

Higher ambition for EU Biotech

PRESS RELEASE

Brussels, 16 December 2025

"The EU Biotech Act has hit the ground running, with a strong baseline for a more competitive EU amidst global geopolitical changes that require urgent and ambitious action. There are plenty of good actions alongside a few notable absences and EuropaBio will roll up its sleeves and get to work" said **Director General of EuropaBio, Dr Claire Skentelbery**.

Whilst the primary focus of the Act Part I is health, EuropaBio recognises initial actions in support of biotechnology in food and feed and will work closely to ensure that these are fully realised in Part I and all following Acts.

The proposals for **biotechnology for health** strengthen the EU's progress towards a future-ready ecosystem. This includes the proposed additional 12 months of SPC, shortened clinical trials approvals (including a more efficient regulatory pathway for ATMPs reflecting maturing ATMP regulatory expertise. The dedicated sandbox for SoHO is also a welcome development.

The Health Biotech Investment Pilot under the stewardship of EIB is strongly welcomed, as it enhances the investment capacity towards innovation and scale up, and we look forward to increasing investment solutions for Europe.

Within **biotechnology for food and feed** in Part I, the pre-advice for EFSA is welcomed, as a long-called for improvement to authorisation processes. This can accelerate time to market in the EU. The Act's intention to revise the GMO Directive, to introduce specific requirements for genetically modified microorganisms (GMM), is also supported by EuropaBio.

However, whilst regulatory sandboxes within EFSA are welcomed, the exclusion of novel food and GMMs must be addressed, with their inclusion guaranteed.

Also relevant to the Biotech Act, the separate Food and Feed Safety Simplification Package published today, clarifies the scope of the GM Food and Feed regulation, a very positive move for Europe's fermentation industry which strengthens the single market.

ENDS

Media contact

Email: communications@europabio.org

About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life; to prevent, diagnose, treat, and cure diseases; to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents corporate and associate members, plus national biotechnology associations and bioregions. Read more about our work at www.europabio.org.