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COMMISSION STAFF WORKING DOCUMENT

European Biotech Act

Accompanying the documents

Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

and

Proposal for a Directive of the European Parliament and of the Council amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs

{COM(2025) 1022 final} - {COM(2025) 1031 final}

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Glossary

Term or acronym	Meaning or definition
AI	Artificial Intelligence
ATMP	Advanced Therapy Medicinal Product
BMWP	Biosimilar Medicinal Products Working Party
CAGR	Compound Annual Growth Rate
CAPEX	Capital Expenditure
CES	Comparative efficacy study
CfE	Call for Evidence
CHMP	Committee for Medicinal Products for Human Use
CMA	Critical Medicines Act
CRO	Contract Research Organization
CT	Clinical Trial
CTR	Clinical Trials Regulation
DNA	Deoxyribonucleic acid
EEA	European Economic Area
EFSA	European Food Safety Authority
EIB	European Investment Bank
EMA	European Medicines Agency

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ERA	Environmental Risk Assessment
EU	European Union
FTE	Full-Time Equivalent
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GMM	Genetically Modified Micro-organism
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practices
GVA	Gross Value Added
HTA	Health Technology Assessment
IMP	Investigational Medicinal Product
IP	Intellectual Property
IVDR	Regulation (EU) 2017/746 on in vitro diagnostic medical devices
MAA	Marketing Authorisation Application
mAB	Monoclonal antibody
MDR	Regulation (EU) 2017/745 on medical devices
MFF	Multiannual Financial Framework
MSC	Member State Concerned
NGOs	Non-Governmental Organisations

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OPEX	Operating Expenses
R&D	Research and Development
R&I	Research and Innovation
RMS	Reporting Member State
SDG	Sustainable Development Goal
SMEs	Small and Medium-sized Enterprises
SoHO	Substances of Human Origin
SPC	Supplementary Protection Certificate
STEP	Strategic Technologies for Europe Platform
TEP	Tissue Engineered Product
TFEU	Treaty on the Functioning of the European Union
VMP	Veterinary Medicinal Product
VNRAs	Variations Not Requiring Assessment

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1 INTRODUCTION

This staff working document summarises the analysis supporting the proposal for a Regulation[1] (the 'proposed Regulation') and the proposal for a Directive[2] (the 'proposed Directive') which were adopted by the Commission on 16 December 2025. These two proposals (collectively referred to as the 'Biotech Act') aim to strengthen the EU's biotechnology and biomanufacturing sectors, particularly in the area of health. They amend key legislation relevant to these sectors.

Biotechnology and biomanufacturing, supported by artificial intelligence (AI) and digital tools, could help modernise entire parts of the EU economy. They hold huge potential to boost competitiveness and innovation, while delivering for patients, public health, food safety, security and other areas. Despite its world-class scientific base, the EU is trailing its competitors when it comes to translating biotechnology research into development, market deployment and manufacturing at scale. Fragmented ecosystems, financing constraints, complex regulatory pathways, and a lag in adapting regulatory frameworks to technological advances, hinder EU biotechnology companies' potential to innovate, bring innovation to market, produce and grow in the EU. As a result, the EU's biotechnology sector does not meet its full potential to tackle major societal challenges and faces a widening global competitiveness gap.

The proposed Regulation and Directive present a series of measures primarily for the health biotechnology sector, with targeted actions addressing other biotechnology areas (food and feed, industrial and agricultural biotechnologies). The two proposals aim to accelerate the way biotechnology innovations, products and services are developed and placed on the single market, while maintaining the highest safety standards. The proposed Biotech Act is one of the flagship initiatives of the Competitiveness Compass[3], designed to unleash the EU's innovation potential. It also contributes to regulatory simplification and administrative burden reduction goals.

The Biotech Act is in line with the United Nations' Sustainable Development Goals (SDGs), in particular SDG 3 'Good health and well-being: Ensure healthy lives and promote well-being for all at all ages'; SDG 9 'Industry, innovation and infrastructure: Build resilient infrastructure, promote inclusive and sustainable industrialisation and foster innovation'; and SDG 12 'Responsible consumption and production: Ensure sustainable consumption and production patterns'. More details on the relevant SDG targets and indicators are available in Annex 3. Regarding specialisation in terms of scientific output, the EU leads *inter alia* in SDGs 9 and 12.[4]

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[1] COM(2025) 1022 final.
[2] COM(2025) 1031 final.
[3] COM(2025) 30 final.
[4] European Commission: Directorate-General for Research and Innovation, *Science, research and innovation performance of the EU, 2024 – A competitive Europe for a sustainable future*, Publications Office of the European Union, 2024, https://data.europa.eu/doi/10.2777/965670 (see Chapter 3: Scientific knowledge production).

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2 BACKGROUND

2.1 Political and legal context

A 'European Biotech Act' was announced by the President of the Commission in the **2024 - 2029 Political Guidelines of the European Commission**[5], to make it easier to bring biotechnology products from the laboratory to the factory and then onto the market, while maintaining high safety standards. It was further reflected in the mission letter of Commissioner Várhelyi[6].

In the **Commission Recommendation on critical technology areas for the EU's economic security**[7], biotechnology was recognised as having "an **enabling and transformative nature** in areas such as agriculture, environment, healthcare, life sciences, food chains or biomanufacturing". The Commission Communication on Biotechnology and Biomanufacturing[8] highlighted the high **growth potential and labour productivity** of biotechnology and biomanufacturing. This makes the sector pivotal to the **competitiveness and modernisation** of the EU's economy, as well as conducive to its **strategic autonomy and resilience**. While the EU's strengths were recognised (i.e. research and innovation base and capacities), the Commission stressed the need to address the challenges faced by companies, users and consumers. It called for both a **supportive regulatory environment and a coordinated approach**, particularly for developing infrastructures, fostering the use of AI, and encouraging private and public investments. Additionally, the **EU's Economic Security Strategy**[9] identified biotechnology as one of the 10 technology areas most likely to present sensitive and immediate risks related to technology security and technology leakage. This strategy launched an EU joint risk assessment with Member States on biotechnology, which identified relevant biosecurity risks that require mitigation measures.

The seminal reports by **Enrico Letta**[10] and **Mario Draghi**[11] also underscored the need to take action in the biotechnology and biomanufacturing sectors. They identified the need for a stronger, more dynamic European industrial policy, including measures for the biotechnology and biomanufacturing sectors to scale up and get products on the market faster. The report by **Sauli Niinistö**[12] also pointed to the need to strengthen biological defence capabilities and preparedness against emerging biological threats, including synthetic pathogens.

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[5] See footnote 1, page 5.
[6] Ursula von der Leyen, Mission Letter – OlivérVárhelyi – Commissioner-designate for Health and Animal Welfare, 17 September 2024.
[7] Commission Recommendation (EU) 2023/2113 of 3 October 2023, OJ L, 2023/2113, 11.10.2023, ELI: http://data.europa.eu/eli/reco/2023/2113/oj.
[8] COM(2024) 137 final/2.
[9] JOIN(2023) 20 final
[10] Enrico Letta, Much more than a Market. April 2024.
[11] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.
[12] Niinistö, Sauli Safer Together – Strengthening Europe's Civilian and Military Preparedness and Readiness, 30 October 2024.

In line with this growing political impetus, reducing the **EU's strategic dependencies in sensitive sectors has become a priority of the European Council**[13], including in health and food, as identified in the **Versailles Declaration** of 2022[14]. The Council[15] has urged the Commission to unlock the potential of biotechnologies for the EU's competitiveness through the European Biotech Act, while maintaining environmental and safety standards. In particular, the Council has encouraged actions to advance the use of regulatory sandboxes, promote research and development (R&D) in advanced therapy medicinal products (ATMPs) and address the falling global share of EU clinical trials (CTs). It also supports the greater use of AI and the development of appropriate skills. In parallel, three Important Projects of Common European Interest (IPCEI) in the biotechnology domain are currently under design[16], reflecting Member States' interest in coordinated, large-scale investment approaches.

The **European Parliament's recommendations** in its resolution 'Future of the EU biotechnology and biomanufacturing sector' **are in line with these priorities**, asking to facilitate "a fast and efficient uptake of biotechnology and biomanufacturing through clear regulatory frameworks"[17]. Recommendations include facilitating the uptake of biotechnology and biomanufacturing; enabling more efficient scale-up and commercialisation of innovations; streamlining and simplifying the time-to-market for biotechnology throughout their life-cycles; streamlining the clinical trials framework by minimising administrative burden and delays; and using regulatory sandboxes. It also recognises the need for a skilled workforce, dedicated support for SMEs to access funding, and biosecurity screening standards. The European Parliament has also prepared an own-initiative **report on the 'Public health aspects of biotechnology and life sciences'**[18], where it puts forward similar recommendations. It has called for the Biotech Act to review, simplify and optimise the regulatory framework for biotechnology in healthcare to foster innovation, as well as for structured EU support to help excellent biotechnology innovation districts in the EU grow and ensure that they have sufficient capacity, resources and the scientific edge to promote new groundbreaking biotechnology discoveries, innovation and commercialisation.

2.2 Related EU legislation

2.2.1 Existing EU legislation

Health biotechnology products are subject to several EU legislative frameworks, in particular **Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use** [19], **Regulation (EC) No 1394/2007 on ATMPs**[20], **Regulation (EU) 2024/1938 on standards of quality and safety for substances of human origin intended for human**

[13] European Council, Special meeting of the European Council (17 and 18 April 2024) – Conclusions, EUCO 12/24.
[14] European Council, The Versailles declaration, 10 and 11 March 2022.
[15] Council of the European Union, A call for action on life sciences for the EU's competitiveness - Council conclusions, 13323/25, approved on 30 September 2025.
[16] https://competition-policy.ec.europa.eu/state-aid/ipcei/design-support-hub_en#ipcei-candidates-in-the-design-support-hub.
[17] European Parliament, 2025/2008(INI), 10 July 2025.
[18] European Parliament: 2025/2087(INI).
[19] Regulation (EU) No 536/2014, OJ L 158, 27.5.2014, pp. 1–76. ELI: http://data.europa.eu/eli/reg/2014/536/oj.
[20] Regulation (EC) No 1394/2007, OJ L 324, 10.12.2007, pp. 121–137. ELI: http://data.europa.eu/eli/reg/2007/1394/oj.

application (SoHO)[21], **Directive 2010/53/EU on quality and safety of human organs intended for transplantation**[22], and **Regulation (EU) 2019/6 on veterinary medicinal products (VMPs)**[23]. These legislative frameworks govern different stages of the product's lifecycle, including research, clinical development, authorisation and the placing on the market of biotechnology products and therapies. Accordingly, the EU biotechnology sector can only flourish if they are efficient, coherent and innovation-friendly.

For food and feed safety, the placing on the market of biotechnology products must comply with requirements set out in the **General Food Law**[24] and with specific legal frameworks, where applicable[25]. Placing products on the market that contain or consist of genetically modified organisms (GMOs), other than food and feed, falls within the scope of the **legislation on the deliberate release of GMOs**[26]. These legislative frameworks ensure high levels of human and animal health, and environmental protection. To foster biotechnology innovation, it is important to keep these objectives front and centre and maximise procedural efficiency and speed, because risk-assessment and authorisation procedures directly affect the time and cost for biotechnology products to reach the market.

The proposed Biotech Act reviews and seeks synergies with other legislation to ensure coherence with the overall EU regulatory system. It complements the **Critical Medicines Act (CMA)**[27] in strengthening EU-based biotechnology research and manufacturing. It is in line with the **pharmaceutical strategy for Europe**[28] and complements the recent **revision of the EU pharmaceutical legislation**[29]. It is also complementary to the Commission's proposal to revise the **EU medical device legislation**[30], sharing the same overall objectives and including common measures such as the single authorisation process for combined device-medicine clinical studies. It also aims to **improve coordination and consultation** between relevant competent authority groups established under other frameworks, such as medical devices[31], medicines, SoHO, health technology assessment[32], etc.

2.2.2 Aligning with the broader priorities of the Commission

As a flagship initiative under the **Competitiveness Compass**[33], the Biotech Act aligns with the EU's broader innovation and competitiveness agenda, turning its priorities into actions in the strategic sector of biotechnology. In particular, the Biotech Act aims to reduce the administrative burden, improve coordination, simplify rules and streamline procedures, in line with both the Competitiveness Compass and the Commission's **Communication on**

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[21] Regulation (EU) 2024/1938, OJ L, 2024/1938, 17.7.2024. ELI: http://data.europa.eu/eli/reg/2024/1938/oj.
[22] Directive 2010/53/EU, OJ L 207, 6.8.2010, p. 14, ELI: http://data.europa.eu/eli/dir/2010/53/oj.
[23] Regulation (EU) 2019/6, OJ L 4, 7.1.2019, pp. 43–167. ELI: http://data.europa.eu/eli/reg/2019/6/oj.
[24] Regulation (EC) No 178/2002, OJ L 31, 1.2.2002, pp. 1–24. ELI: http://data.europa.eu/eli/reg/2002/178/oj.
[25] E.g. genetically modified food and feed is subject to Regulation (EC) No 1829/2003, OJ L 268, 18.10.2003, pp. 1–23. ELI: http://data.europa.eu/eli/reg/2003/1829/oj.
[26] Directive 2001/18/EC, OJ L 106, 17.4.2001, pp. 1–39. ELI: http://data.europa.eu/eli/dir/2001/18/oj.
[27] European Commission website, Critical medicines Act.
[28] COM(2020) 761 final.
[29] European Commission website, Reform of the EU pharmaceutical legislation.
[30] European Commission website, Simpler and more effective rules for medical devices.
[31] Regulations (EU) 2017/745, OJ L 117, 5.5.2017, pp. 1–175. ELI: http://data.europa.eu/eli/reg/2017/745/oj and (EU) 2017/746, OJ L 117, 5.5.2017, pp. 176–332. ELI: http://data.europa.eu/eli/reg/2017/746/oj.
[32] Regulation (EU) 2021/2282, OJ L 458, 22.12.2021, pp. 1–32. ELI: http://data.europa.eu/eli/reg/2021/2282/oj
[33] see footnote 4, page 5.

implementation and simplification[34]. The Biotech Act forms part of the **Commission's Life Sciences Strategy**[35] which recognises biotechnology as a strategic cross-sectoral technology and seeks to strengthen the EU's biotechnology ecosystem, streamline regulatory pathways and boost the EU's competitiveness more broadly in life sciences.

The Biotech Act complements other policy initiatives announced in the Competitiveness Compass. For example, it aims to improve access to risk-tolerant capital for biotechnology firms, aligning with the **Savings and Investments Union**[36] and the **Start-up and Scale-up Strategy**[37], which establishes the Scaleup Europe Fund[38]. Its biosecurity provisions reflect the link between competitiveness and security by strengthening safeguards for biotechnology products of concern. They address the risks identified by the biotechnology joint risk assessment launched under the **EU's Economic Security Strategy**[39] and complement **Regulation (EU) 2022/2371 on serious cross-border threats to health**[40]. The provisions aim at helping to prevent and prepare for such threats and to ensure a coordinated EU-level response, also for arising public health emergencies (including any arising from the misuse of emerging biotechnologies). They also complement the **Medical Countermeasures Strategy**[41] for preparing and responding to health threats, including human-made biosecurity threats.

The Biotech Act reflects the emphasis on talent and contributes to the **Union of Skills**[42]. It aligns with actions under the **European Strategy on Research and Technology Infrastructures**[43]. It aligns with EU funding and investment initiatives that support biotechnology research, innovation and industrial scale-up. It takes into account EU financial support available, including cohesion policy programmes, InvestEU, the European Investment Bank (EIB) Group's TechEU programme[44,45] and the European Innovation Council. The strategic importance of biotechnology is also acknowledged in preparations for the next Multiannual Financial Framework (MFF), namely the next iteration of the **Horizon Europe programme (2028-2034)**. It is acknowledged in the section on collaborative research activities in the Competitiveness component, as well as the proposed **European Competitiveness Fund**, which includes a dedicated 'Health, Biotech, Agriculture and Bioeconomy' policy window.

The Biotech Act is designed to be coherent with related digital policies and pursue **digital transformation** objectives. It aims to support secure, data-driven biotechnology ecosystems and contribute to the EU's technological sovereignty by promoting greater data

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[34] COM/2025/47 final.
[35] COM(2025) 525 final.
[36] COM(2025) 124 final.
[37] COM(2025) 270 final.
[38] Scaleup Europe Fund - European Innovation Council - European Commission.
[39] JOIN(2023) 20 final.
[40] Regulation (EU) 2022/2371, OJ L 314, 6.12.2022, pp. 26–63. ELI: http://data.europa.eu/eli/reg/2022/2371/oj.
[41] COM/2025/529 final.
[42] COM(2025) 90 final.
[43] COM(2025) 497 final.
[44] European Investment Bank. "Tech EU. The EU's largest ever financing programme to support Europe's innovators from idea to IPO and from lab to leadership." European Investment Bank website accessed 12 March 2026, https://www.eif.org/flagship-initiatives/techeuhttps://www.eif.org/flagship-initiatives/techeu.
[45] European Investment Bank. "European Tech Champions Initiative. Overview." European Investment Bank website accessed 12 March 2026, https://www.eif.org/flagship-initiatives/european-tech-champions-initiative/overview.

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use and AI integration in the biotechnology sector. Its emphasis on AI is consistent with the **AI in Science Strategy**[46], **the Apply AI strategy**[47], the **AI continent action plan**[48], the **European AI Act**[49], the **Data Union strategy**[50], as well as the **EU Cybersecurity framework** [51]. The Biotech Act is also consistent with the objectives of the **European Health Data Space Regulation** (EU) 2025/327[52] and of the **Data Union Strategy** [53], in particular with regard to data and metadata semantic interoperability and quality accelerators, data labs, and AI factories. It should also be read in coherence with ongoing interoperability and standardisation work for common European data spaces under Article 33 of Regulation (EU) 2023/2854[54], including the European Trusted Data Framework, insofar as these initiatives are relevant to metadata, discoverability, semantic interoperability and the cross-border re-use of data.

The Biotech Act is consistent with the **Vision for Agriculture and Food**[55], in particular because it amends the **General Food Law** to make the regulatory environment more supportive of innovation and competitiveness in the agri-food sector. The Biotech Act is also consistent with the Commission proposal on plants developed by certain **new genomic techniques** [56] as it continues to adapt the GMO framework to ensure that innovative products are regulated proportionately. The Biotech Act is also designed to build synergies with initiatives such as the recently-adopted **Bioeconomy Strategy** [57].

Climate change has highlighted the need to prioritise the EU's resilience, so the Biotech Act reflects this priority too. It is in line with the Commission's climate neutrality objectives set out in the **EU Climate Law**[58] and the **EU's Strategy on Adaptation to Climate Change**[59]. It also ensures alignment with the **'do no significant harm'** principle. Biotechnology products have the potential to support adaptation to climate change, contribute to health and food security through sustainable biomanufacturing, and protect biodiversity. They may also replace products potentially more harmful for the environment and provide benefits for consumers and users.

The Biotech Act will not affect EU legislation on the **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**[60], **Regulation (EU) 2024/1735 on sustainable biogas and biomethane technologies and biotechnology climate and energy solutions**[61] or the **Directive 2010/63/EU on the protection of animals used for scientific purposes**.

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[46] COM(2025) 724 final
[47] COM(2025) 723 final.
[48] COM(2025) 165 final.
[49] Regulation (EU) 2024/1689, OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj.
[50] COM(2025) 835 final.
[51] Regulation (EU) 2019/881, OJ L 151, 7.6.2019, pp. 15–69. ELI: http://data.europa.eu/eli/reg/2019/881/oj.
[52] Regulation (EU) 2025/327, OJ L, 2025/327, 5.3.2025. ELI: http://data.europa.eu/eli/reg/2025/327/oj.
[53] COM/2025/835 final.
[54] Regulation (EU) 2023/2854, OJ L, 2023/2854, 22.12.2023, ELI: http://data.europa.eu/eli/reg/2023/2854/oj.
[55] COM/2025/75 final.
[56] COM/2023/411 final.
[57] COM/2025/960 final.
[58] Regulation (EU) 2021/1119, OJ L 243, 9.7.2021, pp. 1–17. ELI: http://data.europa.eu/eli/reg/2021/1119/oj.
[59] COM/2021/82 final.
[60] Consolidated text: Regulation (EC) No 1907/2006, ELI: http://data.europa.eu/eli/reg/2006/1907/2025-09-01.
[61] Consolidated text: Regulation (EU) 2024/1735, ELI: http://data.europa.eu/eli/reg/2024/1735/2025-08-17.

2.3 Background on the sector

For the purposes of this document, and as per the proposed Regulation, biotechnology[62] means "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, products and services". On this bases, health, food and feed are the main scope of the proposals.

Biotechnology and biomanufacturing are major **contributors to the EU's economy**. In 2022, the overall biotechnology sector accounted for **EUR 38.1 billion of EU GDP (ca. 1.58% of the European industrial sector),** with health biotechnology being the dominant contributor. Additionally, it contributed to **913,160 jobs**, with around 77%[63] of those jobs coming from the health biotechnology sector. The sector in the EU is characterised by a **large base of small and medium-sized enterprises (SMEs) (47%) and micro enterprises (35%),** complemented by a smaller number of large companies (18%)[64]. The **sector's dynamism** is illustrated by the **5,000 R&D-active biotechnology companies** in the EU[65]. Furthermore, there were **3,232 unique biotechnology startups founded** since 2015 that are still operative in 2025, largely in health[66] (See Annex 5, Figure 1).

The sector's strategic importance is underscored by its rapid **expansion**. Over the last decade, the EU biotechnology industry has almost doubled to the share of GDP it generates, growing by around **7% per year** on average between 2015 and 2024[67] (See Annex 5, Figure 2 for details on the sector GVA comparison).

From a **global perspective**, the EU has significant strengths in biotechnology, but its overall competitiveness position is under increasing pressure (see section 3 on problem definition). The EU is the **largest global exporter** of biotechnology products, demonstrating the sector's strong industrial base and integration into global value chains (see Annex 5, Figures 3 and 4)[68]. It is also a leader in biotechnology **science**, reflected by a publication record comparable to that of the US and China, with all three regions having between 20 – 25% of the top 10% most cited publications across biology, biomedical research and clinical science[69]. The EU also represents 15% of global **patent families** in the biotech field (see Annex 5, Figure 5 for details on the distribution across the EU)[70]. At the same time, other major jurisdictions are accelerating policy and investment efforts to strengthen their biotechnology ecosystems, as shown by recent initiatives in the US at both

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[62] COM(2025) 1022 final, Article 2 (1).
[63] Andreas Haaf and Vera Sale, Measuring the Economic Footprint of the Biotechnology Industry in the European Union, Research Report March 2025, WiFOR (Prepared for EuropaBio – The European Association for Bioindustries).
[64] Landscape analysis study.
[65] Landscape analysis study; Biotech R&D firms are firms that perform biotechnology R&D.
[66] Landscape analysis study.
[67] Landscape analysis study.
[68] Landscape analysis study.
[69] European Commission: Directorate-General for Research and Innovation, *Science, research and innovation performance of the EU, 2024 – A competitive Europe for a sustainable future*, Publications Office of the European Union, 2024, pp. 151-229 https://data.europa.eu/doi/10.2777/965670. https://ec.europa.eu/assets/rtd/srip/2024/ec_rtd_srip-report-2024-chap-03.pdf.
[70] Landscape analysis study.

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congressional and federal level, which frame biotechnology as a core economic and national security priority requiring coordinated action to sustain global leadership[71].

In terms of **projections**, biotechnology and gene technologies are some of the most **impactful technology trends expected to influence business models** over the next five years[72] (i.e. the second most impactful technology in the medical and healthcare devices industry, with similar trends expected in agriculture, forestry, and fishing). In terms of job creation, a strong positive trend has been observed[73]. In the public consultation on the European Biotech Act stakeholders agreed that biotechnology and biomanufacturing products could positively impact the EU's economy[74].

Finally, biotechnology applications have a significant potential to generate **positive societal and environmental outcomes**, making this sector a pillar of the EU's societal wellbeing in key areas in particular in health and food. This potential is positively perceived by stakeholders, recognising in the public consultation the contribution of biotechnology and biomanufacturing products **to society (90%) and to the environment (79%)** and considered that biotechnology and biomanufacturing products that reach the single market are **safe and secure (77%)**[75]. Moreover, around a third of respondents **(38%)** agreed or strongly agreed that the EU regulatory environment **ensures a higher level of safety and security** than in some other countries[76].

Health biotechnology encompasses a wide range of applications, from the development of innovative medicines and new medical devices addressing unmet medical needs, to combating epidemics and transforming the treatment of rare diseases. **Gene and cell therapies**, for example, hold great promise for treating genetic disorders[77] and restoring biological functions. Although the timeline for developing conventional vaccines is lengthy, current biotechnology tools allow **scientists to develop new vaccines** or adapt **existing vaccines** much faster than before[78].

Agri-food biotechnology innovations support farmers and food producers. **Environmental and industrial** biotechnology solutions contribute to the sustainable transformation of our economy. **Genetically modified micro-organisms** (GMMs) play a decisive role in the development of industrial, environmental and agricultural biotechnology, both as a tool for manufacturing and in products. Products containing

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[71] U.S. House of Representatives (2025), *Congressional Biotechnology Caucus announcement*, June 2025; National Security Commission on Emerging Biotechnology (NSCEB) (2025), *Report to Congress*, April 2025; The White House (2022), *Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy* (establishing the National Biotechnology and Biomanufacturing Initiative).

[72] Landscape analysis study. Based on World Economic Forum. (2025, January 7). The Future of Jobs Report 2025. https://www.weforum.org/publications/the-future-of-jobs-report-2025/digest/.

[73] Andreas Haaf and Vera Sale, Measuring the Economic Footprint of the Biotechnology Industry in the European Union, Research Report March 2025, WiFOR (Prepared for EuropaBio – The European Association for Bioindustries).

[74] European Commission, *Open Public Consultation on a European Biotech Act*, 2025, available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act/public-consultation_en.

[75] Public consultation, see footnote 74.

[76] Public consultation, see footnote 74.

[77] Qie B, Tuo J, Chen F, Ding H, Lyu L. Gene therapy for genetic diseases: challenges and future directions. MedComm. 2025;6:e70091. https://doi.org/10.1002/mco2.70091.

[78] Aida V, Pliasas VC, Neasham PJ, North JF, McWhorter KL, Glover SR and Kyriakis CS (2021) Novel Vaccine Technologies in Veterinary Medicine: A Herald to Human Medicine Vaccines. Front. Vet. Sci. 8:654289. doi: 10.3389/fvets.2021.654289.

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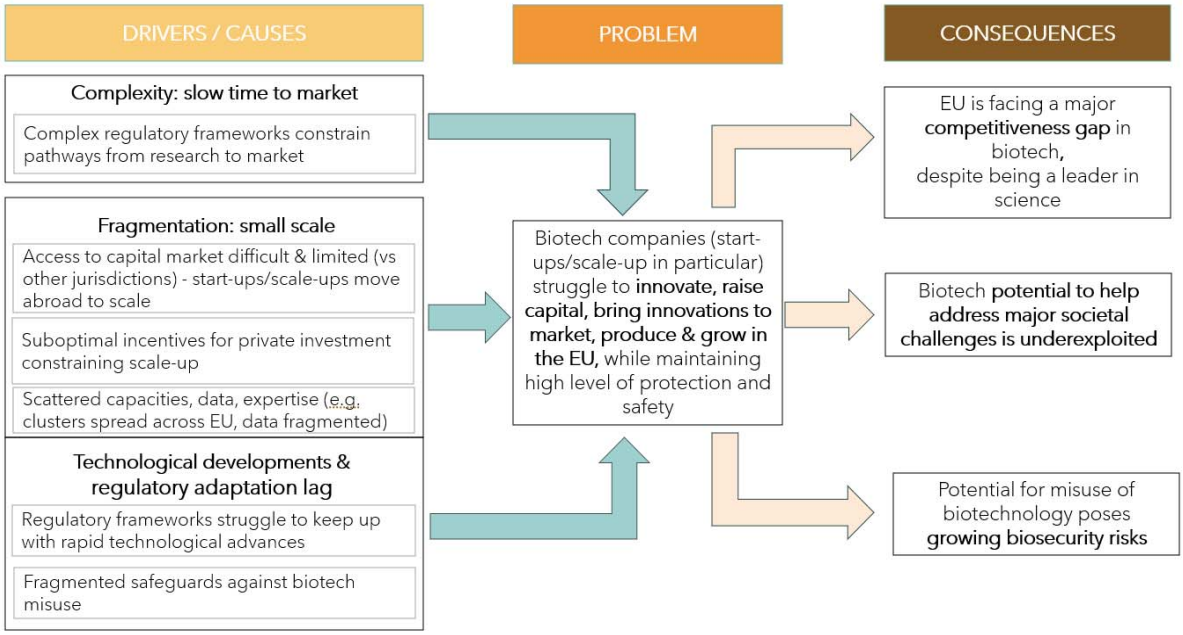
GMMs often yield innovative and beneficial product characteristics that other products cannot achieve or can achieve but with a higher cost or environmental impact. Examples of products containing GMMs already on the market outside the EU or in development include novel biofertilisers, biopesticides, and bioremediation products (i.e. to remove hazardous and toxic substances from the soil or wastewater).

3 PROBLEM DEFINITION

Figure 1. Problem tree



The Commission has refined and clarified the problem tree and intervention logic (see Section 4.4) from the version presented in the Explanatory Memorandum of the Biotech Act. These adjustments do not alter the underlying problem definition or policy rationale but provide a more structured and detailed explanation of the issues and causal pathways.

3.1 Problem: biotech companies struggle to innovate, raise capital, bring innovations to market, produce and grow in the EU, while maintaining high level of protection and safety

Although the EU benefits from a sizeable biotechnology sector and strong scientific capabilities (see section 2.3), it does not meet its full potential for innovation in biotechnology and biomanufacturing. The EU lags behind other regions when it comes to **translating its world-class science and innovation into commercially viable products in the EU**, and even more so **in manufacturing such products at scale**. As a result, **biotech companies often end up investing, growing, employing, creating value and placing their products on markets abroad**. This pattern weakens the EU's ability to retain value creation and industrial capacity from its research base[79].

[79] See also Landscape analysis study, forthcoming, for further details on the aspects summarised here.

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The EU faces a **substantial gap in venture capital** with limited investment by pension funds and other institutional investors. Biotech is especially affected by this market failure due to the particular risk profile of biotech start-ups. Long delays between the initial innovation and first revenue generation due to lengthy regulatory process, massive upfront investments needed for CTs, and a high risk of failure of individual projects deter venture capital investors.

In addition to the fact that the EU accounts for 22% of biotech start-ups, against 49% in the US, the **EU's scale-up capacity also remains limited.** Only a small share of EU biotech firms reaches significant funding levels (12% of agricultural biotechnology start-ups, 10% of health biotechnology start-ups, and 8% of industrial biotechnology start-ups secure over EUR 10 million[80]). Very few exceed EUR 200 million[81]. As many companies struggle to scale in the EU, they increasingly rely on mergers and acquisitions as a common exit route. Around 40% of acquisitions of EU biotech start-ups are executed by US acquirers, highlighting how EU biotech innovation is frequently integrated into global pharmaceutical and life-science value chains instead of growing into large firms in the EU.

AI and data are now foundational to competitiveness in biotechnology, driving rapid advancements in discovery, development and manufacturing. While 20% of EU enterprises with 10 or more employees adopted AI by 2025 - up from 13.5% in 2024 - adoption in EU pharma and biotech manufacturing has surged even further, with large companies integrating AI at scale and shifting from pilot projects to system-level transformation[82]. However, **in-house AI development** and **scaling remain constrained by data and compute bottlenecks - particularly for SMEs.** AI biotech platforms are inherently capital-intensive, relying on costly model training and large-scale data generation, and depend on access to high-quality data and advanced compute infrastructure. As the industry matures, the gap between large pharma industry and smaller players is widening, underscoring the need for equitable access to technology and robust regulatory frameworks.

3.2 What are the problem drivers?

The problem is caused by three main related factors. Firstly, the regulatory and administrative operating environment for biotechnology in the EU is complex which in turn impacts ***speed***.

Secondly, the EU's biotechnology ecosystem operates in a fragmented manner, failing to tap the full ***scale*** of the EU research or testing infrastructure, markets, access to capital or production capacities, thus limiting companies' ability to grow and compete internationally.

Thirdly, ***technological advances*** in biotech can result in obsolete frameworks to govern this fast-moving sector.

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[80] Landscape analysis study.
[81] Landscape analysis study: 12 health biotech firms, 5 industrial biotech firms, one in agricultural biotechnology and none in marine biotechnology have raised more than EUR 200 million.
[82] https://ec.europa.eu/eurostat/web/products-eurostat-news/w/ddn-20251211-2.

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3.2.1 Driver 1: the complexity of the EU regulatory framework, leading to slow time-to-market

A first set of challenges relates to the **regulatory environment**, which stakeholders consistently perceive as complex, time-consuming and difficult to navigate. In the EU, 60% of companies see regulatory burden as a key obstacle to long-term investment[83]. This finding applies to the biotechnology and biomanufacturing sector, as reflected in responses to the public consultation. **Complex regulatory pathways and divergent implementation of EU legislation** were identified as barriers to the expansion of EU companies, particularly start-ups, spin-offs and other SMEs[84]. Respondents **largely agreed that EU rules create regulatory barriers, particularly when products move closer to market entry and formal approval processes**[85].

In addition, the perception of the EU regulatory environment compared to other countries showed a **limited agreement about the level of predictability of the EU regulatory environment[86]**. Also, a small number of respondents agreed or strongly agreed that the EU regulatory environment accelerates access to the market, is less complex and clearer, or leads to lower compliance costs than in some other countries[87].

Such issues linked to the regulatory environment are confirmed across a variety of biotechnology areas. Detailed descriptions are presented in **Annex 5.**

With regards to the **authorisation of clinical trials**, the EU faces growing challenges in maintaining its competitive edge due to (i) lengthy regulatory timelines (particularly for the authorisation of multinational trials), and (ii) higher administrative requirements and costs in the EU/EEA associated with the authorisation and conduct of clinical trials, compared to other regions. As a result, sponsors[88] increasingly favour jurisdictions that offer faster regulatory timelines, simpler and more streamlined approval processes, and improved access for the recruitment of patient populations. This contributes to widening the competitiveness gap. On **ATMPs**, delays and increased costs are caused by administrative complexity and overly stringent requirements for GMO-based gene therapies. This stems from dual regulatory compliance requirements i.e. under the Clinical Trials Regulation and with the fragmented implementation of GMO legislation by Member States, further complicated by a blanket requirement for environmental risk assessment that does not take into account the specificities of low-risk gene therapies.

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[83] See footnote 10.
[84] Public consultation, see footnote 74.
[85] Public consultation: Three-quarter of the respondents indicated regulatory barriers in the assessment and market authorisation (77%). About 70% indicated pre-commercial testing or clinical trials, 68% noted impediments in commercialising products and 67% in scaling-up production or manufacturing, while 64% signalled regulatory barriers in product development matters.
[86] Public consultation: 21% agreed or strongly agreed and 43% disagreed or strongly disagreed that the EU regulatory environment is more predictable in comparison with some countries outside of the EU.
[87] Public consultation: About 9-10% agreed or strongly agreed and between 64% and 68% disagreed or strongly disagreed that EU regulatory environment enables products to reach the market faster, is less complex and clearer, or leads to lower compliance costs in comparison with some countries outside of the EU.
[88] Sponsor as defined in the CTR, Article (2) `means an individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial'.

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In the EU framework for **VMPs**, two main challenges are observed: (i) duplicative, not-fit-for purpose regulatory framework applicable to VMPs that contain or consists of GMOs and (ii) disproportionate administrative burden in the handling of variations not requiring assessment.

There is an increasing focus in the EU and globally on the authorisation of biosimilar medicines, where approval is increasingly based on analytical and functional characterisation to demonstrate similarity to the reference product[89]. However, the EU's regulatory framework can still lead to the conduct of lengthy and costly multi-country comparative efficacy studies, even when robust analytical methods may demonstrate comparability and where a more tailored, risk-proportionate approach could therefore be justified. In the food area, EU law requires pre-market authorisations/approvals for several categories of **food and feed products and related food chain inputs**, the so-called 'regulated products'[90]. In those cases, the European Food Safety Authority (EFSA) must conduct a scientific risk assessment under the applicable sectoral legislation before risk managers at EU and/or national level decide to grant a pre-market authorisation/approval. Delays have been observed in both validation and risk assessment phases as also confirmed by the findings of the ongoing evaluation of the Commission on EFSA's Performance covering the period 2017-2024. These have been linked to: (i) dossier deficiencies and limited effectiveness of pre-submission advice, (ii) procedural consequences linked to non-compliance with study notification requirements; and (iii) governance constraints relating to EFSA's Scientific Committee/Scientific Panels.

As a cross-cutting element of complexity, developers of **AI applications** in biotechnology face a rapidly evolving regulatory landscape due to sectoral legislation and AI-specific requirements, including validation, documentation, explainability and risk-management obligations. The increasing integration of AI across the biotechnology lifecycle requires clarity on how existing EU frameworks apply across different development stages. Limited capacity, especially among SMEs and start-ups, to navigate applicable regulatory frameworks, further constrain the uptake of AI-enabled solutions in biotechnology. Public consultation responses[91] confirm that stakeholders see a need for greater clarity in the practical application of AI-related requirements across the biotechnology lifecycle (58% agreement). Stakeholders report uncertainty regarding how AI-related requirements interact with existing medicinal product and clinical research frameworks, particularly in areas such as model validation, documentation and lifecycle monitoring[92] and highlight the importance of guidance. Taken together, these patterns show that the EU biotech companies' difficulty to thrive is not a science deficit, but rather a **lack of translation and**

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[89] Reflection paper on a tailored clinical approach in biosimilar development: "Based on the advancements in analytical technology and the regulatory experience gained, a tailored approach for clinical development of biosimilar candidates is possible. CES are no longer expected to be required for approval of biosimilars that can be thoroughly characterised using state-of-the-art analytical methods and have demonstrated similarity in physicochemical and functional properties. Comparative clinical PK studies are still essential elements in the biosimilar development and can provide supportive safety and immunogenicity data. This tailored clinical approach is expected to be applicable for the majority of biosimilar candidates. A regulatory option that, under certain conditions, allows authorisation of biosimilars based on demonstrated comparability at the analytical level with a limited clinical data package streamlines the development process without compromising efficacy and safety".

[90] E.g. substances used in food and feed (such as additives, enzymes, flavourings, and nutrient sources), novel foods, food contact materials, genetically modified organisms, plant protection products etc.

[91] Public consultation, see footnote 74.

[92] Based on Landscape analysis study.

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a scale-up deficit shaped by long, complex and capital-intensive pathways from research to market.

3.2.2 Driver 2: Fragmentation of enabling ecosystems and suboptimal incentives for private investment constraining the scale-up of EU biotechnology and biomanufacturing

The EU's ambition to scale and industrialise biotechnology is currently limited by challenges in key enabling factors, in particular fragmented thus insufficient access to finance, development of infrastructures (e.g. clusters), availability of specialised talent and the deployment of AI and use of data.

First, with regards to **access to finance**, the EIB estimates the **sector investment gap at EUR 40 billion annually.**[93] US biopharma start-ups received around nine times more late-stage funding than EU biopharma start-ups, with around EUR 219 billion of venture capital focused on health biotechnology invested in the US compared to EUR 25 billion in the EU, between 2015 and June 2025.[94] **Even larger gaps in access to late-stage capital** have pushed biotech companies to find funding abroad, notably in the US. Between 2015 and 2021, 67 EU biotech companies going for a public listing have targeted the US NASDAQ rather than the European stock markets, with 60% of them only listing on NASDAQ without any listing on an EU exchange.[95]

Similarly, in earlier stages of capital, **although the EU biotech venture ecosystem has expanded materially in recent years, it remains a second-tier venture capital market in global biotechnology**. Annual investment increased from EUR 0.84 billion (2015) to a peak of EUR 5.47 billion (2021) during a rapid expansion phase, before partially normalising to EUR 3.89 billion (2025) (around 29% below the 2021 peak) consistent with post-pandemic slower deployment (see Annex 5, Figure 7). As a comparison, the US operates at a different order of magnitude across the cycle (peaking at around EUR 45 billion in 2021)[96]. In the public consultation[97], stakeholders reported **difficult access to private and some public investment instruments** in the EU in equity, debt, and commercialisation support (for more information, see *synopsis report* in Annex 2). In their answers, companies also noted that public funding mechanisms, while supportive for early R&D stages are also insufficiently tailored to the needs of biotech scale-ups. Specific challenges of start-ups and SMEs were also underlined from both representatives of **business associations and public authorities**. Respondents from **academic and research** also pointed the fragmentation in funding rules and tax incentives across Member States, limited availability of large venture capital funds, and a lack of banking expertise in biotechnology. **Non-Governmental Organisations (NGOs)** also reported challenges related to fragmented and insufficient public funding and a lack of significant grant-making institutions. This shows a need to reinforce de-risking financial instruments and budgetary guarantees in the EU.

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[93] The EIB Group uses industry data of EUR 69.7 billion investment for the US vs EUR 26.5 billion in the EU in 2021, resulting in a gap of ca. EUR 40 billion.
[94] Landscape analysis study.
[95] Kempen & Co analysis, Liquidity slides for dual listed companies, 2021.
[96] Landscape analysis study.
[97] Public consultation, see footnote 74.

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Biological VMPs benefit from two protection mechanisms: regulatory data protection (Articles 39-40 of Regulation 2019/6) and intellectual property (IP) protection (patents and SPCs) under Regulation (EC) No 469/2009[98]. Nevertheless, the veterinary pharmaceutical market presents specific challenges for innovation, such as fragmented species-specific markets, low price levels, and a small overall market size. In this context, there is a need for enhanced incentives to support the development of biotechnological VMPs to diagnose, treat or prevent zoonotic diseases.

Second, with regards to **biotechnology clusters,** their **outreach in the EU remains fragmented**, with significant disparities in scope and resources. Biotechnology clusters foster collaboration across entities at different stages of the biotechnology value chain and across biotech sectors. They enable the transformation and evolution of, for example, university spin-offs into companies ready for the commercialisation of their product[99]. While clusters compete for investment, talent and projects, there is substantial scope for collaboration, exchange of best practices allowing the realisation of scale effects that cannot be achieved at regional level. The few clusters that have an EU-wide relevance provide networking and coordination support, yet the landscape remains fragmented, risking duplication of efforts and limiting impacts. As a result, EU biotechnology clusters cannot fully leverage their collective potential to compete with clusters in other regions, and the EU as a whole underperforms in the field of biotechnology.

Respondents to the public consultation[100] identified **five main barriers** to clusters: insufficient **financial support** (58%), insufficient **public support** (54%), **incapacity to reach a critical mass of stakeholders** (46%), insufficient **collaboration among existing clusters** (46%) and insufficient **start-up incubators or business support infrastructure** (45%). Other barriers were identified, with representatives of companies pointing to the limited involvement of end-users (patients, healthcare providers) and public authorities underlining the insufficient support for product development. In the area of ATMPs, the lack of innovation hubs that combine emerging ATMP specialisation with infrastructure capabilities, regulatory expertise and collaboration among clinical centres, research bodies, industrial participants and commercialisation services, obstructs development in the EU.

Third, productivity gains, acceleration of innovation and efficiency improvements associated with the **use of AI and big data remain below their potential in the EU's biotechnology ecosystem**[101]. Fragmented, heterogeneous, and high-dimensional data is one of the challenges, as datasets generated in healthcare or research contexts are often not readily usable for the training, testing and validation of AI systems without significant curation and standardisation efforts. For health data, ongoing EU initiatives, such as the European Health Data Space, are expected in the coming years to facilitate access and cross-border use; at the same time ensuring that such data are sufficiently curated, annotated and interoperable to support AI development remains a key challenge. Data access challenges affect non-health data relevant to biotech, such as datasets on chemical

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[98] Regulation (EC) No 469/2009 OJ L 152, pp. 1–10 ELI: http://data.europa.eu/eli/reg/2009/469/oj.
[99] Landscape analysis study.
[100] Public consultation, see footnote 74.
[101] Submissions to the Call for Evidence and Public Consultation, as well as stakeholder workshop insights, as analysed in the study supporting the rapid assessment of policy scenarios to strengthen innovation and competitiveness in the field of biotechnology in the EU (Rapid Assessment Scenario Study forthcoming); Landscape analysis study - Annex 2 – Case Studies (forthcoming).

