

## Building beyond the Biotech Act to unlock microbial innovation: EuropaBio calls for the adoption of a dedicated horizontal regulation on Microorganisms

### PRESS RELEASE

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The EU Biotech Act recognises the need for progressive and evidence-driven approach for microorganisms with the welcome proposals to modernise Directive 2001/18/EC. This late 1980s legislation was shaped by plant applications using original GM technologies and to date, no genetically modified microbial products outside healthcare have been approved, making the EU a global outlier, as regions switch to biomanufacturing and biotech-driven industrial and sustainability applications.

EuropaBio welcomes the progress through the Biotech Act and looks to the future with a proposed dedicated horizontal regulation for microorganisms. It will place the EU on an equivalent industrial framework to other major biomanufacturing regions, within the current high safety standards expected by consumers and innovators.

The proposed cross-sectoral regulation (outside health) brings a complete framework; creating predictable innovation, investment and delivery to market and taking the step required to unleash EU biomanufacturing through its global leadership in research.

- It delivers a modern EU biomanufacturing baseline, with:
- A product and risk-based categorization: with type of genetic modification and intended use
- Streamlined procedures for low risk GMMs and targeted simplification elsewhere
- Transparency and legal clarity
- Risk-proportionate labelling and traceability

**Dr. Claire Skentelbery, Director General of EuropaBio**, commented: “Europe must take its place on the world stage as a lead producer from microorganisms and EuropaBio takes in the next step in the journey started so positively through the EU Biotech Act”.

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## **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](http://www.europabio.org).