

| Basic information | |
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| <p>2025/0406(COD)</p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p> | Preparatory phase in Parliament |
| <p>European Biotech Act</p> <p>Amending Regulation 2002/178 2000/0286(COD) Amending Regulation 2007/1394 2005/0227(COD) Amending Regulation 2014/536 2012/0192(COD) Amending Regulation 2019/6 2014/0257(COD) Amending Regulation 2024/1938 2022/0216(COD) Amending Regulation 2024/795 2023/0199(COD)</p> <p>Subject</p> <p>3.50.08 New technologies; biotechnology 4.20 Public health</p> | |

| Key players | | | | | |
|--|---|------------------------|--|---------------------|--|
| European Parliament | Joint committee responsible | | Rapporteur | Appointed | |
| | Pending final decision on the referral | | | | |
| | Committee for opinion | | Rapporteur for opinion | Appointed | |
| | Pending final decision on the referral | | | | |
| | Committee for budgetary assessment | | Rapporteur for budgetary assessment | Appointed | |
| | Pending final decision on the referral | | | | |
| | Council of the European Union | | | | |
| | European Commission | Commission DG | | Commissioner | |
| | | Health and Food Safety | | VÁRHELYI Olivér | |
| European Economic and Social Committee | | | | | |
| European Committee of the Regions | | | | | |

| Key events | | | |
|------------|--------------------------------|-------------------------------|-------------------------|
| Date | Event | Reference | Summary |
| 16/12/2025 | Legislative proposal published | COM(2025)1022 | Summary |

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| Technical information | |
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| Procedure reference | 2025/0406(COD) |
| Procedure type | COD - Ordinary legislative procedure (ex-codecision procedure) |
| Procedure subtype | Legislation |
| Legislative instrument | Regulation |
| Amendments and repeals | Amending Regulation 2002/178 2000/0286(COD) Amending Regulation 2007/1394 2005/0227(COD) Amending Regulation 2014/536 2012/0192(COD) Amending Regulation 2019/6 2014/0257(COD) Amending Regulation 2024/1938 2022/0216(COD) Amending Regulation 2024/795 2023/0199(COD) |
| Legal basis | Rules of Procedure EP 58 Treaty on the Functioning of the European Union TFEU 114 Treaty on the Functioning of the European Union TFEU 168-p4 Treaty on the Functioning of the European Union TFEU 173-p3 |
| Mandatory consultation of other institutions | European Economic and Social Committee European Committee of the Regions |
| Stage reached in procedure | Preparatory phase in Parliament |

| Documentation gateway | | | |
|------------------------------------|--|------------|-------------------------|
| European Commission | | | |
| Document type | Reference | Date | Summary |
| Legislative proposal | COM(2025)1022 | 16/12/2025 | Summary |
| Document attached to the procedure | SWD(2025)1055  | 17/12/2025 | |

| Additional information | | |
|------------------------|-------------------------|------|
| Source | Document | Date |
| European Commission | EUR-Lex | |

Meetings with interest representatives published in line with the Rules of Procedure

Rapporteurs, Shadow Rapporteurs and Committee Chairs

| Transparency | | | | |
|-----------------------------------|-------------------|----------------------|------------|---|
| Name | Role | Committee | Date | Interest representatives |
| WÖLKEN Tiemo | Shadow rapporteur | SANT | 16/04/2026 | European Federation of Pharmaceutical Industries and Associations |
| WÖLKEN Tiemo | Shadow rapporteur | SANT | 16/04/2026 | Médecins Sans Frontières International |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 16/04/2026 | European Federation of Pharmaceutical Industries and Associations |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 16/04/2026 | EuropaBio |

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| TER LAAK Ingeborg | Shadow rapporteur | SANT | 16/04/2026 | European Patients' Forum (EPF) |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 16/04/2026 | Patiëntenfederatie Nederland |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 16/04/2026 | Burson Cohn & Wolfe SRL Ultragenyx Europe GmbH |
| WÖLKEN Tiemo | Rapporteur | SANT | 14/04/2026 | Merck Sharp & Dohme Europe Belgium SRL |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 09/04/2026 | MEDICINES FOR EUROPE |
| WÖLKEN Tiemo | Rapporteur | SANT | 09/04/2026 | Pandemic Action Network |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 08/04/2026 | European Patients' Forum (EPF) |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 08/04/2026 | European Patient Organisation for Dysimmune and Inflammatory Neuropathies |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 07/04/2026 | SANOFI |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 02/04/2026 | Eurogroup for Animals |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 02/04/2026 | CropLife Europe |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 01/04/2026 | Johnson & Johnson |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 31/03/2026 | AstraZeneca PLC |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 31/03/2026 | European Federation of Pharmaceutical Industries and Associations GlaxoSmithKline |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 26/03/2026 | Merck Sharp & Dohme Europe Belgium SRL |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 26/03/2026 | Johnson & Johnson |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 26/03/2026 | Pfizer Inc. |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 24/03/2026 | Vereniging Innovatieve Geneesmiddelen |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 24/03/2026 | European Federation of Pharmaceutical Industries and Associations |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 19/03/2026 | Bayer AG |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 18/03/2026 | Corteva Agriscience International SARL |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 18/03/2026 | Vereniging VNO-NCW |
| BEKE Wouter | Rapporteur | ITRE | 17/03/2026 | EuropaBio EU Health Coalition |
| BEKE Wouter | Rapporteur | ITRE | 17/03/2026 | Pharma.be |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 17/03/2026 | Pandemic Action Network |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 17/03/2026 | Novartis International AG |
| GONZÁLEZ CASARES Nicolás | Rapporteur for opinion | ENVI | 13/03/2026 | AbbVie |