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reactions used in drug discovery and biomanufacturing processes[102]. Public consultation[103] results confirm these challenges. Companies, business associations and academic or research institutions report the highest levels of difficulty. Around two-thirds of companies and research institutions rely on data sourced from outside the EU/EEA, primarily due to higher reliability and quality of available datasets, as well as clearer legal frameworks for data access and lower perceived access costs. This suggests that improving the quality, usability and interoperability of datasets available within the EU could significantly strengthen the competitiveness of the European biotechnology ecosystem.

Fourth, the EU's ambition to scale and industrialise biotechnology also depends on the **availability of specialised talent**. While the EU maintains a strong scientific base, stakeholder evidence points to persistent gaps in the workforce segments critical for scale-up and deployment.

In the EU's biotechnology sector, stakeholders have identified **gaps in the workforce segments** needed for scale-up, progression to commercial scale and manufacturing[104]. There is a significant shortage in the total number of **higher education and vocational education and training graduates entering the biotechnology sector**[105], with shortages particularly observed in the following competences: biomanufacturing and bioprocessing, regulatory and compliance (e.g. ATMPs and pharmacovigilance), and digital skills[106] (e.g. bioinformatics, AI-enabled processes, data governance). Furthermore, for some profiles, stakeholder consultations indicated that technical skills would need to be complemented by additional competencies[107]. This challenge can be explained by several factors[108], such as constrained hands-on training capacity due to the scarcity and high cost of specialised facilities, the fragmentation of qualification systems across Member States, limiting **skills portability and talent mobility** and the **lack of entrepreneurial skills** in the EU (less than 50% of EU students have access to entrepreneurial education in secondary and higher education[109]). Barriers to the **upskilling** of workers are also relevant.

3.2.3 Driver 3: Rapid technological developments & regulatory adaptation lag

EU biotechnology companies also face barriers to manufacture, place products on the market and grow due to EU regulatory frameworks not always keeping up with rapid technological advances. This perception was confirmed in stakeholder consultations, as regulatory frameworks that insufficiently account for the innovative and rapidly developing nature of the biotechnology sector were also identified as a barrier to the expansion of EU companies[110].

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[102] Landscape analysis study - Annex 2 – Case Studies.
[103] Public consultation, see footnote 74.
[104] Landscape analysis study.
[105] Landscape analysis study.
[106] In 2023, only 55.6% of the EU adult population had at least basic digital skills. Digital Decade DESI visualisation tool DESI 2025, DESI indicators, Indicator: At least basic digital skills. https://digital-decade-desi.digital-strategy.ec.europa.eu/datasets/desi/charts/desi-indicators.
[107] Landscape analysis study based on Biotechnology Jobs. (2025, February 12). Building the Ultimate Biotech Skill Set: Technical and Soft Skills Employers Want in 2025.
[108] Landscape analysis study.
[109] EU Startup and Scaleup Strategy, based on European Commission's Entrepreneurship 2020 Action Plan.
[110] Public consultation, see footnote 74.

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One major reason brought forward by stakeholders and some Member States is the complex, not innovation friendly and in part ill-fitting EU legislation on GMOs, in particular as regards GMMs. The EU's legal framework for GMOs (including GMMs[111]) originates from the 1990s and was primarily tailored to genetically modified plants. The framework as it currently stands is **less suitable to handle GMMs given the biological differences compared to plants and the variety of micro-organisms and their applications[112]**. In a recent scientific opinion, EFSA concluded that the potential risk of a microbial product relates to the changes introduced in the micro-organism itself regardless of the method used to introduce them, supporting a more holistic approach to the assessment of micro-organisms based on the characteristics of the final product.[113] It further concluded that for certain GMMs less assessment requirements would be sufficient to ensure safety. In this respect, considering the risks of typical GMMs and derived products and the variety of risk profiles, the current GMO regulatory procedures are considered by many stakeholders and some Member States as **disproportionate, overly rigid and time consuming**, rendering the EU unattractive for investing and bringing such GMMs to the market as products. In addition, the particularly short development cycles of GMMs, with one product frequently being based on a previous product, mean that a quick, efficient authorisation path is very important.

There is also a regulatory gap between the existing EU legal framework on the **quality and safety of human organs** intended for transplantation and current medical practice on organ preservations, leading to **diverging interpretations across Member States and hence legal uncertainty**. The current EU framework was designed for preservation rather than processing and does not provide a clear, harmonised approach for these activities. It does not include a particular framework for authorising processing operations, nor a mechanism for benefit-risk assessment of these interventions, and no provisions for oversight of transplantation centres that seek to apply a specific processing technique. Furthermore, the current framework does not contain a mechanism for coordination between the organ transplant competent authority and the competent authorities operating under other legislative frameworks (e.g. on medical devices, medicinal products, or on SoHO). In 2024, although over 32,000 organ transplants were performed across the EU, the gap between the supply of transplantable organs and clinical demand remained, with over 52,000 patients registered on transplant waiting lists across the EU (as of 31 December 2024)[114].

Similarly, in the **ATMP** area, outdated definitions and technological lag in the regulatory framework are leading to discrepancies between the legal framework (classification

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[111] In line with the definitions provided in Directive 2001/18/EC, GMO means an organism, except for human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. In line with the definition provided in Directive 2009/41/EC (OJ L 125, 21.5.2009, p. 75-97. ELI: http://data.europa.eu/eli/dir/2009/41/oj), a GMM means a microorganism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

[112] Regulatory Framework Study (forthcoming, see Annex 1).

[113] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Jimenez Saiz, R., Ruiz Garcia, L., Aguilera Entrena, J., Schoonjans, R., Kagkli, D. M., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895. https://doi.org/10.2903/j.efsa.2024.8895.

[114] SANTE-SoHO/D2 - European Commission. (2026). *Introducing "organ processing" into directive 2010/53/EU* [Unpublished slideshow]. See Annex 5 for more details.

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uncertainty) and progressing science, hampering market access for these products (e.g. affecting in vivo tissue generation, acellular therapies, and bio-synthetic hybrids).

The rapid technological advances characterising the biotechnology sector challenge existing regulatory frameworks. While these frameworks ensure high safety standards, they offer limited regulatory flexibility in a context of rapid technological advances. As a result, innovative biotechnology applications may struggle to progress efficiently from development to market deployment across these sectors when regulatory frameworks are not sufficiently adapted to emerging technologies. In the health area, existing regulatory frameworks are not fully adapted or adaptable to **complex and hybrid emerging health biotechnology products**, leading to barriers such as a lack of legal certainty on **products classification and evaluation**. In the **VMPs sector**, regulatory uncertainty also represents a serious hurdle to the marketing or use of **novel technologies, methods or products**. In the **food chain sector**, EU legislation requires pre-market authorisations for several categories of food, feed and related food chain inputs but also provide for limited regulatory flexibility.

Biotechnologies are critical for the **Union's defence and security**. And while rapid advances in biotechnology over the last decades have brought considerable benefits for healthcare, research and the economy, such advances also make biological agents more widely accessible, increasing risk of their misuse. For example, the price of synthetic nucleic acids (such as DNA or RNA) has decreased more than 100-fold over the past 20 years[115], making it increasingly feasible to synthesise potentially dangerous genomic sequences, such as the DNA or RNA of viruses, at limited cost.

While some commercial nucleic acid synthesis providers screen orders to identify potentially dangerous sequences and verify the legitimacy of their customers, there are currently no EU-level rules on this. National rules diverge[116], failing to offer a level playing field, fragmenting the single market and undermining the EU's prevention and biosecurity efforts.[117] In stakeholder consultations, several industry actors, including SMEs, have therefore called for harmonised EU biosecurity rules.

Finally, the **potential of data and AI** remains largely untapped in the EU. Despite new regulatory frameworks (European Open Science Cloud, AI regulatory sandboxes mandated in the AI Act, EuroHPC/AI factories/gigafactories), some challenges remain. **AI biotech platforms** are inherently capital-intensive, relying on costly model training and large-scale data generation, and depend on access to **high-quality data** and advanced computing infrastructure, which remain comparatively limited in the EU[118]. Furthermore, the **scaling of AI**[119] in biotechnology requires sophisticated experimentation environments capable of integrating high-performance computing, biological laboratories and advanced

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[115] DNA Synthesis and Sequencing Costs and Productivity for 2025, Rob Carlson, 2025 https://www.synthesis.cc/synthesis/2025/5/dna-synthesis-and-sequencing-costs-and-productivity-for-2025.
[116] https://ibbis.bio/policy-spotlight-french-leadership-defining-and-regulating-genetic-fragments/
[117] See IBBIS mapping of explicit and implicit rules on NA synthesis screening across countries: https://globalsynthesismap.bio/policy?country=FRA.
[118] Landscape analysis study - Annex 2 – Case Studies.
[119] COM(2025) 30 final based on Eurostat data: EU survey on ICT usage and e-commerce in enterprises (January 2025).

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data infrastructures.[120] However, the availability of such integrated environments remains limited in the EU. Stakeholders underlined the importance of collaborative environments that facilitate the responsible testing, validation and deployment of AI-enabled biotechnology solutions while ensuring compliance with EU legislation[121].

3.3 Consequences

3.3.1 EU is facing a major competitiveness gap in biotech, despite being a leader in science

The problem presented in section 3.1. results in a **gap between the EU and the US in terms of entrepreneurial dynamism**. The EU only represents 22% of the global biotech start-up activity (i.e. start-ups founded since 2015) while the US accounts for nearly half (49%) of them (see Annex 5, Figure 6)[122].

This competitiveness gap is observed across the health and agri-food biotechnology sectors:

The EU is becoming less attractive to sponsors for **conducting clinical trials** in global comparison, affecting the economy, public health, and skill capacity building. The number of clinical trials conducted worldwide has increased substantially over the past decade, rising from approximately 13,000 in 2013 to 22,000 in 2023. Over the same period, the geographical distribution of clinical trials has shifted markedly. While the **EEA's share of global clinical trials declined** from 18% in 2013 to 9% in 2023, China's share increased from less than 10% to nearly 30%[123]. A similar trend is observed in cell and gene therapy trials: between 2013 and 2023, Europe's global share steadily declined, whereas China experienced a dramatic rise over the same period, emerging as the leading region.[124] This growth also reflects a different portfolio structure, with China placing stronger emphasis on early-stage and post-marketing development, particularly mononational Phase I and Part IV trials, compared to the EEA's stronger focus on multinational Phase II and Phase III trials[125]. Despite the strong growth in global clinical trial activity, the level of activity in terms of number of clinical trials submissions in the EU remained broadly stable between 2013 and 2025[126]. Consequently, the EU did not capture a proportional share of this growth, leading to a widening competitiveness gap relative to other regions with

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[120] Breakthroughs in in silico, AI-driven and digital-twin approaches can transform biomedical research, diagnostics, and personalised medicine. In silico modelling leverages computer simulations increasingly integrated with AI and can potentially replace some traditional animal testing and clinical trials. AI-driven analytics can enable precise, individualised therapies and accelerating tissue repair (*Healing the Future - Horizon scanning for emerging technologies and breakthrough innovations in the field of cell and gene therapies* https://publications.jrc.ec.europa.eu/repository/handle/JRC141934).

[121] See Annex 2, Synopsis report for more details.

[122] Landscape analysis study.

[123] EFPIA report: assessing-the-clinical-trial-ecosystem-in-europe.pdf.

[124] EFPIA report: assessing-the-clinical-trial-ecosystem-in-europe.pdf.

[125] Fast-track landscape analyses to assess the regulatory clinical trial eco-system in the EU/EEA and in other relevant regions (forthcoming)

[126] The annual number of clinical trial applications submitted in the EU, as well as the shares of mononational, commercially sponsored, and pediatric trials, exhibited little variation over this period, aside from temporary changes during the COVID-19 pandemic. Between 2013 and 2025, the annual average number of clinical trials application is 2,895 with a standard deviation of 303.

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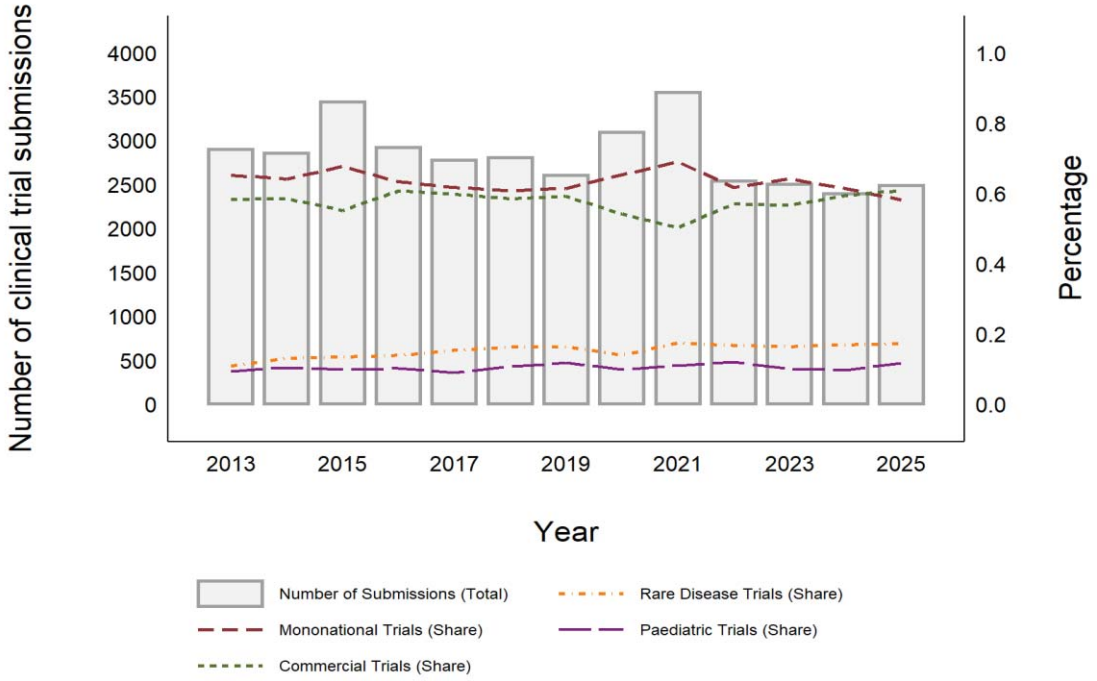
potential implications for economic performance and timely access by patients to innovative treatments[127].

Figure 2. Clinical trial activity in the EU[128]

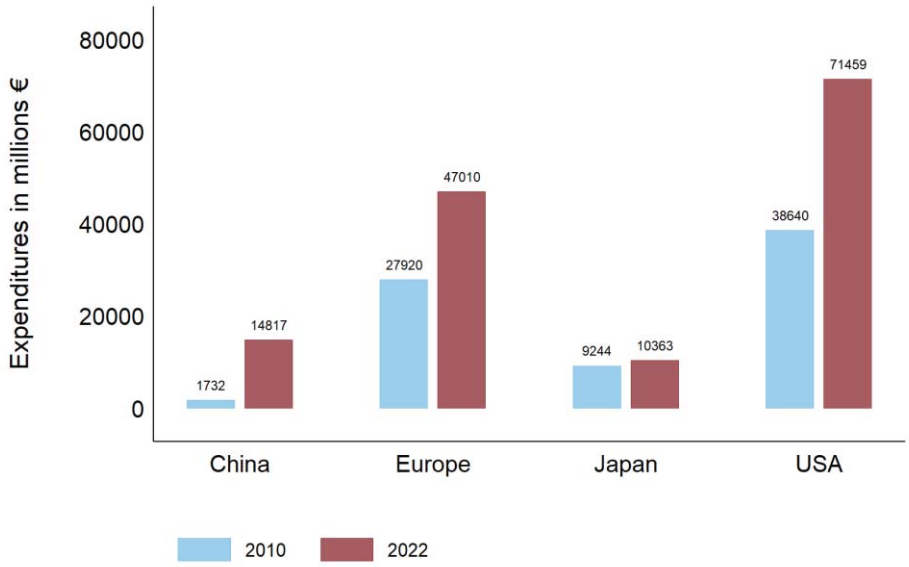


***Note**: Figure 2 describes the trend in the submission of clinical trial applications in the EU between 2013 and 2025. The bars illustrate the total number of applications per year, while the remaining lines show the share of the applications for mononational, commercial, paediatric and rare-disease trials.*

The gap in clinical trial activity between the EU and other markets, particularly China, is also reflected in **changes in annual pharmaceutical R&D expenditure** of which approximately 60% can be on average allocated to clinical trials[129]. Using overall pharmaceutical R&D expenditure as a proxy, China experienced a significantly larger increase in R&D expenditure compared to the other regions[130].

[127] The decline in the EEA share of global clinical trials stems from multiple, interlinked factors, with enhanced regulatory complexity being one of the driving factors.
[128] Calculations done by the European Commission based on data from EudraCT and CTIS.
[129] EFPIA report (2024) The Pharmaceutical Industry in Figures. Key Data. According to the report, 48.4% of the pharmaceutical R&D expenditures are allocated to Phase I to III trials and additional 11.5 % to Phase IV trials. The data is based on a survey with Members of PhRMA and collected in 2022. See further information here: PhRMA_membership survey_single page_70523_es_digital.pdf.
[130] China experienced an increase by a factor of 8.55 compared to a factor of 1.68 increase in Europe.

Figure 3. Pharmaceutical R&D expenditure in selected regions in 2010 and 2022[131].



Note: *Figure 3 illustrates annual pharmaceutical R&D expenditures in 2010 and 2022 for China, Europe, Japan and the USA.*

These trends show that Europe's position in global pharmaceutical R&D, including its clinical trial activity, is facing increasing challenges in maintaining its competitive edge[132].

The relative decline in clinical trial activity is likely to come along with adverse effects on the public healthcare systems, the economy and the development of skills, and capacity within the Union. Although estimating the economic impact of clinical trial activity is inherently complex and dependent on multiple model assumptions, recent studies based on national and EU-wide data indicate that each euro invested in clinical trials generates between EUR 1.60 and 2.50 of added value for the economy, along positive effects on employment[133]. A recent report estimates that commercial trials, which account for 53.1% of the trials authorised in the Union[134], create annually about EUR 35.7 billion in gross value added to the economy in the EEA and support the creation of over 165,000 jobs[135].

In addition, clinical trial activities are estimated to reduce costs for national healthcare systems. For example, two studies conducted in Italy indicate a leverage effect of avoided costs between 2.2 and 3.5; that is, for every euro invested in clinical trials or disbursed by

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[131] EFPIA report (2024) The Pharmaceutical Industry in Figures. Key Data.
[132] Tan et al. (2024) Current landscape of innovative drug development and regulatory support in China | Signal Transduction and Targeted Therapy.
[133] Walter et al. (2020) Economic impact of industry-sponsored clinical trials of pharmaceutical products in Austria - PubMed; Battelle Technology Partnership Practice (2015) Biopharmaceutical Industry-Sponsored Clinical Trials: Impact on State Economies (battelle-2015-study.pdf); Fast-track landscape analyses to assess the regulatory clinical trial eco-system in the EEU/EEA and in other relevant regions (forthcoming).
[134] See EU clinical trials during the 3-year CTR transition period
[135] EFPIA report (2026) the-economic-impact-of-industry-clinical-trials-across-europe.pdf.

sponsoring companies to health facilities, the Italian national health system saved more than two euros[136]. Finally, clinical trial activities also affect the health of European citizens. For example, patients participating in clinical trials can access innovative medicines up to 5 to 10 years before commercial launch in the EU.[137]

The innovation and competitiveness gap in the EU's ATMP sector is also becoming increasingly evident. Although Europe currently holds a **22.1% share** of the global gene therapy market (2025) and the sector is projected to grow at a compound **annual growth rate of 14,6%** (2026–2033), the region **risks falling behind North America and the Asia-Pacific region**. Forecasts indicate that North America will generate the highest revenue in the sector by 2033, while the Asia-Pacific market is expected to reach USD 4,193.1 million in the same year[138]. This trend, also highlighted in the Draghi Report[139], underscores the EU's struggle to strengthen its R&D capabilities and address the **innovation and competitiveness** gap in the region's ATMP market. Slow progress in ATMP development threatens the EU's position in the global healthcare and biotechnology sectors, as innovators may increasingly choose to operate in jurisdictions with more agile regulatory frameworks.

When it comes to **biosimilars**, the EU's biomanufacturing capacity can be further utilised. The EU has significant untapped potential in biosimilar manufacturing. The EU retains the largest cumulative authorisations of biosimilars (151 products vs. 72 in the US and 66 in Canada) and leads the global market in revenue valued at approximately EUR 25.6 billion in 2024, representing around 6% of the total pharmaceutical industry's contribution to GDP. Sales grew at 15% annually between 2020 and 2024 across five core therapeutic areas, and the sector supports around 81,000 jobs in Europe: 16,000 direct (20%), with the remainder split between indirect roles such as clinical research (30%) and induced employment (50%). The sector depends on a highly skilled workforce, with 40% of direct employees (~7,000) in technical roles and 70% holding university degrees.[140] However, manufacturing activity is increasingly migrating to Asia, particularly South Korea and India[141]. While the EU remains a key innovation hub — **supplying over 75% of active ingredients** for innovative biologics — it must develop more dedicated and cost-efficient manufacturing infrastructure to keep pace with international competitors.[142]

Similarly, challenges to bring **novel health biotechnology products** to the market have been observed[143], and are generally expected to increase given the increasing complexity and hybrid nature of novel products. These challenges further weaken the EU's position in

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[136] Cicchetti et al. (2020) Valorization of clinical trials from the Italian National Health Service perspective: definition and first application of a model to estimate avoided costs - PubMed; Polignano et al. (2022) Economic impact of industry-sponsored clinical trials in inflammatory bowel diseases: Results from the national institute of gastroenterology "Saverio de Bellis" - PMC.
[137] EFPIA report (2024) Assessing the clinical trial ecosystem in Europe: Final report, p.37
[138] https://www.grandviewresearch.com/horizon/outlook/gene-editing-market/europe.
[139] See footnote 11, page 6.
[140] Medicines for Europe, European Biosimilar Medicines Sector: Delivering Impact Beyond Health – Economic, Scientific & Strategic Contribution, Biotech Act Factsheet Series, March 2026, Pillar 1-2-3-4-FOOTPRINT-SPC-Biotech-Act-facsheets-ppt.cdr.
[141] Cohen, H. P., Turner, M., McCabe, D., & Woollett, G. R. (2023). Future evolution of biosimilar development by application of current science and available evidence: The developer's perspective. *BioDrugs*, *37*(5), 583–593.
[142] BioPlan Associates (2024). Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production
[143] Maxwell, A. (2025, August 20). *Why EU innovators face growing barriers with EU combination product regulation*. Medtech Insight.

the global innovation race, delaying the availability of these products to patients across the EU.

Regulatory uncertainty also has practical implications for cross-border exchange of processed **organs** and for the scaling of machine perfusion technologies, contributing to uneven uptake and fragmentation within the EU[144], and eventually reducing the potential for optimal matching of organs and recipients. Over the last three years, the cross-border exchange rate of allocated organs fluctuated between 20-23%[145].

In the field of **GMMs**, recent evidence shows that there is significant activity in the development of innovative GMMs by both private and public/academic entities. However, the majority of the identified GMMs originates from the US or China, while **only a limited number were developed within the EU**[146]. Notably, there are **currently no products on the single market that contain or consist of GMMs**, except for medicinal products which are, however, not authorised under the GMO legal framework but under the EU framework on pharmaceuticals. This is particularly affecting the competitiveness of SMEs in the GMM field, since they are typically among the most innovative companies in the biotechnology sector but may lack the regulatory expertise and financial resources to navigate complex legal frameworks that may not adequately fit their innovative products. At the same time, this lack of products on the markets, or prospect to bring products efficiently to the market, is **discouraging investments in R&D, thus negatively impacting the wider science community in the EU**. EU economic sectors, foremost the agricultural, industrial and environmental sectors, are negatively impacted as they cannot easily make use of novel tools available in third countries that make operations more efficient.

As a consequence of the issues outlined under drivers 1 and 3, a competitiveness gap is also observable for biotechnology products in the food chain (**food and feed products)**, including substances (e.g. additives, enzymes etc), and other food chain inputs (e.g. food contact materials).

Finally, as **AI** continues to expand across the biotechnology lifecycle in the health and food sectors, the bottlenecks innovators face when attempting to develop, validate and deploy AI-enabled biotechnology solutions in the EU slow the transition from scientific discovery to real-world deployment. As a result, the Union risks failing to fully capture the productivity gains, efficiency improvements and innovation opportunities associated with the large-scale use of AI in biotechnology. This under-utilisation of AI may therefore translate into a growing competitiveness gap, as other jurisdictions more effectively integrate AI into biotechnology research, development and production across multiple biotech sectors.

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[144] See Annex 5 for more details.
[145] See Rapid Assessment Scenario Study
[146] Ballester, A.R., Roqué, M., Ricci-Cabello, I., Rotger, A., Malih, N. 2023. Horizon scanning on microorganisms and their products obtained by new developments in biotechnology. EFSA supporting publication 2023:EN-8503, 65 pp. doi:10.2903/sp.efsa.2023.EN-8503.

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3.3.2 Biotech's potential to help address major societal challenges is underexploited

Despite its innovation and growth potential, and expected benefits for patients and society at large, the potential of biotechnology remains largely underexploited in the EU, across the different biotechnology areas.

In the health sector, **ATMPs** – such as gene therapies – offer a transformative potential for treating a broad spectrum of diseases, from rare genetic disorders to common chronic conditions. Despite this promise and the innovative potential in the EU, patient access in the EU remains severely limited.

Organ transplantation also increasingly involves *ex-vivo* organ processing, such as machine perfusion to assess and recondition donor organs prior to transplantation. These techniques can expand the pool of transplantable organs, improve matching of organs and recipients, improve clinical outcomes and strengthen health-system resilience. However, there is limited cross-border exchange and slow EU-wide uptake of innovative processing technologies[147].

In the **VMP sector**, the potential of biotechnology to improve animal health and strengthen food supply chain resilience remains underdeveloped. Favourable regulatory conditions for the use of biotechnology in animal health will not only benefit the biotech pharmaceutical industry, but also farmers, animal health, the food supply chain and human health (zoonotic diseases). When disease spreads in food-producing animals, the impact on farmers can be dire and food security can be put at risk. Vaccination is a powerful tool to prevent and control animal diseases and contributes to reducing the use of antimicrobials. As a large share of emerging infectious diseases in humans has a zoonotic origin, preventing animal diseases also has positive effects on human health. Novel biotechnology tools enable the development of safer and more effective vaccines, as well as the distinction of vaccinated animals from those infected, and allow vaccines to be developed or adapted much faster than with conventional approaches, which is critical to prevent and control animal diseases.

When it comes to **innovative GMMs[148]**, their non-deployment in the EU market, in addition to the loss of competitiveness opportunities outlined under the driver 3, result in an unfulfilled potential for GMMs to contribute to other social and environmental objectives. For example, GMMs can now be used as or in biofertilisers, biostimulants, biopesticides, biocides, bioremediation, wastewater treatment, biomining and bioleaching, offering benefits in the wider agri-food, industrial, marine and environmental sectors. As GMM-based products that would be more efficient or environmentally friendly than the alternatives are not being used, EU society and consumers are negatively impacted as they are being deprived of innovative solutions to important challenges linked to climate change, environmental pollution and food and feed security.

Moreover, in the **food and feed sector**, the potential of biotechnology remains underexploited and experimentation in real conditions (e.g. real-world food production and

[147] See Rapid Assessment Scenario Study.
[148] See Annex 7, Section 5.2. for examples.

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processing environments) is constrained. Biotechnology tools can support more efficient production processes across the food chain. These technologies can improve the safety and quality of food products, for example by reducing pathogens and toxins and enhancing nutritional properties[149]. Enzymes and biocatalysts can reduce environmental impacts by replacing chemical processes and improving process efficiency[150]. As regulatory drivers constrain the deployment of innovations in such areas, the single market as well as the contribution of biotechnology to food safety and security, resource efficiency, environmental sustainability and the EU's strategic autonomy, are not fully realised.

Furthermore, the **rapid advancement of technology, including AI, alongside increased data collection and use** are cross-cutting enablers with huge potential across the different areas of the biotech sector, yet to be fully utilised. AI and advanced data use act as key enablers of biotechnology innovation across health and agri-food applications. AI-driven tools support target identification, molecular design, optimisation of biological processes, CT design and manufacturing efficiency, while in the agri-food sector they enable advanced fermentation, strain optimisation and resource-efficient production. These applications can accelerate innovation cycles, reduce development costs and strengthen resilience in areas such as medical countermeasures, disease detection and sustainable food systems. However, the full potential of AI-enabled biotechnology remains underexploited in the EU. The effective deployment of these technologies requires clear lifecycle guidance, as well as access to integrated environments combining experimental and computational capabilities for testing and validation, and high-quality, well-curated datasets that allow AI systems to be trained and deployed reliably. The absence of these enabling conditions limits the EU's ability to fully harness biotechnology to address major societal challenges and strengthen its strategic autonomy in health and food systems.

Regarding the application of biotechnology to defence and security, the primary challenges identified by stakeholders in the public consultation were the **risks to strategic autonomy** in biomanufacturing and availability of countermeasures (50%), **cybersecurity risks** (e.g. biotechnology infrastructure, AI tools used) (45%), vulnerabilities in the **resilience of biotechnology supply chains** (44%), and threats related to biosecurity and biosafety including **misuse of biotechnology** (40%). Finally, **opportunities** in biosecurity were also particularly underlined in the public consultation[151]: the development of new innovative medical countermeasures (45%), detection of biological threats (45%), as well as increased food security (43%).

3.3.3 Potential for misuse of biotechnology poses growing biosecurity risks

In addition, the rapid progress in and increasing accessibility of biotech innovations also increase the likelihood and impact of biosecurity incidents, as certain applications of

[149] Siddiqui SA, Erol Z, Rugji J, Taşçı F, Kahraman HA, Toppi V, Musa L, Di Giacinto G, Bahmid NA, Mehdizadeh M, Castro-Muñoz R. An overview of fermentation in the food industry - looking back from a new perspective. Bioresour Bioprocess. 2023 Nov 28;10(1):85. doi: 10.1186/s40643-023-00702-y. PMID: 38647968; PMCID: PMC10991178.
[150] Palanisamy Vasudhevan, Zhang Ruoyu, Hui Ma, Subhav Singh, Deekshant Varshney, Shengyan Pu, Biocatalytic enzymes in food packaging, biomedical, and biotechnological applications: A comprehensive review, International Journal of Biological Macromolecules, https://doi.org/10.1016/j.ijbiomac.2025.140069.
[151] Public consultation, see footnote 74.

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technologies and products may have the potential for misuse, posing threats to public health and safety.

The exponential decrease in the cost of synthesising DNA and RNA has made the physical material needed to create biological agents, including dangerous pathogens, increasingly accessible. Studies by RAND Europe[152] and CLTR[153], two independent non-profits, estimate the current annual probability of a large-scale biological attack using synthetic nucleic acid at 1%, and accidents from their use at 1.5%, with expected economic harm to the EU of almost EUR 20 trillion for a large-scale event.

The EU joint biotechnology risk assessment carried out under the EU's Economic Security Strategy argues that the likelihood and impact of such incidents is further amplified by advancements in AI and computational tools in biological applications, which can lower the technical barriers to the design, optimisation and misuse application of biological agents.

These advances could significantly expand the pool of individuals capable of conducting technical tasks with biotechnology products that could be misused for malicious purposes, such as synthesising dangerous pathogens. Modelling published in 2025 suggests that, under a set of assumptions about near-term AI capabilities, could increase the annual probability of an epidemic from biological misuse by a non-state actor roughly sixfold, from 0.15% to 1%[154]. This reflects broader concerns that AI tools developed for beneficial applications in life sciences may also present dual-use risks if misapplied.[155]

3.4 What is the baseline from which measures are assessed?

The baseline trajectory through 2038[156] is **expected to show a widening of the competitiveness gap between the EU and its main competitors.** This is driven by the compounding interaction of the identified drivers. Regulatory complexity deters investment; market fragmentation, in particular capital scarcity, constrained innovation; and the expanding pipeline of frontier technologies amplifies administrative burdens and regulatory barriers, within an ecosystem that is not positioned to absorb them. The thematic sections that follow detail these dynamics across five interconnected dimensions[157].

Regulatory landscape and administrative burdens

Under the baseline, biotechnology developers will be confronted with an EU regulatory landscape characterised by three mutually reinforcing deficiencies: the proliferation of overlapping and partially incompatible regulatory frameworks, the persistent national

[152] Zakaria, S. *et al.* (2026). Cost–benefit analysis for synthetic nucleic acid screening in the European Union. Santa Monica, CA: RAND Corporation, 2026. https://www.rand.org/pubs/research_reports/RRA4805-1.html.
[153] Fady, P. *et al.* (2025). Cost-Benefit Analysis of Synthetic Nucleic Acid Screening for the UK. The Centre for Long-Term Resilience. doi.org/10.71172/kyey-h0ya, p.18.
[154] Righetti, 2025 (https://www.governance.ai/research-paper/dual-use-ai-capabilities-and-the-risk-of-bioterrorism-converting-capability-evaluations-to-risk-assessments).
[155] Urbina, F., Lentzos, F., Invernizzi, C. *et al.* Dual use of artificial-intelligence-powered drug discovery. *Nat Mach Intell* **4**, 189–191 (2022). https://doi.org/10.1038/s42256-022-00465-9
[156] Some interventions have been assessed over a different baseline. See Annex 4 for more information on the timeline and baseline.
[157] See Rapid Assessment Scenario Study for more information including on assumptions used.

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heterogeneity in the implementation of procedures, and the absence of structured pathways for innovations that do not fit neatly within existing legislative frameworks.

The most pervasive source of regulatory burden is **procedural duplication across intersecting frameworks**. Under the baseline, developers of **GMO-containing ATMPs** will continue to incur in up to 50 additional days in CT authorisation timelines beyond conventional medicines, with further extensions for substantial modifications. For **VMPs, GMO-containing products** will continue to face approval timelines two to three times longer than non-GMO equivalents despite the fact that no GMO-containing VMP has ever received a negative opinion on the basis of its GMO component, triggering an 'innovation tax', estimated at EUR 269,000-840,000 per year in FTE burden. Such a burden is set to compound, reaching EUR 403,000-1,119,000 by 2040, as the pipeline is projected to encompass approximately 100 GMO-containing VMPs in various stages of development at any point through 2040. In addition, **CT applications** subject to dual-track requirements will increase from 8-15 to 12-20 per year and annual GMO-containing marketing authorisation applications are expected to rise from the current 3-5 to approximately 5-8 per year by 2040. Meanwhile, the administrative burden from variations not requiring assessment (VNRA) is projected to scale proportionally with the expanding marketing authorisation base: the number of active veterinary Marketing Authorisations is expected to grow to approximately 55,000-60,000 by 2040, with annual VNRA volumes scaling accordingly. The aggregate annual VNRA fee burden is projected to grow in proportion.

In the **biosimilar** domain, the **disproportionality of certain regulatory requirements** will also persist. Between 2012 and 2022, 100% of all 36 monoclonal antibody and fusion protein marketing authorisation applications included a Phase III comparative efficacy study, yet in no case did the clinical data determine the regulatory decision. Thus, the most costly component of biosimilar development (EUR 19-26 million per study, representing 20-50% of total expenditure and adding 12-24 months to timelines), is likely to function as a ***de facto* procedural requirement** rather than a scientifically decisive evidentiary input. Indeed, there is increasing experience with tailored clinical efficacy and safety approaches for biosimilars at the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). Based on EMA data, in 2025 more than 70% of adopted scientific advice procedures for biosimilars incorporated a tailored clinical efficacy and safety approach. In addition, among all biosimilar marketing authorisation applications submitted last year under Article 10(4) of Directive 2001/83/EC, approximately 8% proposed a tailored clinical efficacy and safety approach. While there is a gradual shift toward more tailored approaches by EMA[158], a slow uptake of these changes risks putting Europe at a competitive disadvantage compared with other regions that operate under more agile frameworks.

The EU's regulatory framework will be marked by persistent fragmentation in the implementation of clinical trials across Member States. The EU's share of global clinical trial initiations has halved, declining from 18% in 2013 to 9% in 2023. Without fundamental reforms, particularly in streamlining authorisation procedures and simplifying regulatory requirements, the EU risks a further decline in its clinical research

[158] EMA, 2026 (https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf-0).

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competitiveness. Meanwhile, the more centralised markets of the US and China continue to outperform the EU, further consolidating their dominance. China's share of global clinical trials, for instance, has surged from 8% to 29% over the last decade, while the US maintains its strong position. **Current projections suggest that the EU's growth in clinical trial activity will remain sluggish compared to these faster-expanding regions, risking a further relative decline in its standing as a key hub for clinical research.**

However, this does not imply a decline in the absolute number of EEA trials as the Clinical Trial Regulation (fully applicable to all clinical trials since January 2025) is expected to generate a 'learning effect' as sponsors and national authorities gain experience with the Clinical Trials Information System (CTIS). This will lead to moderate improvements in median authorisation times and greater procedural stability over 2025-2030. Between 2025 and 2030, AI tools are projected to achieve 60-70% routine adoption, e.g. in trial design and conduct, and digital trial components are expected to become increasingly integrated into standard protocol design. However, national heterogeneity in ethics review, contracting, insurance, and site activation will persist. Clinical trial activity concentrates further in a few Member States, large firms widen their advantage over SMEs, and clinical translation of the EU's strong scientific output stagnates. SMEs and academic innovators increasingly rely on partnerships with larger companies, slowing EU-based evidence generation and eroding Europe's leadership in emerging technologies. In absolute terms, the number of EU clinical trials has remained broadly stable over the past decade at approximately ~2,400–2,500 trials per year, with no structural upward trend expected under the baseline[159].

For **SoHO**, 50 national competent authorities will continue to oversee blood and tissue establishments (currently at 1,400 and 3,258, respectively), with recurring administrative costs to businesses estimated at EUR 4.14 million over ten years under the incoming risk-based authorisation model. While Regulation (EU) 2024/1938 introduces a more unified SoHO Preparation Authorisation (SPA) model, regulatory uncertainty will persist for novel, complex, and cross-framework SoHO innovations. Meanwhile, **permitting for strategic health biotechnology projects** is projected to remain fragmented and slow under the lack of EU-level priority-project recognition or fast-track governance mechanisms.

These burdens are further aggravated by the **absence of structured innovation support**. In the **food and feed domain**, over 90% of application dossiers assessed by EFSA in 2021-2023 contained administrative or scientific errors leading to the suspension of the legal deadlines for risk assessment (the so-called stop-the-clock procedure) resulting in delays in the overall authorisation process, which are likely to persist under the baseline scenario. For **AI-enabled methodologies**, EMA's Qualification Procedure for Novel Methodologies costs EUR 89,000 per request, takes 160-250 days, and produces confidential, non-reusable outcomes, meaning each new entrant faces identical navigation costs with no cumulative learning. The scale of regulatory demand on the EMA is itself accelerating. It received 635 scientific advice requests in 2024, a figure that grew 16% year-on-year in the first half of 2024 alone, this mismatch between the pace of technological innovation and

[159] Rapid Assessment Scenarios study, forthcoming

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the capacity of existing regulatory infrastructure to absorb it is expected to grow under the dynamic baseline.

Competitiveness and investment attractiveness

The capital base underpinning the biotech sector shows a **pronounced investment gap.** As presented under section 3.2.2, EU biotech venture capital stood at approximately EUR 4.8 billion across 243 rounds in 2024, roughly six times below US levels. The average EU late-stage financing round (approximately USD 49 million) is around half of the US equivalent, and the EIB estimates the structural annual investment gap at approximately EUR 40 billion. This capital shortfall is not merely quantitative; it is structurally embedded (see sections 3.1 and 3.2.2). **Despite the existence of significant public financial engagement, this gap shows no prospect of autonomous closure under the baseline.** The deep dependence on external capital, which weakens strategic autonomy over the direction and location of value creation, is expected to grow. The median time gap between funding rounds has increased from 17 to 20 months, with higher incidence of down rounds at Series C stage (growth stage), signalling that investor confidence in the EU's late-stage pipeline remains fragile. Without sufficient public investment to bridge the late-stage capital gap and catalyse private co-investment, the structural investment deficit is projected to persist through 2038.

The **exit asymmetry** is equally stark and is expected to continue. Only 138 EU biotech healthcare companies completed an IPO compared to 451 in the US (over the period 2013-2023). In 2024, no European biotech raised more than EUR 58.1 million in IPO proceeds.

The commercial viability of biotechnology investments is further conditioned by the existing **IP protection framework**. Health biotech innovators reinvest a large portion of their revenue back into R&D. By ensuring a viable commercial timeframe, the SPC is one of the measures that enables innovative companies to re-invest their revenue in additional research and development, improving patient access to innovative therapies, and generating broader economic benefits. However, intellectual property, including SPC, is just one part of innovators' investment decisions. Without policy change, innovators' decisions on investment location continue to reflect expected lifecycle revenues under protection, alongside market size, access conditions, regulatory predictability and operational considerations. In the immediate baseline period to 2030, effective protection durations are expected to remain broadly stable, with the revised general pharmaceutical legislation not expected to produce observable effects within this period. In the longer term to 2038, effective regulatory protection outcomes are expected to become more heterogeneous across medical products, reflecting the continued shift towards biologics and advanced therapies with longer and more variable development timelines. The EU share of earliest biotech patent filings is projected to remain stable at low single-digit levels (around 3-5%), while global biotech patenting activity continues to expand.

This capital deficit compounds a broader **erosion of the EU's global competitive position** across several dimensions that collectively determine where biotechnology innovation is located, financed, and commercialised. The **global clinical trials market** is expected to grow at approximately 5.7% annually, compared with approximately 4.8% in Europe, indicating a gradual but persistent loss of relative competitiveness for the EU as a location for clinical research in the absence of improvements to the clinical trial ecosystem. In

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biosimilars, the EU's first-mover advantage has declined. While 71% of biosimilars are approved in the EU before the US, there has been a rising share of biosimilars that get approved in the US first, or only received US approval, which indicates the growth of the US market. At the same time, the European biosimilar medicines sector makes a significant contribution to European gross domestic product, contributing EUR 25.6 billion in 2024 and representing approximately 6% of the total pharmaceutical industry contribution.[160] The number of the CHMP of EMA scientific opinions on biosimilars has itself increased markedly, from 8 in 2023 to 25 in 2024 and 40 in 2025, reflecting a growing pipeline that amplifies the stakes of regulatory competitiveness. **Cumulative biosimilar authorisations** are also projected to rise from 151 in 2025 to 250-350 by 2030 and 450-650 by 2038, with new reference product classes entering biosimilar development expanding from approximately 27 to 35-45 by 2030 and 55-75 by 2038. However, 79% of the approximately 100 biologics losing exclusivity by 2032 have no biosimilars in development, representing a 'biosimilar void' valued at approximately EUR 122 billion in global forecast sales at loss of exclusivity. This indicates that a substantial proportion of the projected market value will not materialise without a reduction in per-product development costs.

The competitive erosion is reinforced by the fact that **no single-entry point** exists for health biotechnology innovators to navigate the regulatory and funding landscape. **Investor-innovator** connections will likely remain *ad hoc* and geographically concentrated in a few leading ecosystems. Disparities in innovation capacity and ecosystem maturity across Member States are expected to persist, with Central and Eastern European Member States lacking the **cluster** foundations that sustain leading ecosystems in some Member States. These fragmentation effects are compounding: without a coordinated ecosystem support mechanism, the navigational burden for SMEs is expected to increase further as new regulatory frameworks layer additional complexity and the pipeline of frontier biotechnologies expands. Meanwhile, other **major jurisdictions** are actively accelerating policy and investment efforts to strengthen their biotechnology ecosystems[161], suggesting that, in the absence of intervention, the EU's relative competitive position is likely to continue to deteriorate over time.

Innovation and research

The baseline reveals a **structural and persistent translation deficit** at the centre of the EU biotechnology innovation system. Under the baseline, the EU innovation system's upstream scientific base will remain internationally competitive, while the downstream deficiency in infrastructure for converting that science into products, trials, and market-ready applications will grow.

One of the key innovation-side deficits is the **absence of structured pathways for technologies that do not fit neatly within existing regulatory categories**. Developers of **novel health biotechnology** products will continue to operate simultaneously across two

[160] Medicines For Europe factsheet: Pillar 1-2-3-4-FOOTPRINT-SPC-Biotech-Act-facsheets-ppt.cdr.
[161] See for example US initiatives which frame biotechnology as a core economic and national security priority requiring coordinated action to sustain global leadership: U.S. House of Representatives. (2025). *Congressional Biotechnology Caucus announcement*, June 2025; National Security Commission on Emerging Biotechnology (NSCEB). (2025). *Report to Congress*, April 2025.

