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Remissvar för remiss av PM Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa (dnr S2026/00180)

Linköpings universitet (LiU) har beretts tillfälle att yttra sig över remiss av PM Europeiska kommissionens förslag på förordning och direktiv om bioteknik – hälsa (dnr S2026/00180) och lämnar följande synpunkter.

Sammanfattning

Sammanfattningsvis har LiU följande synpunkter på remissen:

The University welcomes the proposed European Biotech Act and its objective to strengthen Europe's biotechnology ecosystem and valorisation through measures addressing regulatory efficiency, access to capital, data and AI, and biosecurity.

The proposal correctly identifies structural challenges in translating research excellence into marketable innovation. In particular, the focus on strategic projects (Pillar 1), investment measures (Pillar 2), and regulatory simplification is relevant. However, the University notes that the proposal does not sufficiently reflect the systemic role of universities and affiliated environments across the full innovation pathway, nor does it adequately address the role of higher education institutions in competence supply, including the need for upskilling and reskilling of the existing workforce in a rapidly evolving, AI-driven technological landscape.
Furthermore, while the proposal refers to artificial intelligence as an enabling technology, the interaction with existing EU regulatory frameworks and the implications for risk management are not sufficiently specified for implementation.

General Remarks

The proposal covers research, development, manufacturing and market deployment. However, its focus is primarily stages of the innovation process, particularly industrial deployment and scale-up, including concerns related to companies listing outside the EU. While the proposal refers to ecosystem development and collaboration between research organisations, industry and public actors, the role of universities across the full lifecycle is not clearly articulated. From an innovation system perspective, effective translation from research to viable companies requires access to clinical research environments, pilot and demonstration facilities, early-stage funding, structured support for company creation, and long-term collaboration platforms. These elements are not systematically addressed in the proposal. The proposal also includes measures related to intellectual property and incentives. These are important, but their alignment with early-stage innovation and company creation could be further clarified.

Pillars 1 and 2 and Regulatory Measures – Clinical Research, Strategic Projects and Access to Finance

The proposal includes measures to simplify regulatory procedures, establish strategic projects under Pillar 1, and improve access to finance under Pillar 2. The University supports these measures.
At the same time, the proposal places greater emphasis on later stages of the innovation process, in particular industrial deployment, scale-up and growth financing, while early-stage phases such as clinical validation and initial company formation are less developed. The role of academic actors, including universities, clinical research environments and publicly funded research infrastructures, is not sufficiently clarified, particularly in relation to project design, implementation and access to funding.
This creates a risk that conditions for research valorisation and the translation of research into viable companies remain underdeveloped, including access to validation environments, early-stage funding and structured collaboration between academia, healthcare, industry and investors.

The University therefore recommends that implementation clarifies the role of universities, research infrastructures and academic sponsors across regulatory frameworks and under Pillars 1 and 2, ensures that procedures and funding are accessible to both academic and industrial actors, strengthens support for early-stage innovation, including proof-of-concept and company creation, and requires integration of clinical and validation environments where relevant.

Pillar 4 and Biosecurity – Data, Artificial Intelligence and Risk Governance

The proposal identifies data access, interoperability and artificial intelligence as key enablers for biotechnology innovation. The University supports this focus.
However, artificial intelligence is primarily addressed as an enabling technology. The interaction with existing EU regulatory frameworks is not sufficiently specified, in particular in relation to the AI Act and data governance frameworks. This creates uncertainty regarding the classification of AI systems used in research and clinical development, the allocation of responsibilities across actors, and requirements related to risk management and oversight.

The proposal also includes measures on biosecurity and prevention of misuse. However, the interaction between biosecurity frameworks and AI-related risks is not fully developed. The increasing use of AI in biological design reinforces existing dual-use concerns and adds complexity for implementation.
In addition, access to data and computational resources remains uneven across the European ecosystem, which may limit the ability of universities and smaller actors to participate in data-driven innovation.

The University therefore recommends that implementation clarifies the interaction between this proposal and existing EU regulatory frameworks, develops guidance for research and early-stage innovation environments, and ensures that requirements related to risk management and data governance are proportionate. It further recommends that biosecurity and dual-use considerations are integrated with AI-related regulation, and that investments in shared data and computing infrastructures are prioritised to support broad participation.

Innovation, Valorisation and Company Creation

The proposal promotes innovation, SME participation and industrial development. The University supports this orientation.
At the same time, company creation based on research is not clearly addressed as a central objective. While measures focus on scale-up and industrial capacity, earlier stages of valorisation receive less attention

The University therefore recommends that implementation explicitly recognises company creation from research as a core objective, strengthens the link between research, innovation support and industrial development, and includes targeted support for early-stage innovation environments .

Competence Supply and Skills

The proposal highlights the need for a skilled workforce in biotechnology. The University supports this focus.

The development of biotechnology increasingly requires interdisciplinary competence, including the integration of life sciences, artificial intelligence and regulatory knowledge. This is closely linked to the issues identified in the proposal related to data, AI and regulatory complexity.

The University therefore recommends that implementation strengthens the integration between education, research and innovation policy, supports lifelong learning and reskilling of the existing workforce, and promotes mobility between academia, healthcare and industry.

Administrative and Operational Implications

The proposal is expected to increase the involvement of universities in large-scale projects, data-driven environments and regulatory processes.

This will lead to increased demands on coordination, support functions and compliance. In particular, participation in strategic projects and the application of multiple EU regulatory frameworks will require strengthened institutional capacity.

The University therefore emphasises that administrative requirements should be proportionate, that implementation should align with existing national systems, and that adequate support is provided to participating organisations.

Conclusions

The University supports the objectives of the European Biotech Act and considers it an important step towards strengthening Europe's biotechnology ecosystem.

The proposal identifies key challenges related to scale-up, investment and regulatory efficiency. At the same time, it places greater emphasis on later stages of the innovation process, while conditions for research valorisation, early-stage development and company creation are less developed. The role of universities and affiliated environments across the full innovation pathway is not sufficiently reflected.

Effective implementation will require a more integrated approach, where regulatory measures, strategic projects, data and AI frameworks, and investment instruments are aligned with the conditions under which research is translated into innovation. This includes clearer roles for academic actors, improved access to validation environments and early-stage funding, and better coordination with horizontal EU regulatory frameworks.

The University therefore emphasises the importance of ensuring that the Act supports the full innovation system, including competence supply, interdisciplinary skills and institutional capacity to participate in complex regulatory and collaborative environments.

Handläggningen av beslutet

Beslut om detta yttrande har fattats av vicerektor för forskning Louise Ödlund efter utlåtande av rektorsrådet för forskning Peter Påhlsson och innovationsrådgivaren Andreas Nilsson.

Louise Ödlund