Pharmabiotic
Research Institute

EU Biotech act

PRI response to the call for evidence

The Pharmabiotic Research Institute (PRI) is a non-profit European organisation dedicated to advancing regulatory science for microbiome-based innovations. PRI welcomes the initiative to establish a European Biotech Act to support innovation, scale-up, and competitiveness in the EU biotech sector.

1. PRI calls for explicit inclusion of microbiome-based innovations, which represents a fast-growing and strategic area across biotech domains. Microbiome science is central to current innovation in biotechnology. It also plays a pivotal role in the One Health concept. A loss of microbiome diversity is associated with an increased risk of disease in humans, animals, plants as well as reduced soil fertility. Given this large potential, microbiome innovations include medicinal products, novel diagnostics, biostimulants, food and feed, cosmetics, and more. These technologies, often based on complex living systems, directly align with the goals of the Biotech Act, yet remain underrepresented in policy discussions.
2. One of the most pressing challenges for microbiome innovation in the EU is the lack of coherent regulatory pathways. Existing frameworks were not designed to accommodate the scientific features of microbiome-based innovations, leading to uncertainty, delays, and fragmentation across Member States. Consequently, most of the developments are currently done in the USA. The Biotech Act should prioritise the development of tailored, proportionate, and harmonised frameworks that account for the complexity and novelty of microbiome-based innovations.
3. To enable the full potential of biotech innovation, including microbiome innovation, coherence between horizontal and sectoral frameworks is essential. The future Biotech Act must be aligned with existing and evolving EU legislation, including the SoHO Regulation, pharmaceutical legislation, food and feed law, medical devices regulation and any other relevant regulation. This alignment is critical for microbiome innovations, which often sit at the intersection of multiple regulatory frameworks. Fragmented or conflicting interpretations across frameworks hinder innovation and market access. The Act should make sure the agencies or bodies enforcing regulatory frameworks are not overly restrictive and do not over interpret but instead engage constructively with innovative applications to support innovation in Europe.
4. The Biotech Act should promote and facilitate early engagement between innovators and regulators. Early interactions and structured dialogues should be systematically implemented in all regulatory frameworks. Furthermore, investment in regulatory science, including development and validation of methods and models relevant for microbiome innovation is key to ensure disruptive innovations. PRI, as a stakeholder bridging industry, academia, and regulators, can contribute actively to such efforts.
5. Support for secure, FAIR (Findable, Accessible, Interoperable, Reusable) microbiome data is essential. As microbiome technologies span health, food, environment, and agriculture, interdisciplinary and cross-sectoral collaboration must be actively encouraged. Open science should be a priority, and accessibility of the data should be encouraged for both academic and industrial research. The objective of the EU biotech act to “accelerate the transition from lab to market” is only possible if public and private sectors are working together.

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Conclusion

Microbiome science is no longer exploratory – it is entering the biotech pipeline, with applications in the three pillars of the One health concept (human, animal, and environmental health). As such, the microbiome must be recognised as a strategic pillar of EU Biotech Act. PRI stands ready to support the preparation and implementation of the Biotech Act. As a regulatory science centre, PRI ensures that regulations reflect both the scientific consensus and the real-world technical requirements necessary for microbiome R&D.

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