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INFORMATION

From:	Services of the Commission
To:	Delegations
Subject:	European Biotech Act proposal - Presentation by the Commission

Delegations will find attached a PowerPoint presentation from the services of the Commission (DG SANTE), as delivered under agenda item 5(a) (CM 1078/26 REV1) at the Working Party on Intellectual Property on 21 January 2026.

European Biotech Act
Commission proposal

[redacted]
DG SANTE



European Commission | #HealthUnion

Focus areas of the Biotech Act

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Regulatory streamlining and facilitation (time-to-market)

Health Biotech

- Make the authorisation procedure for clinical trials, including multinational, faster, simpler and more predictable
- Regulatory facilitation for borderline and combination products

Food and other Biotech

- Enhance EFSA's role to provide scientific pre-submission advice to companies
- Regulatory sandboxes
- Ensure appropriate treatment of genetically modified microorganisms (GMMs)

Industrial enablers

(High Impact) Strategic Projects

Strategic projects at MS or EU-level including to:

- Boost biomanufacturing capacity
- Enhance biotech skills
- Connect biotech clusters across Europe

Boost Innovative Biotech + Biosimilars

- Incentivise the development of innovative biotech medicines with 1 year of extra IP protection
- Enhance competitiveness in biosimilars through dedicated support

Access to Finance

De-risk private investment into Biotech with the EIB Group, with a pilot to be reviewed after 2 years + project mobilising €10bn over the next 2 years

AI and data:

Accelerate AI-enabled innovation throughout the health biotech lifecycle with improved access to quality data, testing environments and guidelines

Biosecurity & Biodefence

Guard against misuse of biotech with a screening framework while boosting biodefence capacity

Industrial policy enablers: boost innovation – extension SPC for innovative medicines

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Why: Incentivise biotech products with therapeutic advantage to patients



12 month SPC extension

Conditionality

2 product categories

(1) MP developed by biotech processes or (2) ATMPs

(SPC protected or patent protected qualifying for SPC)

4 conditions

- New active substance
- New mode of action
- CT in 2 or more MS
- At least 1 manufacturing step in EU

A similar incentives scheme will apply to VMP biotech products for zoonotic diseases

Thank you





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