

**Dear President, Ursula von der Leyen
cc Commissioners, Várhelyi, Zaharieva and vice president Séjourné**

We, the undersigned Members of the European Parliament, believe the European Biotech Act must be broad in scope to deliver on its potential.

As Commissioner Várhelyi's Mission Letter suggests that the Biotech Act will focus only on the pharmaceutical industry, we ask the Commission to clarify whether the scope will extend to other sectors, such as industrial, agricultural, and marine biotechnologies?

We believe that giving the Biotech Act a broad scope to work as a coherent regulatory framework is essential for Europe to maintain its leading position in the most innovative biotechnologies across all biotech sectors.

As the Commission has identified, Europe's biotech sector has the potential to accelerate Europe's economy towards a sustainable, resilient and competitive future. In addition to pharmaceuticals, biotechnologies can help transform a range of sectors; from agriculture and food – to energy and industrial production. They reduce our dependence for fossil-based resources, chemicals, energy, and water by helping European industry remain competitive while decarbonising.

In March 2024, the Commission published a [Communication on Strengthening Biotechnology and Biomanufacturing in the EU](#). The communication outlined actions for boosting research and innovation and streamlining regulatory pathways in the EU for a broad range of biotechnologies.

Crucially, the communication highlighted the need for a Biotech Act based on a Regulatory Study analysing how the legislation that applies to biotech and biomanufacturing could be streamlined to ensure faster approvals and time to market. It is therefore essential to maintain the same scope as mentioned in the communication.

Furthermore, in November 2024, Denmark and Finland, with the support of France, Germany, Ireland, Latvia, Slovakia, and Spain, presented a note titled "[Reaping the Full Benefits of the Biotech Revolution](#)". In this note, Member States called on the Commission to address regulatory obstacles for biotechnology horizontally across sectors. In this context the biotech sector must have regulatory pathways that are fast, simple, and straightforward. The note was verbally supported by Lithuania, Sweden, Portugal, Estonia, Belgium, and the Netherlands.

The innovation and potential of the EU's biotechnology sector are unmatched globally. However, biotech companies, especially the most innovative start-ups and SMEs, suffer from the lack of a coherent regulatory framework at the EU level, which results in delays and lack of transfer to market for biological innovations.

For these reasons the undersigned members urge the Commission to abide by its own timeline concerning proposal of the Biotech Act as we face a crucial time for European competitiveness and there is an urgent need for this key regulatory framework during the prospective biotech revolution. A revolution that is anticipated to strengthen the competitiveness and clean transition of the EU as a whole.

Lastly, we would appreciate the opportunity to discuss why it is essential to have a broad range of biotechnology applications covered within the scope of the European Biotech Act proposal.

Kind regards,

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