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to three regulatory frameworks, with no structured cross-framework anticipatory dialogue in place. Forecast analyses project that up to 30% of such products could be stalled by regulatory uncertainty between 2030 and 2038, even as the volume of novel, hybrid health technologies is expected to increase by approximately 20% between 2025 and 2030. In **ATMPs**, as the current definitions fail to capture emerging modalities, this is projected to widen progressively as in vivo genome editing and cell-device combinations advance over 2030-2038. Without clarification of tissue-engineered product and related definitions, more products are likely to require case-by-case classification by EMA and bespoke scientific advice from 2030 onwards, increasing regulatory workload and amplifying unpredictability for the SME dominated ATMP developer base (over 60% of ATMP developers are SMEs). For **GMMs** used outside food and feed, the EU's process-based framework has resulted in no market authorisations for deliberate release under Directive 2001/18/EC, effectively excluding the EU from the specific parts of global markets in biofertilisation, biocontrol, bioremediation, and bioleaching using GMMs. Taking into account GM and conventional products, these markets have a combined value exceeding EUR 29 billion and growth rates of 9-14% annually. These global GMM-relevant markets are projected to grow significantly under the baseline: biofertilisers from EUR 1.18 billion (2024) to EUR 2.42 billion by 2030; microbial biocontrol from EUR 5.55 billion (2025) to EUR 14.2 billion by 2032; bioremediation from EUR 14.1 billion (2024) to EUR 32.9 billion by 2033; and bioleaching from EUR 8.66 billion (2024) to EUR 18.2 billion by 2033. Under the baseline scenario, the EU's partial exclusion from these markets persists indefinitely, and European companies developing GMM products will increasingly serve non-EU markets or relocate R&D and commercialisation activities to jurisdictions such as the US, where a product-based regulatory approach has already enabled commercial deployment. Similarly, under the baseline, **organ processing practices** would be driven by local institutional arrangements rather than a coherent EU standard. Under the baseline, the share of EU transplantation programmes with active processing capability is projected to rise from an estimated 27% to approximately 35-38% by 2030 and 42-48% by 2035, before plateauing at approximately 48-55% by 2040. This plateau reflects the absence of an EU-level framework.

Regulatory sandboxes, which could provide structured testing environments for such innovations, are either absent or fragmented and underused across the relevant domains. No EU-level sandbox exists for veterinary innovation. Similarly, the EU food acquis does not provide for the operation of regulatory sandboxes; any existing food and feed sandboxes remain weakly connected to food law and unevenly available across Member States. The incoming SoHO risk-based authorisation model does not incorporate a sandbox mechanism under the baseline. In the SoHO domain specifically, expert estimates indicate that sandbox-eligible cases represent 5-10% of overall SoHO activities, translating to 90-250 eligible cases per annum; based on comparable sandbox acceptance rates observed in other regulatory domains (7-16%), between 6 and 40 sandboxes could be established per annum, illustrating both the latent demand for structured innovation pathways and the scale of innovation potential that remains unexploited under the current baseline.

The **innovation investment consequences** of these constraints are illustrated in the biosimilars domain. Under the current framework, the sector’s contribution to European CTs for biosimilar medicine candidates amounts to EUR 4.9 billion. Under the baseline, the near-term biosimilar MAA volume is projected at 25-45 per year, with the lower bound reflecting persistence of the biosimilar void and the upper bound assuming gradual

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spontaneous adaptation; the medium-term range rises to 35-55 per year. However, without formalised regulatory streamlining, per-product development costs remain at EUR 90-280 million over 6-9 years, with the CES representing the single largest component (EUR 19-26 million per product, approximately 57% of total clinical development costs being clinical), constraining the commercial viability of biosimilar development for lower-value reference biologics

Public health and safety

Under the baseline, while the EU maintains among the highest regulatory safety standards globally, aspects of the current regulatory architecture - particularly complexity, fragmentation and procedural duplication - can constrain the pace at which patients, consumers, and citizens benefit from biotechnological innovation. This tension will continue to manifest across the following interconnected dimensions:

First, delayed and uneven patient access to biotechnology-derived treatments will continue. The most consequential public health gap in the baseline concerns the widening distance between the availability of advanced biotechnology therapies and the speed at which EU patients can access them. The EU's share of global **clinical trial** initiations has halved from 18% in 2013 to 9% in 2023, with trial authorisation taking 100-120 days compared to approximately 30-60 days in the United States and China. For **ATMPs**, the current provisions of the CTR will continue to add up to 50 additional assessment days. In addition, foresight analyses projecting that up to 30% of **novel health biotechnology products** could be stalled by 2030-2038.

- Under the baseline, annual healthcare system savings from **biosimilars** are projected to rise from approximately EUR 13 billion in 2024 to EUR 16-22 billion per year by 2030 and EUR 22-35 billion per year by 2035-2038, but the upper bounds of these projections are constrained by the biosimilar void, meaning that the full savings potential depends on whether per-product development costs can be reduced sufficiently to make lower-value biologics commercially viable targets for biosimilar competition.
- In **organ transplantation**, the absence of a harmonised EU-level authorisation framework for organ processing means that advanced ex-vivo machine perfusion techniques diffuse unevenly, with no systematic mechanism for capturing processing-related safety data. Under the baseline, with a transplant growth trajectory of 1.54% CAGR annual transplant volumes are projected to rise to approximately 35,350 by 2030, 38,200 by 2035, and 41,200 by 2040. However, demand-side growth will outpace supply-side gains: waiting lists are expected to grow at approximately 0.5% per year to approximately 55,000-56,500 active patients by 2035 and 57,000-58,000 by 2040, meaning waiting-list mortality is projected to decline only marginally from approximately 3,366 deaths per year to approximately 3,100-3,200 by 2035 and 2,900-3,100 by 2040. The EU's dialysis-dependent population is projected to rise from approximately 310,000 to 330,000-340,000 by 2035 and 350,000-365,000 by 2040, with demand-side growth driven by population ageing, rising diabetes and hypertension prevalence, and widening dialysis initiation criteria outpacing the supply-side gains from transplant volume increases. The organ discard rate is projected to decline from approximately 12-13% to 10–11% by 2035 and 9-10.5% by 2040 under organic, centre-led adoption,

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but these gains will be concentrated in liver and lung organs in a small number of advanced Member States and will remain below the levels achievable with wider processing adoption.

Second, in the food and feed area, although safety standards will be maintained, innovation will remain constrained. EFSA's rigorous risk assessment framework continues to underpin world-leading food safety standards. In the area of nutrition, biotechnology can enhance nutritional properties. However, the current legislation faces limitations in addressing the scientific aspects given the limited mandate of EFSA to deliver scientific advice in relation to nutrition matters. This may become even more relevant in the future considering the expected increase in the prevalence of diet-related health issues in the coming years. Similarly, regarding the **One Health risks from veterinary regulatory design,** the dual-track system for GMO-containing VMPs generates an 'innovation tax' of 2-3 times longer approval periods without commensurate safety benefit: no GMO-containing VMP has ever received a negative opinion on its GMO component. The absence of a legal 'firewall' clarifying that animals treated with **GMO-derived VMPs** are not themselves classified as GMOs will continue to create commercial risk. It could deter farmer uptake of next-generation biotech vaccines, sustaining reliance on antimicrobials and impeding progress towards the EU's target of halving antimicrobial sales by 2030.

Third, the baseline presents a structural gap in the EU's capacity to detect and prevent biological threats. Wastewater-based surveillance beyond SARS-CoV-2 and influenza remains limited (only 11 Member States monitor antimicrobial resistance, six monitor emerging pathogens), with no agnostic detection layer for novel or engineered threats. Concurrently, synthetic nucleic acid screening remains voluntary and fragmented: only 69 of over 700 global custom synthesis providers are confirmed to screen. The RAND analysis estimates that the expected monetised annual loss due to biological threats across all event categories amounts to approximately EUR 184 billion for large-scale events (1% annual probability; EUR 19.6 trillion expected harm), supplemented by small-scale events (22% annual probability, EUR 72 million expected harm), agricultural events (4% probability, EUR 75.5 billion expected harm), and non-transmissible events (5–25% probability, EUR 121 million expected harm). For attacks specifically, the probability that they involve synthetic nucleic acid ordered from providers ranges from 30% to 70% depending on event type, while for accidents the corresponding probability ranges from 6% to 17%.

The biosecurity and biodefence baselines expose a separate category of public health vulnerability. In the domain of synthetic nucleic acid synthesis, the EU market (estimated at approximately EUR 850 million in 2024, representing approximately 0.2% of the European biotechnology market[162]) is expected to grow at an annual rate of 10-20%, but competitiveness is shaped by the absence of a level playing field: companies that voluntarily screen their customers face competitive disadvantages against providers that do not screen, and as DNA synthesis prices continue to decline, the cost of screening represents an increasing share of the final order price. Without a change in biosecurity

[162] Based on Grandview Research estimates of the DNA synthesis market https://www.grandviewresearch.com/horizon/outlook/dna-synthesis-market/europe and the Biotech market more generally https://www.grandviewresearch.com/horizon/outlook/biotechnology-market/europe

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policy, the annual probability of a large-scale biological attack or accident is estimated at 1%, with expected economic harm to the EU of a large-scale event of ca. EUR 20 trillion. The risk is set to increase further as synthetic DNA and RNA continues to become cheaper and more widely available. Meanwhile, pathogen surveillance remains reliant on clinical surveillance networks and targeted wastewater-based monitoring for known agents, with no systematic agnostic detection capacity for novel or engineered biological threats.

Environment and sustainability

The baseline reveals a tension at the intersection of the EU's biotechnology regulatory architecture and its environmental policy ambitions: while these frameworks uphold high environmental and safety standards, certain features – such elements of their process design and limited risk differentiation - can delay or constrain the deployment of biotechnology applications with significant potential to advance the environmental and sustainability objectives. This tension manifests most acutely across three intervention areas.

The most consequential environmental baseline deficit concerns **GMMs**. No GMM has been authorised for deliberate environmental release under Directive 2001/18/EC. As innovations utilising genetic engineering are not brought to the market in the EU, the EU is therefore entirely absent from this important segment of rapidly growing global markets in biofertilisation (EUR 1.18 billion in 2024, growing at 12.8% CAGR), microbial biocontrol (EUR 5.55 billion in 2025, 14.3% CAGR), bioremediation (EUR 14 billion in 2024, 9.9% CAGR), and bioleaching (EUR 8.65 billion in 2024, 8.9% CAGR), sectors with a combined global market exceeding EUR 29 billion and projected growth rates of 9-14% annually. In contrast, a product-based regulatory approach in the US has already enabled commercial deployment. Under the baseline scenario, this partial market exclusion persists indefinitely, and European companies developing GMM products will increasingly serve non-EU markets or relocate, while the environmental benefits of GMM-based microbial solutions for resource-efficient agriculture, pollution remediation, and sustainable extraction remain unrealised within the EU.

In the **veterinary domain**, the dual-track regulatory system for GMO-containing VMPs results in a regulatory friction that can slow the uptake of next-generation biotech vaccines in food-producing species, with potential ramifications for animal health, farmers and food security.

The **food chain sandbox landscape** is characterised by fragmentation and lack of coherence with Union law; only a few Member States operate sandbox-type mechanisms, none anchored in a harmonised EU framework under the General Food Law. As a result, findings and best practices cannot be systematically integrated into the evolution of the existing legal framework. This limits structured, pre-market testing of sustainable food production technologies, leaving innovation potential for the food system's environmental transition partly unexploited.

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4 APPROACH TO THE BIOTECH ACT

4.1 Objectives of the proposal

4.1.1 General objectives

The **general objective** of the proposed Regulation and Directive 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 single market, of biotechnology innovations, products and services, (iii) while safeguarding high standards for the protection of human health, animal health, patients and consumers, food and feed safety, the environment, and biosecurity.

4.1.2 Specific objectives

This general objective translates into the following **specific objectives,** as presented in the proposed Regulation and Directive: (i) strengthen the biotechnology sector and reinforce the EU's research, development and production capabilities; (ii) support funding of, investments in, and access to capital for, biotechnology companies and projects; (iii) improve the EU manufacturing capacity of, and expertise in biosimilars, including through international cooperation; (iv) facilitate the application of AI into the EU's biotechnology and health technology manufacturing ecosystems and frameworks, in line with the AI Act[163]; (v) ensure a legislative framework that encourages innovation and takes account of technological and scientific developments and progress; (vi) prevent the misuse of biotechnologies and strengthen biodefence capabilities and (vii) enable the effectiveness of the above specific objectives through a legislative framework conducive to the use of biotechnology innovations.

4.2 Choice of the legal instruments and legal basis

4.2.1 Choice of the legal instruments

A **Regulation** is the most suitable for measures requiring uniform application across the EU, such as those concerning recognition and support for heath biotechnology strategic projects and high impact health biotechnology strategic projects, and measures to boost EU biodefence and biosecurity and prevent biotechnology misuse. The Regulation is also justified to amend existing EU regulations in the area of health and food law. Its directly applicable nature ensures consistent implementation without national transposition. A **Directive** is the appropriate instrument for amendments to Directive 2001/18/EC and Directive 2010/53/EU.

4.2.2 Legal basis

The appropriate legal bases are therefore as follows:

- **Article 114 TFEU** is the basis for the adoption of measures that increase harmonisation and remove fragmentation and, therefore, seek to create a level playing

[163] Regulation (EU) 2024/1689, OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj.

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field within, and fully exploit the scale of the single market for biotechnology products and biomanufacturing. The proposal also seeks to achieve the objective of a high level of health and safety protection as per **Article 114(3)**.

– **Article 168(4) TFEU** is the basis for the adoption of certain measures that contribute to achieve a high level of human health protection, i.e. standards of quality and safety of organs and SoHO, blood and blood derivatives; measures in the veterinary and phytosanitary fields, and standards of quality and safety for medicinal products and devices for medical use.

- **Article 173(3) TFEU** is the basis for measures in support of Member States' action for the competitiveness of the EU's industry, in particular the provisions regarding the EU Health Biotechnology Investment Pilot.

4.3 Subsidiarity: necessity for EU action and EU added value

Under the subsidiarity principle, the Union may act in areas of non-exclusive competence only where the objectives of the proposed action cannot be sufficiently achieved by the Member States.

4.3.1 Necessity for EU action

The objectives of the proposed Biotech Act cannot be achieved by Member States acting alone, as the identified drivers are cross-border and systemic, affecting the functioning of the single market and the global competitiveness of EU companies. These challenges may differ in intensity across Member States and regions, but their nature is Union-wide. Access to finance is fragmented and EU biotechnology companies lack the capacity to access private finance at a competitive scale, including at later stages of development. European biotechnology clusters are dispersed and lack continental scale to compete globally. The development and deployment of AI in biotechnology remains limited, also due to the insufficient cross-border availability and sharing of relevant data.

While several Member States have taken action, these bottlenecks persist and improvements would remain slow and uneven. National measures alone cannot provide the scale, coordination and speed required, although in certain areas (e.g. access to finance, development of regional innovation ecosystems and clusters, and support to research infrastructures, etc.), Member States may still take complementary action alongside Union measures.

Important regulatory barriers stem from existing EU legislation, such as lack of legal clarity, complex or outdated rules, disproportionate administrative burden and additional national requirements. As these drivers originate in Union law, they cannot be effectively addressed by Member States acting individually. Union action is therefore necessary to facilitate innovation, enhance legal clarity and improve market access.

4.3.2 EU added value

The proposed actions focus on areas where there is a demonstrable value added in acting at EU-level due to the scale, speed and scope of the efforts needed.

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A harmonised but simplified EU regulatory framework, supported by strengthened collaboration in selected policy areas (access to capital, AI and data) is expected to ensure patients, users and citizens across the EU can benefit from biotechnology innovations.

A large market with a streamlined, fit-for-purpose regulatory framework ensures a level playing field and reduces compliance costs in the single market, thereby supporting biotechnology market uptake. Coordinated EU action in the field of biotechnologies will generate economies of scale, reduce duplication of efforts, increase legal certainty for cross border entrepreneurs, and unlock investments, infrastructures and skills development that Member States alone could not achieve. Union-level coordinated action is expected to yield higher benefits than fragmented national measures.

Regulatory streamlining and clarification measures will reduce administrative burden, accelerate time-to-market and improve the functioning of the internal market, also by addressing the observed diverging national interpretations and additional requirements. The proposed Biotech Act also seeks to reinforce the EU's strategic autonomy in a critical technological area while fostering adequate biosecurity safeguards and biodefence capabilities.

4.4 Intervention logic of the proposal

Figure 4.[164]

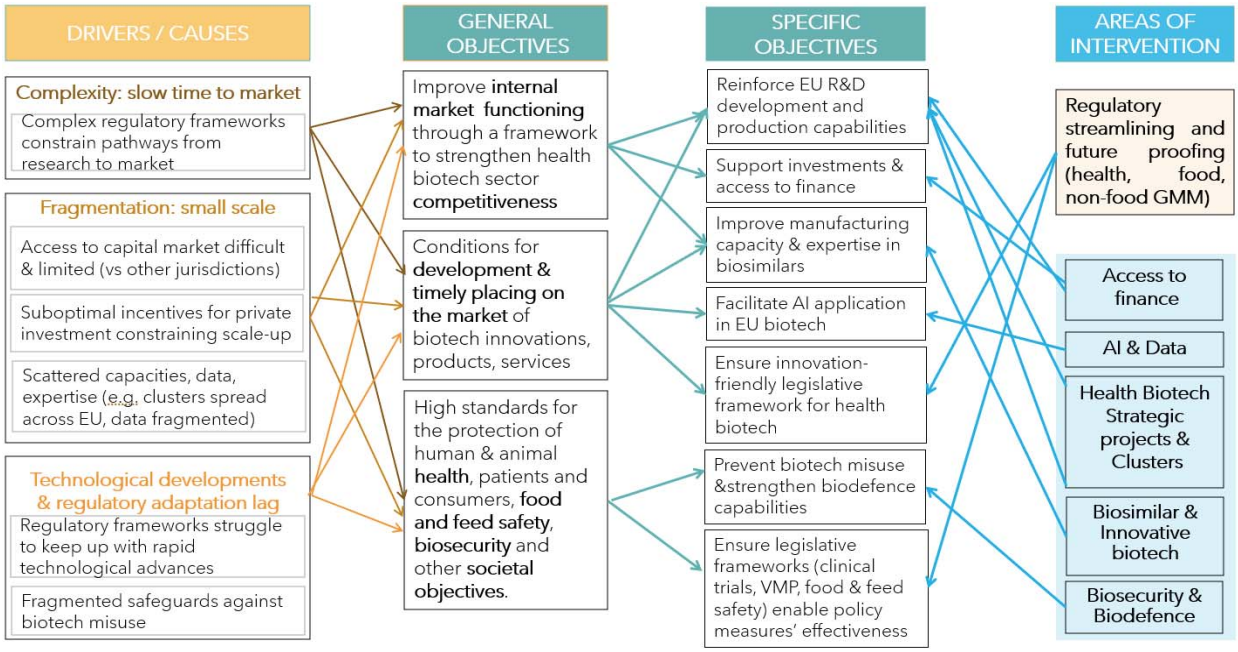

Figure 5 illustrates the overall architecture of the Biotech Act, highlighting the two complementary pillars of regulatory streamlining and facilitation to accelerate time-to-market and industrial enablers to strengthen the EU biotechnology ecosystem.

[164] Revised version of the intervention logic (see first version in COM(2025) 1022 finalhttps://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52025PC1022).

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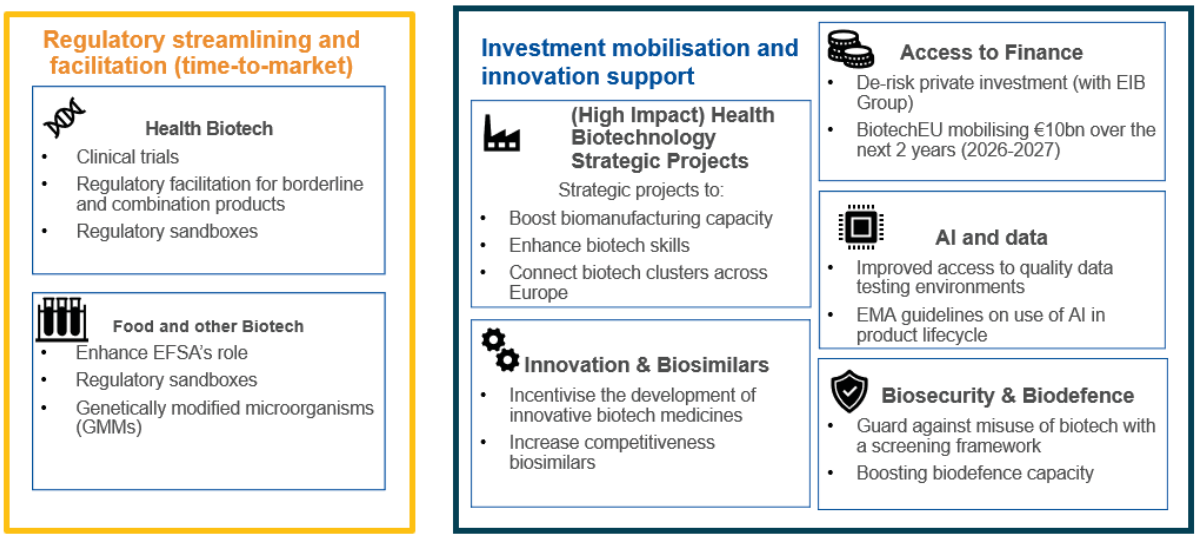
Figure 5. Biotech Act architecture



5 DESCRIPTION OF THE PROPOSED MEASURES AND ANALYSIS OF THEIR MAIN IMPACTS

The measures described below are outlined in the proposal for a Regulation and the proposal for a Directive[165]. They are presented in 17 packages of interventions, which fall under two categories: eight interventions related to regulatory streamlining and facilitation measures aiming at regulatory simplification (addressing drivers 1 and 3), and nine interventions linked to industrial enablers (addressing drivers 2 and 3). They are presented in more detail in Annex 7.

The summary assessment of measures[166] below includes tables capturing the key impacts across standard impact categories[167]. Where sufficiently robust evidence is available, key impacts are quantified and expressed using numerical estimates. Where quantification is not feasible, impacts are assessed qualitatively using a standardised rating scale[168], indicating the direction and relative magnitude of effects. For certain measures, tables are not used where the nature of the impacts or the available metrics are better suited to alternative forms of presentation (e.g. narrative analysis or visual representations), to ensure a more accurate and meaningful representation of the expected effects.

5.1 Interventions for regulatory simplification: measures and expected impacts

Chapter IX of the proposed Regulation and Directive include amendments to EU legislative frameworks in the areas of health, food and feed safety as well as GMMs, which aim to simplify existing procedures and accelerate time-to-market. These amendments are

[165] Annex 6 presents a mapping of the policy measures and the corresponding articles in the proposed Regulation and proposed Directive respectively.
[166] The assessment of impacts draws on the supporting studies presented in Annex 1.
[167] COB = conduct of business; Admin = administrative costs on businesses, including SMEs; CTI = competitiveness, trade and investment flows; Int Mar = functioning of the internal market and competition; I&R = innovation and research; PA = public authorities; H&S = public health and safety.
[168] ++ significant positive; + moderate positive; 0/+ marginal positive; 0 negligible/neutral; 0/– marginal negative; – moderate negative, -- significant negative.

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needed to ensure the effectiveness of the self-standing measures on industrial enablers laid down in the proposed Regulation.

5.1.1 Intervention n°1: Regulatory facilitation for novel health biotechnology products

The Regulation proposal sets out the provision of **regulatory assistance or support by the EU Health Biotechnology Support Network** to developers. This targeted, early-stage support will be particularly valuable for SMEs, which often lack extensive in-house regulatory expertise. The support will consist of facilitating information on, and access to, applicable legislative frameworks, including procedures for seeking guidance on regulatory status, rules applicable to products combining different technologies or regulatory frameworks, and access to regulatory sandboxes.

Further, the Regulation proposal establishes a **publicly available regulatory status repository** containing decisions, opinions and scientific recommendations regarding the regulatory status of health innovations across the EU. This repository aims to ensure transparency and consistency in regulatory determinations. It also aims to support advisory bodies mandated under sectoral legislation to determine the regulatory status of health products promptly and without undue delay, as well as to assist developers in shaping their regulatory strategy based on existing practice.

In addition, the proposal establishes a **foresight panel for emerging health innovation** comprising scientific and regulatory experts from the SoHO Coordination Board ('SCB'), the Medical Devices Coordination Group (MDCG), the Coordination group on Health Technology Assessment, the EMA, and the competent authorities of the Member States. The panel would provide early recommendations to the Commission, relevant EU agencies, and Member State competent authorities.

Moreover, a **cross-framework coordination for regulatory sandboxes in the health area** aims to allow for dialogue and information exchange among authorities operating regulatory sandboxes for health biotechnology products across different Union legislative frameworks (MDR, IVDR, SoHO Regulation, Pharmaceutical Regulation). Member State and Union-level authorities operating sandboxes under different frameworks would have to consult with each other and with the foresight panel regarding sandbox design and implementation, ensuring the potential integration of cross-framework aspects, which is needed given the increasing cross-cuting nature of health product innovations. The Commission, the EMA, the MDCG and the SCB facilitate cross-framework exchanges through the above-mentioned foresight panel, focusing on knowledge sharing (regulatory approaches, technological challenges, best practices) and regulatory learning (identifying implications for future legislative adaptations).

Finally, the proposal includes the possibility for **regulatory sandboxes for novel health biotechnology products**. These Commission-led sandboxes are designed for products that, due to their very early stage of development cannot be accommodated in existing sectoral sandboxes for novel products and whose development is hindered by challenges in identifying suitable regulatory procedures. They offer a framework – in the form of a subsidiary sandbox – for continued engagement with regulators and eventually a recommendation on the applicable existing framework for marketing authorisation. Upon

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substantiated request from developers, the Commission would assess applications and establish such a regulatory sandboxes through implementing act. These sandboxes would operate under time-limited sandbox plans specifying objectives, scope, participants, risk mitigation measures, and supervision arrangements. When assessing the applications for the establishment of such a subsidiary regulatory sandbox, and when developing and implementing the sandbox plan, the Commission may consult the EMA, the SCB, the MDCG and the Foresight Panel. Upon termination of the regulatory sandbox, the Commission would, upon a request from a developer, provide a recommendation on an existing appropriate regulatory procedural pathway for authorising the placing on the market and post-market surveillance and vigilance of the products concerned under an existing framework and may publish reports on lessons learned from the regulatory sandboxes.

Expected impacts:

It is crucial for research, business, investment and patients that the EU regulatory system can efficiently and adequately assess highly innovative health biotechnology products. With the above proposed measures, the Regulation proposal aims to introduce a comprehensive set of regulatory tools designed to make the EU regulatory system more predictable, efficient, and innovation-friendly without compromising safety requirements.

Conduct of business: These tools are expected to generate positive effects, as the repository would provide guiding documented regulatory interpretations for similar products, enabling firms to benchmark approaches. Navigation assistance by the Support Network will deliver targeted, early-stage support particularly valuable for SMEs, which often lack extensive in-house regulatory expertise and often rely on costly external consultancy. The foresight panel for emerging innovation would increase the regulatory readiness of the legislative frameworks in the health area by allowing them to integrate approaches to new technologies in a timely way. The panel, offering a forum for structured dialogue across the frameworks, also aims to ensure a cross-framework perspective on emerging technologies, which is needed as innovation increasingly develops across the silos of the different frameworks. This would make the existing frameworks more conducive to processing products based on new biotechnologies.

Regulatory sandboxes offer a controlled environment where developers of truly disruptive innovations are supported by regulators to identify suitable authorisation routes. Evidence from analogous sandboxes already applicable in other sectors, notably the UK Financial Conduct Authority study[169], suggests that **sandbox participation can reduce time-to-market by 20-40%, increase funding probability by 15-50%, and improve firm survival and patenting by 20-30%, with benefit-to-cost ratios ranging from 3/1- 10/1 over three to five years**.

The measures are also expected to have a positive impact on **administrative costs for businesses (including SMEs)**, through reducing administrative burden and costs by eliminating duplicative work and regulatory unpredictability for businesses and

[169] "Regulatory Sandboxes and Fintech Funding: Evidence from the UK" by G. Cornelli S. Doerr L. Gambacorta O. Merrouche (2020) act 2025: FCA Strategy.

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innovators. The measures aim to avoid undue delays and inefficiencies in regulatory pathways at an early stage of development.

R&I: The measures are also expected to generate positive impacts. Clearer pathways for researchers would reduce the chilling effect that uncertainty currently has on frontier research, encouraging more high-risk, high-novelty projects being developed and retained in Europe. The repository and regulatory assistance would help research institutions and firms plan development activities with confidence, while the sandboxes would ensure that truly disruptive research in novel products is still accommodated by the regulatory system. The foresight panel aims to connect the research world, where innovation emerges, with regulators. This would allow to reflect collaboratively on how to process products based on new technologies in the best way. These measures combined would guide funding bodies and researchers toward promising areas likely to be facilitated in a system conducive to innovation, eventually unlocking the potential for increasing EU gross domestic expenditure on research and development and better translating scientific breakthroughs into clinical applications.

Competitiveness, trade and investment: The Biotech Act as a whole is expected to address structural weaknesses that currently deter investment and early-stage scaling in Europe. Greater regulatory clarity and predictability, through the repository and navigation assistance, should reduce perceived regulatory risk, making the EU more attractive for biotech investment. The sandbox might signal to global investors that tailored regulatory tools exist for disruptive innovations, providing viable pathways to market and reducing uncertainty. The foresight panel demonstrates that the EU actively incorporates emerging trends into regulatory planning, aligning long-term policy with cutting-edge innovation and supporting confidence that governance and rules will adapt to technological progress. These measures have the potential to reverse declining trends in EU biotech and partially close the investment and commercialisation gap with the US and China.

Functioning of the internal market: Its functioning is expected to improve through greater harmonisation and transparency, as the repository promotes convergence by making consistent regulatory interpretations visible across Member States and reducing divergent classifications that fragment the market and distort competition. Navigation assistance and structured guidance minimise interpretive disputes and streamline cross-border compliance. For public authorities, the Biotech Act is designed to improve efficiency and preparedness by reducing duplication through the shared repository reference base, streamlining pre-authorisation interactions through navigation assistance, and building anticipatory capacity through the sandbox and foresight panel. Although establishing the sandbox and operating the foresight panel require upfront investment, these costs are limited given the expected low number of such sandboxes, borne at EU-level with no additional burden on Member States, and are expected to be offset by efficiency gains, reduced uncertainty, and scale effects. For public health and safety, the combined regulatory tools aim to offer a more innovation-conducive regulatory system, bringing more breakthrough products with potential major patient benefit to the market through a more efficient and adapted regulatory process – without compromising safety standards.

Public authorities: The proposed measures will entail only limited costs, while delivering long-term efficiency gains, particularly through streamlined authorisation processes that reduce administrative workload. Regulatory assistance via the support network will leverage existing national structures, adopting an antenna approach to better coordinate and deploy assistance providers at the national level. The regulatory status repository, though requiring initial development, will build upon existing or planned resources—such as the SoHO compendium or the Medical Devices Manual on Borderline and Classification—or simply reference national publications, thereby minimising duplication and resubmissions by developers. This, in turn, will further alleviate the burden on public authorities by reducing uncertainty and improving procedural efficiency. The foresight panel, while incurring marginal costs for logistical support, staff allocation, and expert compensation, is designed to strengthen anticipatory governance, ensuring greater preparedness for emerging technological shifts and ultimately lowering the future regulatory burden for complex, innovative products. Though no data exists on the cost-benefit ratio of a regulatory sandbox for novel health biotech products, its use will be highly targeted, keeping expenses minimal. Importantly, investments to establish the sandbox and operate the foresight panel will be fully funded by the Commission, imposing no additional financial obligations on Member States.

On **public health and safety**, no impacts are expected as safety standards remain untouched by these provisions.

Table 1. Summary assessment of the effects due to the intervention n°1

Policy measure	COB	Admin	CTI	Int mar	I&R	PA	H&S
Union regulatory status repository	+	+	+	+	+	n/a	0
Foresight Panel for Emerging Health Innovation	+	0	+	+	+	n/a	0
Regulatory sandboxes	+	+	+	+	+	n/a	0

5.1.2 Intervention n°2: Targeted regulatory reform of the General Food Law[170]

First, the Regulation proposal includes measures to accelerate and improve EFSA risk assessment processes for products subject to pre-market authorisation under Union food and feed law. These include:

- the **broadening of the scope of general pre-submission advice** (currently limited to administrative and regulatory requirements) to cover scientific matters, such as study design and testing strategies, while merging it with the renewal-related advice into a single, unified and simplified procedure;

[170] Regulation (EC) No 178/2002, OJ L 31, 1.2.2002, pp. 1–24. ELI: http://data.europa.eu/eli/reg/2002/178/oj.

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- a shortening to **three months** of the **procedural delay for non-compliance with the study notification requirements at pre-submission phase**;
- a targeted and limited **revision of the Scientific Committee/Scientific Panel governance** while maintaining the composition of the Scientific Committee;
- the **expansion of EFSA mandate** to provide scientific advice on all aspects of human nutrition.

Secondly, the proposal establishes a **comprehensive regulatory sandboxes framework within Union food law**, enabling Member States to create controlled environments for testing innovative technologies, products and substances at pre-market stage, data requirements and alternative regulatory requirements for food production, processing and distribution, feed produced for food-producing animals, food contact materials, and GMO-containing products. The proposal, however, **does not allow** the establishment **of regulatory sandboxes** for the following categories of products: **(a) Novel foods:** Experience has shown that certain types of novel foods involve highly innovative processes and complex scientific considerations, which require thorough oversight even at testing/experimental phase. This makes such foods less suited to the flexible, experimental nature of sandboxes. Furthermore, experience has shown that certain types of novel foods trigger ethical or cultural concerns among various consumer segments regarding their acceptability. Therefore, all aspects of novel foods in general are best addressed solely within the applicable rigorous regulatory framework established by Regulation (EU) 2015/2283 of the European Parliament and of the Council and should not be subject to regulatory sandboxes[171]; **(b) Recycled plastic food contact materials:** As regards innovations concerning novel plastic recycling technologies for plastics intended to come into contact with food, chapter IV of Commission Regulation (EU) 2022/1616 already establishes a framework that is meant to encourage the development of such novel technologies without prior authorisation. To ensure uniform rules on the development of novel recycling technologies that safeguard the health of the consumers, it is appropriate to exclude the development of recycling technologies from the possible use of regulatory sandboxes and rely instead on the procedure established in chapter IV of Regulation (EU) 2022/1616;[172] and, **(c) GMOs regulated under Part B of Directive 2001/18/EC:** For certain GMOs legal pathways already exist to allow testing of innovations, such as under Part B of Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) for purposes other than placing on the market, and therefore there should not be a duplication of paths in the interest of legal certainty. For this reason, regulatory sandboxes should be restricted to products containing or consisting of GMOs subject to authorisation under Part C of Directive 2001/18/EC.

[171] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1, ELI: http://data.europa.eu/eli/reg/2015/2283/oj).
[172] Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243, 20.9.2022, p. 3, ELI: http://data.europa.eu/eli/reg/2022/1616/oj).

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Regulatory sandboxes established in the context of Regulation (EC) No 178/2002 would not replace or circumvent existing pre-market authorisation procedures, as any product subject to pre-market authorisation – for example a new feed additive tested within a sandbox – would still need to undergo the full authorisation process before being placed on the EU market.

Expected impacts:

Conduct of business: The proposed extension of the scope of EFSA's general pre-submission advice to cover also scientific aspects is expected to significantly improve application dossier quality, reduce validation timelines and limit 'stop-the-clocks' during the risk assessment phase, thereby contributing to shorten time-to-market. By enabling applicants, especially SMEs and first-time applicants, to clarify study design, endpoints and methodologies in advance, with EFSA staff and external experts, the measures should increase predictability without undermining the 'non-committal' character of the pre-submission advice and without altering the applicant's burden of proof or EFSA's independence. Shortening the procedural delay for non-compliance with study notification obligations from six to three months further reduces procedural delays at pre-submission phase. In parallel, the introduction of a framework for regulatory sandboxes allows companies to test innovative technologies, products and processes in controlled environments before pre-market authorisation procedures, helping them to understand data requirements and regulatory expectations while maintaining oversight and safety. Overall, the conduct of business along the food chain is expected to become more innovation-friendly and less encumbered by avoidable procedural obstacles.

Administrative costs on businesses (including SMEs): the reform is expected to reduce unnecessary burdens linked to incomplete or poor-quality application dossiers. The enlarged scope of pre-submission advice should help applicants tailor their data generation more precisely to EFSA's requirements, avoiding mis-designed studies and decreasing the likelihood of repeated information requests and related delays. This is particularly important for SMEs and one-time applicants, for whom administrative and compliance costs weigh more heavily and who currently underuse existing advice instruments. By clarifying notification obligations and other procedural requirements at an early stage, the reform can streamline compliance and reduce the cumulative administrative effort over the life cycle of an application.

Competitiveness, trade and investment flows: The targeted amendments are expected to strengthen the EU's competitive position by making the regulatory environment more conducive to innovation while preserving high safety standards. Faster and more predictable risk assessment processes, fewer unnecessary administrative hurdles and reduced non-compliance penalties should lower the cost of bringing new products to market and make the EU a more attractive location for R&D and investment. By facilitating the development and approval of innovative products and related technologies, the reform supports the ability of EU firms to compete globally, leveraging the existing reputation of EU standards as a quality benchmark and reinforcing the EU's capacity to shape international norms.

Functioning of the internal market and competition: the reform is not expected to materially alter the baseline. The measures would apply horizontally and uniformly to all

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operators and Member States, and do not change the core harmonised framework established by the General Food Law and sectoral legislation. The level playing field across the internal market, underpinned by common risk-analysis principles and centralised EFSA risk assessment, would therefore remain intact.

Innovation and research: The new legislative framework for regulatory sandboxes is expected to be potentially transformative. By allowing supervised experimentation with technologies, products and substances in real-world conditions before pre-market authorisation, sandboxes significantly reduce both technological and regulatory risks for innovators, particularly start-ups and SMEs. Shorter learning cycles, direct feedback on safety, usability and acceptance, and clearer insight into data and evidentiary expectations should accelerate development and derisk investment in more ambitious, less incremental innovations. Participation in regulatory sandboxes established by Member States in accordance with the proposed amendment of the General Good Law, with visible regulatory engagement, is also likely to signal credibility to investors and industrial partners, facilitating access to finance and strategic collaborations. Overall, the measures are expected to improve the innovation climate in the EU food and feed sector, while keeping full pre-market authorisation requirements in place for products entering the market.

Public authorities: Concerning public authorities, notably national competent bodies, as well as EFSA, the reform is expected to improve the efficiency and the quality of scientific and regulatory outputs. Enhanced pre-submission advice, including scientific aspects and delivered by EFSA staff and external experts who may also support subsequent risk assessment, should improve dossier quality, reduce the frequency and duration of stop-the-clock procedures, and allow better allocation of EFSA's resources along the application process. Adjustments to EFSA's scientific panel governance – having EFSA staff chair panels and the Scientific Committee – are expected to reinforce coherence, methodological consistency and timeliness across assessments. While the expanded advice function may require some additional staff and coordination efforts, these are expected to be offset by savings from fewer procedural delays and less remedial work on weak-quality dossiers. For national authorities, participation in regulatory sandboxes offers a vehicle for systematic regulatory learning, enabling them to test data requirements and alternative regulatory approaches in a controlled setting and to feed robust evidence into EU-level scientific guidance and regulatory standards.

Public health and safety: the targeted amendments are designed to preserve, and potentially enhance in the longer term, the high level of safety standards currently afforded by EU food law. The streamlining of EFSA procedures and the extension of pre-submission advice aim to ensure that risk assessments are supplied with more relevant, better structured data, thereby supporting robust scientific opinions within shorter timelines. The expanded mandate of EFSA on nutrition matters, enabling EFSA to provide advice on all nutrition matters aim at further equip EU regulators with the necessary scientific knowledge to address challenges relating with the increasing prevalence of diet-related health issues. The regulatory sandbox framework, under strict safeguards, is expected to function as a regulatory learning tool, generating richer real-world evidence on exposures, hazards, patterns of use and the effectiveness of risk-management options. This should enable more accurate risk characterisation, more proportionate and effective risk-management measures, and earlier detection of potential safety issues in a controlled

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environment. Provided that capacity is available to analyse and use sandbox generated data, the overall effect is expected to be at least the maintenance, and potentially the strengthening, of the EU's high standards of public, animal and plant health protection and environmental safety.

Table 2. Summary assessment of the effects due to the intervention n°2

Policy measure	COB	Admin	CTI	Int Mar	I&R	PA	H&S
Improved timeliness and coherence of EFSA risk assessment processes	++	++	++	**0**	**0/+**	++	+
Regulatory framework for sandboxes in relation to food, feed, and GMOs	++	**0**	+	**0**	++	+	+

5.1.3 Intervention n°3: Targeted regulatory reform of the Advanced Therapy Medicinal Products (ATMPs) framework[173]

The proposed regulatory simplification and future-proofing of ATMPs includes two interconnected changes. First, it establishes a **risk-proportionate approach for clinical trials involving ATMPs containing or consisting of GMOs**. Under this approach sponsors would be exempted from submitting environmental risk assessments (ERAs) for products presenting no or negligible risks. Second, it aims at **future-proofing the regulatory framework** by amending the definition of tissue-engineered products to reflect technical and scientific advances, without extending the scope of the definition.

Expected impacts:

Overall, the reform is expected to strengthen the EU's attractiveness for high-risk biotech investment and support the growth of a rapidly expanding ATMP sector across Member States. The proposed amendments are expected to contribute to the EU's global competitiveness in biotechnology. Predominantly positive impacts are expected for businesses (in particular SMEs), research and innovation, the internal market, and public health.

Conduct of businesses, innovation and research: The introduction of a targeted exemption from ERA requirements **during the CT application phase** for clearly defined categories of low-risk investigational ATMPs directly addresses a key barrier to conducting clinical trials in Europe. Even where the recently agreed pharmaceutical legislation reform addresses the fragmentation of ERA requirements across Member States by centralising/harmonising the ERA procedure, requiring sponsors to obtain ERA approval prior to, or alongside, a CT authorisation, imposes a disproportionate regulatory

[173] Regulation (EC) No 1394/2007, OJ L 324, 10.12.2007, pp. 121–137. ELI: http://data.europa.eu/eli/reg/2007/1394/oj.

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burden at an early stage of development where the risk profile of the product is already well-characterised and low. This deters sponsors –particularly SMEs – from choosing the EU as a trial location, diverting early-stage innovation to jurisdictions with more streamlined processes. This competitive disadvantage is evident when comparing with the US: the Food and Drug Administration grants an exclusion from ERA for the vast majority of gene therapy Investigational New Drud (IND) applications at the clinical trial stage. That regulatory efficiency accelerates development timelines and explains why a significant share of ATMP clinical trials are conducted in the US rather than in the EU. While an ERA will still be required at the marketing authorisation stage, removing this requirement during clinical development removes a critical friction point. This provision is expected to attract clinical research on certain categories of ATMP in the EU even if it is not possible to quantify the precise impact at this stage.

An empowerment which would allow the Commission to amend the ATMP Regulation via delegated acts, in order to amend the definition of tissue engineered products will future-proof the ATMP framework by allowing to take into consideration **technical and scientific advancements** in the field of ATMPs. The need for such adaptations is underscored by concrete cases. For example, an acellular tissue-engineered vascular graft intended for urgent revascularisation in severe arterial injury has faced 18 years of classification uncertainty in the EU. Its acellular nature excluded it from the existing tissue-engineered product (TEP) definition. Meanwhile, the FDA approved the same product, demonstrating how regulatory rigidity can drive innovation away from Europe.

Both measures are expected to **lower operational costs** by **removing non-value-adding regulatory steps**, potentially removing a burden of 0.15-0.3 FTE-years per clinical trial application, and **reducing uncertainty.** Together, they **speed the transition** from research to clinical development, particularly for SMEs, while making the EU a more competitive and predictable environment for ATMP innovation.

Functioning of the internal market and competitiveness: The impact of streamlining Regulation (EU) No 536/2014, in conjunction with modifications to ERA requirements for investigational GMO-ATMPs and amendments to ATMP definitions, is expected to be profound and multifaceted concerning internal market dynamics and EU competitiveness. By exempting certain investigational ATMPs containing GMOs from full ERA submissions, this change not only facilitates faster progression from trial initiation to product development, but also significantly influences sponsors' decisions to conduct clinical trials in Europe. Consequently, the EU could emerge as a leading destination for biotech investment, accelerating the development of innovative therapies. Future-proofing ATMP definitions allows EU to enhance its scientific and technological leadership in biotechnology and regenerative medicine, while further cementing its reputation as a regulator pioneer. The reform is also expected to attract more high-risk capital, support the growth of more than 580 ATMP companies across over 20 Member States, and help maintain EU competitiveness.