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| BEKE Wouter | Rapporteur | ITRE | 10/03/2026 | AstraZeneca PLC Boehringer Ingelheim European Venture Philanthropy Association Novartis International AG Lif BioArtic |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 10/03/2026 | AstraZeneca PLC Läkemedelsindustriföreningen Novartis International AG |
| ANDRIUKAITIS Vytenis Povilas | Rapporteur | SANT | 10/03/2026 | EuropaBio |
| GONZÁLEZ CASARES Nicolás | Rapporteur for opinion | ENVI | 04/03/2026 | ASOCIACIÓN ESPAÑOLA DE MEDICAMENTOS BIOSIMILARES |
| BOSSE Stine | Shadow rapporteur | SANT | 26/02/2026 | Novozymes A/S |
| TER LAAK Ingeborg | Shadow rapporteur | SANT | 25/02/2026 | Raad voor Dierenaangelegenheden |
| CICCIOLI Carlo | Shadow rapporteur | ITRE | 24/02/2026 | Bristol-Myers Squibb Company Cattaneo Zanetto Pomposo & Co. |
| GONZÁLEZ CASARES Nicolás | Rapporteur for opinion | ENVI | 18/02/2026 | HIPRA, S.A. |

Other Members

| Transparency | | |
|--------------------------|------------|---------------------------------------|
| Name | Date | Interest representatives |
| LØKKEGAARD Morten | 24/03/2026 | Genmab A/S |
| GYŪRK András | 12/03/2026 | MEDICINES FOR EUROPE |
| SOKOL Tomislav | 04/03/2026 | Bayer AG |
| LØKKEGAARD Morten | 27/02/2026 | AstraZeneca PLC |
| LØKKEGAARD Morten | 16/02/2026 | Novo Nordisk Foundation |
| GONZÁLEZ CASARES Nicolás | 10/02/2026 | Gilead Sciences |
| GONZÁLEZ CASARES Nicolás | 04/02/2026 | Juvenile Diabetes Research Foundation |
| GONZÁLEZ CASARES Nicolás | 04/02/2026 | ASOCIACION ESPAÑOLA DE BIOEMPRESAS |
| ANDREWS Barry | 27/01/2026 | Ibec Biopharmachem Ireland |

European Biotech Act

2025/0406(COD) - 16/12/2025 - Legislative proposal

PURPOSE: to establish an EU Biotech Act to strengthen the competitiveness, resilience and strategic autonomy of the Union's biotechnology and biomanufacturing sectors,

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Biotechnology is one of the fastest growing sectors in the EU. It currently accounts for more than 900 000 jobs – 75% of which are in the health sector - and contributes close to EUR 40 billion to the European economy. Biotech can revolutionise healthcare, as a source of ground-

breaking new treatments and therapies, more precise diagnoses and personalised medicines. However, the EU lags behind other global regions when it comes to translating its worldclass science and innovation into commercially viable products, and even more so in manufacturing such products at scale.

The proposed Biotech Act will increase Europe's biotechnology potential by supporting the transition of innovative ideas from laboratory to market. It will explore new means of funding and investment for biotech companies, through a new health biotech investment pilot to be developed in cooperation with the EIB Group. It will aim to boost bio-manufacturing via targeted support.

CONTENT: the Commission proposal on a European Biotech Act establishes a **comprehensive EU framework** to strengthen the competitiveness, resilience and strategic autonomy of the Union's biotechnology and biomanufacturing sectors, with a particular focus on health-related applications. It introduces measures to facilitate investment, innovation and scale-up of biotechnological and biomanufacturing activities, including improved access to funding, infrastructure and skills.

The general objective of this Regulation is threefold:

(i) to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the health biotechnology sector, from research to production;

(ii) to create the conditions for the development and timely placing on the EU market, of biotechnology innovations, products and services;

(iii) to safeguard high standards for the protection of human health, animal health, patients and consumers, the environment, ethics, quality, food and feed safety, and biosecurity.

This general objective translates into the following specific objectives:

- strengthen the biotechnology sector and reinforce the EU's research, development and production capabilities, by establishing a framework for the recognition of, and support measures for, strategic health biotechnology projects and high impact strategic health biotechnology projects;

- **support funding of, investments** in, and access to capital for, biotechnology companies and projects, including through the setting up of an EU health biotechnology investment pilot to fill the gap in spending on biotechnology innovation;

- improve the **EU manufacturing capacity** of, and expertise in **biosimilars**, including through international cooperation;

- facilitate the application of **AI into the EU's biotechnology and health technology** manufacturing ecosystems and frameworks, in line with the Regulation (EU) 2024/1689;

- ensure a legislative framework that encourages innovation and takes account of technological and scientific developments and progress, by establishing provisions for health biotechnology products;

- prevent the **misuse of biotechnologies** and strengthen **biodefence** capabilities;

- enable the effectiveness of the above-mentioned measures through a legislative framework conducive to the use of biotechnology innovations, by amending Union legislation in particular on clinical trials, veterinary medicinal products, food and feed safety and related legislation.

Budgetary implications

Without prejudice to the outcome of the negotiations on the next Multiannual financial framework (MFF) proposal, strategic health biotechnology projects and high-impact strategic biotechnology projects may be supported by Union programmes, funds and instruments, in accordance with the objectives set out in the regulations establishing those funds and programmes. A contribution is expected to come from the 'health, biotechnology, agriculture and bioeconomy' window under the European Competitiveness Fund which, according to the proposal of the Commission, would receive a total allocation of EUR 20.4 billion over the MFF 2028-2034.

Two agencies, EMA and EFSA are proposed to be reinforced in staff and financially to conduct tasks related to these projects. The necessary financial resources will be compensated from applicable programmes under the agencies' headings in the 2028-2034 MFF and where possible by additional income to be generated from third parties.