Proposed amendment |
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| | ***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, with the objective of accelerating innovation and progressively replacing animal testing in research, development, manufacturing and regulatory safety assessment*** |
| **Justification**<br>*Under subject matter and scope, it is important to consider also the promotion of scientific freedom and collaboration as cornerstones of EU life science, and provide support to innovative non-animal technologies.* | |

**Article 3 - Health biotechnology strategic projects, paragraph 1 (b)**

| EC Proposal | Proposed amendment |
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| (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.*** |
| **Justification**<br>*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.* | |

**Article 15 - Networks of health biotechnology clusters - paragraph 2**

| EC Proposal | Proposed amendment |
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| d) provide transparent, open, and non-discriminatory cross-border access at market prices to research organisations, SMEs, start-ups and scale-ups, healthcare providers, and industrial actors from across the Union | (d) provide transparent, open, and non-discriminatory cross-border access at market prices to research organisations, SMEs, start-ups and scale-ups, healthcare providers, and industrial actors from across the Union, ***including access to shared validation platforms and reference infrastructures for non-animal methodologies*** |
| **Justification**<br>*When referring to networks and clusters, also shared validation platforms and infrastructures for non-animal NAMs shall also be referenced.* | |

**Article 22 - EU health biotechnology investment pilot (3)**

| EC Proposal | Proposed amendment |
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| The pilot shall be designed as a mechanism that may use and leverage different funding streams and instruments to accelerate and catalyse investments into the health biotechnology sector. It may be used to provide Union support through Union programmes. | The pilot shall be designed as a mechanism that may use and leverage different funding streams and instruments to accelerate and catalyse investments into the health biotechnology sector. It may be used to provide Union support through Union programmes. ***In this context, dedicated Moonshot programmes focused on health biotechnologies, including NAMs, could be leveraged to support their development, validation, standardisation, scale-up, market uptake and regulatory integration across the full innovation and value chain.*** |
| **Justification**<br>*The inclusion of dedicated Moonshot programme for innovative biotechnologies, including NAMs, would ensure a coordinated and mission-oriented approach to overcoming current fragmentation in their development and uptake. Such an initiative would support the full value chain (from early research and validation to regulatory acceptance and market deployment) thereby accelerating their translation into practice. This proposal is consistent with the reference to Moonshot-type initiatives already included in the Explanatory Memorandum of the Horizon Europe 2028–2034 Regulation proposal, which highlights the need for ambitious, large-scale EU actions targeting strategic technologies with high transformative potential.* | |

**Article 25 - Funding for high impact health biotechnology strategic projects (1)**

| EC Proposal | Proposed amendment |
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| High impact health biotechnology strategic projects may be given particular consideration for financial support under Union funds, | High impact health biotechnology strategic projects may be given particular consideration for financial support under Union funds, |

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| programmes and instruments in accordance with the objectives set out in the regulations establishing those funds, programmes and instruments. | programmes and instruments, ***including Moonshot programmes,*** in accordance with the objectives set out in the regulations establishing those funds, programmes and instruments. |
| **Justification**<br>*Specific reference to Moonshot programmes, particularly for high impact health biotechnologies, including NAMs, would ensure a coordinated and mission-oriented approach to overcoming current fragmentation in their development and uptake.* | |