Public health and safety: The Biotech Act targets procedural simplification rather than substantive relaxation of safety standards. The ERA exemptions only apply to ATMPs which fall into clearly defined categories with no or negligible risks. **Safety oversight** is maintained through the review of sponsor declarations within the clinical trial assessment process, comprehensive risk–benefit evaluation and long-term follow-up requirements.

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By reducing unnecessary procedural delays and shortening assessment timelines, the measures are expected to facilitate **earlier initiation of CTs** and potentially earlier **access** for EU patients to safe, effective and often transformative advanced therapies.

Furthermore, the ability to adapt ATMP definitions to scientific progress helps reduce the risk of regulatory blind spots for **emerging technologies**, ensuring that innovative therapies remain subject to the most appropriate regulatory oversight.

Table 3. Summary assessment of the effects due to the intervention n°3

Policy measure	COB	Admin	CTI	Int mar	I&R	PA	H&S
1. targeted ERA exemption	+	0	+	+	+	0	0
2. revised definition	+	+	+	+	+	0	0

5.1.4 Intervention n°4: Targeted regulatory reform of clinical trials[174]

The amendments to the CTR aim to shorten authorisation timelines, strengthen collaboration between Member States, and enhance regulatory efficiency without compromising safety, quality, or ethical standards.

The proposed amendments articulate around five pillars:

(i) Faster authorisation procedures

Authorisation timelines for initial clinical trial applications are reduced from 106 to 75 days, or from 75 to 47 days, where no additional information is requested from the sponsor. For substantial modifications[175], timelines are reduced from 96 to 47 days or from 64 to 33 days where there is no additional request for information. The additional 50-day assessment period for ATMPs is removed.

(ii) More predictable and efficient authorisation procedures

The shorter authorisation timelines are supported by procedural changes to increase efficiency, cooperation, and consistency across Member States. The reporting Member State (RMS) leads the evaluation of Part I[176] of the trial application, with other Member

[174] Regulation (EU) No 536/2014, OJ L 158, 27.5.2014, pp. 1–76. ELI: http://data.europa.eu/eli/reg/2014/536/oj.
[175] Substantial modifications as defined in the proposed amendments to Regulation (EU) No.536/2014, Art. 2 mean '*any change to any aspect of the clinical trial which is made after the notification of a decision referred to in Article 8 in at least one Member State concerned and which is likely to have a substantial impact on the safety or rights of the subject or on the reliability and robustness of data generated in the clinical trial.*'
[176] The application dossier for the authorisation of a clinical trial in the EU is split into Part I and Part II. Part I contains overarching scientific, medical, and technical information about the investigational medicinal product (IMP), the clinical trial design and participants' safety. The RMS leads the assessment of Part I. Part II contains the national, ethical, and national information (e.g., informed consent, recruitment related information, site and investigator suitability, insurance) assessed separately by each Member State concerned.

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States concerned providing complementary considerations. For initial applications, the validation of Part I will be carried out solely by the RMS without coordination and consolidation steps with the other Member States concerned. It is also allowing the RMS to initiate the assessment already during the validation phase, shortening the overall assessment time by two weeks. The ethics committee of the RMS will be mandatorily engaged in the review of Part I to ensure that the ethical review is fully integrated with scientific and regulatory assessments. The scope of the ethical review and the mandate of the Member States concerned in the assessment are clarified. Maximum timelines are designed to allocate seven day-periods per assessment step, ensuring deadlines do not fall on weekends and thereby avoiding automatic extensions. This approach ensures predictability in timelines for sponsors and regulatory bodies. Substantial modifications to Part I and/or Part II for changes that may significantly affect participants' rights, safety, or data reliability can be assessed in parallel, with significantly shorter assessment times.

Efficiency is further improved through the establishment and re-use of a single investigational product core dossier containing documents common to all trials with the same investigational medicinal product (IMP), a mandatory use of harmonised EU templates, and by shifting translation checks from Part I to Part II. An upgraded EU portal enhances communication between sponsors and assessing Member States during assessments.

The amendments also encourage participation of vulnerable populations in clinical trials, by carefully weighing the potential risks and benefits of their exclusion versus inclusion in trials. Additionally, women who become pregnant or start breast-feeding during their trial participation will not be automatically excluded from the trial. Their continued participation will instead be evaluated by assessing the risks and benefits involved.

(iii) Context-specific clinical trial authorisation procedures

The Regulation proposal sets out three tailored authorisation procedures to streamline regulatory requirements to the specific context and risks of the clinical trial.

1. It introduces a single assessment procedure for combined studies involving both medicines and medical devices or medicines and *in vitro* diagnostic medical devices, rationalising the relevant provisions of three EU regulations (i.e. CTR, MDR, and IVDR).
2. It introduces a fast-track authorisation procedure with simplified requirements for multinational clinical trials to ensure availability of crisis-relevant medicines to prevent/contain health threats, provide timely treatment options, or facilitate diagnosis in the context of an emerging or a recognised serious cross-border threat to health at Union level[177]. The procedure will be automatically applicable in a recognised serious cross-border threat to health at Union level. The Commission would be further empowered to define, through implementing acts, transparent criteria and a process for declaring the procedure applicable in the context of an emerging serious cross-border threat to health.

[177] In accordance with Article 23 of Regulation (EU) 2022/2371 (see footnote 40, page 9).

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3. It strengthens the risk-proportionate approach by more precisely aligning regulatory requirements with the level of risk associated with a clinical trial. A new risk category, minimal intervention trials, is introduced to cover post-marketing authorisation trials, which will require ethical review only for the authorization itself.

(iv) Innovation and Harmonised Data Governance

The proposal facilitates the integration of AI and digital tools (e.g. e-informed consent), reinforces direct shipment of IMPs to patients and improves trial design, execution and oversight. It introduces regulatory sandboxes to test innovative approaches and establishes a single legal basis under the requirements of the GDPR for processing of personal data to provide legal clarity and streamline multinational trials.

(v) Governance and Enforcement

The proposal strengthens EU governance by improving cooperation among Member States' authorities and Ethics Committees by expanding the role for the Clinical Trials Coordination and Advisory Group. National competent authorities and ethics committees must have sufficient personnel and resources to perform assessments. National competent authorities gain stronger inspection powers, including unannounced and joint inspections, which may be delegated to other Member States or agencies. Harmonised guidelines standardise IMP distribution oversight. The Commission can verify compliance within the EU and assess whether clinical trials outside the EU meet good clinical practice and ethical standards.

Expected impacts:

The policy measures outlined above aim to make the EU more attractive to sponsors, by reducing administrative burden and shorten time to market, thereby increasing the number of clinical trials conducted within the EU. The impact of the regulatory changes is assessed both quantitatively and qualitatively through a two-step procedure (Figure 6). First, the expected effect on the total number of EU-based clinical trials resulting from the simplification and acceleration of the authorisation process and conduct of clinical trials is examined. Second, the broader economic implications and public health benefits arising from the increased number of clinical trials conducted across Member States are assessed.

Figure 6. Schematic illustration of the assessment of possible impacts of the proposed regulatory changes to the Clinical Trials Regulation

Step 1 - Expected impact on the number of clinicals run in the EU

Faster, more efficient and better coordinated procedures, as well as the uptake of AI and digital tools are expected to increase the number of clinical trials conducted in the EU/EEA[178,179] and encourage participation by a wider set of Member States. This can reduce current concentration in a few jurisdictions, level the playing field for SMEs and support a more integrated EU clinical research market.

According to one survey with sponsors[180], the anticipated increase of clinical trial authorisations for selected individual policy changes lies between 5% and 28%, and by 32% for a bundled sub-set of policy measures included in the proposed Biotech Act[181]. Another study, based on limited empirical evidence, suggests that the proposed revision of the CTR could increase the number of clinical trials by on average of 10%[182]. In addition, sponsors believe that the regulatory change will foster multinational trials in the EU with a broader geographic scope (see Figure 7).

To quantify the economic and public health impacts of the regulatory change, we assume that the number of clinical trials will increase by 10% to 30%. These estimates draw on two separate studies[183]. The lower bound reflects the average projected increase in clinical trials of 10%. This estimate also aligns with the ACT EU target of having additional 500 multinational clinical trials over the next five years[184]. Meanwhile, the upper bound is derived from survey responses collected from sponsors as part of the second study[185]. The range was selected to reflect the differing findings of the two studies, while accounting for the respective strengths and limitations of each. The wide disparity in these estimates highlights the challenges in assessing the reform's impact on clinical trial activity, given data limitations and inherent uncertainties about future developments.

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[178] *Regulatory Framework Study (forthcoming)*

[179] Between January 2022 and December 2025, on average 2,484 new trial applications were submitted per year. This includes the transition period to the Clinical Trial Regulation which went from 31 January 2022 to 31 January 2025. Source: EU clinical trials during the 3-year CTR transition period.

[180] A survey with 48 sponsors, among those commercial sponsors, was conducted. It is to note that not all respondents replied all questions. For further information, see *Regulatory Framework Study (forthcoming)*

[181] In the survey, sponsors were asked to assess the impact of selected policies individually on the expected change in clinical trials. For the policies comparably to the changes included in the proposal of the Biotech Act the impact of the single measure lies between 5% and 28%. It is to note that the survey replies are subjective assessment from the respondents considering the difficulties that come along with projecting the future. Nevertheless, these figures can be used as indicative evidence. For further information see *Regulatory Framework Study (forthcoming).*

[182] *Rapid Assessment Scenario Study (forthcoming).* The study, based on limited empirical evidence, distinguishes between two hypothetical scenarios regarding the potential impact of the BioTech Act on the projected number of clinical trials in the EU. In the first scenario, a moderate increase in the number of clinical trials by 4% to 8% is anticipated. This is attributed to improved efficacy and attractiveness of performing clinical trials in the EU, driven by increased domestic uptake among sponsors already operating within the region. The second scenario assumes that, in addition to increased domestic uptake, sponsors relocate clinical trial activities from other regions to the EU/EEA as a result of the reforms in the Biotech Act, leading to an estimated increase of 8% to 16%. As the Biotech Act is expected to simplify authorisation processes and the conduct of trials for sponsors, it is considered plausible that some sponsors may relocate their clinical trials to the EU following the amendments of the Regulation. Therefore, the average of both scenarios is used as a benchmark for the lower bound.

183 Studies *Regulatory Framework Study (forthcoming)* and *Rapid Assessment Scenario Study (forthcoming).*

[184] For further information, see: New targets for clinical trials in Europe | European Medicines Agency (EMA). For the purposes of this analysis, the same 11.1% increase is also assumed for mononational clinical trials. For Q1/2026 the KPI has been evaluated for the first time. This quarter, 19 additional multinational trial applications have been submitted. If extrapolated annually, this would represent an 8% increase in trials without any changes to the regulatory framework.

[185] *Regulatory Framework Study (forthcoming)*

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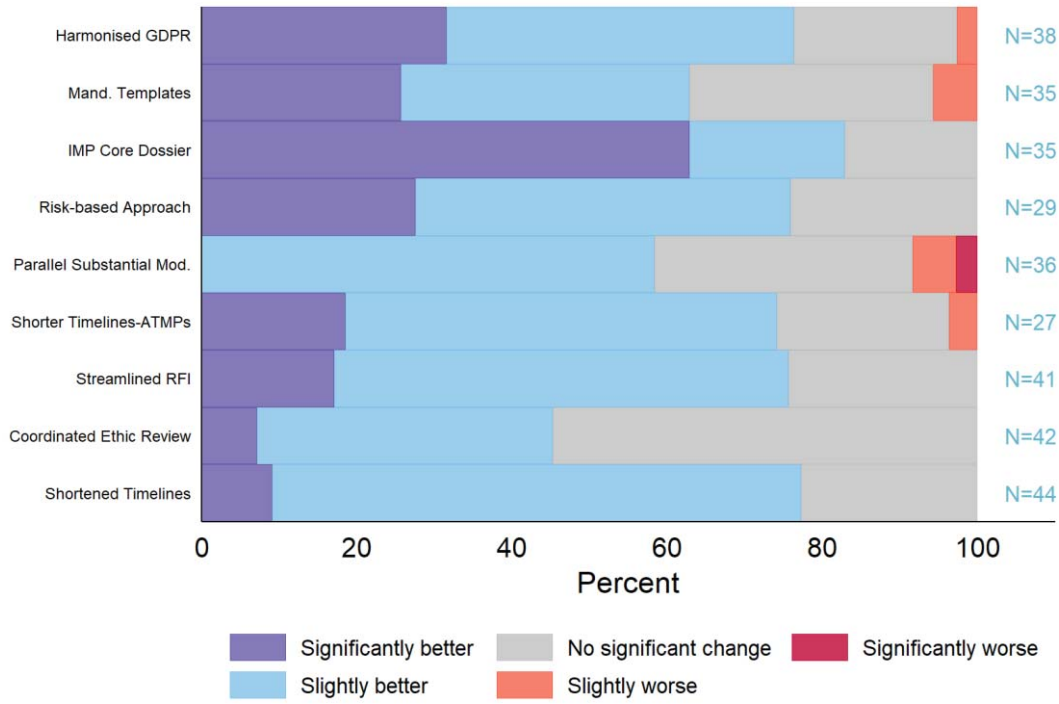
Figure 7: Survey replies from sponsors to the following question: "*To what extent would each of the following policies expand the geographic scope of multinational clinical trials in the EU, by increasing the number of participating Member States in a clinical trial in the EU?*"[186]



Step 2 – Economic and Public Health Impact

The subsequent section assesses the expected impact of the increase in the number of authorised clinical trials on economic and public health outcomes. Economic impacts are evaluated along the following dimensions: competitiveness, gross-value added (GVA), work productivity, employment, R&D spillovers, a simplified cost-benefit analysis for sponsors, and relevant EU and national actors involved. The public health impact is measured by the expected change in number of enrolled participants and the composition of the participant populations.

(a) Economic impacts

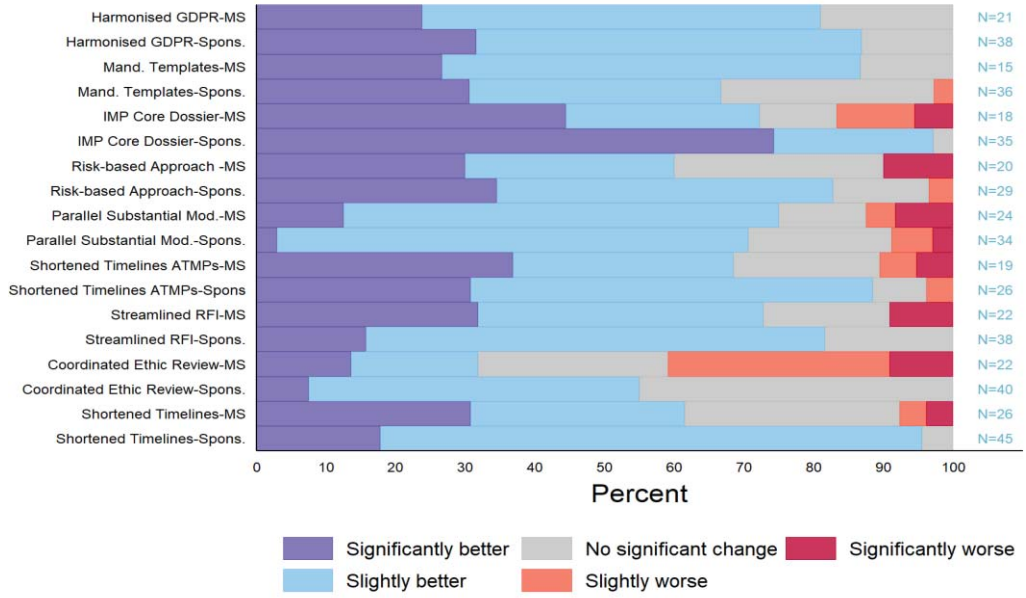
Survey responses from sponsors and Member State representatives[187], including national competent authorities, ethics committees and ministries, suggest that a subset of policy

[186] *Regulatory Framework Study, forthcoming*. In the survey, sponsors were asked to assess the impact of selected policies individually. The policies presented in this figure are those most closely to the ones included in the Commission proposal adopted on 16 December 2025. Please note that there is still some slight deviation between the described policy scenarios assessed in the survey and the policy changes proposed in the Commission proposal.

[187] For further information, see report *Regulatory Framework Study, forthcoming*. The policies presented in this figure are those most closely to the ones included in the Commission proposal adopted on 16 December 2025. Please note that there is still some slight deviation between the described policy scenarios assessed in the survey and the policy changes proposed in the Commission proposal.

measures introduced in amendments to the CTR are expected to strengthen the EU's **competitiveness** (see Figure 8).

Figure 8: Survey replies to the following question "*To what extent would the policies increase/decrease the competitiveness of the EU compared to the baseline in terms of, e.g. R&D expenditures in the pharmaceutical sector including revenue for healthcare providers, number of marketing authorisations and patents granted in the EU/EEA, Gross Value Added in the pharmaceutical sector*?[188]



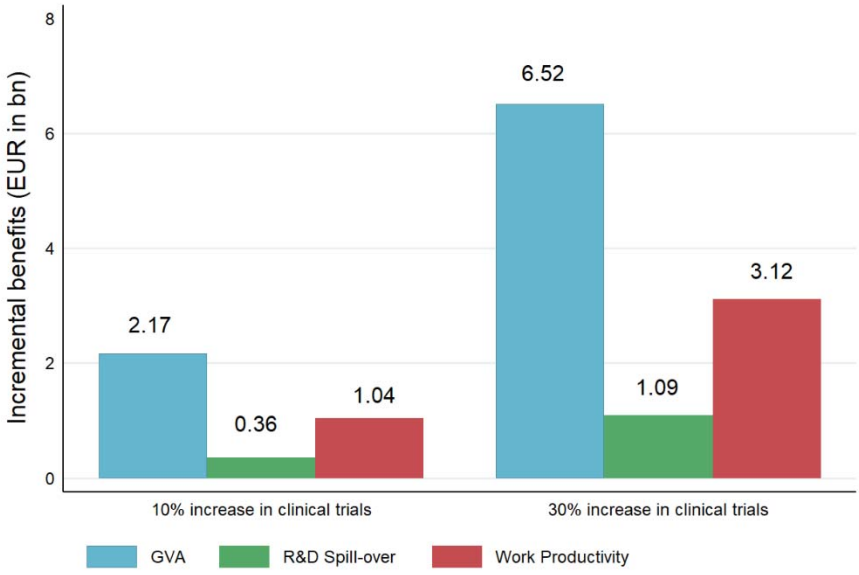
The **economic impact** for commercially-sponsored clinical trials is likely to differ from that of non-commercial/academic ones due to systematic differences in their characteristics. In particular, 71.5% of applications submitted by commercial sponsors involve multinational trials, whereas 85.6% of applications submitted by academic sponsors relate to mono-national trials.[189] Academic sponsors are also more likely to conduct late-phase clinical trials, particularly post-marketing authorisation trials[190], which may entail different cost structures[191]. These differences suggest that the economic impacts of commercial and non-commercial clinical trials should be assessed separately.

Between January 2022 and January 2025, commercial trials accounted for 53.1% of all clinical trials authorised in the EU. Figure 9 illustrates the incremental benefit for an increase in clinical trials across three economic dimensions, *i.e.* **GVA, R&D spill-over**

[188] *Regulatory Framework Study, forthcoming.* In the survey, sponsors and Member State representatives were asked to assess the impact of selected policies individually. The policies presented in this figure are those most closely to the ones included in the Commission proposal adopted on 16 December 2025. Please note that there is still some slight deviation between the described policy scenarios assessed in the survey and the policy changes proposed in the Commission proposal.
[189] EU clinical trials during the 3-year CTR transition period (see p.9).
[190] EU clinical trials during the 3-year CTR transition period (see p.26).
[191] Fast-track landscape analyses to assess the regulatory clinical trial eco-system in the EU/EEA and in other relevant regions (forthcoming)

and work productivity[192] assuming an increase of 10% or 30% in commercial clinical trials as a result of the legislative changes proposed in the amendments to the CTR. A 10% increase in clinical trials is estimated to generate approximately **EUR 3.6 billion** in economic gains and create roughly **16,500 additional jobs** across the EU, while a 30% increase could result in approximately **EUR 10.7 billion** in economic gains and **49,500 additional jobs**[193].

Figure 9. Economic impacts assuming a 10% and 30% increase in commercial clinical trials[194]



The value of non-commercial trials on the economy has been recently demonstrated for some regions and countries, such as the UK[195]. Due to a lack of sufficiently robust and comparable data for the EU, this analysis does not attempt to quantify the economic impacts of the proposed regulatory changes for non-commercial trials. Therefore, the estimated economic impacts presented for commercial trials should be considered a lower bound estimate of the overall economic gains associated with the increase in the number of authorised cinical trials.

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[192] The GVA measures "*the value of output less the value of intermediate consumption; it is a measure of the contribution to GDP made by an individual producer, industry or sector*" (OECD; National Accounts at a Glance 2009 (EN)). R&D spill-overs measure clinical research activities creating knowledge, products, and processes which can be used by other companies. Workforce productivity measures how improved treatment options enhance people's health and thereby reducing sick days (EFPIA report 2026; the-economic-impact-of-industry-clinical-trials-across-europe.pdf).

[193] The values are calculated based on the following assumptions/parameters: (1) between 2022 and 2025 the annual number of authorised industry commercial trials was 1,509 (EU clinical trials during the 3-year CTR transition period); (2) The reported values in EFPIA 2026 the-economic-impact-of-industry-clinical-trials-across-europe.pdf are used to calculate incremental effects per trial. (3) There is a linear relationship between the increase in clinical trials and the incremental benefits.

[194] Commission own calculations based on information from EFPIA (2026) the-economic-impact-of-industry-clinical-trials-across-europe.pdf and EU clinical trials during the 3-year CTR transition period.

[195] Frontier Economics The value of non-commercial clinical research | Frontier Economics.

The proposed regulatory changes are expected to encourage more non-commercial trials, particularly minimal-intervention and low-intervention trials, by simplifying authorisation requirements and streamlining the conduct of trials typically conducted by academic sponsors[196]. Survey replies support the assumption that these amendments would reduce administrative barriers and make academic research easier, including increased availability of data from comparative trial [197] or the Health Technology Assessment (HTA) procedures. The primary advantages extend beyond the authorisation stage, encompassing risk-proportionate safety reporting, more targeted monitoring, and flexible models for the supply and distribution of investigational medicinal products.

To assess the efficiency of the amendments proposed to the Clinical Trial Regulation, a **simplified cost-benefit analysis** has been carried out as part of two supporting studies. These analyses provide a broad indication of the range of expected cost savings based on different methodologies.

One study evaluates the impacts using estimates from sponsors and public authorities, collected through targeted surveys, on expected changes in costs and the number of clinical trials[198]. Based on these estimates annual cost savings for setting up and the conduct of trials are approximately EUR 1.24 billion for a subset of policy measures included in the Commission proposal. However, it should be noted that response rates for some survey questions have been low (N<10), which may limit the representativeness of conclusions on cost patterns. The policy measures assessed are largely aligned with, but not identical to, those in the Commission's proposal. Additionally, not all the proposed changes are captured therein, and those are expected to have a positive effect on clinical trials in Europe. Important policy changes, such as the introduction of a single assessment procedure for combined studies, the integration of artificial intelligence, and new structures for governance and enforcement measures, are not part of the assessment as the survey was designed prior to the finalisation of the proposed amendments. Therefore, the calculations can be used as suggestive evidence rather than precise estimates of the cost savings.

The assessment of a second study[199] considers the total set of measures included in the Commission proposal. It estimates direct annual cost-savings for sponsors of approximately EUR 1.5 billion to EUR 3.1 billion through more effective administration and faster authorisation procedures and indirect annual savings of equal amounts through an accelerated conduct of clinical trials. The calculations are based on the assumptions that the amendments reduce the total costs of a clinical trial by 5% due to more effective administration, a clinical trial runs on average 2 to 2.5 years, the average costs of a clinical trial amount EUR 30-50 million and the number of clinical trials remains unchanged. It is to be noted that the limited data availability on the average costs of a clinical trial may substantially impact the estimated cost reductions due to the proposed regulatory changes.

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[196] Over 90% of low intervention trials are conducted by non-commercial sponsors (EU clinical trials during the 3-year CTR transition period).
[197] *Regulatory Framework Study (forthcoming)*
[198] See *Regulatory Framework Study (forthcoming)*
[199] See *Rapid Assessment Scenario Study (forthcoming).*

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(b) Expected Impact on Public Health

Clinical trials provide early access to innovative treatments for European patients, up to five to ten years before the commercial launch. In the case of rare diseases, clinical trials often present the only available treatment option for patients[200]. In this context, a crucial indicator is not only the number of clinical trials conducted but also the number of participants enrolled in those trials.

Between 2023 and 2025, the estimated average annual number of newly enrolled participants was 163,643 for commercial trials and 341,632 for non-commercial trials[201]. Assuming a 10% to 30% increase in the number of authorised clinical trials, with the median number of participants per trial remaining constant, this would result in an additional 7,847[202] to 23,540 newly enrolled participants included in commercial trials and 10,381 to 31,145 in non-commercial trials per year.

The increase in the number of participants is expected to contribute to improved patient health outcomes and quality of life, while at the same time generating more robust evidence to inform Europe's treatment guidelines and HTA decisions, and potentially facilitating faster market authorisation of the medical products under investigation.

In addition to increasing access to innovative and improved treatment options through clinical trials, the new provisions should also support efforts to reduce health inequalities. For example, pregnant and breastfeeding women would no longer be automatically excluded from trial participation, as is the case under the current regulatory framework. Instead, their participation would be evaluated based on the associated risks and benefits. Furthermore, the inclusion of vulnerable populations, such as minors and pregnant or breastfeeding women, is encouraged, provided that the potential benefits of participation are carefully weighed against the associated risks.

Finally, the anticipated increase in clinical trial activity is expected to foster science, innovation, and skill development. Conducting clinical trials generates knowledge, products, and technologies that stimulate further innovation, drive economic activity, and contribute to the development of a more highly skilled workforce across the sector. These spillover benefits from R&D extend beyond the returns captured by private investors, creating broader societal gains. The associated economic impact of these spillover effects for commercial trials is quantified and presented by the value of the R&D spillover in Figure 9.

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[200] See *Regulatory Framework Study (forthcoming)* and EFPIA (2024) assessing-the-clinical-trial-ecosystem-in-europe.pdf

[201] The data are retrieved from CTIS and represents the estimated mean number of participants by year of clinical trial authorisation for all initial applications between 2023 and 2025.

[202] The calculations rely on the **median** number of participants in commercial trials (52) and non-commercial trials (78) for 2023–2025, rather than the **mean**, to mitigate bias from outliers. This approach yields a more conservative estimate than using average participant numbers (108 per commercial trial and 257 per non-commercial trial).

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Table 4. Summary assessment of the effects due to the policy measure

Policy measures	COB	ADMIN	CTI	INT MAR	I&R	PA	H&S
Accelerated and streamlined clinical trial authorisation procedures	++	++	++	+	0/+	0/+	+
Clinical trial regulatory sandboxes	0/+	+	+	+	++	++	0/+
Digital innovation and harmonised data governance for clinical trials	+	++	++	++	+	+	+
Combined Studies	+	+	+	++	++	++	0/+
Governance and enforcement	+	+	+	++	0/+	+	++

5.1.5 Intervention n°5: Targeted regulatory reform of Veterinary Medicinal Products (VMPs)[203]

First, the regulatory framework for **VMPs containing or consisting of GMOs is streamlined** by exempting from EU GMO legislation VMPs containing or consisting of GMOs authorised or manufactured in accordance with VMP Regulation, which are to be assessed solely under the VMP Regulation. Additionally, it is clarified that animals treated with VMPs do not become, for this sole reason subject to the GMO legislation.

Second, the **handling of variations not requiring assessment is simplified:**

- For variations not requiring assessment with no impact on the product information, submissions can be consolidated on a yearly basis.
- For all variations not requiring assessment, confirmation by the competent authorities is no longer required.

Third, the **SPC** for biotechnology VMPs treating zoonoses is extended under certain conditions:

- the product must be developed by means of a biotechnology process as defined in Article 42(2)(a) of Regulation 2019/6;
- it must be intended to diagnose, treat, or prevent zoonotic diseases;
- it must contain a new active substance distinctly different from any authorised medicinal product in the EU;
- it must have a mechanism of action distinctly different from existing products for the same zoonotic disease, with at least equivalent safety and efficacy;

[203] Regulation (EU) 2019/6, OJ L 4, 7.1.2019, pp. 43–167. ELI: http://data.europa.eu/eli/reg/2019/6/oj.

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- and at least one manufacturing step (excluding packaging, quality testing, and certification) must be performed in the EU.

Fourth, the Regulation proposal establishes a **regulatory sandbox framework** for innovative technologies, methods or products related to animal health.

Expected impacts:

The measure related to the **VMPs containing or consisting of GMOs** delivers procedural simplification (1-3 month CT application saving; cumulative EUR 5-14.5 million in CTA administrative savings; EUR 560,000 in marketing authorisation dossier savings over the period 2026-2040) and cross-Member States harmonisation, with a high-value, zero-cost legal clarification on GMO status of treated animals eliminating a latent risk. While standard marketing authorisation timelines are unaffected, the benefit materialises under accelerated/emergency pathways (estimated at 30-60 days for 1-3 products/year). While no measurable increase of marketed products is expected, the measure contributes to preventing the progressive offshoring of the innovation process to other jurisdictions where next generation veterinary biotechnology would be developed and trialled.

The proposed SPC extension for VMPs is a low to medium impact signalling instrument. No near-term commercial benefit is expected due to the virtual non-existence of veterinary biosimilar competition and the fact that existing data protection periods already outlast patent/SPC terms. Therefore, the impact of this measure is not appropriately captured through quantification of direct commercial or cost effects, because the primary function of the SPC extension is not to deliver measurable near-term revenue protection but to serve three signalling and future-proofing purposes:

1. **Policy signalling:** The measure communicates EU institutional commitment to veterinary biotechnology innovation addressing zoonotic diseases, potentially influencing long-term R&D allocation decisions at the margin.
2. **Future-proofing:** Should veterinary biosimilar competition eventually materialise at scale (plausibly from the mid-2030s onward), the mechanism would already be in place, avoiding the need for reactive legislative intervention.
3. **EU manufacturing incentive:** The requirement that at least one manufacturing step be performed in the Union introduces an explicit industrial policy lever.

There is no centralised EU database publicly listing how many VMPs have obtained SPCs, and national patent office data are not often broken down by human vs. veterinary use. However, based on data provided by the EMA, out of the 28 biotechnology VMPs for zoonotic diseases approved between 2010 and 2025, only 8 fulfilled all eligibility criteria for the SPC extension. On average, this is 1 product for each 2 years. A forward-looking estimate would foresee **an average of 3 eligible products per year over 2026-2040**, based on the retrospective eligibility analysis (8 out of 28 over 16 years ≈ 2/year) and adjusted upward modestly to reflect the growing share of biotech vaccines in the pipeline. The targeted SPC extension is designed to be cost-neutral for the EMA. Given the narrow scope of the measure, the EMA is expected to handle a very low volume of applications.

The possibility of using a regulatory sandbox for animal health innovation provides a structured framework to facilitate the development and marketing or use of products, methods or technologies that are not regulated under EU legislation. Expected utilisation is modest (~1 sandbox per five years; 2-3 established over 2026-2040). Its primary value is qualitative: pathway creation, evidence generation for adaptive regulation, and investment signalling. The proposed measure creates new EMA/Commission responsibilities (application assessment, implementing acts, reporting).

Finally**, the reduction of burden for the handling of variations not requiring assessment** delivers the most quantifiable and immediately realised benefits with a central estimate of EUR 22.5 million present-value cumulative staff cost savings (2025-2040) and 45-55% reduction in submission events. This will result in approximately EUR 2.5 million/year in fee savings for applicants. The removal of the confirmatory step reduces the national competent authorities workload. It creates a one-off IT cost for EMA of EUR 150,000-300,000. The measure is a purely administrative reform and has no impact on safety or efficacy. The proposed measure has received positive feedback from industry.

Table 5. Summary assessment of the effects due to the intervention n°5

Policy measure	COB	Admin	CTI	Int mar	I&R	PA	H&S
1. GMO exemption	+	+	+	+	+	**0**	+
2. Variations revision	+	++	**0**	**0**/+	**0**	+	**0**
3. SPC extension	**0**/+	**0**	**0**/+	**0**	**0**/+	**0**	**0**
4. Regulatory sandbox	**0**/+	0	**0**/+	**0**	+	-	**0**/+

5.1.6 Intervention n°6: Targeted regulatory reform of the substances of human origin (SoHO) framework[204]

First, the **SoHO regulatory status consultation procedures** is streamlined by empowering the Commission to adopt implementing acts establishing **binding time limits** for regulatory status consultation processes within the SoHO framework.

Second, the Regulation proposal establishes a **regulatory sandbox framework for SoHO,** enabling Member States to create time-limited controlled environments for developing and

[204] Regulation (EU) 2024/1938, OJ L, 2024/1938, 17.7.2024. ELI: http://data.europa.eu/eli/reg/2024/1938/oj.

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testing innovative SoHO products, services, processes, or substances that cannot yet fully comply with standard regulatory requirements.

The new regulatory sandbox framework allows a Member State (or several jointly) to set up a regulatory sandbox upon a substantiated request from a SoHO entity, providing a time-limited controlled environment to facilitate the development and testing of innovative SoHO products, services, processes or substances under the supervision of one or more competent authorities. Two eligibility conditions should be met: (a) the innovation is expected to contribute distinctively to SoHO safety, quality, including effectiveness, or to significantly improve patient access to treatment; and (b) applying the SoHO Regulation's requirements would impede or significantly delay development due to scientific or regulatory challenges inherent to the innovation.

The regulatory sandbox is an evidence-generating mechanism: it should enable assessment in a real-world environment under strict regulatory supervision, producing the data needed to demonstrate safety and quality, including effectiveness, in view of subsequent distribution decisions. Derogations from the SoHO Regulation may be included, but only if clearly described, strictly necessary, and justified in a sandbox plan. Derogations may take the form of adapted, enhanced, waived or deferred requirements. Sandboxes cannot derogate from the SoHO Regulation's standards on voluntary and unpaid donation.

Operationally, activities must follow a sandbox plan developed by the SoHO competent authorities, informed by data and consultations with the innovation's developers, and specifying participants and roles; which SoHO requirements cannot be complied with and the resulting derogations and adaptations; risk-mitigation measures; the sandbox duration; and the monitoring framework. The competent authorities must consult the SoHo Coordination Board (SCB) where appropriate, and the SCB is tasked with supporting and fostering a common approach. The SCB may also collaborate with the Foresight Panel for Emerging Health Innovation established by the Biotech Act, linking sandbox practice to upstream horizon-scanning and cross-framework learning.

The proposed amendments create a structured route for SoHO innovations, which cannot yet be developed in full compliance with the SoHO Regulation, or if compliance would impede or significantly delay development due to inherent scientific or regulatory challenges. The proposed amendments also formalise cross-authority collaboration and information exchange, which improve transparency and comparability across Member States while retaining core safeguards.

A SoHO preparation resulting from an innovation developed as part of a regulatory sandbox may be distributed for human application only where authorised in accordance with Article 38(1) of Regulation (EU) 2024/1938. The purpose of the regulatory sandbox is therefore to make authorisation feasible by enabling supervised testing and evidence generation in novel or complex cases where applying the current regulation's requirements would impede or significantly delay development. These are, for example, new technologies for which there are currently no fitting technical safety and quality requirements by the Expert Bodies (EDQM, ECDC); new technologies that are only partially covered by SoHO rules.

Sandbox-eligible cases would be a minority of cases which could not be authorised under the SoHo Preparation Authorisations (SPA) model established in the 2024 SoHO Regulation, but would bring in high extra value. Expert interviews suggested that SoHO products eligible for the sandbox route likely represent 5–10% of overall SoHO activities, i.e. **90-250 eligible cases per year**[205]. Sandbox use cases demonstrate **acceptance rate of between 7-16%** of sandbox applications, demonstrating great interest from developers in the sandbox instrument but limited capacity of the regulators to establish sandboxes[206]. Considering the high resource requirements of a regulatory sandbox, we can further assume that only a share of eligible cases will be pursued. If all eligible cases apply for the sandbox tool, between **6 and 40 regulatory sandboxes can be established pear year**.

Expected impacts:

Since the regulatory sandboxes are a first-of-its-kind instrument, the initial take-up could be slow, also as, in the first years, most innovations are expected to be well regulated under the new model for SPA in the 2024 SoHO regulation.

Conduct of business: Regulatory sandboxes offer a pathway for addressing complex cases that would otherwise not be pursued. We estimate a slowly growing interest in the regulatory sandbox from SoHO entities, leading to regulatory sandbox requests, particularly in strong innovation nations and for SoHO innovations where no safety and quality requirements are prepared by the expert bodies.

Administrative costs on businesses, including SMEs: Regulatory sandbox is expected to have similar costs to high-risk authorisations (between EUR 1,200 and EUR 6,000 per patient) due to the need to involve a certain number of data subjects and a thorough assessment process[207]. Therefore, while there would not be any extra cost for high-risk cases, if low- or medium-risk cases are pursued using the sandbox route, the direct cost of each case will increase. We assume that half of the cases directed to the sandbox route will be high risk cases and half of the cases will be medium risk cases. Under the low estimate, the additional cost of regulatory sandbox route for SoHO entities will be EUR 718,500 (under the assumption that six sandboxes are established per year) and EUR 4,790,000 (under the assumption that 40 sandboxed are established per year).

As a positive secondary effect this would allow SoHO entities to engage with authorities early in an environment that tolerates iterative learning, prototyping, and co-development of evidence strategies, thereby lowering the volume of redundant work and iterative back-and-forth that currently inflates administrative burdens.

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[205] Rapid Assessment Scenario study, assuming that currently, a share of SoHO activities is not pursued for authorisation due to exceedingly high costs of evidence generation and/or difficulty reaching full compliance. However, this share could not be estimated.

[206] Rapid Assessment Scenario study based on: Medicines and Healthcare products Regulatory Agency. (2025). *AI Airlock sandbox pilot programme: Report*. UK Government. https://assets.publishing.service.gov.uk/media/68ee1fb88427701993d5e02c/AI_Airlock_Sandbox_Programme_Report._Final.pdf and Commission nationale de l'informatique et des libertés. (2022). *Dossier de presse : Bilan 2021 et enjeux 2022*. https://www.cnil.fr/sites/default/files/atoms/files/dossier_de_presse_cnil_bilan_2021_et_enjeux_2022_vf.pdf.

[207] Rapid Assessment Scenario Study, based on assumptions provided by the European Commission.

Competitiveness, trade and investment flows: By providing a flexible, but coordinated and proportionate pathway for novel SoHO activities, regulatory sandboxes will reduce uncertainty and transaction costs for innovations. This could improve EU attractiveness for certain R&I projects. Particularly strong competitiveness effects can be expected in the forerunner countries with strong innovation potential. Such effects will come from two sources. First, projects that are authorised thanks to sandbox evidence, which would not be pursued otherwise.

Second, under the assumption that sandbox route allows for a responsible approach with limited or more flexible types of appropriate evidence, and for less authorisations to be obtained, innovative SoHO activities will become more attractive for SoHO entities.

Functioning of the internal market and competition: The regulatory sandboxes might have an indirect effect if the outcomes obtained in one Member State are reused in other Member States when assessing similar innovations. This can in particular be expected given the central role of the SoHO Coordination Board in supporting and monitoring sandboxes, including joint sandboxes undertaken by two or more Member States. The overall approach of open access innovation in the largely public SoHO sector will also contribute to a fast and harmonized roll-out of novel technologies.

Innovation and research: The regulatory sandboxes provide a pathway to authorisation and a signal to the R&I stakeholders. As the immediate response to the sandbox measure, we can therefore expect to see an increase in the actor activity in this segment. These changes in risk and incentives and the reduction of the administrative burden could attract more public entities into innovation and stimulate innovation activity in novel, borderline cases and cases requiring cross-framework coordination.

Innovation in SoHO is continuous, often incremental and largely driven by activity in public organisations, with knowledge diffusion through publications and professional societies rather than patents[208]. In leading Member States, major public hospitals treat research as a regular part of their activity and are linked to universities and research institutes. This creates a favourable ecosystem for SoHO innovation, which is nevertheless dependent on the availability of public and private research grants. However, high administrative costs deter these actors from innovative and novel SoHO activities.

Controlled testing environments created through the regulatory sandboxes would enable experimentation under protection from disqualification due to a mismatch with the current framework. By allowing for adapted standards of regulatory evidence generation, regulatory sandbox pathway can enable innovative research that might otherwise be abandoned for fear of regulatory rejection. Therefore, these proposed amendments support the ‘throughput’ phase of the innovation process. Innovation and research impacts at Member State level are expected to be positive mainly via risk reduction, faster evidence generation, increase in academic research, and regulator capability-building, but uneven across Member States depending on capacity and ecosystem maturity.

[208] Rapid Assessment Scenario Study, based on SWD(2022) 190 final.

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Regulatory sandboxes could be expected to shorten the path from innovation to safe clinical use, especially where the baseline suffers from uncertain borderlines and divergent evidence thresholds. In the financial technology area, firms that went through the regulatory sandboxes had, on average, a 40% shorter time from engagement with the regulator to market authorisation than similar firms using the standard process. In SoHO, therefore, gains can also be expected. However, no baseline data is available for quantification as these gains would be realised in the cases that otherwise would not be pursued due to difficulty gathering evidence for authorisation.

Public authorities: The addition of the sandbox instrument is expected to expand the mandate and increase the workload of public authorities in the short and medium term for the benefit of significant cost reduction in the longer term due to achieved system efficiency.

To quantify the operational costs of the regulatory sandboxes on public authorities, person-day cost of the sandbox should be compared with person-day cost of the SPA model, taking into account both the costs of learning by doing and the cost reduction expected in the medium term due to cross-Member State learning leading to improved efficiency of operations when novel SoHO activities are concerned. Furthermore, OECD guidance indicates that investments are needed for regulators in terms of time, expertise, and organisational capacity when instituting a sandbox instrument.

These costs would be borne primarily by national competent authorities but also by the Commission due to (i) the role in supporting the regulatory sandbox activities and hosting the EU SoHO Platform, and (ii) the engagement of the SCB as a key operational and consensus-building mechanism. Experts interviewed for this study assessed the role of the EU-level guidance as high for organisation of SoHO activities on the Member State level[209]. Commission-defined principles and formal mandates are essential to stimulate cross-body collaboration among relevant public authorities within Member States and to harmonise common national procedures for multi-framework cases.

We calculate the cost of regulatory sandbox for public authorities as follows: 1) assessing request (no change per risk category), 2) workload of regulatory sandbox (50 person-days) and 3) assessment of clinical evidence (reduced by 40%). This brings the workload on a medium-risk case to 75-94 person-days per case (EUR 22,575 – EUR 28,294); and on the high-risk case to 98-149 person-days per case (EUR 29,498 – EUR 44,849).

Public health and safety: The sandbox instrument grants earlier access to therapies for patients involved in the clinical evidence collection, before the activity is approved. As illustrated above, regulatory sandbox has similar evidence requirements as a high-risk authorisation process. In total, regulatory sandboxes are expected to involve 450-3,000 patients p/a. The impact of such access could be significant in the case when sandboxes provide evidence generation for SoHO activities that would otherwise not be feasible to authorise, for example, in the cases of rare diseases or niche treatments. Follow-up monitoring and assessment should consider whether these patients would have been served at all if the sandbox route did not exist, since authorisations for sandbox-eligible cases

[209] Rapid Assessment Scenario Study, based on stakeholder consultation (interview).

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would be very difficult to obtain ordinarily. A key condition of sandbox eligibility is a significant expected public benefit, which further implies that sandboxes will address the needs that would otherwise not be met.

Longer-term effects are expected to arise due to institutionalisation of cross-Member State learning and publication of sandbox reports on the EU SoHO Platform. The proposal constrains derogations to standard SoHO procedures to what is strictly necessary and requires explicit risk mitigation and monitoring and therefore disallows derogations on voluntary or unpaid donation standards.

Table 6. Summary assessment of the effects due to the intervention n°6

Policy measure	COB	Admin	CTI	Int mar	I&R	PA	H&S
Regulatory sandbox	++	+	0/+	0	+	++	+

5.1.7 Intervention n°7: Targeted regulatory reform of the Directive on the deliberate release into the environment of GMOs[210]

The proposal introduces specific provisions in Part C of Directive 2001/18/EC addressing the placing on the market of GMMs as or in products other than food and feed with the aim of creating a tailored, more efficient and streamlined regulatory framework for the placing on the market of GMMs as or in products, while maintaining a high safety level for human and animal health and the environment. The proposed provisions relate to the risk assessment, to the validity of the consent granted for their placing on the market, and to detection methods applicable to all GMMs. In addition, the proposal introduces the concept of low-risk GMMs and a specific set of rules for adapted information requirements and a streamlined authorisation procedure for this subgroup of GMMs to be detailed by way of Commission delegated and implementing acts. The requirement for post-market environmental monitoring of low-risk GMMs is equally adapted in the proposal, providing the possibility to a notifier, based on certain conditions, to propose to omit post-market environmental monitoring.

Expected impacts:

Conduct of business: The proposed regulatory framework for GMMs as or in products other than food and feed is expected to improve some framework conditions for companies being active in the GMM field. By shifting towards more product-specific risk assessment criteria, introducing specific modalities for detection methods, granting unlimited validity for market consents and creating an accelerated pathway for low-risk GMMs, where certain data requirements would be waived in consideration of an existing Qualified Presumption of Safety delivered by EFSA, the intervention should shorten time-to-market and reduce procedural rigidity. This is expected to pave the way for GMM-related consents for placing on the EU market of GMMs as or in products. Earlier market entry would

[210] Directive 2001/18/EC, OJ L 106, 17.4.2001, pp. 1–39. ELI: http://data.europa.eu/eli/dir/2001/18/oj.

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mitigate income losses from regulatory delays and improve the business case for investment, particularly for SMEs and start-ups that are more sensitive to regulatory timelines and uncertainty.

Administrative costs on businesses (including SMEs): The impacts are expected to be very positive. While quantitative estimates are lacking for non-food GMMs, a qualitative assessment indicates that a more product-focused risk assessment and a dedicated low-risk GMM pathway should substantially reduce the burden associated with preparing extensive dossiers under the current GMO regime. Streamlined, more predictable procedures, the unlimited validity of consents and the possibility to waive post-market environmental monitoring where justified would lower recurring costs, especially for GMMs considered to be low risk. This is expected to make compliance more manageable for resource-constrained SMEs and start-ups, to stimulate exploration of novel products and partnerships between large firms and smaller innovators, and to reduce the incentive to relocate development activities to jurisdictions such as the US or China with more flexible GMM frameworks.

Competitiveness, trade and investment flows: The new regulatory framework is expected to act as an enabler and accelerator. By reducing regulatory costs and uncertainty and clarifying a route to market for GMMs, the intervention could render more projects investable, thereby supporting an expansion of the innovation pipeline in sectors such as biofertilisation, biocontrol, bioremediation, and bioleaching. Over time, this is expected to translate into a larger portfolio of authorised GMM products and more robust EU-based value chains in these areas. The more predictable pathway from laboratory to market would likely attract additional venture capital and corporate investment and may encourage non-EU companies with established GMM products to enter the EU market. The number and resilience of biotech start-ups and SMEs operating in GMM-related domains is likewise expected to increase, as founders and investors gain confidence that commercialisation in Europe can realistically be achieved within acceptable timeframes. However, all these effects would be gradual and path-dependent, unfolding over several years and dependent on how the regulatory scrutiny process works in practice.

Functioning of the internal market and competition: There are no adverse impacts expected. The new regulatory framework for GMMs modifies a horizontal framework and will apply across all Member States and to all economic operators, so no distortions of intra-EU trade or competition between Member States are anticipated. The analysis notes that competition and displacement may arise between GMM-based products and their non-GM counterparts; however, in the absence of concrete evidence and given that many firms are likely to offer both types of products, no material changes in internal market functioning or competition patterns are expected as a direct consequence of the new GMM framework.

Innovation and research: The proposed intervention is projected to have a positive and potentially substantial effect. By reducing administrative barriers, shortening authorisation timelines and providing regulatory clarity, the framework could stimulate R&D investment by universities, research organisations and companies. This is particularly important in the EU context, where excellent early-stage biotech research has historically struggled to translate into scaled-up applications and competitive firms. A more innovation-friendly regulatory environment is expected to improve the EU's relative position vis-à-vis other

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major innovation regions such as the US and China, increase private funding for GMM-related research, and help retain and attract talent in this domain. Over the longer term, the biotechnology innovation system around GMMs could therefore become more dynamic, better leveraging Europe's strong scientific base.

Public authorities and their administrative workload: The effects of the new regulatory framework for GMMs are difficult to assess. The average effort for national competent authorities per GMO authorisation of a non-food/non-feed GMM would fall. However, the extent to which burden will be reduced will fall in a wide range, resulting from the fact that the adaptation of risk assessment (applicable to all GMMs, and expected to go further for low-risk GMMs) will be case-by-case and may lead to considerable variability of data requirements. In the most conservative scenario, risk assessment would require roughly the same amount of data as today, and only a small fraction of products would qualify for the low-risk procedure (interviews suggested that national authorities may be cautious in designating GMMs as low-risk, based on a precautionary approach and no practical experience with non-medical GMM releases), translating in very limited gains for competent authorities. In less conservative scenarios, the tailoring of risk assessment to GMMs is expected to deliver efficiency gains for national authorities. In addition, the harmonisation of criteria for low-risk products will allow the effective use of that procedure, delivering further efficiency gains and reduction of administrative burden. Further savings, in the phase following the initial authorisation, would result from the unlimited authorisation validity and waivers of post-market environmental monitoring. These were not quantified and would accrue mainly at national level. At EU-level, the mechanisms regarding EFSA's role in resolving disagreements between Member States is not modified, and the considerations above apply in those instances where -following a disagreement- EFSA would need to conduct an assessment. Both at national and EU-level, if application numbers rise significantly under the new framework, total administrative effort may increase or decrease depending on how many of these applications would have occurred under the existing regime and on the effective use of the low-risk pathway.

Public health and safety: The proposed measures are designed to maintain the high protection standards of the current EU GMO regime while making their implementation more proportionate to the specific characteristics of GMMs. The intervention does not lower safety standards or abandon mandatory risk assessment but rather tailors information requirements and allows for more flexible approaches where risks are low and well understood. This is expected to reduce unnecessary regulatory burdens without compromising the high level of protection of human and animal health and the environment.

At the same time, by enabling the deployment of beneficial GMM applications that are currently discouraged or displaced to other regions, the new framework could help realise **environmental and sustainability benefits**, for instance by supporting more resource-efficient agriculture, cleaner industrial processes or enhanced bioremediation. In doing so, it may contribute to broader EU policy objectives such as the European Green Deal and the 2030 Agenda for Sustainable Development, while preserving robust safeguards for health and the environment.

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Table 7. Summary assessment of the effects due to the intervention n°7

Policy measure	COB	Admin	CTI	Int mar	I&R	PA	H&S
Regulatory framework for GMMs as or in products other than food and feed	+	+	+	**0**	+	+/**0**	**0**

5.1.8 Intervention n°8: Targeted regulatory reform of the Directive on human organs intended for transplantation[211]

The proposal amends Directive 2010/53/EU to reflect technological developments in organ preservation and processing and to provide EU-wide legal clarity and standards for innovative practices which aim to improve organ quality and expand transplantation opportunities.

First, the scope of the Directive is extended to explicitly include the processing of organs prior to transplantation, with a definition of "processing" being introduced by the proposal, encompassing any operation involving the handling of organs performed to maintain or improve the functional status of an organ prior to transplantation.

Second, a specific authorisation regime for organ processing per processing technology and per transplantation centre is established. A transplantation centre is to submit an application for authorisation to the competent authorities including a benefit-risk assessment where scientific evidence and clinical data are available. In the absence of such evidence and data, e.g. when no other EU transplantation centre has been authorised to apply the same organ processing technology, a clinical outcome monitoring plan must be submitted for approval. A clinical outcome monitoring plan must also be submitted for approval where the benefit-risk assessment identifies a significant risk. The extend of the clinical monitoring will be proportionate to the risks identified. Detailed rules on the authorisation procedure are to be established through Commission implementing acts and guidance on the benefit risk-assessment is to be established by the competent authorities.

Transplantation centres must request the written agreement of competent authorities prior to making significant changes to authorised processing steps. The competent authorities have the prerogative to suspend an authorisation where there is reasonable ground to suspect non-compliance. A central EU list of authorised processing techniques or with an approved clinical outcome plan is to be established by the Commission. This will serve as reference point to simplify later authorisations of similar processing technologies used in other EU transplant centres, and hence to facilitate the roll-out and uptake of the same processing technology for other centres and authorities.

[211] Consolidated text: Directive 2010/53/EU, ELI: http://data.europa.eu/eli/dir/2010/53/2010-08-06.

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Third, the proposal clarifies coordination with other Union health legislation. Where organ processing involves medicinal products, medical devices or SoHO preparations, national competent authorities must verify compliance under the relevant Union frameworks and cooperate with the corresponding national competent authorities under Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EU) 2017/745 and Regulation (EU) 2024/1938 to ensure coherent and more efficient oversight.

These amendments aim to provide EU-wide and cross-sector legal certainty, support innovation in transplantation, and ensure high standards of quality and safety while facilitating timely clinical uptake of advanced processing technologies.

Expected impacts:

Measure 1 – the enlarged scope is textually modest but **legally consequential** as the foundational enabler of Measures 2 and 3. On its own, however, it generates no direct operational requirements, administrative obligations or supervisory mandates. Its independent effect operates through a single channel: the provision of legal certainty by formally recognising organ processing as a regulated activity within the EU legislative framework. This **resolves the legal ambiguity** identified in the problem definition and sends a **regulatory signal to transplantation centres and technology developers**, but the substantive operational, administrative, and health impacts materialise only through Measures 2 and 3.

Measure 2 – on organ processing authorisation regime - is crucial and derives in nearly all quantified impacts for this intervention area.

The conduct of business is assessed as moderate positive: the framework relates to the operational model of transplantation centres by introducing a prior authorisation obligation per centre and per processing technology. However, the **net effect is positive because the certainty channel** (removing the legal ambiguity that functions as a structural drag on adoption) outweighs the compliance channel, yielding an **estimated 70-110 additional programmes** with active processing capability and approximately **1,435 additional transplants** per year by 2035.

Administrative costs on businesses are assessed as **marginal negative**: the per-application cost is estimated at **EUR 11,500-16,750** (Track 1/Track 2), with a cumulative EU burden of approximately **EUR 2.5 million over 2029-2035**, costs that are real but proportionate and partially offset by replacing fragmented and duplicative baseline compliance arrangements. Moreover, only the first centre in the EU has to complete the full pathway at the full cost, since subsequent centres can apply a shortened pathway by using evidence from the central list. This leads to significant administrative savings for the overall EU transplant community. Further, transitional measures are envisaged to avoid the authorisation of practices already in place, so that these are not to be re-authorized.

Competitiveness, trade and investment flows are **marginally positive**: the transparent authorisation pathway reduces the regulatory risk premium for private investment in organ processing technologies, but the effect is indirect given the niche character of the market. The **internal market** benefits from standardised authorisation procedures that create mutual trust for cross-border exchange of processed organs, with an estimated **120-250**

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additional cross-border exchanges per year by 2035, while the published list of authorised operations generates de facto EU-wide convergence of practice.

Innovation and research are **moderate positive**: the dual-track system provides a structured pathway for next-generation technologies (Track 2 conditional authorisation), an **estimated 15-36 active monitoring plans** generate structured EU-level evidence, and the "Processing" data field in the Annex creates the taxonomic infrastructure to disaggregate processing-attributable outcomes.

Public authorities face a **marginal negative** impact: the transition-phase assessment cost is approximately **EUR 850,000 over three years** across the EU, declining to approximately **EUR 60,000-85,000 per year** in steady state; the net incremental cost is moderated by the replacement of ad hoc national arrangements but represents a genuine, if manageable, expansion of the supervisory mandate.

Public health and safety is the strongest effect, assessed as significant positive: **1,435 additional transplants per year by 2035; 570-945 fewer organ discards; 57-72 waiting-list deaths averted annually; approximately EUR 158 m in cumulative dialysis cost savings** over 2028–2035; and a structural improvement in safety oversight through the mandatory benefit-risk assessment and clinical-outcome monitoring mechanisms.

Measure 3 addresses the **multi-regulatory-domain nature of organ processing**, which require competent authorities to verify that products used in processing (medical devices, medicinal products, SoHO preparations) are duly authorised under their respective EU frameworks, and mandate cross-authority collaboration for the exchange of clinical outcome data. Its impact profile is narrower and more targeted than Measure 2.

The **conduct of business** is marginal positive: the cross-framework verification adds a structured step to the centre's processing workflow but also brings EU harmonization and reduces the ad hoc legal uncertainty that centres currently face regarding the permissibility of specific product combinations.

Administrative costs are marginal negative: the verification dossier imposes a modest additional documentation requirement, functionally embedded within the Measure 2 application process. However, there is a significant simplification in administration by other centres, aiming to implement an organ processing step already authorized in other EU transplant centres, facilitating uptake of novel processes across the EU.

Competitiveness, trade and investment flows are marginal positive: the clearer multi-domain regulatory landscape marginally improves investment predictability for manufacturers of perfusates, gene therapy vectors, and other products used across regulatory frameworks.

The **internal market** is the principal beneficiary of this measure: the mandatory cross-authority coordination directly addresses the regulatory silo problem identified in Section 3.2.3 and creates legally binding cooperation obligations that facilitate the acceptance of processed organs involving multi-domain products across Member State borders.

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Innovation and research are marginal positive: the mandated exchange of clinical outcome data between regulatory frameworks generates research-valuable evidence on multi-domain processing outcomes, contributing to a more coherent EU-level evidence ecosystem.

Public authorities face marginal negative costs from establishing inter-authority communication protocols, though Member States with existing cooperation infrastructure will face limited marginal effort.

Public health and safety benefits indirectly but materially: the cross-framework verification ensures that all products used in processing meet their respective EU safety standards, and the mandated data exchange improves pharmacovigilance and device vigilance for processing-related adverse events, closing a surveillance gap that currently exists between regulatory silos.

Table 8. Summary assessment of the effects due to the intervention n°8

Policy measure	COB	Admin	CTI	Int Mar	I&R	PA	H&S
1. Enlarged scope	**0/+**	**0**	**0/+**	**0/+**	**0/+**	**0**	**0/+**
2. Organ processing authorisation regime	+	**0/–**	**0/+**	+	+	**0/–**	++
3. Cross-border and cross-framework coherence	**0/+**	**0/–**	**0/+**	+	**0/+**	**0/–**	+

5.2 Interventions on industrial enablers: measures and expected impacts

5.2.1 Interventions n°9, 10 and 11: Strategic projects, high-impact projects and ecosystem support framework

The proposed Regulation establishes a comprehensive framework to structure and coordinate the selection, development and scaling-up of strategic health biotechnology capacities and projects, encompassing:

- **(i) the recognition and the support of health biotechnology strategic projects (Intervention n°9),**
- **(ii) a targeted EU-level framework for high-impact strategic projects (Intervention n°10)[212], and**
- **(iii) an ecosystem support framework (Intervention n°11).**

[212] The proposal sets out five types of high impact projects. For the purpose of the analysis in this section, two of these project categories (biotechnology development accelerators - trusted testing or demonstration facilities with state-of-the-art equipment and staff – and centres of excellence for advanced therapies) are taken into consideration, while three others (concerning access to finance, AI-enabled biotechnology innovation and biodefence) are considered under the respective intervention areas, namely Interventions 14, 15 and 17.

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Together, these measures aim to boost the EU's competitiveness and resilience in health biotechnology, by strengthening biomanufacturing capacity, value chains, research and technology infrastructures in the sector, accelerating innovation and technology deployment and addressing ecosystem fragmentation through coordinated support mechanisms.

Strategic projects (recognised by Member States) would benefit from administrative support (including single points of contact at Member State level), accelerated procedures (including for permitting, subject to a maximum ten-month deadline, as well as for dispute resolution and litigation), a public interest status and measures to facilitate access to funding at national and EU-level. Provisions also proposed support to pro-competitive collaboration between projects, networks and clusters. High-impact projects (recognised at EU level) represent a limited flagship portfolio of systemic importance, including biotechnology development accelerators and centres of excellence for advanced therapies. These projects benefit from similar support but with priority status, including an accelerated eight -months permitting timeline and stronger signalling for Union financial support.

These project-level measures are underpinned by ecosystem support instruments:

(i) a strategic mapping of the EU biotechnology ecosystem to identify capacities, gaps and investment needs;
(ii) an EU health biotechnology support network with national and regional antennas to assist innovators in navigating regulatory and funding pathways and accessing scaling and networking opportunities; and
(iii) a European Health Biotechnology Steering Group to coordinate Member States and the Commission, facilitate exchange of best practices and ensure effective implementation for strategic and high impact health biotechnology projects.

The EU Health Biotechnology Support Network is not intended to duplicate existing EU-level SME support structures, such as the Enterprise Europe Network or future horizontal instruments under the European Competitiveness Fund. Rather, it operates as a sector-specific coordination and support layer, building on existing structures where appropriate, and providing health biotechnology-specific navigation, ecosystem coordination and cross-border integration functions. In particular, while existing networks may support firms on general business, innovation or internationalisation aspects, they are not designed to provide structured support for navigating complex, multi-framework health biotechnology regulatory pathways. The design of the Support Network is therefore intended to remain compatible with and complementary to future EU-level SME support architectures, including the envisaged EU for Business Network, notably by leveraging existing capacities while ensuring the availability of specialised expertise.

Expected impacts:

Conduct of business and administrative costs: Taken together, the measures are expected to generate significant positive impacts on conduct of business and administrative costs for firms, with positive but more incremental contributions to competitiveness, internal market functioning, innovation and, indirectly, public health and safety. Impacts on public authorities are expected to be front-loaded but moderate overall due to reliance

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on existing structures. The principal transmission channels operate at two complementary levels. At project level, impacts arise from reduced execution risk through more predictable and coordinated administrative handling, including time-bound permitting (ten months for strategic projects, eight months for high-impact projects), structured single points of contact model and facilitated access to finance. At ecosystem level, impacts arise from reduced transaction and navigation costs, improved access to investors and infrastructures, and strengthened cross-border collaboration through network and cluster effects.

Uptake is a key uncertainty across all components, therefore the scale of impacts should be interpreted as proportional to the number and maturity of projects applying for recognition and to the utilisation of ecosystem support services. This reflects the voluntary nature of the mechanism and the fact that promoters will weigh the administrative effort of application against the expected benefits of more predictable administrative pathway and improved access to support, consistent with observed dynamics in comparable strategic-project regimes[213].

To illustrate the potential order of magnitude, three uptake scenarios can be defined for each of the project categories. As a calibration point, other EU-level priority-project frameworks[214] have operated at volumes ranging from several dozen to over one hundred projects, providing a useful order-of-magnitude reference (rather than a direct comparator) for the potential scale of project pipelines under coordinated policy frameworks. Against this backdrop, an indicative range for health biotechnology strategic projects could be framed as: (i) low uptake: around 25-30 recognised projects by 2038, (ii) medium uptake: around 60-70 projects, and (iii) high uptake: around 100-120 projects. For high-impact projects, reflecting a limited flagship portfolio, ranges would be: low uptake (six to –eight projects), medium uptake (12–15), and high uptake (20–25).

Conduct of business: Significant positive impacts are expected through greater predictability, shorter effective administrative lead times for strategic and high-impact projects, alongside reduced coordination frictions. Greater clarity and time-bound procedures are expected to improve planning horizons, milestone sequencing and time-to-revenue, reduce volatility in project schedules and strengthen firms' capacity to align procurement, construction and staffing decisions with a clearer administrative pathway. Delay and uncertainty remain economically material for capital-intensive investments, with an indicative benchmark suggesting that regulatory delays of more than 12 months beyond initial projections have been associated with an average 34% increase in total development costs, alongside a high incidence of additional funding rounds and some programme abandonment.

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[213] See Commission SWD on establishing a framework of measures for strengthening Europe's Net Zero Industry Act: COM(2023) 219 final (https://single-market-economy.ec.europa.eu/publications/net-zero-industry-act_en).

[214] E.g. projects recognised under Union frameworks with explicit strategic project provisions, such as those established by the Net Zero Industry Act and the Critical Raw Materials Act, as well as earlier coordinated frameworks such as the first Union list of energy Projects of Common Interest (PCIs) and Projects of Mutual Interest (PMIs) comprising 166 projects and approved IPCEIs in the microelectronics value chain comprising 100 projects across 14 Member States. While the scale of such projects is influenced by Member State participation, fiscal capacity and policy priorities, they remain informative as to the potential scale of coordinated project pipelines. The ranges presented here are therefore illustrative and adapted to the specific design and incentives of the present measure.

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For high-impact projects, these effects are reinforced through access to promoter-led shared late-stage translation infrastructures with cross-border relevance, supporting more efficient development and scale-up. Impacts can be evidenced through utilisation indicators such as the number of firms served, including SMEs, the number of service engagements (e.g. testing, validation and small-batch GMP runs), and utilisation rates, reflecting improved coordination and access to critical capabilities.

Ecosystem support measures contribute indirectly by improving visibility of strategic projects, facilitating collaboration and enhancing firms' ability to navigate the EU regulatory and funding landscape. While these effects are not directly attributable in isolation, they reinforce the overall improvement in business conditions generated by the project-level measures. Overall, once implementation stabilises, a significant share of recognised projects is expected to complete permit granting within the applicable timelines.

Administrative costs on businesses, including SMEs: Significant positive impacts on administrative costs are expected, driven by reduced transaction costs, simplified administrative interactions and more predictable, time-bound procedures. For strategic and high-impact projects, reductions arise from fewer parallel interfaces, fewer iterative information exchanges and greater reuse of existing evidence, supported by single points of contact and structured administrative facilitation. These effects are expected to lower compliance costs and administrative burden, with avoided delay costs for capital-intensive investments constituting the main economic benefit.

For high-impact projects, impacts are more targeted, reflecting prioritised handling and faster decision-making for a limited number of catalytic projects, reducing schedule uncertainty rather than generating system-wide burden reductions. Ecosystem support measures further reduce navigation and search costs, particularly for SMEs and start-ups, through a single-entry point and improved preparedness for regulatory interactions. Overall, impacts are expected to be proportionately stronger for SMEs lacking in-house administrative capacity.

Competitiveness, trade and investment flows: Positive impacts on competitiveness, trade and investment flows are expected through improved bankability, stronger investment signalling and reduced time-to-market. For strategic and high-impact projects, more predictable delivery and prioritised handling are expected to lower risk premia and improve conversion from planning to financial close, supporting higher investment mobilisation and leverage, particularly for mature and bankable projects. High-impact projects are expected to generate stronger effects per project due to their scale, visibility and systemic relevance.

Ecosystem support measures reinforce these effects by improving access to investors through structured matchmaking and by reducing delays linked to incomplete or immature submissions, thereby shortening time-to-market[215]. Overall investment mobilisation will

[215] Evidence from the EIC Business Acceleration Services demonstrates that structured matchmaking can generate measurable outcomes (over 20,000 meetings, 595 deals, EUR 350 million raised since 2021). On time-to-market, EMA data indicates that applicant-side clock-stops represent a substantial portion of total procedure time (198 days average vs

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depend on project maturity and uptake, but the combined framework is expected to strengthen investment attractiveness and facilitate greater mobilisation of both public and private capital in the Union health biotechnology sector. Existing Union financing instruments can also amplify these effects through leverage: where support is backed by an EU budget guarantee, this can reduce risk for implementing partners and crowd in additional public and private investment beyond the direct Union contribution.

Internal market: Positive impacts on the functioning of the internal market are expected through a more visible and comparable pipeline of strategic projects and reduced information asymmetries for promoters, authorities and investors. Cross-border recognition for projects located in two or more Member States is expected to reduce duplicative processes and improve consistency of treatment, supporting more contestable investment conditions across Member States, while take-up patterns will remain sensitive to underlying administrative capacity and clustering effects. Internal market effects are expected to strengthen as uptake increases and the pipeline becomes sufficiently broad and geographically distributed to improve comparability and transparency across Member States.

These effects are reinforced by improved cross-border accessibility of infrastructures and shared capabilities in the context of high-impact strategic projects, facilitating resource pooling and multi-country collaboration. The Support Network is expected to reduce fragmentation of support services by providing comparable[216] antennas across Member States. Cluster networks further contribute by structuring cross-border ecosystems, enabling access to biomanufacturing and research infrastructures and supporting the formation of cross-border consortia[217].

Innovation and research: Impacts are expected through faster and more efficient translation of research and innovation into industrial deployment, supported by strategic projects and reinforced by a limited number of high-impact catalytic assets addressing late-stage bottlenecks. Strategic projects contribute through strengthening biomanufacturing infrastructures and innovation assets, while high-impact projects further enhance the **number and speed of projects progressing through late-stage development**, particularly for advanced therapies and other complex applications.

These effects are complemented by ecosystem measures, notably cluster networks and support structures that strengthen research-industry linkages and facilitate cross-border collaboration, thereby enhancing firm-level innovation capacity and access to shared infrastructures. Overall, innovation impacts are expected to scale with uptake and portfolio composition, with the main effect being improved translation and deployment rather than system-wide shifts in innovation performance.

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204 days assessment time in 2023), with 42% of applicants requesting extensions due to immature data. By helping SMEs come better prepared to interactions with regulatory bodies, the Support Network could address submission readiness gaps that contribute to these delays.

[216] This comparability is ensured through common selection criteria set by the Commission, standardised service functions, and EU-level coordination via the Steering Group and strategic mapping, which together support consistent service delivery across Member States. See Rapid Assessment Study – forthcoming – for further elaboration.

[217] Evidence from the ECCP Cluster Panorama and sector comparators (e.g., Silicon Europe with 2,500+ companies) supports the potential of cluster structures to facilitate cross-border consortia.

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Public authorities: They are expected to be front-loaded mainly due to process design, workload reallocation and coordination needs to operate single points of contact and provide structured support, as well as participation in governance and coordination structures. In many Member States, single points of contact may be established by designating or adapting existing administrative coordination mechanisms rather than creating entirely new structures, which may reduce upfront costs. Over time, efficiency gains are expected as procedures standardise, and administrative experience accumulates. Incremental impacts attributable specifically to the high-impact designation are expected to be limited and concentrated in selection, monitoring, coordination and reporting for a limited flagship portfolio, without duplicating cost drivers associated with general permitting operations and routine administrative facilitation. Administrative workload will scale with the number of recognised projects and monitoring cycles required.

The intervention also introduces additional obligations for Member States, including participation in the Steering Group, data provision for ecosystem mapping and facilitation of support network activities, but these are expected to build on existing structures, resulting in marginal set-up costs. Comparable initiatives (NZIA, CRMA) estimate 1–2 FTEs for one-stop shop functions and around two FTEs for governance participation. These initial obligations are expected to yield efficiency gains over time, as Member States gain access to a systematic evidence base and coordination forum that should improve national decision-making and reduce duplicative investments. At EU-level, technical assistance appropriations of approximately EUR 2.6 million annually (EUR 18.4 million over the MFF period) cover relevant coordination functions.

Public health and safety: Impacts are expected to be positive but indirect, mediated by the realised project portfolio and the extent to which faster delivery translates into earlier EU-based capacity for strategic products and a contribution to supply resilience outcomes. The scale of both administrative workload and resilience-relevant capacity effects is expected to increase with uptake, subject to project mix and implementation performance. For high-impact projects, the core impact pathway will be potentially faster, safer and more efficient development of innovative therapies, notably advanced therapies, supported by improved access to specialised testing, validation, small-batch GMP and quality control services and, where relevant, links to data and digital infrastructures.

Impacts are expected to materialise over the medium term and remain conditional on uptake by developers and manufacturers, as well as on broader regulatory, reimbursement and health system conditions affecting downstream patient access. Ecosystem support measures are not expected to have direct effects but may indirectly reinforce these outcomes by facilitating collaboration and improving system preparedness.

The tables below provide an illustrative, scenario-based quantification[218] of the expected impacts by 2038 under three uptake cases for the recognition and support framework for strategic health biotechnology projects (Table 9) and for high impact health biotechnology projects (Table 10) for each impact category. Impacts should be interpreted as orders of

[218] See Annex 7 and relevant sections of the Rapid Assessment Study – forthcoming for further elaboration on the calculations of impacts

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magnitude and as broadly proportional to the number, maturity and operationalisation of recognised projects over the period.

Table 9. Illustrative uptake scenarios and order-of-magnitude impacts for strategic health biotechnology projects

Impact category	Summary assessment of the effects due to the policy measure	Key indicators expected evolution under different project uptake scenarios		
		Low uptake (25-30 projects)	Medium uptake (60-70 projects)	High uptake (100-120 projects)
COB	++	Projects completing permit granting within 10 months: ~18-26	~42-60	~70-102
Admin	++	Avoided delay costs (cumulative): ~EUR 90-410 million	~EUR 214-952 million	~EUR 357-1,632 million
CTI	++	Total investment mobilised (cumulative): ~EUR 6-12 billion	~EUR 15-28 billion	~EUR 25-48 billion
Int mar	+	Cross-border projects (≥2 Member States): ~3-6	~6-14	~10-24
I&R	+	Projects with material R&I or innovation infrastructure outputs: ~5-9	~12-21	~20-36
PA	0/+	Recognition decisions per year (average): ~2-3; indicative single point of contact capacity: ~0.5-1 FTE	~5-6; ~1-2 FTE	~8-10; ~2-3 FTE
H&S	+	Capacity-relevant strategic deployments: ~8-15	~18-35	~30-60

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Table 10. Illustrative uptake scenarios and order-of-magnitude impacts for high impact strategic health biotechnology projects

Impact category	Summary assessment of the effects due to the policy measure	Key indicators expected evolution under different project uptake scenarios		
		Low uptake (6-8 projects)	Medium uptake (12-15 projects)	High uptake (20-25 projects)
COB	++	Shared-capability throughput: ~60-120 firms/year, ~120-480 engagements/year	~120-360 firms/year, ~240-1,440 engagements/year	~240-600 firms/year, ~480-2,400 engagements/year
Admin	++	Avoided delay costs (cumulative): ~EUR 20.4-85 million	~EUR 51-204 million	~EUR 91.8-340 million
CTI	+	Total investment mobilised (cumulative): ~EUR 2-6 billion	~EUR 4-12 billion	~EUR 6-20 billion
Int mar	+	Cross-border users supported: ~12-48 firms/year	~24-144 firms/year	~48-240 firms/year
I&R	+	Clinical trial applications linked to capability layer: ~4-8/year	~8-24/year	~16-40/year
PA	0/+	Incremental workload: ~6-8 recognition decisions plus monitoring cycles, limited multi-country coordination	~12-15 decisions plus monitoring, moderate coordination workload	~20-25 decisions plus monitoring, higher coordination workload but still bounded by portfolio design
H&S	+	Therapy programmes supported with improved development pathway: ~2-4/year	~4-12/year	~8-20/year

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Table 11. Summary assessment of the effects of Intervention n°11: Health biotechnology ecosystem support framework

Policy intervention	COB	Admin	CTI	Int Mar	I&R	PA	H&S
Ecosystem support measure	0	++	+	+	+	-	0

5.2.2 Intervention n°12: Biosimilars competitiveness framework

The proposal includes two measures focusing on biosimilars:

First, it proposes the development and update of **EMA guidelines** on tailored and risk-proportionate regulatory approaches for biosimilar development, reflecting manufacturing and analytical testing advances. Most importantly, the guidance will set out the criteria and provide for the potential reduction of clinical data requirements for biosimilar development and approval without affecting quality, safety and efficacy. The revision would be guided by the assessment and conclusions of the reflection paper on tailored clinical approach in biosimilar development by EMA and the CHMP Biosimilar Medicinal Products Working Party (BMWP), published on 27 March 2026[219]. The reflection paper concludes that "a tailored approach for clinical development of biosimilar candidates is possible. Comparative Efficacy Studies (CES) are no longer expected to be required for approval of biosimilars that can be thoroughly characterised using state-of-the-art analytical methods and have demonstrated similarity in physicochemical and functional properties". Comparative clinical pharmacokinetics/pharmacodynamics (PK/PD) studies can in this context provide supportive safety and immunogenicity data. Over the past three years, applications concerning monoclonal antibodies and fusion proteins have represented more than 90% of all biosimilar marketing authorisation applications (see Annex 5 - additional background on the sector and problem definition). The proposed measure is therefore expected to have a broad practical impact, as it applies to the majority of current and future biosimilar development programmes.

Second, it proposes the establishment of a framework for the **recognition and the support of health biotechnology strategic projects focused on biosimilar** research, development, manufacturing and marketing authorisation. The support package outlined in intervention n°9 applies to these projects. Furthermore, the proposed measure promotes international cooperation between economic operators and biotechnology clusters active in the area of biosimilars, including in the context of health biotechnology strategic projects.

The two measures are complementary and the intervention logic goes as follows: The EMA guidelines are expected to reduce the evidentiary burden and associated cost and time of biosimilar development, thereby lowering barriers to market entry. Simultaneously, biosimilar strategic project recognition aims to provide administrative, financial, and permitting support for biosimilar manufacturing and development projects within the EU.

[219] Reflection paper on a tailored clinical approach in biosimilar development.

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Furthermore, eligibility criteria for biosimilar strategic projects enable projects developing analytical methodologies that reduce clinical data needs to qualify for support under the measure, creating a feedback loop between regulatory modernisation and industrial investment.

Expected impacts of measure 1: update and development of EMA guidelines

Conduct of business: If, following EMA guidelines, CES requirement was waived for biosimilar mAb products where analytical similarity is comprehensively demonstrated, developers could reduce direct Phase III clinical trial costs by an estimated EUR 19–26 million per product[220], with a broader range of EUR 14–46 million across all trial types[221]. Clinical development accounts for approximately 57% of total biosimilar development costs[222], with the CES representing the single largest component.

Of the 27 biosimilar marketing authorisation applications (MAAs) resolved in 2024[223], approximately 24 concerned monoclonal antibodies or fusion proteins, the product classes for which CES have historically been required (see Annex 5)[224].

On this basis, **three scenarios** are considered regarding the uptake of a tailored development approach including CES waivers.

An estimated CES cost of EUR **19–26 million** per product for monoclonal antibody and fusion protein biosimilars is used to estimate the **gross annual cost savings** for industry.

Residual clinical requirements are expected to persist. Comparative PK/PD studies (estimated at EUR 5.7–7.8 million per product) will remain necessary for all biosimilars, and immunogenicity assessment will continue to be required, particularly for antibody-based products. Accounting for these residual costs, **total net savings** are assumed to be reduced by approximately 30%[225].

In the near term (2025–2030), assuming 25–45 biosimilar marketing authorisation applications (MAAs) per year, with approximately 90% relating to monoclonal antibodies and fusion proteins, and that 50–75% of these would benefit from a tailored development approach including a CES waiver, the **gross annual cost savings** for industry are estimated at EUR 214–790 million.

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[220] Ranbhor, R., & Kulkarni, P. (2026). Net present value impact of FDA's Phase 3 waivers on monoclonal antibody biosimilar development programs. *Biosimilars and Targeted Therapy*. https://www.dovepress.com/net-present-value-impact-of-fdas-phase-3-waivers-on-monoclonal-antibod-peer-reviewed-fulltext-article-BTT.

[221] Moore, T. J., Mouslim, M. C., Blunt, J. L., Alexander, G. C., & Shermock, K. M. (2020). Assessment of availability, clinical testing, and US Food and Drug Administration review of biosimilar biologic products. *JAMA Internal Medicine, 181*(1), 52–60. https://doi.org/10.1001/jamainternmed.2020.3997.

[222] Ranbhor, R., & Kulkarni, P. (2026). Net present value impact of FDA's Phase 3 waivers on monoclonal antibody biosimilar development programs. *Biosimilars and Targeted Therapy*. https://www.dovepress.com/net-present-value-impact-of-fdas-phase-3-waivers-on-monoclonal-antibod-peer-reviewed-fulltext-article-BTT.

[223] Of the 27 MAAs 25 were authorised and 2 withdrawn or refused; source: EMA Medicines Database, 2026.

[224] European Medicines Agency. (2026). *Medicines output report* [dataset]. Retrieved 2 March 2026 from https://www.ema.europa.eu/en/medicines/download-medicine-data; European Medicines Agency. (2025). *Annual report 2024*. Publications Office of the European Union. https://doi.org/10.2809/7433636.

[225] The share of European investment into biosimilar development, which is not allocated to CES, which in turns makes up for the 70% as outlined above.

After accounting for residual clinical development requirements—primarily comparative PK/PD studies and immunogenicity assessments **net annual savings** are expected in the range of EUR 150–552 million.

Over the **five-year period (2025-2030), cumulative net savings** are therefore estimated at:

Scenario	Uptake	Gross annual cost savings for industry	Total net annual savings	Five-year period, cumulative net savings
Low scenario (50%)	12 products per year transition to CES waivers	EUR 222–312 million	EUR 155–218 million	EUR 0.75 billion
Central scenario (≈60–65%)	14–15 products per year	EUR 266–390 million	EUR 186–273 million	EUR 1.5–1.8 billion
High scenario (75%)	18 products per year	EUR 342–467 million	EUR 239–326 million	EUR 2.8 billion

The projected annual range of 25–45 marketing authorisation applications (MAAs) reflects a normalisation following the exceptional peak observed in 2025, notably linked to denosumab-related applications. At the same time, projections remain constrained by the 'biosimilar void' [226, 227].

The lower bound (25/year) assumes the void persists; the upper bound (45/year) assumes that the guidance (issued by 2027) begins attracting developers. Under current conditions, it is estimated that only around 10% of the approximately 100 biologics expected to lose exclusivity in the EU by 2032 will face biosimilar competition[228].

In the medium term (2030–2038), assuming that the tailored approach to CES waivers is widely implemented, and that complementary investment support measures partially mitigate the 'biosimilar void', it is projected that 35–55 biosimilar MAAs may be submitted annually. Of these, approximately 90% are expected to concern monoclonal antibodies and fusion proteins, with 70–80% benefiting from a tailored development approach including a CES waiver.

On this basis, the **gross annual cost savings** for industry are estimated at EUR 418-990 million.

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[226] Approximately 100 biological medicines are expected to lose exclusivity in Europe by 2032. However, 79% currently have no biosimilars in development, and only 10% of biologics nearing loss of exclusivity are likely to face biosimilar competition in Europe when accounting for the geographic footprint of clinical trials (IQVIA, 2026). The void is concentrated in biologics with projected global sales below USD 100 million, where current development costs remain prohibitive.

[227] IQVIA, The Impact of Biosimilar Competition in Europe, 2026, iqvia-the-impact-of-biosimilar-competition-in-europe-2026-01-26-forweb.pdf.

[228] IQVIA, The Impact of Biosimilar Competition in Europe, 2026, iqvia-the-impact-of-biosimilar-competition-in-europe-2026-01-26-forweb.pdf.

After accounting for residual clinical development requirements **net annual savings** are expected in the range of EUR 293–700 million.

Over a five-year period within this timeframe, cumulative **net savings** are therefore estimated at:

- **Low scenario**: EUR 1.5 billion
- **Central scenario**: EUR 2.3–2.8 billion
- **High scenario**: EUR 3.5 billion

These projections reflect a scenario in which reduced development costs, increased regulatory predictability, and targeted policy support measures contribute to higher biosimilar uptake and increased market entry. As such, the economic impact of CES waivers is expected to be significantly amplified compared to the near-term period.

Overall, the medium-term scenario suggests that the full implementation of a tailored, risk-based regulatory approach could generate substantial and sustained cost efficiencies for industry, while supporting improved competition and access to biological medicines in the Union.

According to the Biosimilar Medicines Group[229], a sector group of the Medicines for Europe organisation, under the current framework, the sector's contribution to European clinical trials for biosimilar candidates amounts to EUR 4.9 billion over five years, with approximately 71% allocated to CES. The implementation of CES waivers could free an estimated **EUR 3 billion over five years** in clinical spending. These resources could be reallocated to European research and development and manufacturing, including the development of next-generation biosimilar medicines, new technological platforms (e.g., antibody-drug conjugates, cell and gene therapies), and modernisation of manufacturing operations).[230]

While the cost impact of biosimilars has been evaluated, the potential time savings are expected to be limited, as many development streams run in parallel rather than sequentially. A CES waiver would accelerate one stream, while the remaining streams continue to constrain the overall development timeline. However, shorter development pipelines would allow developers to start later, once the originator's market trajectory—including geographic penetration, therapeutic positioning and real-world outcomes—is clearer, thereby reducing commercial risk without affecting the ultimate timing of market entry.

Administrative burden: The dominant cost saving is associated with the CES waiver and not with the reduction in dossier preparation labour. According to reported estimates, the preparation of a full CES-based dossier requires approximately 328 person-days (EUR 131–197 thousand), compared to 253 person-days (EUR 101–152 thousand) for a tailored package. This represents a reduction of approximately 75 person-days (EUR 30–45 thousand) per application. Applied to 12–18 affected MAAs annually, this yields an aggregated administrative savings of **EUR 0.36–0.81 million per year at current**

[229] https://www.medicinesforeurope.com/biosimilar-medicines/who-we-are/ .
[230] Medicines For Europe factsheet: Pillar 1-2-3-4-FOOTPRINT-SPC-Biotech-Act-facsheets-ppt.cdr.

conditions. While measurable, these savings are secondary relative to clinical trial cost reductions (see Annex 5 for reported detailed dossier preparation calculations).

Innovation and research: The proposed intervention is expected to reallocate innovation incentives toward advanced analytical science. As outlined in the section 'conduct of business' above, savings generated from the elimination of superfluous comparative efficacy studies (CES) are estimated at **EUR 717 million- 2.76 billion in five years,** as regulatory reliance shifts from clinical trials to analytical comparability. According to another recent industry report[231], approximately EUR 3 billion in R&D expenditure will be freed up over five years out of the current EUR 4.9 billion —to be reinvested in the development of additional biosimilar products, new technology platforms, and the modernisation of manufacturing operations.

Public health: The tailored approach is expected to accelerate patient access without compromising safety. Therapeutic coverage is expected to expand from approximately 27 reference products to 35–45 by 2030 and to 55–75 by 2038. The cumulative number of authorised biosimilars is expected to grow from 151 in 2024 to 250-350 between 2025-2030[232] and to 450-650 between 2030-38[233]. This expansion is projected to generate significant system-level savings, increasing from approximately **EUR 13 billion in 2024 to EUR 16–22 billion annually by 2030 and EUR 22–35 billion/year by 2035–2038,** driven by increased competition and broader treatment availability. The introduction of a tailored regulatory approach is not expected to alter the underlying safety standard, as it modifies evidentiary requirements rather than regulatory thresholds for approval[234]. The safety outlook therefore remains unchanged, with **no increase in withdrawals on safety grounds anticipated**.

However, the upper bounds of these projections are tempered by a structural gap in the market. Of approximately 100 biologics expected to lose exclusivity by 2032, 79% have

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[231] Medicines for Europe, Biosimilar Medicines Sector Group. (2025). Reforming Regulations, Market Entry and Competition for Biosimilar Medicines (Pillar 2) [Factsheet]. Brussels: Medicines for Europe. https://www.medicinesforeurope.com/wp-content/uploads/2026/03/FOOTPRINT-Biotech-Act-factsheet.pdf.

[232] 151 biosimilars already authorised in 2024. To this, we add the expected new approvals between 2025 and 2030 i.e. between 25 and 45 new applications, of which ~89% will be successful over 5 years

- Low estimate: 25 × 5 × 0.89 = ~111 new products → total ~262
- High estimate: 45 × 5 × 0.89 = ~200 new products → total ~351

[233] ~300 authorised products in 2030, to this we add 35–55 annual applications between 2030 – 38 × 8 years ~89% success rate

- Low estimate: 35 × 8 × 0.89 = ~249 new products → total ~549
- High estimate: 55 × 8 × 0.89 = ~392 new products → total ~692

[234] *Risk based tailoring of clinical evidence requirements for biosimilar marketing authorisations does not lower safety standards; it reflects the maturity of the EU regulatory framework for biosimilars and advances in analytical science used to demonstrate comparability with the originator product. The EU has the longest global experience with biosimilars, with the first EU biosimilar approved in 2006, and since then over 100 biosimilars authorised across around 30 reference products, with no withdrawals on safety grounds. This long-standing experience confirms the robustness of the comparability-based regulatory approach.*
At the same time, analytical methods have significantly evolved. High-resolution structural characterisation, advanced functional assays, and improved immunogenicity testing now allow very sensitive detection to demonstrate comparability with the originator medicinal product.
This is complemented by strong post-authorisation safety monitoring through the European Medicines Agency. In this context, streamlined clinical requirements do not weaken safety; they align regulatory expectations with current scientific capability while preserving continuous real-world pharmacovigilance.

no biosimilar versions in development and only 10% are likely to face biosimilar competition in Europe[235].

Expected impacts of measure 2: biosimilar strategic projects recognition and support

The projects this proposed measure would target benefit from the same framework described in intervention n°9 *i.e. recognition and the support of health biotechnology strategic projects***:** administrative support (including through single points of contact at Member State level), accelerated procedures (including for permitting, subject to a maximum ten-month deadline, as well as for dispute resolution and litigation), a public interest status and measures to facilitate access to funding at national and EU-level.

Administrative costs on businesses: As for the projects described in intervention n°9, the greatest efficiency gain is expected to be the reduction of execution risk through more predictable and coordinated administrative handling, notably through a structured single point of contact model and a maximum 10-month permit-granting timeline, complemented by facilitated access to finance.

Conduct of business: The measure is expected to mobilise additional investment in EU biosimilar manufacturing and development infrastructures. The magnitude depends on Member State implementation. To estimate the order of magnitude, three uptake scenarios are used, consistent with the approach applied in the strategic projects and high impact projects assessments. Biosimilar projects are framed as a subset of the total strategic project pipeline:

- **Low uptake**: 3–5 biosimilar projects recognised by 2038 (~0.3 per year)
- **Medium uptake**: 8–12 biosimilar projects (~1 per year)
- **High uptake**: 15–20 biosimilar projects (~1.5 per year)

See annex 7 for an overview of the illustrative order-of-magnitude impacts for biosimilar strategic projects derived by proportional scaling from the Strategic Projects of chapter II (intervention n°9).

Competitiveness, trade and investment flows: The effectiveness of the proposed measure is expected to scale with its uptake, with higher levels of recognised projects leading to greater mobilisation of investment in EU-based biosimilar manufacturing. The investment mobilisation estimated at **EUR 0.9–7.6 billion cumulative by 2038** reflects the total capital deployed in biosimilar manufacturing and development projects. This includes private investment, STEP-supported instruments, and any national co-financing. The per-project investment range of **EUR 200–400 million** is consistent with the capital requirements for dedicated biosimilar biomanufacturing facilities, as documented by industry sources.[236]

[235] IQVIA, The Impact of Biosimilar Competition in Europe, 2026, iqvia-the-impact-of-biosimilar-competition-in-europe-2026-01-26-forweb.pdf.
[236]Alira Health. (2025, November 6). 2025 global biosimilars report: Market size, growth drivers, regional dynamics. https://alirahealth.com/biosimilars-market-2025-market-size-growth-drivers-regional-dynamics/

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Further, the proposed measure supports EU based manufacturers' competitiveness in biosimilars, by promoting **international partnerships** among economic operators as a mean to share expertise and diversifying and strengthening supply chains. Recent studies identified an increasing number of partnerships involving ex-EU biosimilar companies that collaborate with European manufacturers to launch products in Europe. Historically, these partnerships were relatively uncommon, but their prevalence has increased. Between 2006 and 2013, ex-EU partnerships represented 30% of all approvals, but more recently this figure increased to 45% (2014–2024).[237] The proposal aims to leverage this trend by encouraging promoters of biosimilar projects to establish or strengthen cooperation with **international partners**, including with a view to fulfilling the conditions for the recognition of biosimilar strategic projects.

When it comes to **research and innovation (R&I)**, as per specific eligibility criteria proposed in Article 29, the recognised projects could contribute to R&I through setting up or extending infrastructures for biosimilar analytical testing; strengthening the use of platform technologies for research, development and marketing authorisation; and developing analytical methodologies that would reduce the need for clinical data for the development and approval of biosimilars. The impact of the measure on R&I will depend on how many recognised projects will focus on material research or analytical innovation outputs. As mentioned in the conduct of business section above, biosimilar projects are framed as a subset of the total strategic project pipeline. Out of all 3-5 biosimilar strategic projects in a low uptake scenario, we assume 1-2 to be R&I focused; 2-4 out of 8-12 in a medium uptake scenario; and 3-6 out of 15-20 in a high uptake scenario (see Annex 7 for full table of scenarios uptake).

The administrative costs for public authorities are part of the overall cost analysed in chapter II for strategic projects. The initiative does not create a separate approval architecture for biosimilar strategic projects specifically. Efficiency gains are expected to emerge over time as procedures standardise, and administrative experience accumulates. By 2030–2038, as the recognition process matures and uptake increases (estimated at 8–12 biosimilar projects under the medium scenario), the net effect is expected to be decisively positive for the sector.

Table 212. Summary assessment of the effects due to the policy intervention

Policy measure	COB	Admin	CTI	Int Mar	I&R	PA	H&S
1. Tailored regulatory approach (Art. 28)	++	+	+	+	+	-	+
2. Strategic project support (Art. 29-30)	+	+/-	+	+	+	-	0/+

[237] Troein, P., Newton, M., Stoddart, K., Travaglio, M., & Arias, A. (2025, January). *The impact of biosimilar competition in Europe*. IQVIA. http://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2024.pdf.

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5.2.3 Intervention n°13: SPC extension for biotechnology medicines

Supplementary protection certificates (SPCs) are an intellectual property right. They serve as an extension to a patent right and aim to offset the loss of patent protection for pharmaceutical that occurs due to the compulsory testing these products require prior to obtaining regulatory marketing approval. An SPC can extend a patent right for a maximum of five years[238].

The Regulation proposal introduces an extension of 12 months of the **SPC for medicinal products developed by means of biotechnology processes and for Advanced Therapy Medicinal Products.**

Eligible medicinal products would have to contain a new active substance which is effective via a mechanism of action distinctly different to that of any other product already authorised in the EU for preventing or treating the same disease. The clinical trials evaluating the efficacy of the product and supporting its marketing authorisation would need to have been conducted in more than two Member States and at least one manufacturing step, excluding packaging, quality and testing certification, would need to be performed in the Union.

This provision is intended to target highly innovative biotechnology-based products that are expected to deliver significant therapeutic advantages to patients, particularly those who currently have limited or no treatment options.

The proposed SPC extension does not affect in any respect the existing legal framework in Regulation (EC) No 469/2009[239] or related measures, nor the ongoing reform of that framework. In accordance with the principle of legal certainty, this includes how the SPC extension will be applied in the future. The SPC extension has a different scope. Its purpose is not to replace the existing SPC legal framework but to complement it.

Intended objective:

The SPC, by prolonging IP protection, provides a very robust shield from competition for the relevant product[240]. Additionally, on average, products for which SPC is the last form of protection to expire have higher revenues than medicines that rely on regulatory protection (RP) or patent (see Annex 7 for details on protection length). This further underscores the attractiveness and effectiveness of this incentive.[241]

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[238] Six-month additional extension is available in accordance with Regulation (EC) No 1901/2006 if the SPC relates to a medicinal product for children for which data has been submitted according to a Paediatric Investigation Plan (PIP). PIPs are required to support the authorisation of medicines for children. They ensure that enough data is collected on the effects of the medicine on children.

[239] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L 152 16.6.2009, p. 1 httphttp://data.europa.eu/eli/reg/2009/469/2019-07-01.

[240] Max Planck Institute for Innovation and Competition (2018), Study on the Legal Aspects of Supplementary Protection Certificates in the EU.

[241] Impact assessment accompanying the revision of the pharmaceutical legislation https://health.ec.europa.eu/publications/impact-assessment-report-and-executive-summary-accompanying-revision-

Innovation and patenting behaviour in biotechnology are closely linked to firms' expectations around the future commercial value and appropriability of inventions. However, intellectual property is just one part of innovators' investment decisions. The Biotech Act proposal includes explicit conditions to link the SPC extension to conducting late-stage clinical trials and manufacturing in Europe, because the incentive is precisely meant as a stimulus to modify sponsors' behaviour at the margin, thereby helping generate economic and societal gains for Europe.

Analysis and limitations:

It is acknowledged that modelling the costs and benefits of this measure necessitates certain assumptions and it is subject to inherent limitations, such as the need to work with small samples of medicines given the medicine characteristics being studied, and simplified representations of complex real-world health biotech innovators' behaviour. These limitations have been mitigated by using robust data sets reflecting observations of actual product lifecycles and market entry patterns (market data from the IQVIA MIDAS® databases) and assessments on products eligibility (data provided by the European Medicines Agency which will be in charge of assessing eligibility), to ensure that the resulting estimates of the measure's potential remain grounded and reliable rather than being based on a more theoretical model.

To make an estimation of the costs of the SPC extension, an analysis was performed of the 198 innovative medicines which lost patent or regulatory protection between 2016 and 2024 and that have not so far been withdrawn from the market. Of those medicines 31 were found to be biologics, 12 of which rely on SPC as the last protection to expire (40%). Of these 12, 10 fulfil the proposed Regulation's SPC eligibility criterion of being a medicine developed with a biotechnology process. In order not to limit the sample size unduly, the other SPC eligibility criteria have not been used to exclude medicines from the sample as they should not a priori affect the market characteristics of the medicine. The sample studied was restricted to these 12 products in order to ensure that the medicines considered are representative of those for which the SPC extension would be relevant[242]. The model specifically looked at how sales volumes and prices shift when a product loses patent protection and biosimilar versions enter the market. On this basis, the model made it possible to calculate how much additional profit accrues to the originator and how much additional cost is borne by the healthcare system and patients when an extra year of protection is added.

Expected impacts:

Figure 10 charts the course of revenue and volume for the average medicine in the sample across 20 years: 15 years before expiry of protection and 5 years after expiry. This represents our baseline in the absence of SPC extension. As biosimilar entry drives prices

general-pharmaceutical_en supports this statement, furthermore data analysed for the impact of the SPC extension measure confirm the same trend. Of the 31 biological products in the nine-year cohort studied, 12 had SPC as last protection to expire and 10 had RDP. While the SPC-reliant products averaged EUR 740 million during their last year of protection collectively, the 10 RDP-reliant medicines averaged EUR 83 million.

[242] To accurately measure economic impact, we shouldn't just count all eligible products. We must isolate those where the SPC extension is the sole factor preventing biosimilar entry (last layer of protection to expire). If other protections remain in place after the SPC expires, the extension has no real-world economic effect.

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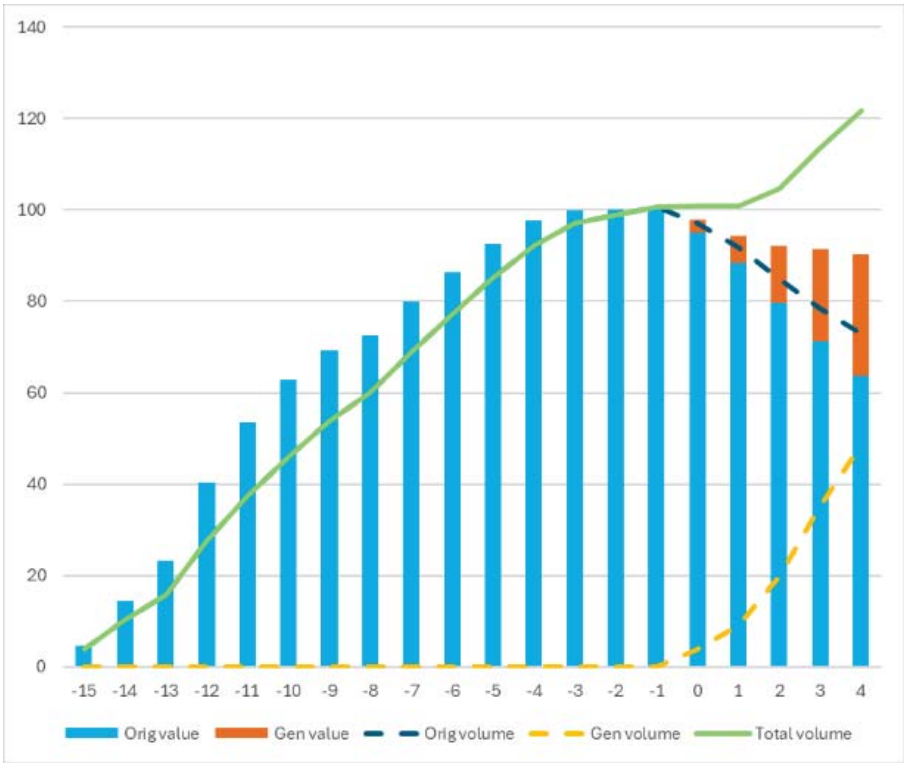
down, it is associated with an accelerated increase in volume, effectively allowing for a higher number of patients to be treated (green line). Because prices are lower, overall revenues fall, despite the higher volumes. This process is somewhat restrained in the case of biologics by the higher barriers to entry for biosimilars as compared to generics for small molecules, including due to stricter regulatory pathways and more complex production processes, resulting in a relatively shallow decrease in overall revenue.[243]

Figure 10. Normalised sales and volume for SPC-reliant biological medicines with current duration of SPC

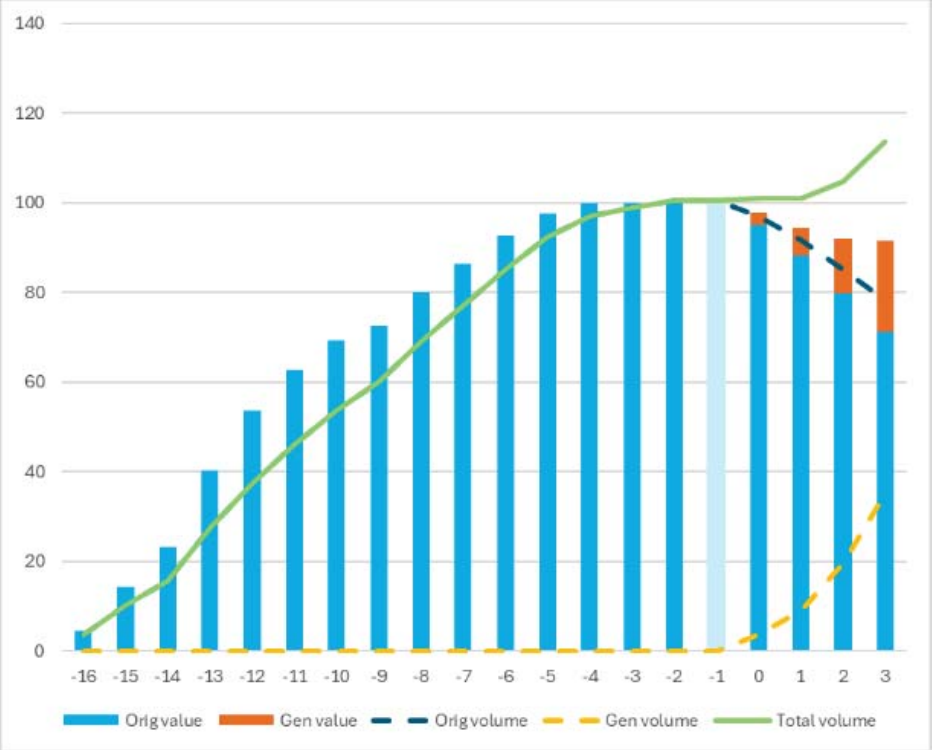


Author analysis based on IQVIA MIDAS data

To assess the impact of an additional year of protection, the same twenty-year reference period was maintained, but with an additional year of uncontested sales with revenues and volumes equal to those in the year before expiry and one year fewer of contested sales. The effect is depicted in Figure 11 (light blue bar). The result is a fall in the number of patients treated accompanied by an increase in spending.

[243] For the purposes of this graph, one medicine from the sample, with particular outlier characteristics was excluded. The product is a moderately high revenue medicine with no biosimilar entry even after several years and a far shorter lifecycle than all the other SPC-reliant biologicals in the sample.

Figure 11. Normalised sales and volume for SPC-reliant biological medicines products with a 12- months SPC extension



Author analysis based on IQVIA MIDAS data

To assess how many products per year would be eligible for the measure, data from EMA was analysed covering the period from 2011 to 2025. If the SPC extension existed, over the past ten years, there would have been on average **5 products per year** among all those centrally authorised that fulfil all the criteria to obtain the SPC extension, and **6** per year over the past 5 years, albeit with considerable variation per year. As stated above, out of the 31 biologics we analysed, 40% (i.e. 12 products), relied on SPC as their last effective protection[244]. Thus, assuming the proportion of products relying on SPC remains constant, the SPC extension would have an economic impact on **2-3 products per year**.

Conduct of business: The average revenue of a product in the sample in the year prior to protection expiry is EUR 740 million. Impacts in the model are calculated as a percentage of revenues in this last protected year. Taking into account the expected impact of the measure, as shown in Figure 11, an additional year of protection results in an additional direct cost to public payers in the EU of approximately EUR 70 million per medicine, corresponding to approximately EUR 210 million annually at aggregate level (considering three medicines per year). The relatively **moderate increase in spending** reflects the shallow post-expiry revenue decline characteristic of SPC-reliant biologicals.

[244] To accurately measure economic impact, we shouldn't just count all eligible products. We must isolate those where the SPC extension is the sole factor preventing biosimilar entry (last layer of protection to expire). If other protections remain in place after the SPC expires, the extension has no real-world economic effect.

Functioning of the internal market and competition: For the reasons set out above, biosimilar competition produces slower price reductions than generic competition, limiting the price differential between the extension scenario and the baseline. Instead, the main effect of the extension relative to the baseline is the temporary postponement of additional product entry, implying fewer available treatment options and delayed expansion of supply for patients during the extension period. By postponing competitive entry, the extension maintains higher average prices for an additional year and delays the expansion of supply associated with follow-on products.

Public health: In addition to the direct cost impact of approximately EUR 70 million per medicine, there is a delay in the expansion of coverage (the upward pivot of the green line is delayed by a year). This is expressed in a patient monetised loss of EUR 135 million per product and EUR 405 million for three products (see table below) calculated as the additional spending required to achieve baseline coverage at policy scenario prices. Additional details in Annex 7. Additional protection for originators results in a transfer of revenue and profit from biosimilar makers to originators as well as a transfer of economic surplus from payers and patients to the pharma industry, as set out in the table below[245].

Table 13. Impact of change of +1 SPC extension for biotechnology medicines

1 year increase in protection	Per medicine	Annual (3 meds)
Originator gross profit	230 m	690 m
Biosimilar gross profit	-80 m	-240 m
Cost to public payer	70 m	210 m
Patients monetised gains/losses	135 m	405 m
Patients + payer monetised gain/loss	205 m	615 m

***Source**: Author analysis based on IQVIA MIDAS data*[246]

Due to data availability and confidentiality around price negotiation, this calculation is based on list prices and cannot capture discounts and clawback mechanisms that apply at national pricing and reimbursement stage. If it were possible to use net prices, the cost calculation would be lower.

Competitiveness, trade and investment flows: According to EMA data from 2016 to 2025, in addition to the 5-6 products that would have met all the criteria each year, a further five products would have met all the criteria except the "geographic" ones, i.e. conducting trials in more than two Member States and having part of their manufacturing in the EU.

[245] As set out in Annex 11, this latter transfer can be approximated by the combined total of the monetised loss to patients and the additional costs to the public payer of EUR 205 million per medicine.
[246] Internal analysis by the authors using IQVIA MIDAS® quarterly sales data 2008-2024. Geographical coverage: EU27 without Cyprus, Malta and Denmark. which were obtained under license from IQVIA and reflect estimates of real-world activity. Copyright IQVIA. All rights reserved. The statements, findings, conclusions, views, and opinions contained and expressed herein are not necessarily those of IQVIA.

It was assumed again that about 40% of the products are SPC-reliant. Thus, the SPC extension could potentially be awarded to 4-5 products annually (rather than 2-3) if developers changed their behaviour in response to the incentive i.e. conduct clinical trials in more than one Member State and part of the production of the medicinal product in the EU.

This measure is designed to incentivise late-stage clinical trials as part of the product's marketing authorisation. Clinical trials generate sizeable economic benefits in several ways as outlined in the economic impact section of intervention n°4 (Clinical Trial Regulation Revision). A further potential benefit of more clinical trials is avoiding the healthcare expenditure which would normally be associated with sponsor-funded medicines, diagnostics and monitoring. As an illustrative benchmark, Polignano et al. (2022)[247] estimate a leverage ratio of **3.67**, implying **EUR 3.67 of avoided healthcare expenditure for every euro of sponsor investment** in industry-sponsored clinical trials. While the SPC extension conditionality of conducting clinical trials in the EU can only impact behaviour at the margin of a limited set of products, the combined impact with measures proposed in the Biotech Act on streamlining clinical trials can be non negligeable[248].

The measure is also designed to encourage sponsors to incorporate an EU-based manufacturing step as part of their manufacturing and scale-up strategies. As underscored by public consultations, literature and empirical evidence, intellectual property, including SPC extension, is an important part of the broader set of elements that drive biotechnology investment decisions. While the decision to invest in a biotechnology manufacturing facility cannot be attributed to any single product or regulatory incentive, similarly to the conditionality concerning the conduct of clinical trials in the EU, the positive impulse created by the SPC extension could contribute to broader investment and employment effects at the margin.

The effect of these measures is expected to be **amplified and completed by other measures** set out in the Biotech Act, especially those aimed at supporting and derisking investment in manufacturing in the EU (e.g. high impact biotechnology health strategic projects and biotechnology health strategic projects) and the amendment to the Clinical Trials Regulation to facilitate the conduct of multi-national clinical trials in the EU. These changes will make the incentive to conduct clinical trial and manufacturing activity to Europe introduced by the SPC extension more effective. It must also be noted that the SPC extension complements other measures in the Regulation proposal and in the reform of the general pharmaceutical legislation[249] that are aimed at facilitating development of innovative products and reducing time to market (e.g. use of AI and regulatory sandboxes, combined trials and shortening marketing authorisation timelines).

Research & Innovation: Between 2004 and 2011, just over one product per year would have been eligible for the SPC extension, according to EMA's data. This number grew to five in the last decade and to six in the last 5 years. While the long-term trend reflects a

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[247] Polignano, M. G., et.al. (2022). Economic impact of industry-sponsored clinical trials in inflammatory bowel diseases: Results from the national institute of gastroenterology "Saverio de Bellis". Frontiers in pharmacology, 13, 1027760. https://doi.org/10.3389/fphar.2022.1027760.

[248] Refer to the relevant section of the SWD on the Clinical Trials Regulation for a full assessment of costs and benefits

[249] COM/2023/193 final and COM/2023/192 final.

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growing health biotech pipeline, we observed high variability in product eligibility year-over-year, reflecting the unique risk profile of the health biotech sector. With the **development of biotechnology pipelines** and scientific advances, we can expect this measure's economic impact to increase, but in parallel it is also expected to bring new transformative products to the market.

Administrative costs on businesses, including SMEs: Under the current regulatory framework, companies applying for SPCs incur **administrative costs** associated with preparing and submitting applications, assessing eligibility, and interacting with patent and regulatory authorities. SPC applications require legal interpretation of patent and marketing authorisation scope and prior use of products protected by the patent and the medicinal product which has been authorised. They require internal legal and regulatory staff time and, in many cases, recourse to external legal advisors. For SMEs, SPC-related administrative and advisory costs can weigh more heavily, given their more limited in-house legal and regulatory resources and greater dependence on outsourced expertise[250]. Evidence from the impact assessment of the Commission proposals for a unitary SPC[251] shows that overall administrative and advisory costs for filing SPC extensions across multiple Member States typically range between approximately EUR 80,000 and EUR 150,000 per product.

Public Authorities: The proposed SPC extension does not introduce new standalone administrative procedures beyond those already required for obtaining SPC protection under the baseline framework. Companies seeking to benefit from the SPC extension would follow the same application process as for a standard SPC, with the addition of the documentation provided by EMA demonstrating that the eligibility criteria for the extension are fulfilled. As these elements are largely based on information already provided during the marketing authorisation process and associated regulatory documentation, the additional administrative effort required from companies is expected to remain negligible. Therefore, overall costs would remain between EUR 80,000 and 150,000 per product.

The SPC system is subject to **disputes over eligibility, duration and scope**, which generate administrative and legal costs for companies, public authorities and courts[252].

The proposed SPC extension, by introducing novel eligibility criteria, especially in the early years of application might also entail the same litigation risks which currently characterise the existing legal framework with increased risk of administrative costs and burdens. This is because the generics manufacturers are well placed to contest any form of SPC extension. In addition, the Court of Justice interprets the conditions for grant narrowly

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[250] European Commission (2023), Commission Staff Working Document – Impact Assessment accompanying the proposals on supplementary protection certificates, SWD (2023) 118 final, Brussels, 27 April 2023, Section 2.3.2 and Annex 6 (SME Test).

[251] European Commission (2023), Commission Staff Working Document – Impact Assessment accompanying the Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) and the Proposal for a Regulation on the unitary supplementary protection certificate for medicinal products, SWD (2023) 118 final, Brussels, 27 April 2023, Section 2.3.2 and Annex 5B.

[252] Technopolis Group (2018) Effects of supplementary protection mechanisms for pharmaceutical products. Final report, May 2018. Amsterdam/Vienna: Technopolis Group.

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as it considers that all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should be considered.

Conclusions

Providing an additional year of protection for innovative biotech medicines rewards the **delivery of transformative treatments** for high-burden conditions, ranging from oncology to metabolic and neurological disorders, while sending an important **signal to companies** regarding investment priorities. The geographical conditions ensure that this additional incentive also favours investment in the EU and helps strengthen the EU's health biotech sector, which is crucial both for European patients and for the competitiveness of one of Europe's most valuable industries.

Table 14. Summary assessment of the effects due to the policy measure

Policy interventions	COB	Admin	CTI	Int Mar	I&R	PA	H&S
SPC extension	++	0/-	+	-	+	0	-

5.2.4 Intervention n°14: Facilitating Access to Funding

The proposed Regulation establishes an **EU Health Biotechnology Investment Pilot** in order to mobilise substantial private investment into the sector. This is a partnership with the European Investment Bank and European Investment Funds (together the "EIB Group") and other implementing partners, bringing together equity instruments and venture-style debt tailored to biotechnology-specific risk profiles. In synergy with existing EU investment initiatives, the Pilot would support the full lifecycle of health biotechnology companies and projects. As early as 2026 and 2027, the EIB Group will aim to mobilise EUR 10 billion of total investment into the sector through the BioTechEU initiative.

Projects that contribute to an **EU late-stage Capital Booster Pilot** will be recognised by the Commission as high-impact health biotechnology strategic projects. These projects are expected to strengthen cross-border investment, mobilise long-term and institutional capital, improve investor access and issuer visibility, and enhance biotechnology-specific investment expertise.

More broadly, health biotechnology is recognised as a strategic technology eligible for Union and national financial support in line with applicable rules, including State aid rules. High-impact health biotechnology strategic projects may receive particular consideration under relevant Union programmes and may combine Union funding with financing from the EIB Group, national promotional banks and private investors, in line with applicable

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rules[253]. These measures aim to address structural financing gaps, particularly at late development stages, and to crowd in private capital.

Expected impacts:

Over the last 10 years, health biotechnology was a strategic financing priority for the EIB Group, underpinned by close cooperation with the European Commission through EU budgetary resources[254] and complementary EIB Group own resources. Over the period 2015-2025, the Group has scaled its activity across the full financing chain, combining (i) EIF-backed investments into specialised venture capital and growth equity funds ('fund of funds' approach) to support more than 1000 health biotechnology projects and emerging startups with (ii) direct EIB loans to more than 145 later-stage innovative SMEs and midcaps ('venture loans') or (iii) established pharma companies ('corporate loans').

With all these investments, the EIB Group mobilised more than EUR 100 billion for the benefit of the health biotech sector over this period. Table 15 summarises this activity across instruments, including the EU budget guarantee backing those investments and how much funding the original EIB Group investment mobilised by crowding in private capital. Figures are reported as annualised run rates over the 2015-2025 period. **These are indicative averages only and should be interpreted with caution: actual annual volumes vary significantly from year to year, driven by market conditions, pipeline timing and the availability of EU budgetary guarantees.**

Table 15. Average annual EIB Group contribution to health biotech financing and investment mobilisation (2015–2025)

Instrument	EU guarantee/year	EIB Group Investment/year	Total Investment mobilised/year
Venture debt	EUR ~150 million/yr	EUR ~350-400 million	EUR ~3.1-3.5 billion
Corporate loans	EUR ~70 million/yr[255]	EUR ~730 million	EUR ~1.9 billion
EIF fund investments	EUR ~100 million/yr	EUR ~520 million	EUR ~5.5 billion
Total EIB Group	EUR ~320 million/yr	EUR ~1.6 billion	EUR ~10.8 billion

However, the EIB estimates that an annual investment gap of EUR 40 billion remains between the EU and US Biotech sectors[256]. To address this gap, the Biotech Act proposes the creation of a dedicated EU Health Biotech Investment Pilot. The pilot would deploy a toolbox of financial instruments, tailored to the specific risk and maturity profile of health

[253] Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union, OJ L, 2024/2509, 26.9.2024.
[254] InvestEU guarantee in the current MFF, EFSI and COSME-EFG in the previous MFF.
[255] Over the time period 2015-2025, out of the EUR 7 billion EIB corporate life-sciences loans (730/year), only EUR 2 billion (EUR 200 million/year) were backed by a guarantee of EUR 700 million (EUR 70 million/year). The remaining EUR 5 billion were financed from EIB own resources.
[256] The EIB Group uses industry data of EUR 69.7 billion investment for the US vs EUR 26.5 billion in the EU in 2021, resulting in a gap of ca. EUR 40 billion.

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biotech companies. With the support of these instruments, the pilot aims to crowd in substantially more private capital and respond more effectively to unmet market needs across the financing chain.

Table 16 outlines three scenarios for the pilot across different ambition levels. The scenarios assume a positive review after an initial two-year pilot period, and initial evaluation of crowd-in ratios, after which it will continue for a total of seven years. A longer time horizon helps with attracting substantial private investment, particularly from institutional investors such as pension funds, insurers and corporates, and reflects the long investment and value-creation cycles characteristics of the health biotechnology sector. In addition, sustained and predictable public support is critical for investor confidence, while sufficient time is needed to deploy and test the different instruments in the toolbox and adjust the mix in response to market uptake, geopolitical shifts and observed outcomes. The first scenario assumes a continuation of the level of EIB Group's average investment level over the last 10 years, with the second and third illustrating the additional level of EC guarantees and investment by the pilot needed to mobilise sufficient investment to close, respectively, 25% or 50% of the EUR 40 billion annual investment gap in the Health Biotech sector.

These scenarios are illustrative sensitivity cases rather than forecasts and depend on strong assumptions: linear scalability of deployment by the investment pilot over seven years, with the same distribution of investment across instruments as the EIB Group over the last 10 years, sufficient absorption capacity in the EU health biotech pipeline, no material displacement of private finance and no binding implementation constraints (including risk appetite, deal flow, administrative throughput and the availability of EU budgetary guarantees).

Table 16. Scenarios for the EU Health Biotechnology Investment Pilot

Scenario	EC guarantee over 7 years	Direct investments by the pilot over 7 years	Total investment mobilised over 7 years
Continuation scenario	EUR 2.2 billion	EUR ~10.4 billion	EUR ~70 billion
Closing 25% of EU-US investment gap	EUR 4.5 billion	EUR ~20.7 billion	EUR ~140 billion
Closing 50% of EU-US investment gap	EUR 6.7 billion	EUR ~31.1billion	EUR ~210 billion

5.2.5 Intervention n°15: Use of Artificial Intelligence and Data

The Regulation proposal provides for the publication and regular update of **EMA guidance, in agreement with the Commission**, on the use of advanced technologies, including AI, in the lifecycle of medicinal products. This guidance is expected to establish overarching principles to enhance clarity on the use of advanced technologies across the lifecycle, including development, manufacturing, regulatory evaluation and approval, and post-authorisation monitoring. The proposal also provides for the recognition of high-impact health biotechnology strategic projects in the form of **trusted AI-enabled**

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biotechnology testing environments (to facilitate integrated experimentation and translational validation) and **biotechnology data quality accelerators** to support the curation, standardisation and annotation of high-quality datasets required for the training, testing and validation of AI systems used in biotechnology applications.

Expected impacts:

The effects of the proposed measure are driven by several mechanisms:

- the establishment of common principles for the clarity of the use of AI across the medicinal product lifecycle, supporting consistent validation approaches and alignment of regulatory expectations;
- the complementing and structuring of case-by-case regulatory interactions through publicly available guidance, improving predictability and supporting the consistent deployment of AI across the medicinal product lifecycle;
- the provision of shared AI-enabled biotechnology testing environments combining experimental, computational and data-driven capabilities, reducing firm-level constraints and facilitating faster validation and scale-up of innovations;
- the improvement of data quality for AI applications, through the curation, annotation, standardisation and provenance of datasets to support the training, testing and validation of AI systems in biotechnology.

These mechanisms are interdependent and reinforce each other, with outcomes scaling with the number and maturity of recognised projects in the form of testing environments and data quality accelerators.

By combining improved regulatory clarity, enhanced validation infrastructure and higher-quality datasets, the measures are expected to help address key structural bottlenecks that currently limit the translation of Europe's scientific excellence into scalable innovation and thereby facilitate the translation of research into scalable innovation and contribute to strengthening the EU's competitiveness in AI-enabled biotechnology[257].

Uptake of high-impact projects (testing environments and data quality accelerators) is a key variable, and the scale of effects should be interpreted as proportional to the number, capacity and maturity of recognised projects. This reflects the project-based nature of the intervention and the reliance on public and private co-investment, which make different uptake scenarios possible.

Conduct of business: These impacts include less regulatory uncertainty and better access to validation and scale-up capacity. The guidance introduces a shift from case-by-case regulatory interactions to a publicly available reference point, replacing confidential and non-reusable exchanges and reducing transaction costs and internal deliberation time. This allows firms to take development decisions earlier and with greater confidence. Testing environments and data quality accelerators address the limitations in terms of access to shared pilot and scale-up infrastructure, with time-to-access effects being material. Under

[257] See further findings in the *Study to support the rapid assessment of policy scenarios to strengthen innovation and competitiveness in the field of biotechnology in the EU*, Rapid Assessment Scenario Study.

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baseline conditions, firms must independently finance or secure validation capacity, which entails high fixed costs, long lead times and coordination challenges. Shared infrastructure converts firm-level capital expenditure into pooled capacity, reducing delays in accessing pilot-GMP capacity and limiting the risks of overall project delay. Providing access to such infrastructure operates as an enabling condition for commercialisation.

Administrative costs on businesses, including SMEs: These costs are expected to evolve in a balanced manner. While guidance can reduce repeated clarification processes and improve predictability, care may be needed to ensure sufficient flexibility in its application. Participation in testing environments and data quality accelerators may entail certain administrative steps, such as application, reporting and knowledge-sharing; however, these are expected to be proportionate and to support transparency, collaboration and the generation of shared evidence. Appropriate design of support frameworks, including streamlined procedures, can help facilitate participation and ensure that administrative processes remain aligned with the pace of technological development.

Competitiveness, trade and investment flows: These reflect the availability of validation infrastructure and AI-ready data. Testing environments contribute by addressing key R&D constraints, providing integrated capacity for validation and supporting development of such activities within the Union. Data accelerators contribute by reducing 'data friction', improving data usability, interoperability and quality, and thereby lowering costs associated with fragmented datasets. Both interventions require sustained capital and operational support to ensure effective utilisation and maximise their impact on innovation and investment decisions.

Functioning of the internal market and competition: Changes in data readiness and interoperability across Member States are expected, with fragmentation and heterogeneity in data readiness remaining significant. Legal access to data does not ensure technical usability, due to differences in formats, metadata and validation criteria. Data accelerators help enlarge the effective market for data-driven development by improving standardisation, curation and interoperability. At the same time, differences in absorptive capacity and digital maturity across Member States may lead to uneven uptake in certain instances. This underlines the importance of ensuring coordinated implementation over time, so that these measures support convergence and avoid the emergence of a multi-speed internal market.

Innovation and research: Impacts are expected to reflect changes in regulatory uncertainty, validation capacity and data usability. The guidance helps reduce the 'option value of waiting', thereby accelerating investment decisions in R&D. Testing environments contribute through addressing limitations in access to integrated validation capacity, enabling validation activities under more efficient and coordinated conditions, and supporting improved validation timelines, regulatory submissions and standardisation, including platform effects. Data quality accelerators contribute through improving data quality and reducing dataset fragmentation, and interoperability, reducing the data preparation burden, generating research productivity effects, and enabling discoveries that fragmented datasets cannot support.

Public authorities: These stakeholders may need to support supervision, coordination, infrastructure maintenance and the development of specialised human capital in relation to

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testing environments and data quality accelerators. This includes ensuring appropriate technical capacities and skills of their staff, as well as the ability to adapt to evolving technological developments. Data quality accelerators require sustained investment in high-quality data curation and annotation capacities. This highlights the importance of ensuring continuity and coordination of funding mechanisms to support their long-term operation and maximise their impact.

Public health and safety reflect changes in the validation of AI-enabled biomedical tools prior to deployment. Testing environments contribute by reducing the real-world performance gap, improving reliability through structured multi-system validation, and supporting the use of more diverse datasets. In combination with the guidance, this supports the consistent application of validation and risk management principles across the lifecycle of AI-enabled medicinal products. These developments align with evolving regulatory validation frameworks and support safer deployment of AI-enabled tools.

Table 17. Summary assessment of the effects of Intervention n°15: Use of Artificial Intelligence and Data

Policy intervention	COB	Admin	CTI	Int Mar	I&R	PA	H&S
Use of Artificial Intelligence and Data	++	0/+	++	+	++	0/-	+

Scenario-based quantification of the expected impacts under different uptake cases has also been developed[258] to illustrate such potential impacts, which should be interpreted as proportional to the scale, maturity and utilisation of recognised projects.

Table 18. Illustrative uptake scenarios and order-of-magnitude impacts and estimation of associated impacts

Impact Category	Low uptake	Medium uptake	High uptake
What this scenario entails	2–3 recognised testing environments (Art. 32) and 2–3 data quality accelerators (Art. 33); upgrade-focused investment in existing facilities; primarily public funding with limited private co-investment	5–8 recognised testing environments and 5–8 data quality accelerators; mix of upgrades and new greenfield investments; mixed public-private funding on PPP model	10–15 recognised testing environments and 10–15 data quality accelerators; industrial-scale greenfield and upgraded facilities; public-private leverage at the largest nodes
Direct employment created	160–420 FTE (testing environments + data accelerators)	1,000–2,640 FTE	3,300–7,500 FTE
Companies and data users served per year	120–495 (20–45 companies; 100–450 data users)	1,100–3,400 (100–200 companies; 1,000–3,200 data users)	4,250–12,600 (250–600 companies; 4,000–12,000 data users)

[258] See Annex 7 and relevant sections of the Rapid Assessment Study – forthcoming – for further details.

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Total infrastructure investment (public and private CAPEX combined)	EUR 85 million –EUR 205 million	EUR 650 million– EUR 1.3 billion	EUR 2.4 billion–EUR 7.2 billion
Annual operational funding required	EUR 6–18 million/year (data accelerators) + testing environment OPEX	EUR 40–120 million/year + testing environment OPEX	EUR 150–450 million/year + testing environment OPEX
EU-level supervisory burden	1–3 FTE	2.5–8 FTE	5–15 FTE
Regulatory interaction cost avoided per firm (Article 31)	Reduction in regulatory interaction costs and timelines through publicly available guidance; effects consistent across scenarios	same across all scenarios	same across all scenarios
SME infrastructure barrier addressed	82% of SMEs currently unable to self-finance validation; shared access reduces per-firm fixed costs	same direction; scales with number of environments	same direction; scales with number of environments
Data usability gap addressed	87% of biomedical datasets currently not readily usable for ML; accelerators begin conversion to AI-ready	scales with number of accelerators	scales with number of accelerators
Key implementation risk	Limited number of environments and accelerators reduces coverage and competitiveness signal	Need to ensure efficient access conditions and interoperability alignment; OPEX sustainability	Need for continuous technological upgrading and balanced. access conditions across users

5.2.6 Intervention n°16: Prevention of biotechnology misuse

The proposed Regulation sets out a regulatory framework for customer screening of biotechnology products of concern, focused on custom-made and potentially dangerous sequences of synthetic DNA or RNA (synthetic nucleic acids, synthetic 'NA'). Custom NA synthesis is a small but crucial part of the biotech sector, representing around 0.1% of the European Biotech market[259]. The EU is home to around 100 companies in scope of the Chapter's provisions (ca. 20% of global NA synthesis companies) [260], with companies outside the EU selling custom nucleic acids to the Union market also in scope.

[259] Estimations based on GrandViewResearch estimates of the overall EU DNA synthesis market https://www.grandviewresearch.com/horizon/outlook/dna-synthesis-market/europe and EU Biotech market https://www.grandviewresearch.com/horizon/outlook/biotechnology-market/europe, assuming 50% of the overall EU DNA synthesis market (0.2% of the Biotech sector) is custom DNA synthesis, based on the number of companies – see footnote 260 and Annex 4 *Additional methodological information on specific measures* for details.

[260] IBBIS has identified 215 companies in the NA synthesis market in the EU, of which 66 companies performing custom synthesis, including oligos and data storage. The EU also has 4 benchtop manufacturers and 40 third-party vendors. The

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The exponential decrease in the cost of synthesising DNA and RNA has transformed biotechnology and made innovation more accessible. However, it has also increased the risk of misuse. A particular concern is that, given information on the genomes of viruses and other pathogens is publicly available, access to the physical DNA or RNA is an increasingly eroding chokepoint to create and weaponise pathogens to carry out biological attacks. **These could have consequences similar to, or worse than, those seen during the Covid-19 pandemic**, with economic costs of EUR 20 trillion for the EU alone. In 2024, MIT researchers demonstrated the ability to order synthetic genetic fragments sufficient to reconstruct the 1918 pandemic influenza virus, with their order fulfilled in almost all attempts[261].

Williams et al. (2025) estimate the near-future annual probability of biological attacks at 1% and accidents from their use at 1.5%. In recent years, multiple individuals in the EU attempted to carry out biological attacks by weaponising biological agents[262]. As synthetic NA continues to become cheaper and more widely available, this increases the risk that future biological attacks could be much more damaging, using transmissible viruses instead of toxins.

Table 19. Estimated risk from accidents with or misuse of Synthetic Nucleic Acids[263]

Type of events	Annual likelihood	Expected monetised harm to EU if event occurs
Large scale event[264]	1%	EUR 19.6 trillion
Small scale event[265]	22%	EUR 72 million
Agricultural event	4%	EUR 75.5 billion
Non-transmissible events	5-25%	EUR 121 million

To reduce this risk, the Biotech Act introduces a mandate for custom NA synthesis companies to verify the identity and legitimacy of customers purchasing potentially dangerous NA sequences. Companies that make benchtop NA synthesis devices available would also be obligated to implement a screening mechanism to prevent the synthesis of biotechnology products of concern with the device.

In the Biotech Act Call for Evidence[266], several industry representatives were supportive of such harmonised rules on NA synthesis screening at EU-level, given the significant

share of EU synthetic DNA providers is calculated following IBBIS number, namely 215 over 1,023 globally identified providers.

[261] Esvelt K. (2024), https://drive.google.com/file/d/1hNUnU8i2yubt5uesmmV17aTJXhYYDgTY/edit?pli=1

[262] https://jamestown.org/ricins-round-two-germany-prevents-another-islamic-state-motivated-bioterrorism-attack/, https://www.dw.com/en/germany-teens-home-searched-over-suspected-ricin-plot/a-72272711, https://health.ec.europa.eu/document/download/1be3e462-bd50-4c64-b147-add9d1d5a580_en?filename=com_2025-529-1_act_en.pdf on page 5.

[263] RAND 2026.

[264] Large-spreading events, global pandemics on the scale of COVID-19 or the 1918 influenza

[265] Expected to result in 65 deaths in case the event happens.

[266] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act/F3565340_en

heterogeneity in security practices[267] and the difficulty in complying with diverging rules across Member States[268]. Customer screening for potentially dangerous NA synthesis orders is frequent industry practice, with companies representing over 50% of global NA synthesis capacity being members of the International Gene Synthesis Consortium[269], an industry association that supports its members to follow its harmonised screening protocol.

However, companies implementing such biosecurity measures risk being undercut on price and turnaround time by providers without such measures. While the cost of screening for companies is currently minimal, as the cost of NA synthesis will continue to decline, the 'fixed' cost of screening could represent an increasing share of the final order price[270], further worsening this dynamic.

The provisions in the Biotech Act would aid to prevent such a 'race to the bottom' on biosecurity practices and enable competition by removing burden for companies that screen[271]. The RAND study assumes that a mandate would result in companies screening 98% of EU synthesis orders, while also indirectly increasing screening rates for non-EU orders by around 10%. **This is modelled to reduce misuse risk by 35% and accident risk by 86%[272]. This risk reduction would result in expected annual monetised benefits[273] of EUR 2.9 billion in 2027, increasing to EUR 5.5 billion in 2036.** Around EUR 1.2 billion of the benefits in 2027 stem from accident prevention, while around EUR 1.8 billion stem from attack prevention. This risk reduction would indirectly also benefit the biotech sector itself, avoiding severe regulatory backlash or a research pause as a consequence of such an event, which RAND estimates could represent EUR 10 billion in lost future research value.

These benefits significantly outweigh the estimated costs of the measure. Screening measures represent a minor cost for NA synthesis companies. In a Commission workshop on biosecurity[274], an EU NA synthesis SME who screens all their orders and customers highlighted how screening is practical and efficient for them, not hindering innovation or commercial timelines. Industry interviews suggest that SMEs of 40-50 staff dedicate around 0.5-1 FTE to biosecurity screening measures[275]. For cost calculations, we assume 30% of the ca. 100 custom NA synthesis companies in the EU already have customer

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[267] https://pmc.ncbi.nlm.nih.gov/articles/PMC11319849/

[268] See IBBIS mapping of explicit and implicit rules on NA synthesis screening across countries: https://globalsynthesismap.bio/policy?country=FRA.

[269] Harmonized screening protocol v2.0 (2017). International Gene Synthesis Corporation.

[270] If not matched by a similar decrease in the cost of screening with advancements in AI, as investigated in Acelas *et al.* (2026) cited below.

[271] https://www.weforum.org/publications/biosecurity-innovation-and-risk-reduction-a-global-framework-for-accessible-safe-and-secure-dna-synthesis-582d582cd4/

[272] Zakaria, S. *et al.* (2026). Cost–benefit analysis for synthetic nucleic acid screening in the European Union. Santa Monica, CA: RAND Corporation, 2026. https://www.rand.org/pubs/research_reports/RRA4805-1.html; The analysis is conducted over **ten years** and assumes a mandatory screening policy for all synthetic nucleic acids longer **than 50bp** bought and sold in the EU.

[273] The benefits quantify the reduction in the probability of biological events, such as another pandemic or an agro-terrorism attack, and the resulting reduction in expected public health and economic costs.

[274] Held on the 18th February 2026 in the context of stakeholder consultations for the Rapid Assessment Scenario Study (forthcoming).

[275] Evidence from SME expert interviews.

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screening policies in place[276]. We estimate the direct costs for the remaining 70% of EU companies in scope to hire an additional biosecurity FTE, implement IT tools to screen sequence orders[277] and direct compliance costs for the regulatory introduction and adjustment efforts are estimated at EUR 10.5 million annually, compared to a market size of roughly EUR 500 million[278].

The RAND Europe study estimates costs on a per-order rather than per-company basis, taking the full NA synthesis market as a basis. Adjusting their model to only cover the custom NA synthesis market in scope of the regulation and EU wages, direct legitimacy screening costs are estimated at EUR 22.2 million[279]. However, per-order costs are expected to significantly decrease with AI tools becoming more powerful and more widely available, with Acelas *et al.* (2026) estimating their cost to decline from EUR 1 to EUR 0.20 per customer as the verification step becomes increasingly automated[280].

For researchers and other customers, mandatory screening introduces additional administrative costs linked to documentation, procurement adjustments, and compliance procedures. For custom NA synthesis orders, these costs are estimated at approximately EUR 16.4 million annually. Public sector implementation costs should remain relatively small at around EUR 15 million (for EU and MS together), as the provisions do not rely on a licensing regime and costs for both the EU and Member States would be mostly limited to monitoring and inspection activities.

Table 20. Annual direct costs of screening measures[281]

EU enforcement cost	EUR 1.3 million
MS enforcement cost	EUR 14 million
Direct costs to companies	EUR 10.5 - 22.2 million
Direct cost to customers	EUR 16.4 million
Total	**EUR 42.2 – 53.9 million**

[276] Estimation based on the average between minimum (15%) and maximum (45%) values of the proportion of EU gene companies that voluntarily screen now, from the RAND analysis. The number is also in line with the global results of the survey conducted by Sentinel Bio on major screening tool providers and Response to the European Biotech Act - Call for Evidence. See details on methodology in Annex 4 *Additional methodological information on specific measures* for Intervention No 16.
[277] Assumed to be relatively moderate at EUR 1.5 million for all companies, given the availability of free tools to screen for sequences of concern: https://github.com/ibbis-bio/common-mechanism; and Response Call for Evidence for EU Biotech Act.
[278] Estimations based on https://www.grandviewresearch.com/horizon/outlook/dna-synthesis-market/europe. Assuming 50% of the overall DNA synthesis market is custom NA synthesis.
[279] Estimations based on RAND analysis, but adjusted for EU average labour costs, number of custom providers, and orders by the share of the market belonging only to custom providers (110 custom providers/215 total companies in the synthetic DNA= 0.51).
[280] Acelas, A., Palya, H., Flyangolts, K., Fady, P. E., & Nelson, C. (2026). Evaluating AI-Assisted Customer Verification for Synthetic Nucleic Acid Screening. *bioRxiv*. https://www.biorxiv.org/content/10.64898/2026.02.27.708645v1?ct=
[281] Calculation based on 2027 numbers. Costs may rise in the long run as the market also continues growing.

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In addition to these direct costs, a screening mandate may also result in different types of indirect costs which are more difficult to estimate. It might produce a "chilling effect" on research activities if some organisations delay or abandon projects due to concerns about delays or rejected orders. RAND Europe estimates potential research losses at EUR 97 million annually under very conservative assumptions. It assumes around 10% of researchers shifting to in-house synthesis, which carries significantly higher costs per order. In addition, introducing an additional regulation, even if not very costly to follow, may result in productivity loss for custom NA synthesis companies due to higher 'regulatory intensity', estimated at EUR 12.3 – 24.8 million.

Table 21. Comparing annual costs and benefits

Estimated benefits	EUR 2,900 million
Estimated costs (conservative estimate[282])	EUR 176 million

Even taking those conservative estimates of indirect costs into account, **the estimated benefits are 16 times higher than estimated costs.** This reflects the expected reduction in the probability of a biological attack with catastrophic public health and economic consequences, achievable through a targeted intervention with minimal costs for businesses and innovation.

5.2.7 Intervention n°17: Biodefence

The proposed Biotech Act establishes two categories of high-impact strategic projects for biodefence. Article 42 covers biodefence capability projects with a broad mandate, supporting activities from misuse prevention to surge capacity for diagnostics and countermeasures. Article 41 creates a more targeted instrument: the EU Biothreat Radar, focused on detection, characterisation, identification, analysis and assessment of biological threats, including novel, unknown and engineered pathogens, and on pathogen-agnostic cross-border surveillance.

These measures respond to a deteriorating threat environment. The ongoing Russia invasion on Ukraine[283] and war in Iran has raised concerns about the risk of pathogen release from biological weapons programmes[284], while advances in AI and biological engineering lower barriers to designing or modifying pathogens[285]. The assessment of impacts focuses on the EU Biothreat Radar, which provides a sufficiently detailed project scope for structured impact analysis.

Expected impact:

[282] Taking the upper bound of all cost estimates and including the relatively high RAND estimate of indirect costs.
[283] Russia has expanded site of past bioweapons research, satellite images show - Washington Post.
[284] Nelson, C., The Threat No One is Talking About in Iran, RUSI Commentary, 23 March 2026.
[285] Williams *et al.* (2025), Forecasting LLM-Enabled Biorisk and the Efficacy of Safeguards, Research Forecasting Institute.

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Deploying a surveillance system geared towards novel and engineered pathogens would represent a significant change from current systems focused on surveillance of known communicable diseases, with significant upfront and operational costs. By building on existing **EU surveillance capacities and initiatives**, ECDC estimates that coordinating Biothreat Radar activities at EU-level over seven years would require an operational budget of EUR 25 million for coordination, governance, and information-sharing platforms and 10 FTEs for the full period. A possible EU Reference Laboratory for Biothreat Security is estimated to cost EUR 20 million for the 7-year period.

The larger cost lies in updating and integrating existing **surveillance infrastructure**: syndromic, clinical, laboratory and environmental surveillance combined with metagenomic sequencing. The Biotech rapid assessment scenario study uses a model by SecureBio Detection (2025)[286] for a US pathogen surveillance system[287] at ~USD 52 million/year as a basis. Adapting this to the EU[288] yields two scenarios: Scenario 1 scales proportionally to EU transport and wastewater networks as complementary surveillance activities (~EUR 46.5 million/year), while Scenario 2 expands environmental collection and sequencing capacity as investing in traditional public health surveillance (~EUR 110 million/year).

Table 22. Estimated annual costs of pathogen surveillance systems

Cost component	US model (EUR)	EU Scenario 1 (EUR)	EU Scenario 2 (EUR)
Traveller genomic surveillance	19,516,259	22,635,734	7,543,733
Sequencing, processing & analysis	23,967,648	23,470,428	101,883,439
Environmental detection	425,610	416,374	832,748
Total (annual)	**43,909,518**	**46,522,536**	**110,259,919**

Traveller Genomic Surveillance (aircraft wastewater + nasal swabs). Sequencing/processing covers metagenomic sequencing, bioinformatics and analysis. Scenario 1 scales the US model proportionally. Scenario 2 expands environmental sampling and sequencing while discontinuing passenger swabbing. US figures from SecureBio Detection (2025) converted to EUR.

Benefits are harder to quantify but potentially substantial. Despite gaps in EU-wide standardised evaluation frameworks analysing the benefits of surveillance, studies exist that have quantified the number of infections prevented, deaths avoided, and costs saved in specific hospital and outbreak settings[289]. The advantages of early detection (through modelling) and the impact of infection control interventions informed by pathogen agnostic sequencing have been documented. However, whereas genomic and epidemiological surveillance are likely to deliver greater real-world value, they are much

[286]SecureBio Detection (2025), Scaling US Pathogen Detection. See details on methodology in Annex 4 *Additional methodological information on specific measures* for Intervention No 17.
[287]Based on swabs of airport travellers, municipal monitoring and aircraft wastewater analysis.
[288]See Methodology Annex for scenario descriptions and cost calculations.
[289] Nascimento de Lima, P. *et al.* (2024), The value of environmental surveillance for pandemic response, Scientific Reports, 14, 28935.

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harder to measure in economic terms. On the other hand, environmental surveillance is population and ecosystem-wide by design, produces early signals and is easy to plug into economic models. There are thus more quantified studies available proving the value of this type of surveillance.

Empirical evidence from European wastewater surveillance studies documents lead times of 5 to 19 days for SARS-CoV-2 detection relative to clinical identification.[290] Modelling by Nascimento de Lima *et al.* (2024) shows that an environmental surveillance system providing a five-day early warning relative to clinical detection could reduce deaths from 149 to 134 per 100,000, lower illness costs from ~EUR 1,271 to ~EUR 1,118 per person, and shorten lockdowns from 121 to 89 days in the first year of a COVID-19-type pandemic.[291]

Set against the broader costs of pandemics, these gains are substantial. Global viral epidemics cause estimated annual mortality of ~3.3 million people[292], and COVID-19 alone caused economic losses in the trillions across the EU. For a pathogen-agnostic system capable of detecting novel and engineered threats, the marginal benefit could be substantially higher, as limited surveillance currently exists for novel threats.

Beyond public health, the Biothreat Radar would generate indirect gains in research capacity and technological sovereignty, through investments in metagenomic infrastructure, bioinformatics pipelines and EU-based data sharing via the European Nucleotide Archive.

6 CUMULATIVE ECONOMIC, SOCIAL, ENVIRONMENTAL AND OTHER IMPACTS OF THE PROPOSAL

While many of the measures included in the proposed Biotech Act are technical and targeted in nature, their combined effect has the potential to be transformative. Together, they create a framework for competitiveness where regulatory simplification, investment mobilisation and innovation all support and reinforce one another.

This interaction is expected to generate impacts that are materially greater than the sum of each measure assessed in isolation, because it addresses the key structural bottlenecks affecting the EU biotechnology sector simultaneously. The measures also ensure that the sector contributes more effectively to societal objectives, such as economic growth, job creation and improved health outcomes.

The proposed Biotech Act's impacts materialise across four interconnected areas. The first three: **regulatory simplification**, **competitiveness and investment attractiveness**, and **innovation and research**, capture the primary economic impacts. They also generate indirect social impacts through employment creation, skills development and better access to innovative treatments driven by faster innovation. They address, respectively, the cost of operating within the EU regulatory environment, the EU's capacity to retain and attract

[290] ECDC (2025), Framework for integration of wastewater-based surveillance; Viviani *et al.* (2025).
[291] Nascimento de Lima, P. *et al.* (2024), The value of environmental surveillance for pandemic response, Scientific Reports, 14, 28935.
[292] Bernstein, A. S. *et al.* (2022), The costs and benefits of primary prevention of zoonotic pandemics, Science Advances, 8(5).

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productive capital, and the conditions needed to translate scientific excellence into marketable products. These areas are causally sequenced: regulatory simplification lowers the cost base, which strengthens the investment proposition, which in turn accelerates innovation throughput. The fourth area, **public health and safety**, captures the Act's ultimate societal return in terms of health outcomes, safety and resilience, complemented with an assessment of the expected **environmental impact**. The combined effects of the preceding areas materialise in benefits such as earlier patient access, supply resilience, and proactive biosecurity governance. The following assessment draws on 17 intervention-level assessments of impacts presented above, synthesising quantitative estimates and directional findings into a coherent account of the Act's expected effects. The estimates presented below should be interpreted in light of several **cross-cutting** factors that may influence their magnitude, while not changing the overall direction of the effects identified. First, the magnitude of investment mobilisation critically depends on the availability of EU budgetary guarantees under the next MFF, with estimates for the EU Health Biotechnology Investment Pilot and strategic projects frameworks assuming sufficient budgetary headroom. Second, the realisation of benefits depends on consistent implementation by Member States, particularly for clinical trials, the organ processing authorisation regime, strategic project permitting, and biosecurity screening, among others. Third, uptake-dependent measures, such as strategic and high-impact project recognition, regulatory sandboxes, and the AI and data framework, are presented under illustrative scenarios (low, medium, high). Actual impacts will be determined by the number, quality and maturity of projects. Finally, estimates assume broadly stable global market conditions; significant shifts in competitor jurisdictions' regulatory frameworks could alter the EU's relative competitive position.

6.1 Regulatory simplification and administrative burden

The Biotech Act delivers its most immediate effects in two distinct but mutually reinforcing ways: by eliminating procedural duplication across intersecting regulatory frameworks, and by shortening authorisation timelines. Where the Act removes entire procedural layers, it also shortens the remaining ones. Because these savings compound over multiple applications, modifications, and jurisdictions, the cumulative reduction across a full clinical development programme is substantially larger than any individual measure assessed alone[293]. These effects complement other simplification efforts in related Union frameworks. For instance, the pharmaceutical and medical devices legislation, in combination with the Biotech Act, are expected to generate significant simplification effects for the biotechnology sector[294].

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[293] The cumulative programme-level impact results from a combination of a) measure stacking within a single application (e.g., a single clinical trial application can benefit from several reforms simultaneously); and b) lifecycle accumulation (i.e., the same per-application saving recurs across many transactions and jurisdictions in one clinical development programme.

[294] The indicated complimentary simplification effect stems for example from: a) the revised Pharma Package, which has already transferred ERA for investigational medicinal products from the GMO legislation to the CTR, and which the Biotech Act builds directly on by introducing risk-proportionate ERA derogations for specified categories of low-risk GMO-ATMPs; b) the Commission's proposal of 16 December 2025 on the MDR and IVDR, which the Biotech Act's combined-studies measure complements by replacing parallel CTR-MDR/IVDR tracks with a single coordinated assessment; and c) for novel biotechnology products that currently span pharmaceutical, medical devices, and SoHO frameworks simultaneously, the Biotech Act's regulatory status repository and Foresight Panel resolve cross-framework classification ambiguity that neither the pharmaceutical nor the medical devices reforms can address in isolation.

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Significant burden reduction is expected in **clinical development**, one of the most cost-intensive stages of the biotech value chain[295]. For **human medicinal products**, the **proposed amendments to the CTR** are expected to reduce authorisation timelines from 106 to 75 days (47 without a request for information) and to simplify and streamline the authorisation procedure, as well as the conduct of clinical trials. Key improvements include a new single assessment procedure for combined studies involving medicinal products and medical devices or in-vitro diagnostics, a new single investigational product core dossier, and the possibility of submitting applications for substantial modifications to the clinical trial in parallel after the notification of the authorisation decision. It is expected to yield direct cost savings in EU sponsor expenditure of approximately 5% (EUR 1.5-3.1 billion per year). Indirect savings of a similar order are anticipated through shorter time-dependent costs, yielding aggregate **annual financial gains for sponsors potentially exceeding EUR 5 billion**. Applying the Standard Cost Model (SCM), each multinational trial stands to save approximately EUR 2,700-4,500 in sponsor administrative costs through alone a reduction in the staff time for regulatory interactions by 15-25%. Additionally, electronic submission and digitalisation measures are estimated to generate EUR 112-225 million in industry savings over fifteen years. A simplified version of the cost-benefit analysis, considering a subset of the policy measures included in the Biotech Act, suggests an overall annual cost-saving of EUR 1.24 billion[296]. The Biotech Act proposal is expected to result in an increase in commercial clinical trials by 10% to 30%, estimated to generate approximately **EUR 3.6 billion to 10.7 billion in economic gains and 16,500 to 49,500 additional jobs.**

These gains extend into adjacent product domains, where parallel reforms are addressing sources of procedural duplication there. In the **biosimilars** domain, the rationalisation of Comparative Efficacy Studies requirements removes EUR 19-26 million in direct trial costs per product and shortens development timelines by 12-24 months, translating into sector-level savings of EUR 222-467 million annually for the 12-18 affected MAAs per year. Thus, **combined annual regulatory cost relief for health biotech sponsors across clinical trial and biosimilar reforms approach (and potentially exceed) EUR 5.2-5.5 billion per year.** Regarding **ATMPs**, eliminating the additional 50-day assessment period and granting risk-proportionate ERA exemptions for qualifying GMO-ATMPs is expected to reduce regulatory timelines and remove non-value-adding procedural steps, potentially removing a burden of 0.15-0.3 FTE-years per clinical trial application, a reduction that disproportionately benefits the SME-dominated ATMP developer base, and is also expected to significantly influence sponsors' decisions to conduct clinical trials in Europe.

For **VMPs** containing GMOs, the single regulatory pathway eliminates 30-90 days of process delay per CTA, aggregating to 240-1,350 product-days of delay removed annually at current pipeline volumes, with cumulative administrative cost savings of EUR 5-14.5 million till 2040. The uniform handling regime for variations not requiring assessment adds a further EUR 22.5 million in present-value savings over the same period.

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[295] Farid et al. (2020) Benchmarking biopharmaceutical process development and manufacturing cost contributions to R&D - PMC.

[296] See *Regulatory Framework Study (forthcoming).* The simplified costs-benefit analysis focus on operational costs, not considering costs arising from transitioning to new regulatory requirements.

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Beyond clinical development, the Act addresses the **regulatory fragmentation** that so often compounds costs. Divergent national practices in risk classification, product categorisation, and procedural interpretation currently force applicants to navigate several different Member State-specific requirements for what is nominally the same regulatory procedure. The Act responds by establishing shared infrastructure, harmonising regulatory pathways, reducing legal ambiguities, and offering regulatory and procedural guidance.

Within this context, the Act's benefits are structurally tilted toward **SMEs and start-ups**, for whom the reforms remove barriers to participation rather than merely reducing costs of ongoing operations. This happens in two distinct ways. First, regulatory simplification measures reduce fixed-cost compliance burdens (e.g., legal support, regulatory affairs staffing, dossier preparation, external consultancy, multi-jurisdictional coordination) that are largely invariant to firm size and therefore represent a substantially higher share of total expenditure for smaller firms. This is particularly pronounced in ATMPs, where SMEs constitute the majority of developers, and in GMMs, where SMEs and start-ups represent the predominant developer base. Second, the Act addresses infrastructure and data access barriers that structurally exclude smaller firms from the innovation pipeline, most pronouncedly in the AI and data domain.

These regulatory simplification gains for businesses come with new **governance obligations for public authorities and Member States**. The Act introduces an expanded public sector role in certain areas, which includes new coordination and project permitting responsibilities, more clinical trial governance and enforcement, biosecurity screening and inspection obligations, and ecosystem coordination through the Steering Group and Support Network. The resulting costs are expected to be front-loaded with activities such as designating competent authorities, establishing or adapting single points of contact, resource permitting functions, and developing sector-specific expertise. However, the Act’s provisions are also designed in a way that limits the incremental burden to the extent possible by designating or adapting existing administrative coordination mechanisms rather than creating entirely new institutions. Over time, efficiency gains are expected as procedures standardise, digital handling matures, and coordination platforms reduce the unit cost of multi-authority interactions, partially offsetting the initial burden. Thus, the net balance is structurally positive: by removing procedural layers, the Act generates savings for businesses and healthcare systems that substantially exceed the incremental institutional costs and administrative burdens borne by public authorities.

Aggregated across the full package of simplification interventions, the Act delivers **direct annual cost savings** for businesses in the order of **EUR 5.2-5.5 billion**, driven overwhelmingly by the clinical trials reform and biosimilars CES rationalisation, and supplemented by cumulative electronic-submission savings and VMP-related administrative and variation savings. Under the One-In-One-Out (OIOO) accounting, new administrative burdens on businesses of approximately EUR 16.6 million/year (dominated by biosecurity customer-side compliance) are partially offset by removed burdens totalling approximately EUR 4.3-8.0 million/year, yielding a **net administrative increase** of approximately **EUR 8.6-12.4 million/year**. In parallel, **adjustment costs on businesses** amount to **EUR 8.16-27.32 million/year**, with a further **EUR 48.6-112.6 million/year** in recurrent monetised costs falling on public administrations, mainly stemming from biodefence collection infrastructure (EUR 46-110 million/year).

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Even at the upper bound of identified incremental costs, and before accounting for the Act's downstream health, supply-resilience and innovation-enabling benefits, the **direct business-level savings from regulatory simplification far exceed the full sum of monetised countervailing items**, confirming that, in cumulative terms, the Biotech Act operates as a substantial **net simplification instrument** for the EU biotechnology sector, with the residual OIOO increase concentrated in a single, security-motivated intervention whose justification rests on a distinct benefit-side case (biosecurity risk prevention monetised at EUR 2.9 billion/year in 2027, rising to EUR 5.5 billion/year by 2036).

Distributional impacts

While the aggregate cost-benefit balance of the package is firmly positive, the Act produces material intra-EU transfers whose direction warrants explicit recognition (see Annex 3). The principal redistributive vector is the **SPC extension**, which is explicitly designed to transfer approximately EUR 690 million/year in additional originator gross profit from biosimilar developers (around EUR 240 million/year in foregone profits) and from payers and patients (combined social cost of around EUR 615 million/year), in exchange for conditional EU-based manufacturing and multi-Member State trial commitments. A second, structural transfer runs **across firm size**: because fixed compliance costs are largely size-invariant, simplification gains in clinical trials, ATMPs, GMMs and the AI and data framework accrue disproportionately to SMEs and start-ups, for whom they typically remove barriers to participation rather than merely reduce operating costs. A third runs **across the public-private interface**: businesses and healthcare systems capture the bulk of regulatory and efficiency savings, while Member State authorities absorb front-loaded governance costs, which nonetheless remain orders of magnitude smaller than the corresponding business-side relief and associated prevention benefits. Crucially, the combination of measures generates additional distributional effects not visible at intervention level: CES rationalisation and strategic-project eligibility partly offset the SPC-driven loss to biosimilar developers; the SPC geographical conditionalities recycle part of the payer-to-originator transfer back into EU clinical and manufacturing activity; and the Support Network and cluster infrastructure narrow the capacity gap that would otherwise leave smaller firms less able to exploit complex regulatory architectures. On balance, patient welfare is strongly positive, as biosimilar-driven healthcare savings outweigh the SPC-related delay costs.

6.2 Competitiveness and investment attractiveness

The competitiveness rationale for the Biotech Act rests on a well-documented structural deficit[297], as evidenced by the EU's limited capacity to scale innovative firms, and a persistent investment gap (estimated at EUR 40 billion annually) in the EU biotechnology sector. Regulatory simplification is a necessary condition for closing this gap, but it is not enough on its own. The Act therefore deploys a set of instruments that collectively alter the return profile for biotech investments in the EU by targeting the specific stages and segments where market failures are most acute. The Act's competitiveness provisions are designed to address a structural erosion of the EU's position relative to its principal global

[297] See section 3 for further elaboration.

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competitors and to reverse specific competitive disadvantages on the dimensions that drive investment and location decisions.

The **project recognition frameworks** (strategic and high-impact) turn what is currently an opaque, variable permitting landscape into a bounded, time-limited pathway, directly improving the bankability of industrial-scale deployments. The combined potential for investment mobilisation is substantial. Strategic project recognition alone could mobilise EUR 15-28 billion cumulatively by 2038 (under medium uptake; 60-70 recognised projects), while the high-impact flagship tier adds a further EUR 4-12 billion (medium, 12-15 projects) targeting catalytic infrastructure with cross-border reach, such as integrated biotech testing and scale-up facilities and centres of excellence for advanced therapies. Together, these frameworks could mobilise EUR 19-40 billion in total investment by 2038, depending on uptake and project composition, and avoid combined delay costs of EUR 265 million-1.16 billion (under medium uptake). Critically, these project pipelines also serve a signalling function; creating a structured 'investability' channel that did not previously exist, facilitating faster financial close and more crowding-in of private capital.

The **financing instruments** reinforce this logic. The proposed EU Health Biotechnology Investment Pilot targets the sector's structural EUR 40 billion annual investment gap, as estimated by the EIB. The already launched BioTechEU initiative backed by InvestEU is expected to mobilise up to EUR 10 billion in biotechnology investments in 2026-2027 alone. Under the medium-ambition scenario (closing 25% of the EU-US investment gap), the Pilot would result in approximately EUR 6.2 billion in direct investments over two years, supported by EC budgetary guarantees. It is expected to raise total investment mobilisation to approximately EUR 41.6 billion over the same period (compared with approximately EUR 21.6 billion under the baseline), consistent with reducing the annual investment gap by approximately EUR 10 billion per year.

A distinct competitive dimension concerns **biosimilars**, where the EU holds the world's largest market (approximately EUR 17 billion at list prices[298]), but is experiencing manufacturing migration to Asia. Streamlining CES requirements serves a competitiveness objective: by reducing the cost threshold for biosimilar development, it accelerates market entry by 12-24 months per product and strengthens EU-based developers against jurisdictions already formalising such flexibility. Strategic project eligibility for biosimilar manufacturing reinforces this supply-side effect. While the share of EU-headquartered companies in EU biosimilar MAs is 49% in 2025, projected to fall to 40-50% without intervention, it can be potentially maintained at 45-55% with the proposed measures. On the other hand, the **SPC extension** incentivises a very targeted set of innovative biotechnology medicines. The SPC extension could potentially be awarded to about three products annually[299]. According to EMA's data from 2016 to 2025, the three products could grow to **about five** per year if developers changed their behaviour in response to the incentive (i.e. conducting part of their clinical trials and manufacturing in the EU), thus bringing **new transformative products** to the market and a **marginal positive impact** on the **conduct of clinical trials** and **manufacturing in the EU**.

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[298] IQVIA Institute for Human Data Science (2026), *The Impact of Biosimilar Competition in Europe*, estimating the EU biosimilars market at approximately USD 18 billion (list prices).
[299] The average is 2-3 products per year rounded to 3 for ease of illustrating the systemic impact.

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The extension comes with an additional gross economic gain of approximately EUR 230 million per qualifying medicine per year, and a direct payer expenditure and monetised cost of delayed patient access which together amount to approximately EUR 205 million per medicine. This corresponds to a cost of approximately EUR 615 million every year at aggregate level, based on an average of three qualifying medicines per year.

The extension focuses specifically on rewarding innovations that bring the **greatest value to patients**[300], sending an important **signal to companies** regarding investment priorities. The geographical conditions ensure that this additional incentive also favours investment in the EU and helps strengthen the EU's health biotech sector.

Clinical research is equally critical to the competitiveness proposition. Despite significant global growth in clinical trials between 2013 and 2023, the EU's share of global commercial trials halved from 22% to 12%, failing to capture the proportional share of the growth. Improved regulations, including simplified and more predictable procedures, as well as sandboxes work in concert to make the EU/EEA more attractive for sponsors as a location for conducting clinical trials. Consequently, a better regulatory environment is expected to increase the number of clinical trials in the Union and possibly, depending on the development in other regions, reverse the structural decline of the EEA share of global trials. The increase in trials is expected to range between 10% and 30% based on two studies supporting the assessment[301]. Together, these interventions form a coordinated competitiveness package.

6.3 Innovation and research

The EU's core innovation challenge in biotechnology is not insufficient scientific output. European research organisations rank among global leaders in biotechnology publications, but there are persistent barriers to translate that output into clinical and commercial development. This is reflected in significantly weaker late-stage financing and a persistent investment gap in the EU compared to global peers[302]. While the competitiveness measures described above address the conditions under which capital is deployed in the EU, the innovation provisions target the conditions under which scientific discoveries are developed, validated and translated across the full R&D continuum, including clinical research and scale-up activities, ensuring that innovation can progress effectively from early-stage research to market deployment in the Union. The Act addresses this structural translation gap through three mutually reinforcing channels.

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[300] Example of the value for patients of biotechnology medicines include: Jönsson B, Hampson G, Michaels J, Towse A, von der Schulenburg JG, Wong O. Advanced therapy medicinal products and health technology assessment principles and practices for value-based and sustainable healthcare. Eur J Health Econ. 2019 Apr;20(3):427-438. doi: 10.1007/s10198-018-1007-x. Epub 2018 Sep 18. PMID: 30229376; PMCID: PMC6438935.
Ohashi T. The impact of monoclonal antibody drugs on healthcare economics in the treatment of multiple sclerosis and neuromyelitis optica spectrum disorders. Clin Exp Neuroimmunol. 2022;13(3):166–171. https://doi.org/10.1111/cen3.12718.

[301] According to one study (*Regulatory Framework Study forthcoming*), the number of clinical trials is expected to increase by 32% considering the outcomes of a survey with sponsors. A second study (*Rapid Assessment Scenarios study, forthcoming*) suggests an average increase of 10 %. Additionally, the lower bound aligns with the ACT EU target of an increase of 11.1% of multinational clinical trials in the EU in the next five years.

[302] US biotech firms have raised approximately 870% more Series C capital over the past decade and 945% more in IPO proceeds (USD 53 billion versus USD 5 billion), while EU venture capital in biotech and healthcare fell from 34% of global share in 2013 to 18% in 2022.

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First, introducing **regulatory sandboxes** across clinical trials, food and feed, SoHO, and veterinary products creates, for the first time, structured pathways for innovations that currently face regulatory uncertainty or do not fit neatly into existing EU frameworks. In the absence of such mechanisms, highly novel products risk delays, fragmented assessments or the absence of a clear route to market, constraining their development and deployment in the Union and delaying or preventing the Union from capturing benefits in terms of patient outcomes, innovation and economic activity.

Second, the Biotech Act addresses late-stage attrition by combining **dedicated financing instruments** with catalytic infrastructure. The EU Health Biotechnology Investment Pilot targets the sector's EUR 40 billion annual funding gap, as estimated by the EIB, building on the EUR 10 billion in mobilisation expected in 2026-2027 through the BioTechEU initiative and illustrative scenarios projecting a gap reduction of EUR 10-20 billion per year at full scale. Simultaneously, high-impact project infrastructures are expected, under illustrative uptake scenarios, to support 4-40 additional clinical trial applications per year and serve 60-600 firms annually. These ranges reflect very low to very high uptake scenarios, with impacts driven by de-risking translation services and compressing development cycles. Together, the sandboxes are expected to resolve pathway uncertainty for novel products, while financing instruments and catalytic infrastructure ensure that developers of products with a clear regulatory route can access the capital and facilities needed to reach the market.

Third, the **AI and data framework** addresses a cross-cutting enabler that conditions the effectiveness of the first two channels. Depending on uptake, the recognised testing environments and data quality accelerators could serve approximately 1,100-3,400 companies and data users annually (under medium uptake projections), and trigger infrastructure investments of EUR 650 million to EUR 1.3 billion. Along with the harmonised guidance on deployment and use of systems based on advanced technologies, including AI in the lifecycle of medicinal products, these measures are expected to deliver an 14-month average reduction in development timelines versus fragmented multi-vendor outsourcing, with best-case savings of up to 34 months across Phase I–III[303] , with potential trial timeline reductions of 18% as AI integration matures, collectively positioning the EU to capture a greater share of the rapidly expanding AI-enabled drug discovery market.

Together, these three channels constitute the most comprehensive intervention the EU has undertaken to address the structural disconnect between its scientific output and its capacity to translate that output into clinical and commercial innovation. The Act strengthens the **EU's capacity to innovate** in biotechnology by simultaneously lowering the three barriers that currently determine whether a viable scientific discovery acquires a path to market in the EU: regulatory pathway uncertainty (addressed by sandboxes, the regulatory status repository, and the Foresight Panel), capital scarcity at the translation stage (addressed by the Investment Pilot and high-impact project infrastructure), and the absence of shared enabling infrastructure for AI-enabled development (addressed by testing environments and data quality accelerators). These interventions could also create

[303] Evidence from integrated shared-facility models, based on DiMasi, J., Dirks, A., & Getz, K. (2025). "The Net Financial Benefits of Single Vendor Integrated CDMO and CRO Drug Development Services." Tufts Center for the Study of Drug Development. Announced June 16, 2025.

synergies with other Union initiatives, including potential Important Projects of Common European Interest (IPCEIs[304]), where relevant.

6.4 Public health and safety

The regulatory and economic reforms described in the preceding sections are not ends in themselves; their ultimate justification lies in their capacity to deliver measurable public health benefits. The Biotech Act's public health impact comes through three reinforcing channels: accelerating patient access to biotechnology-derived treatments, strengthening supply resilience for essential medicines, and establishing a preventive framework against biosecurity risks.

The most quantifiable **patient-access gains** come from biosimilars and organ transplantation. Accelerating and widening biosimilar competition is projected to increase annual healthcare system savings from approximately EUR 13 billion in 2024 to EUR 22-35 billion per year by 2035-2038 (cumulative EUR 300-450 billion), while preserving an unblemished safety record; no biosimilar has been withdrawn on safety grounds in 19 years. In parallel, reforms to organ processing standards are estimated to yield approximately 1,435 additional transplants per year by 2035, set against a waiting list exceeding 52,000 patients and approximately 3,366 waiting-list deaths annually, generating cumulative dialysis cost avoidance of approximately EUR 158 million. Beyond these gains, the organ processing reforms are expected to prevent 570-945 organ discards per year and avert 57-72 waiting-list deaths annually by 2035 (248-311 cumulatively over 2028-2035, valued at approximately EUR 285-537 million using the Commission's standard value of a statistical life year). Thus, the total monetised public health benefit of organ processing reforms over 2028-2035 is approximately EUR 443-695 million.

The reforms to **clinical trial authorisation and the ATMP framework** compound these effects. Given that around 5% to 10% of clinical trials result in a medicinal product reaching the market (an average of 8%), the proposed amendments to the Clinical Trial Regulation could enable roughly 100 of the 2,500–3,000 products tested annually to launch up to six months earlier, while ATMP reforms accelerate access to potentially curative therapies in high-unmet-need areas where the EU already lags behind competing jurisdictions. The biosimilars framework further strengthens both access and affordability: by reducing the cost threshold for biosimilar development, the Act addresses a 'biosimilar void'; some 79% of the approximately 100 biologics losing exclusivity by 2032 have no biosimilars in development.

On **supply resilience**, the strategic projects framework is expected to deliver 18-60 capacity-relevant EU-based biomanufacturing deployments by 2038 (depending on uptake), directly countering the structural vulnerability created by growing import dependence, currently increasing at 12% annually for biosimilars alone.

Supporting these four impact areas is a set of **ecosystem-level enabling measures**, comprising the EU Health Biotechnology Support Network, networks of health

[304] E.g. three Important Projects of Common European Interest (IPCEI) in the biotechnology domain are currently under design (https://competition-policy.ec.europa.eu/state-aid/ipcei/design-support-hub_en#ipcei-candidates-in-the-design-support-hub).

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biotechnology clusters, the strategic mapping of the EU's biotechnology ecosystem, and the European Health Biotechnology Steering Group, which provide the coordination, advisory, and connectivity infrastructure needed to translate individual regulatory reforms into system-level outcomes. The Support Network provides a single, locally accessible entry point for health biotechnology developers (particularly SMEs and start-ups) to navigate regulatory pathways, identify funding instruments, and connect with investors, while cluster networks facilitate cross-border collaboration, infrastructure access, and knowledge transfer. Together, these mechanisms **reduce the transaction costs** that would otherwise limit the uptake and cumulative impact of the substantive reforms.

Finally, the **biosecurity framework** introduces a screening framework for synthesised nucleic acids, addressing the specific risk that arises as biotechnology products become more accessible and AI lowers barriers to misuse.

6.5 Environmental impacts

Beyond its primary economic and public health objectives, the Act is expected to generate material environmental and sustainability co-benefits across several interventions. The GMM regulatory reform enables the deployment of microbial applications in biofertilisation, biocontrol, bioremediation, and bioleaching (sectors with a combined global market exceeding EUR 29 billion and projected growth rates of 9-14% annually), which are currently entirely blocked in the EU, where no GMM has been authorised for deliberate release under the existing framework. The veterinary medicines reform facilitates uptake of next-generation biotech vaccines in food-producing species, reducing reliance on antimicrobials in support of the EU's target of halving antimicrobial sales by 2030; empirical evidence associates a 10% reduction in livestock disease levels with an 800 million tonne decrease in greenhouse gas emissions, equivalent to the annual emissions of 117 million Europeans. The biosecurity screening framework provides a direct environmental safeguard: mandatory nucleic acid screening, modelled to prevent 35% of deliberate attacks and 86% of accidental releases, yielding expected benefits of EUR 2.9 billion in 2027, rising to EUR 5.5 billion by 2036, set against implementation costs that are orders of magnitude smaller. In addition, the biothreat radar and biodefence provisions address the extreme tail of biological risk where market mechanisms cannot ensure preparedness. Meanwhile, the food chain sandbox framework creates structured pathways for pre-market testing of sustainable food production technologies, such as GM food, food enzymes, as well as methodologies thereof, such as new approach methodologies for risk assessment. These provisions collectively position the Act as a contributor to the EU's broader sustainability commitments under the European Green Deal and the 2030 Agenda for Sustainable Development.

Taken together, these effects position the Biotech Act as a structural enabler of a more competitive, innovative and resilient EU biotechnology ecosystem, while contributing to societal objectives and embedding safeguards against emerging biosecurity risks, with system-level benefits materialising over time. While the magnitude of these benefits will depend on uptake, implementation and broader market conditions, the assessment indicates that the cumulative benefits of the package are expected to significantly outweigh the associated costs.

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6.6 Digital by default principle

The Biotech Act supports the digital transformation of the EU biotechnology ecosystem by embedding a digital-by-default approach across regulatory, scientific and administrative processes. Through measures dedicated to AI and data, but also other measures embedded across the act, digitalisation operates as a horizontal enabler that amplifies the effectiveness of the regulatory simplification, competitiveness and innovation interventions described in the preceding sections.

Measures under the Biotech Act promote the use of electronic submissions and coordinated approaches to data governance. This contributes to reducing administrative costs for businesses and streamlining interactions with public authorities.

The AI and data framework (Intervention n°15) establishes a coherent structure for the development, validation and regulatory use of advanced technologies, including AI, across the lifecycle of medicinal products. The provision of non-binding guidance at Union level reduces uncertainty around data requirements and validation standards, enabling developers to design evidence generation strategies more efficiently and with greater regulatory certainty. In parallel, trusted testing environments and biotechnology data quality accelerators are bound to create shared infrastructures that allow companies, particularly SMEs and start-ups, to access high-quality datasets and computational resources that would otherwise remain out of reach.

Taken together, these contribute to strengthening innovation and research capacity and shortening timelines for innovations to reach the market, reinforcing the competitiveness and investment effects described in Section 6.2 by improving the risk-return profile of data-driven biotechnology projects and increasing the attractiveness of the Union as a location for AI-enabled development.

For public authorities, the transition to digital-by-default entails upfront adjustment costs related to the development of digital infrastructures, data governance frameworks and technical expertise. These costs are expected to be largely offset over time as procedures standardise, digital handling matures and coordination across authorities improves. As systems scale, the unit cost of regulatory processing is expected to decline, contributing to greater administrative efficiency and more consistent decision-making.

Overall, through measures touching upon both regulatory and innovation aspects, the digital-by-default approach therefore acts as a systemic multiplier across the Biotech Act.

7 MONITORING AND EVALUATION

Five years after the Regulation proposal's entry into application, and every five years thereafter, the Commission will evaluate its implementation, effectiveness and impact. As regards the proposed Directive, it will also be evaluated in accordance with Better Regulation policy.

Progress towards the objectives of the proposed Regulation would be monitored using a set of quantitative and qualitative indicators. This assessment will draw on the **strategic mapping of the EU's biotechnology ecosystem** that will be established and periodically

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updated by the Commission. It will also be based on continuous data and other information available through the implementation of existing legislation and initiatives in the Commission and the European Medicines Agency.

Such monitoring shall be based on key performance indicators:

Indicator	**Source**
Venture-capital investment flows in biotechnology in the Union[305]	Invest Europe Annual activity statistics
Number of strategic projects and high-impact strategic projects	European Commission
Number of products granted a supplementary protection certificate	National patent offices
Number of additional multinational clinical trials authorised in the Union over the 5-year period of the reporting, compared to the average number of such clinical trials authorised per year in the Union as of 2025	Clinical Trials Information System (CTIS)
Number of clinical trials concerning ATMPs authorised in the EU	Clinical trials information system (EMA)
Number of ATMPs with EMA authorisation in the EU	EMA annual report
Number of GMM products authorised under Directive 2001/18/EC to be placed on the EU market	European Commission

[305] Calculation methodology to ensure that short-term volatility and year-to-year fluctuations do not distort the assessment of underlying investment trends, such as by using three-year moving average of annual investment flows.

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COMMISSION

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PART 2/2

Addendum to
COM(2025) 1022 and COM(2025) 1031 adopted on 16.12.2025

COMMISSION STAFF WORKING DOCUMENT

European Biotech Act

Accompanying the documents

Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act)

and

Proposal for a Directive of the European Parliament and of the Council amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs

{COM(2025) 1022 final} - {COM(2025) 1031 final}

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1. Lead DG, Decide Planning/CWP references

The legislative proposal for the European Biotech Act was prepared under the lead of the Directorate-General for Health and Food Safety (DG SANTE). In the DECIDE Planning of the Commission, the process is referred to under item PLAN/2025/176. The Act was announced in the political guidelines for the European Commission 2024-2029.

2. Organisation and timing

An Inter-Service Coordination Group (ISCG) assisted DG SANTE in the preparation of legislative proposal. It included Commission services of Directorate-Generals AGRI, BUDG, CLIMA, CNECT, COMP, DEFIS, ENER, ENV, GROW, HERA, JRC, REGIO, RTD, TAXUD, TRADE, together with the Commission's Legal Service and Secretariat General.

Three Interservice Coordination Groups have been organised between February and November 2025, informing the preparation of the proposed Act.

A Call for Evidence was open for feedback between 14 May and 11 June 2025. A Public Consultation was published on 4 August 2025 and closed on 10 November 2025.

An ISCG meeting on the analytical Staff Working Document took place on 23 March 2026.

3. Consultation of the RSB

The RSB was not consulted on an impact assessment. Considering the politically urgent need to address the policy challenges identified, an impact assessment could not have been delivered in the timeframe available before the proposal. A derogation from the accompanying impact assessment was granted and this analytical Staff Working Document (SWD) explains the proposal and presents the underlying evidence and impact analysis, including cost-benefit assessment.

4. Evidence, sources and quality

The major competitiveness gap in biotechnology and the market and regulatory barriers faced by European companies were identified in the Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU'[1] and in the Draghi and Letta reports[2].

External studies have been commissioned by the Commission which have been used to prepare the SWD:

[1] COM(2024) 137 final/2.
[2] Draghi, Mario. The future of European competitiveness: A competitiveness strategy for Europe, European Commission, 9 September 2024.; Enrico Letta, Much more than a Market. April 2024.

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- **'Analysis of the Regulatory Framework for Biotechnology and Biomanufacturing in the EU'[3]** (*Regulatory Framework Study, forthcoming*)**.** This study was announced in the Commission Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' and was launched in December 2024. It provides a mapping of the main pieces of EU and national legislation that apply to biotechnology and biomanufacturing products and processes – whether they are horizontal or sector-specific – and identifies related challenges, their causes and the consequences for stakeholders. The study also assesses the impacts of policy measures related to the EU rules applicable to clinical trials and genetically modified micro-organisms.
- **'Landscape analysis study of the biotechnology sector in the Union with a view to foster its competitiveness and innovation'[4]** *(Landscape analysis study, forthcoming)***:** This study, launched in August 2025, provides an analysis of the challenges faced by the various biotechnology sectors, an overview of the market as well as a landscape of EU and national measures supporting competitiveness and innovation of the sector and the resulting successes and gaps.
- **'Study to support the rapid assessment of policy scenarios to strengthen innovation and competitiveness in the field of biotechnology in the EU'[5]** *(Rapid Assessment Scenarios study, forthcoming)***:** The study, launched in December 2025, assesses all significant impacts of measures for the proposed European Biotech Act.
- **'Study supporting the Evaluation of the European Food Safety Authority 2017-2024'[6]:** This study supports the Evaluation of EFSA, covering the evaluation criteria of effectiveness, coherence, EU added value and relevance.
- **JRC case study[7] and pipeline analysis on GMMs[8]**.
- Scientific opinions from EU agencies have been considered where relevant to specific areas of the Act (see e.g. Annex 7, intervention n°7 on GMMs).
- **'Fast-track landscape analyses to assess the regulatory clinical trial eco-system in the EU/EEA and in other relevant regions'[9]** *(forthcoming).* This study supports the assessment of the clinical trial eco-system in the EU and other regions and its impact on the economy, public health, and skill formation.

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[3] "Analysis of the Regulatory Framework for Biotechnology and Biomanufacturing in the EU" Deloitte, empirica et al., (forthcoming).
[4] Technopolis et al, *Landscape analysis study of the biotechnology sector in the Union with a view to foster its competitiveness and innovation,* (forthcoming).
[5] PPMI (part of the Verian Group), Fraunhofer ISI, *Study to support the rapid assessment of policy scenarios to strengthen innovation and competitiveness in the field of biotechnology in the EU*, (forthcoming).
[6] Intellera, Ipsos, Tetra Tech, *Study supporting the Evaluation of the European Food Safety Authority 2017-2024*, Final Report, December 2025 (forthcoming).
[7] Burren, S., Palacios, J., Areal, F.J., Rodriguez-Cerezo, E., Barreiro-Hurle, J. (2026). The potential of genetically modified microorganisms to reduce nitrogen loads in the EU agricultural sector. JRC Technical Report, Publications Office of the European Union, Luxembourg (publication forthcoming).
[8] Lowe, C.R., Ponferrada, V., Ruiz Aquino C., Compaño, R., Nanda, A.K. (2026). Current and future market applications of genetically modified microorganisms (GMMs) to be placed on the market or for environmental release. JRC Technical Report, Publications Office of the European Union, Luxembourg (publication forthcoming).
[9] This study has been conducted by Technopolis Consulting Group.

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ANNEX 2: STAKEHOLDER CONSULTATION

1. Introduction

The synopsis report covers all consultation activities that have been conducted to support the preparation of the proposal for a European Biotech Act and this analytical SWD. Information was collected through consultations via a **Call for Evidence** (CfE), **Public Consultation** (PC), and **Targeted Consultations** (TC).

The feedback period of the CfE ran from May 2025 to June 2025 and the PC was opened for contributions from August 2025 to November 2025. These were complemented by targeted consultation activities between December 2024 and March 2026. The first two stakeholder consultations were carried out by the Commission services but were analysed by an external contractor (see Landscape Analysis Study below and presented in Annex 1). The targeted consultation activities were carried out, among others, in the context of the following three studies (see Annex 1 for more details on the studies):

- Analysis of the Regulatory Framework for Biotechnology and Biomanufacturing in the EU
- Landscape Analysis Study of the biotechnology sector in the Union with a view to foster its competitiveness and innovation
- Study to support the rapid assessment of policy scenarios to strengthen innovation and competitiveness in the field of biotechnology in the EU

The consultation was addressed to citizens, innovators, entrepreneurs, industry, financial institutions, investors/venture capitalists, researchers/research organisations, civil society (including consumer, patient and environmental organisations), other users of biotechnologies (e.g. farmers and foresters), trade unions, national and regional authorities, and other stakeholders.

2. Methodology of the consultation activities

Call for Evidence (CfE)

The CfE was launched on the Commission's *Have Your Say* platform[10]. It received 222 valid responses[11] and 149 attachments. Participants were primarily based in Belgium (33%, 74/222), Germany (12%, 29/222) and France (9%, 20/222). Responses from non-EU countries came mainly from the US (5%, 10/222), Switzerland (3%, 7/222) and the UK (2%, 4/222).

[10] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act_en

[11] 3 submissions were received from a single respondent and have been counted as 1 response. 2 further submissions were received from another respondent and have been counted as 1 response. Thus, the total number of responses considered in this analysis is 222 instead of 225.

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With respect to the type of stakeholder groups[12], responses came from business association[13] (60), companies or businesses (50), non-governmental organisations (44), academic, research institutions (20), public authorities (14) and from EU-citizens (14). No campaign was identified. All feedback and position papers were analysed in the context of the Landscape Analysis Study.

Public Consultation (PC)

The PC was published on the Commission's *Have Your Say*[14] platform. A total of 464 answers were received and 119 attachments were submitted. The majority were position papers, while some included answers to open questions. Most of the responses were submitted by respondents from France (20%, 91/464), Belgium (19%, 87/464) and Germany (12%, 54/464). Contributions from non-EU countries mainly came from the US (3%, 12/464), followed by Switzerland (2%, 8/464). With respect to the type of stakeholder groups[15], most respondents were from individual companies or businesses (25%, 114/464), followed by business associations (19%, 89/464), and citizen (16%, 73/464). Among businesses, most identified themselves as SMEs (55%, 63/114)[16]. Among public authorities, 14 self-identified as national, ten as regional respectively, two as local, and three as international.

The questionnaire consists of nine sections, which can be roughly divided into three thematic blocks: The first block (Sections 1–3) addresses general views on biotechnology, the presence of businesses in the EU market, and the regulatory environment in the EU. The second block (Sections 4–6) focuses on biomanufacturing, specifically biotechnology clusters, production, and the availability of workforce. The third block (Sections 7–9) centres on data and artificial intelligence, defence, and security, and a final section to submit attachments.

Duplicates or campaigns from stakeholders had not been identified. All feedback and position papers were analysed in the context of the Landscape Analysis Study.

A Factual Summary Report has been published on 23 December 2025, based on 359 responses on the Have Your Say webpage[17]. This report presents the outcome of the Public Consultation based on all 464 contributions received.

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[12] Among the stakeholders who reported themselves as 'other' are notably network organisations, multi-stakeholder platforms, and non-profit organisations. Given their non-commercial nature and similarities with NGOs, these respondents were grouped together with NGOs for the purposes of the analysis.
[13] 3 respondents identified as trade unions but are analysed as business associations as they represent industries.
[14] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act/public-consultation_en
[15] 5 self-reported trade unions were analysed under business associations, and 1 contribution self-reported public authority was analysed coming from an EU citizen.
[16] Comprising: 16 medium, 19 small-, and 28 micro-sized enterprises.
[17] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act/public-consultation_en

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Targeted Consultation (TC)

Analysis of the Regulatory Framework for Biotechnology and Biomanufacturing in the EU

The Regulatory Framework Study consists of two Pillars.

- Pillar A focused on the assessment of impacts of policy scenarios defined by the EC. It consists of a supporting assessment of impacts related to genetically modified micro-organisms (GMM) and a supporting assessment of impacts related to clinical trials in Europe (CT).
- Pillar B focused on mapping the relevant EU and national legislations related to biotechnology and biomanufacturing; identifying regulatory challenges, causes and consequences relevant for the biotechnology and biomanufacturing ecosystems; and identifying policy areas for potential simplification and streamlining.

Targeted stakeholder consultations were carried out across all the listed activities:

On genetically modified microorganisms (GMM), targeted **stakeholder interviews and a consultation of subject matter experts** were conducted. It included **25 interviews** comprising seven large enterprises, six SMEs, five public authorities, one EU agency, four EU business associations, one national business association, and one NGO.

On clinical trials (CT) in Europe, **targeted interviews, surveys and consultations** with the study team's subject matter experts were conducted. Two rounds of stakeholder interviews were conducted, comprising a total of **ten interviews with nine stakeholders**, representing four industry associations, two large enterprises, and one each from a European agency, a research network, and a private non-profit organisation.

On CTs, three **surveys** were also launched. One survey targeted **sponsors and contract research organisations** (CROs) involved in clinical trials. It received 48 responses, 32 from commercial sponsors, six from non-commercial sponsors, three from CROs, and seven from other stakeholders (including non-profits, hospital owners, advocacy groups, research infrastructures, trade associations, and life sciences providers). Thus, the response rate for this survey was approximately 23.8% (48/202). A second survey was directed at **public authorities** (including ethics committees and national competent authorities). It yielded 44 responses from public authorities with approximate response rate of 32.6%, including 20 responses from ethics committees and national competent authorities each, three responses from ministries or government bodies, and one respondent identified as both a ministry and an ethics committee. A third survey aimed at **patient representative organisations**, collecting only one response from a national, disease-specific patient organisation active in clinical trials across eight EU Member States and two third countries. This resulted in a response rate of 8.3% (1/12).

With regards to Pillar B of the study (see above), **two surveys** were conducted, along with **ten interviews and five workshops**. One **survey** was focused on **public authorities** across the EU Member States. A second survey was broader in scope and covered **all types of stakeholders** (e.g. NGOs, business associations at EU and national levels, industry, academia, etc.). In total, 334 responses were received in both surveys. Considering

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duplications in entries from stakeholders, 274 responses were considered for the analysis. Ten **interviews** were carried out to understand the regulatory challenges that stakeholders encounter, the legislation currently impacting them, and potential policy areas for simplification. **Five workshops** were carried out to gather insights into regulatory challenges that stakeholders face and identify potential legislation that brings such challenges. Each workshop focused on a specific sector, i.e. health/pharma, agriculture/environment, food and feed, bio-based chemicals and plastics, and bio-based materials. For each sector, relevant actors active in the specific field of the workshop were invited to participate.

Landscape Analysis Study of the biotechnology sector in the Union with a view to foster its competitiveness and innovation

The Landscape Analysis Study draws on evidence from the CfE, PC and **targeted stakeholder interviews, workshops and case studies.** It includes 28 **interviews** with organisations, covering the five pillars Access to Finance (eleven interviews, five with private sector funders and six with public sector funders), AI and Data (six interviews, two businesses, one trade association, two research organisations and one public-private partnership), Cluster (three interviews with clusters), Skills (four interviews with research and training, and education organisations/infrastructures), and Security and Defence (five interviews with two private sector companies and three research intermediaries).

Four **workshops**[18] were conducted on Access to Finance (three public funders, four private funders, one institutional investor, two industry associations), Skills (11 research organisations and research infrastructure, two businesses, one intermediary, five business associations), Clusters (eight representatives of European and regional cluster organisations, one infrastructure provider, one ecosystem intermediary and one EU institution), AI and Data (three businesses, four research organisations, two industry associations, one public organisation) respectively.

Study to support the rapid assessment of policy scenarios to strengthen innovation and competitiveness in the field of biotechnology in the EU

As part of the study, the project team carried out a stakeholder consultation programme comprising three targeted workshops and a series of semi-structured interviews. Consultations were conducted between January and March 2026 and covered the main policy intervention areas addressed in the study

The online **workshops** were organised to gather stakeholder views on specific thematic areas of the European Biotech Act: Clusters and Strategic Projects Workshop (11 participants), AI and Data Workshop (eight participants), Biosecurity Workshop (Ca. 100 participants).

[18] The AI and Data and Cluster workshops were organised jointly with the contractor on the Rapid Assessment Scenario study, with dedicated sessions focusing separately on the topics of each study.

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34 **interviews** (including one written response) were conducted across seven policy intervention areas of the proposed European Biotech Act. Interviews were held between January and March 2026.The policy intervention areas were:

- SPC extension for biotechnology medicines (four interviews)
- Biosecurity and Recognition and support of high impact biodefence projects (six interviews)
- Targeted regulatory reform of Veterinary Medicinal Products (eight interviews)
- Regulation of novel health biotechnology products, ATMPs framework and Targeted regulatory reform of clinical trials framework (seven interviews)
- Regulatory framework for genetically modified micro-organisms (GMMs) in products other than food and feed (four interviews)
- Regulatory framework on the substances of human origin (SoHO) (two interviews)
- Regulatory framework on standards of quality and safety of human organs intended for transplantation (three interviews)

The interviews were distributed across the following stakeholder groups: industry (ten interviews), regulatory authorities (EU and national, 12 interviews), academia and research (four interviews), policy experts and think tanks (five interviews), and other (three interviews).

Other targeted consultation activities

On clinical trials, evidence has also been collected through three workshops[19] organised by the European Commission in June, September, and November 2025, with representatives of national competent authorities and ethics committee members from each Member States across the EU to exchange views with experts to inform how policy options would be defined.

Finally, targeted consultation activities were also conducted as part of the supporting study for the evaluation of EFSA (see Annex 1 for information the study).

3. Overview of Responses

The regulatory environment

Respondents to the PC perceive significant regulatory barriers across the authorisation, testing and commercialisation chain in the biotechnology sector. The EU framework is considered complex and cost-increasing compared with non-EU countries despite ensuring high safety standards.

Three-quarter of the respondents indicated regulatory barriers in the assessment and market authorisation (77%, 357/464). About 70% (326/464) indicated pre-commercial testing or clinical trials, 68% (314/464) noted impediments in commercialising products and 67% (311/464) in scaling-up production or manufacturing, while 64% (298/464) signalled regulatory barriers in product development matters. Regarding other stages and cross-

[19] CTAG: Clinical Trials Advisory Group; MedEthics-EU, the Clinical Trials Coordination Group of the Heads of Medicines Agencies (HMA) was also invited to the workshop. The EMA is an observer to the CTAG.

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cutting aspects, between 44% (204/464) and 49% (226/464) agreed or strongly agreed that EU rules lead to regulatory barriers in early-stage or pre-clinical development, techno-economics (outside health), health technology assessments, and post market activities.

Stakeholders also provided views as part of the feedback to the CfE. On **Clinical trials**, submissions highlighted delays, fragmentation, and excessive bureaucracy as key barriers. Stakeholders argued that protracted timelines, divergent national requirements, and administrative burdens (e.g., for trial modifications or ethics reviews) undermine Europe's competitiveness and delay patient access to innovative therapies. Pharma and biotech industry groups also pointed to the lack of coordination between Member States, proposing centralised approval systems, binding deadlines, and digital tools (e.g., CTIS optimisation) to cut duplication and speed up trials.

Research institutes and SMEs pushed for regulatory sandboxes for **advanced therapies** (ATMPs) and simplified rules for academic studies (e.g., reduced fees, streamlined exemptions), while patient organisations stressed the need for **real-world data** (RWD) and cross-border collaboration (e.g., for rare diseases) to enable faster, patient-centred trials. Individual biotech firms additionally called for early scientific dialogue with regulators and prioritised pathways for **breakthrough therapies** to boost investment confidence.

Stakeholders also addressed **Advanced Therapy Medicinal Products** (ATMPs), highlighting their transformative potential but also critical barriers to development and patient access.

The overarching consensus emphasised that regulatory complexity, fragmented approval pathways, and funding gaps (especially for rare/ultra-rare diseases) hinder ATMP innovation in the EU. Stakeholders called for streamlined, risk-based frameworks, including regulatory sandboxes, harmonised GMO/clinical trial rules, and centralised ethics reviews, to accelerate development while ensuring safety.

Industry groups called for simplified manufacturing rules (e.g., decentralised production, platform-based assessments) and financial incentives (e.g., innovation procurement, social impact funds) to offset high costs. Academics and research bodies demanded dedicated pathways for non-profit developers, including reduced fees and tailored regulatory support, while patient advocates stressed equitable cross-border access via harmonised Hospital Exemption rules and EU-wide reimbursement alignment. Regulatory experts proposed joint GMO/CTR reforms and ATMP-specific sandboxes to cut redundancy and enable faster, scalable therapies.

On the **Supplementary Protection Certificate** (SPC), some stakeholders underlined that the current SPC framework needs reform to compensate for regulatory delays, enhance competitiveness, and ensure robust intellectual property protection in the EU, while their proposals differ in scope and specificity.

Some stakeholders addressed **Substances of Human Origin** (SoHO), flagging critical regulatory gaps in its interaction with other frameworks (e.g., GMO, ATMPs, medical devices). The overarching concern is fragmentation and legal uncertainty, which is seen as to stifle innovation in human-derived therapies like cell/gene therapies and microbiome-based products.

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In the context of the consultations for the study on the regulatory framework for biotechnology and biomanufacturing in the EU, SMEs but also larger companies identified the complexity of the legislation governing genetically modified organisms (GMOs) in the EU, together with the complexity of the risk assessment and authorisation procedures as aspects posing challenges for biotech innovation, including for bringing innovative products to the EU market. The regulation of **genetically modified micro-organisms** (GMMs) was identified as one concrete example in this regard. In addition, when consulted on concrete policy scenarios for the authorisation of products containing, consisting of or produced from GMMs, many stakeholders, including public authorities, considered that a more product-centric approach that differentiates between low-risk and other GMMs has the potential to provide faster, more cost-effective assessments of GMM products. These stakeholders also considered that the biological properties of a GMM and the status of qualified presumption of safety (QPS) would be suitable to determine the category of a GMM, i.e. low-risk or other, and with that the regulatory path of a GMM product.

Access to capital

The different stakeholder consultation activities (CfE, PC and targeted consultations) draw a consistent picture of the challenges in Europe's biotechnology sector, particularly regarding access to risk-tolerant capital. The findings show that Europe's biotech industry suffers from a chronic shortage of long-term financing, which limits the ability of start-ups and SMEs to scale, innovate, and compete globally.

According to the CfE, there is broad agreement that Europe lags behind the U.S. and China in biotech financing, with only a fraction of global venture capital available. Fragmented and risk-averse capital markets force European companies to seek funding abroad, jeopardizing technological sovereignty and contributing to offshoring. Early-stage firms, especially those without clinical data, struggle due to long development timelines, high capital expenditures (CAPEX), and regulatory uncertainty. Stakeholders are calling for a comprehensive financial and regulatory framework that would mobilize public and private investment while reducing structural barriers to funding. Proposed solutions include the creation of dedicated EU biotech funds with a mix of grants, convertible loans, and guarantees, the establishment of an EU Biotech/Life Sciences Index or NASDAQ-style exchange to improve equity access, and Fund-of-Funds mechanisms to de-risk early-stage innovation. Additionally, public-private partnerships (PPPs) and Important Projects of Common European Interest (IPCEIs) are recommended as tools to attract private co-investment.

The PC reinforces these findings with concrete data on the accessibility of financing instruments. Only 19% of respondents state that public grants or subsidies are easy to access, while for other public funding types, agreement drops to below 10%. Nearly 50% of respondents disagree that public financing instruments are easily accessible. For private investments, strategic research or sales partnerships (21%) and angel investors (15%) are perceived as the most accessible, while venture capital in the expansion stage was seen as particularly lacking (43.5%). The high number of "don't know" or "N/A" responses suggests a lack of awareness or clarity regarding available funding options.

As key drivers for biotech investments, respondents highlight groundbreaking technology, regulatory certainty, innovative science, and strong IP protection (up to 80% agreement),

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followed by experienced management teams, robust supply chains, and solid financial projections (67–71% agreement). Access to data held by public sector bodies is identified as a less prominent driver, with 49% of respondents agreeing or strongly agreeing that it influences investment decisions.

The Landscape Study emphasizes that biotech financing is influenced by a complex interplay of economic factors and sector-specific risks. While some challenges, like the structure of financial markets, require systemic shifts, others could be addressed through targeted policy interventions. As part of this Study, a workshop was held with representatives from EU institutions, industry associations, venture capital investors, and institutional investors. The key finding of the workshop was that while the EU has a strong biotech research base, it faces critical financing gaps, particularly at early-stage.

Biotechnology clusters

The five most critical challenges recognised by respondents to PC, which hamper EU biotechnology clusters in achieving their full potential, were: insufficient financial support (58%, 270/464), insufficient public support (54%, 251/464), incapacity to reach a critical mass of stakeholders (46%, 215/464), insufficient collaboration among existing clusters (46%, 213/464) and insufficient start-up incubators or business support infrastructure (45%, 209/464).

Biomanufacturing

The responses gathered from both the CfE and the PC reveal several critical challenges and priorities related to biomanufacturing, with stakeholders across industry, academia, and research institutions highlighting key areas for improvement.

A major concern is infrastructure and facility capacity, with NGOs and "other" contributors (16 submissions in the CfE) stressing the need for better-equipped biomanufacturing sites, particularly those compliant with Good Manufacturing Practices (GMP). They also called for interoperable digital platforms, such as the European Health Data Space (EHDS), and clinical trial networks to support scalable production). Additionally, some contributions emphasised the importance of resilient supply chains, suggesting decentralised or point-of-care biomanufacturing as a potential solution.

The PC responses reinforced these concerns, with 58% to 67% of stakeholders identifying global competition, lengthy permitting processes for new facilities, scaling challenges from pilot to industrial production, high energy costs, and expensive raw materials as the most significant barriers. Around half of respondents also highlighted supply chain vulnerabilities and inconsistent sustainability policies as major obstacles.

Financing and investment risks were another recurring theme. In the CfE, businesses pointed to weak late-stage capital and the need for targeted incentives, guarantees, and de-risking tools to support pilot, demonstration, and full-scale manufacturing projects. The PC similarly underscored high operational costs as a key challenge, further complicating scaling efforts.

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Business associations called for training in advanced biomanufacturing, among other needs. A few companies specifically advocated for EU-wide multidisciplinary training programmes, while academic and research institutions stressed the need for co-created curricula, including modular courses, vocational training, and industry placements in Contract Development and Manufacturing Organisations (CDMOs).

Finally, sustainability and innovation in manufacturing were addressed, with one academic respondent (EU citizen) highlighting plant-based production and microbial technologies as promising but currently hindered by inadequate infrastructure and regulatory frameworks.

AI and data

The results of several stakeholder consultation activities (CfE, PC, targeted consultations) emphasize the critical role of AI and data in Europe's biotechnology sector, while exposing significant barriers that hinder their effective deployment. Across all stakeholder consultation activities, a recurring theme emerges data access, governance, and interoperability represent the most pressing bottlenecks, compounded by regulatory uncertainty, infrastructure limitations, and skills shortages, which together threaten Europe's ability to compete globally in AI-driven biotechnology innovation.

The CfE responses reveal broad consensus that Europe's biotech sector suffers from fragmented, non-interoperable data and ambiguous governance frameworks, severely limiting the potential of AI applications. Despite rapid advancements in AI technologies, their adoption remains constrained by these structural barriers. Stakeholders emphasize the need for EU-wide bio-data infrastructures, European biotechnology dataspaces, and secure computing resources, particularly to support SMEs and start-ups that lack the infrastructure to leverage AI effectively. They also call for FAIR-aligned data-sharing ecosystems tailored to genomics, proteomics, synthetic biology, and clinical data, alongside federated datasets, supercomputing resources, and AI testing facilities.

Stakeholders in the CfE also stress the importance of AI-ready data formats, reliable data connectors, and harmonized metadata standards to enable seamless integration of AI tools. They advocate for aligning the proposed European Biotech Act with existing frameworks such as the AI Act, GDPR, European Health Data Space (EHDS), and AI in Science Strategy, while demanding clarity on rules governing AI model training, validation, and deployment, particularly in highly regulated sectors like pharma and healthcare. The PC quantifies these challenges, with 61% of stakeholders citing technological barriers and 58% pointing to difficulties in implementing regulatory frameworks as the primary obstacles to AI adoption in R&D. Over half of the respondents view these issues as the main barrier to deploying AI-based biotechnology products, underscoring the need for regulatory sandboxes to facilitate safe testing of AI-driven tools in areas like drug discovery and clinical trials.

A cross-cutting concern is the shortage of interdisciplinary talent, namely individuals proficient in both data science and biotechnology. The PC quantifies this gap, with stakeholders ranking skills development as the top priority (65%) for supporting AI adoption in biotech, followed by access to annotated datasets (64%), partnerships with

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public research institutions or AI hubs (63%), dedicated funding (62%), regulatory sandboxes (59%), and roadmaps for AI implementation (65%).

Despite these challenges, stakeholders in the CfE highlight AI's transformative potential across the biotech value chain, including drug discovery, bioprocessing, healthcare, agriculture, and cosmetics.

To address these barriers, stakeholders propose investing in trusted data-sharing ecosystems and European-scale bio-data infrastructures, as well as developing harmonized standards for interoperability and security. They also advocate for targeted support for SMEs, including dedicated funding, AI testing centres, and collaborative projects, alongside promoting open science and FAIR principles as guiding frameworks.

Security and defence

The results of stakeholder consultation activities (CfE, PC, and targeted consultations) highlight the dual-use risks, biosecurity challenges, and strategic vulnerabilities associated with Europe's biotechnology sector, while emphasizing the need for proportionate governance frameworks that balance innovation with safeguards. Stakeholder responses reveal a shared concern that while biotechnology offers transformative potential for defence, healthcare, and food security, its misuse, fragmented regulation, and supply chain dependencies pose significant threats to Europe's strategic autonomy and public safety.

The CfE responses underscore that biotechnology's rapid advancement brings ethical dilemmas and dual-use risks, particularly in areas like synthetic DNA, AI-driven biotech, and data exploitation. Stakeholders stress the need to embed ethical principles and standards from the outset to prevent misuse, protect societal trust, and ensure public acceptance of biotech innovations. However, they caution against excessive security-driven regulation, which could stifle innovation if not designed proportionately. Key proposals include screening customers of synthetic DNA orders, regulatory sandboxes for controlled testing of novel biotechnologies, and tiered risk-based frameworks for GMOs and recombinant therapeutics. There are also calls for a European Biotechnology Security Strategy to enhance supply chain resilience and intellectual property protection, alongside international coordination to address dual-use risks globally. Stakeholders further advocate for harmonized EU rules to ensure consistency across Member States, while warning against overly restrictive approaches that could impede progress.

The CfE highlights the need for proportionate, risk-based governance that integrates security considerations without imposing unnecessary burdens. The PC identifies strategic autonomy risks, cybersecurity threats, supply chain vulnerabilities, and biosecurity concerns as the top challenges, with 50% of stakeholders citing risks to biomanufacturing autonomy and medical countermeasures, followed by cybersecurity risks (45%), supply chain vulnerabilities (44%), and biosecurity threats (40%). Conversely, stakeholders see opportunities in innovative medical countermeasures (45%), biological threat detection (45%), and enhanced food security (53%).

To address these challenges, stakeholders propose EU-wide governance frameworks that align with international best practices, such as the Australia Group Biological Agent List and IGSC Harmonised Screening Protocol.

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The responses from PC further emphasize the need for risk-based, innovation-friendly regulation that keeps pace with advances in synthetic biology and AI, while the response from CfE call for strategic autonomy in biomanufacturing and resilient supply chains to mitigate dependencies.

Skills

The results of all stakeholder consultation activities (CfE, PC, and targeted consultations) highlight the critical skills challenges facing Europe's biotechnology sector, with stakeholders across all three sources underscoring the need for targeted interventions to develop a workforce capable of driving innovation and competitiveness.

In the CfE responses, stakeholders reveal broad consensus that developing a skilled workforce represents a central challenge for Europe's competitiveness in biotechnology. Industrial companies identify skills development as a key priority for the biotech ecosystem, particularly highlighting the need for competencies in data and AI alongside traditional biotech skills. This perspective is echoed by healthcare and pharmaceutical companies, which similarly underscore the urgency of skills development, while business associations consistently prioritize building a skilled workforce as fundamental to sectoral growth. Third-country stakeholders reinforce these themes, particularly emphasizing skills development as part of a broader package that includes regulatory and financing improvements. A dominant concern across these responses is the need to address skills shortages through specialized training programs, effective talent attraction strategies, and entrepreneurial education initiatives, with human capital widely regarded as foundational to Europe's competitive position in the global biotech landscape. Third-country research organizations align with EU institutions in calling for targeted investment in skills at the intersection of biotechnology, artificial intelligence, and data science, recognizing that future competitiveness will depend on mastery of these converging disciplines. Academia and research institutions place particular emphasis on skills development and talent retention, advocating for EU-level initiatives that support career mobility and foster interdisciplinary education bridging biotechnology with digital and engineering competencies. NGOs similarly stress the necessity for stronger skills infrastructure to underpin sectoral advancement. Companies and businesses highlight skills as a critical factor in 24 separate contributions, while business associations, through 14 dedicated submissions, call for comprehensive training programs in regulatory science, AI applications, data management, and advanced biomanufacturing techniques, complemented by measures to attract and retain global talent. Third-country contributors mirror concerns raised within the EU-27, consistently emphasizing investment in skills as a core requirement for sustainable biotech development.

The PC provides validation of these insights, with stakeholders demonstrating strong alignment regarding the specific skills challenges confronting the EU workforce. The consultation reveals particularly acute shortages in financial and entrepreneurial skills (57%, 263/464), vocational skills for biotechnology and biomanufacturing (53%, 247/464), regulatory and quality assurance expertise (53%, 244/464), and digital and data science competencies (45%, 211/464). These findings underscore the breadth of skills gaps across both technical and managerial domains, suggesting that Europe's biotech sector faces multifaceted workforce challenges that extend beyond scientific competencies to include commercial and operational capabilities.

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As part of the Landscape Study, a targeted workshop was organised, gathering EU institutions, industry associations, research infrastructures, universities, hospitals, training institutes, and individual companies, providing perspectives across the full biotechnology value chain. The workshop aimed to validate, prioritise, and add granularity to preliminary findings. Discussions highlighted shortages in specialised roles, limited hands-on industrial experience in higher education, and the need for scalable, competency-based training models, while emphasising EU-level opportunities modular lifelong learning, industry-academia collaboration, and shared training infrastructures as horizontal enablers.

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ANNEX 3: WHO IS AFFECTED AND HOW?

1. Practical implications of the initiative

Businesses and the research community

The proposed amendments to the Clinical Trials Regulation shorten clinical trial authorisation timelines from 106 days to 75 days, or to 47 days where no request for further information is issued. They also simplify and streamline both the approval process and the conduct of clinical trials.

Applying the Standard Unit Cost Model suggests that these efficiencies could cut administrative time—the period sponsors spend engaging with regulators—by 15–25%, equating to savings of EUR 2,700 to EUR 4,500 per multinational trial application. Such reductions in administrative costs would particularly benefit SMEs, which face a disproportionately higher regulatory burden. Electronic submission and digitalisation measures contribute a further EUR 112 to 225 million cumulatively over fifteen years.

At an aggregated level considering the total set of measures included in the Commission proposal, the economic impact of the Biotech Act's reform for sponsors can be approximated using current baseline data. Around 2,500 clinical trials are conducted annually in the EU, at an average cost of EUR 30–50 million per trial and a duration of 2–2.5 years, implying total annual sponsor expenditure of roughly EUR 30–62.5 billion. Streamlined approvals and reduced administrative burdens are expected to yield direct cost savings of about 5% (EUR 1.5–3.1 billion per year) and indirect savings of a similar order through faster technical execution (around a 0.1-year reduction in time-dependent costs).

Combined, these efficiencies could generate several billion euros in annual financial gains for sponsors, with total savings potentially exceeding EUR 5 billion. Considering a potential increase in the number of trials, these gains would increase proportionally.

The reforms are also expected to improve the EU's attractiveness for clinical research. Current projections suggest that the number of clinical trials in the EU could rise between 10% and 30%, compared with the existing volume of trial applications. These estimates draw on two separate studies: one, based on sponsor survey data, forecasts a 32% increase, while the other, relying on limited empirical evidence, projects a more modest growth of 4% to 16%[20]. The wide disparity in these estimates highlights the challenges in assessing

[20] Rapid Assessment Scenario Study (forthcoming). The study, based on limited empirical evidence, distinguishes between two hypothetical scenarios regarding the potential impact of the Biotech Act on the projected number of clinical trials in the EU. In the first scenario, a moderate increase in the number of clinical trials by 4% to 8% is anticipated. This is attributed to improved efficacy and attractiveness of performing clinical trials in the EU, driven primarily by increased domestic uptake among sponsors already operating within the region.. The second scenario assumes that, in addition to increased domestic uptake, sponsors relocate clinical trial activities from other regions to the EU/EEA as a result of the reforms in the Biotech Act, leading to an estimated increase of 8% to 16%. As the Biotech Act is expected to simplify authorisation processes and the conduct of trials for sponsors, it is considered plausible that some sponsors may relocate their clinical trials to the EU following the amendments of the Regulation. Therefore, the average of the both scenarios is used as a benchmark for the lower bound

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the reform's impact on clinical trial activity, given data limitations, and inherent uncertainties about future developments. To account for these constraints, the evaluation of the impact adopts a broad range of potential outcomes.

Costs to sponsors are limited and front-loaded. One-off investments in harmonised standard operating procedures are not quantified but are expected to be absorbed within existing budgets. Sandbox participation introduces upfront overhead, though the net lifecycle direction is a reduction in burden. The proposed measures restructure conditions for new applications rather than imposing new obligations on active trials, limiting compliance exposure for sponsors with existing portfolios.

SMEs and start-ups

SMEs and start-ups are disproportionately exposed to the current regulatory landscape: administrative expenses account for 11 to 29% of total clinical trial costs, and this burden falls proportionally harder on smaller entities with limited internal capacity. The proposed measures therefore carry a higher marginal value for this group than for large sponsors.

Benefits operate through two channels. On ecosystem navigation, the EU Health Biotechnology Support Network provides a dedicated support channel for health biotechnology innovators as regards regulatory pathways, funding, and investor connections across EU27. Firms receiving comparable network support report 14 percentage points higher knowledge sharing and collaboration capability than unsupported firms (69% versus 55%). Articles 32 and 33 address a further structural barrier: 82% of SMEs cannot self-finance the validation infrastructure required for AI-enabled biotechnology development. At medium uptake, shared testing environments and data quality accelerators are expected to serve 1,100 to 3,400 companies and data users per year.

On direct regulatory relief, the elimination of the additional 50-day ATMP assessment period and the reduction of substantial modification timelines from 96 to 47 days benefit a developer base of which over 60 % are SMEs. ERA exemptions for qualifying GMO-ATMPs remove a further 0.15 to 0.3 FTE-years per application. The harmonised AI guidance under Article 31 replaces bilateral EMA interactions currently valued at EUR 89,000 per qualification request and 160 to 250 days per interaction with freely accessible public guidance, a measure whose value is asymmetrically concentrated in smaller actors that cannot absorb bilateral engagement costs.

Costs to SMEs are limited by design. Strategic project participation is voluntary, and biosecurity compliance obligations fall on nucleic acid synthesis providers rather than the broader SME research and development population.

Biosimilar developers

Biosimilar developers are affected by three intersecting mechanisms that do not all pull in the same direction.

Following EMA guidelines adoption, Comparative Efficacy Studies (CES) requirement may be waived for biosimilar products where analytical similarity is comprehensively

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demonstrated. The CES removal would deliver the most economically significant relief, eliminating EUR 19 to 26 million in direct trial costs per product (20 to 30 per cent of total development expenditure for standard indications, up to 50 to 60 per cent for complex monoclonal antibody biosimilars) and shortening timelines by 12 to 24 months. Across 12 to 18 marketing authorisation applications per year where the tailored clinical package reform applies, aggregate annual savings are estimated at EUR 222 to 467 million. The competitive dimension is equally important: South Korea, the UK, the US, and Canada are all moving toward CES flexibility, and without this reform the EU would risk regulatory disadvantage. EU-based companies currently hold approximately 49 per cent of EU biosimilar authorisations, a share under increasing pressure from South Korean and Indian developers. The strategic project framework reinforces these gains on the supply side, projecting stabilisation of the EU-based companies share at 45 to 55 per cent through 2038 and mobilising EUR 0.9 to 7.6 billion in cumulative biosimilar manufacturing investment by 2038.

The SPC extension works in the opposite direction. The additional year of originator exclusivity is estimated to reduce biosimilar gross profits by approximately EUR 80 million per qualifying medicine (sensitivity range EUR 60 to 110 million), or EUR 240 million annually at three qualifying medicines per year. Development programmes are unlikely to be abandoned over a one-year delay, but marginal programmes targeting smaller or more uncertain markets face a measurably reduced return on investment. The net balance across the two instruments is positive in aggregate, but the distributional effect varies depending on product class and the overlap between SPC-eligible originators and active biosimilar pipelines.

Remaining costs to developers are limited to voluntary strategic project recognition, which entails preparation and reporting costs of one to two FTEs per project per year, equivalent to approximately one to two per cent of project value.

Originators and SPC-holding companies

The SPC extension generates approximately EUR 230 million in additional gross profit per qualifying medicine (sensitivity range EUR 140 to 290 million). With the measure being relevant for about 3 medicines per year, aggregate additional originator gross profit is estimated at approximately EUR 690 million annually.

According to EMA data from 2016 to 2025 and assuming the proportion of SPC reliant medicines remain constant, the SPC extension could potentially be awarded to 4-5 products annually (rather than 2-3) if developers changed their behaviour in response to the "geographical" condition of the incentive i.e. conduct clinical trials in more than one Member State and part of the production of the medicinal product in the EU.

The principal costs fall on biosimilar developers, payers, and patients through delayed competitive entry, addressed in the respective sections. The measure is explicitly redistributive, transferring value from follow-on developers and healthcare systems to originators while incentivising manufacturing and trial location.

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SoHO entities and organ processing establishments

SoHO entities using the regulatory sandbox face evidence generation costs of EUR 718,500 per year under the low scenario (six sandboxes per year) and EUR 4,790,000 per year under the high scenario (40 sandboxes per year), with per-case costs comparable to high-risk SoHO authorisations at EUR 1,200 to 6,000 per patient. Medium-risk cases directed through the sandbox will incur higher costs than under the standard route. These costs are concentrated in a small subset of novel applications that would otherwise lack a viable pathway.

For organ processing establishments, the authorisation framework introduces per-application costs of approximately EUR 11,500 for full authorisation and EUR 16,750 for conditional authorisation, with a weighted average of EUR 12,800 during the transition phase. At 60 to 145 applications across EU27 over 2029 to 2031, the aggregate transition-phase burden is EUR 768,000 to EUR 1,856,000, rising to a cumulative EUR 1.2 to 2.5 million by 2035. Establishments under conditional authorisation additionally face mandatory clinical outcome monitoring costs of approximately EUR 9,000 per monitoring plan per year, aggregating to EUR 405,000 to EUR 980,000 across EU27 over the transition phase.

These costs are substantially outweighed by the benefits. The authorisation regime is expected to generate 1,435 additional transplants per year by 2035, with 570 to 945 fewer organ discards annually. Total monetised benefits are estimated at EUR 443 to 695 million, comprising EUR 285 to 537 million in statistical lives saved from 248 to 311 cumulative waiting-list deaths averted over 2028 to 2035, and EUR 158 million in cumulative dialysis cost avoidance derived from the reduction in the dialysis-dependent population by 2035, attributable to additional kidney transplant recipients who would otherwise have remained on dialysis.

GMM developers, veterinary medicine companies, and food chain operators

The Act creates the most structurally transformative change for GMM developers: the introduction of a viable EU market authorisation pathway where none currently exists. The EU has zero authorised GMMs for deliberate release, a direct consequence of a regulatory framework designed for genetically modified plants and ill-suited to micro-organisms. The reform introduces a tailored, product-based pathway with an accelerated route for low-risk GMMs, unlocking potential access to biofertilisation, biocontrol, bioremediation, and bioleaching sectors. These collectively represent a combined global market for microbial products of EUR 29.1 to 33.4 billion growing at 9 to 14% per year, though GMM-specific products constitute only an emerging share of these totals and the figures should be understood as indicative of the upper bound of commercial opportunity rather than immediately accessible demand.

For veterinary medicine companies, three measures deliver quantifiable gains. The single GMO pathway for VMPs removes 30 to 90 days per clinical trial application, eliminating 240 to 1,350 product-days of aggregate delay annually and generating cumulative administrative cost savings to 2040 estimated at EUR 5 to 14.5 million. Uniform handling of VMP variations not requiring assessment yields present-value savings of EUR 15 to 30 million to 2040 (central estimate EUR 22.5 million). The VMP sandbox creates an entirely

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new pathway for innovative products outside existing categories, with utilisation expected at approximately one sandbox every five years; its primary value lies in pathway creation and investment signalling rather than immediate commercial volumes.

Food chain operators benefit from the sandbox mechanism for pre-market testing of sustainable food production technologies, including GMO-containing products. The exclusion of novel foods from sandbox scope, whilst justified on grounds of scientific complexity and consumer sensitivities, - as explained in Section 5.1.2 of the Staff Working Document represents a genuine constraint on the benefits available to this group and has been characterised by industry stakeholders as a missed opportunity.

Sequence synthesis providers

Providers of nucleic acid synthesis services face the most direct and quantifiable compliance burden under the biosecurity provisions. Mandatory sequence and legitimacy screening obligations impose direct annual compliance costs estimated at EUR 10.5 to 22.2 million per provider sector, comprising legitimacy screening (EUR 19 million in 2027 rising to EUR 34 million by 2036), sequence screening (EUR 1.6 million rising to EUR 2.8 million), and procedure introduction and regulatory adjustment costs (EUR 1.7 million rising to EUR 2.5 million). Customers and researchers face additional compliance costs of approximately EUR 16.4 million per year for documentation, procurement adjustments, and per-order verification. Indirect costs compound these figures: research chilling effects from concerns about order delays or rejections are estimated at EUR 97 million in 2027 rising to EUR 170 million by 2036, whilst productivity losses to providers from compliance intensity are estimated at EUR 8.6 to 24.8 million per year. Approximately 10% of researchers may shift to in-house synthesis at substantially higher per-order costs.

These costs must be assessed against a strongly asymmetric benefit profile. The mandatory screening regime is estimated to prevent 35% of deliberate bioattacks and 86 % of accidental release events, generating expected annual prevention benefits of EUR 2.9 billion in 2027 rising to EUR 5.5 billion by 2036. A further EUR 10 billion in future research value is preserved by averting the regulatory backlash that would follow a major biosecurity incident. The compliance burden, whilst material, represents well under one precent of the prevention benefits the regime is expected to deliver.

Applicants for strategic and high-impact projects

Entities seeking recognition under either framework face preparation, submission, and ongoing reporting costs estimated at one to two FTEs per project per year, equivalent to approximately one to two % of total project value. In the most demanding governance configurations, worst-case participation costs might reach EUR 700,000 to 800,000 per firm (as an upper bound). Participation is entirely voluntary.

The returns are substantial. The strategic project framework is expected to mobilise EUR 15 to 28 billion in total investment at medium uptake (60 to 70 projects), with the high-impact tier adding a further EUR 4 to 12 billion (12 to 15 projects), yielding a combined EUR 19 to 40 billion by 2038. Both frameworks additionally reduce permitting delay costs, with cumulative avoided delay-related capital costs estimated at EUR 265 million to

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EUR 1.16 billion by 2038 across the two tiers at medium uptake, concentrated in the most capital-intensive projects where schedule adherence directly affects bankability and time-to-revenue.

Public authorities

European Medicines Agency

The proposed EU Biotech Act would generate a series of incremental workload increases for EMA, none of which are individually large. Finalisation of the biosimilar draft reflection paper into adopted guidance is estimated at 0.5 to 1.0 FTE-year as a one-off cost, with ongoing maintenance at 0.2 to 0.5 FTE-year. SPC eligibility verification introduces a maximum annual workload of 28 to 30 working days across the Agency, at approximately one working day per application. Lifecycle-wide AI guidance development under Article 31 requires one-off capacity building and training at Union and national levels, not yet quantified. For VMPs, adaptation of the Union Product Database to remove the approve/reject functionality for national competent authorities is estimated at EUR 150,000 to 300,000 for a three-to-six-month IT engagement.

These costs are partially offset by two workload reductions. CHMP verification of sponsor declarations for qualifying GMO-ATMP clinical trial applications, submitted in place of full ERA dossiers, represents a net reduction in assessment workload relative to the baseline. Additionally, the CES removal for biosimilars reduces the number of multi-country Phase III trial authorisations requiring ethics committee review and GCP inspection oversight across Member States, easing NCA burden across the network. In aggregate, EMA's incremental costs under the Act are modest and absorbable within existing institutional capacity.

National competent authorities

NCAs face new and expanded obligations across several distinct areas, the most significant of which is the biosecurity enforcement mandate. Member State enforcement and coordination costs for the biosecurity screening regime are estimated at approximately EUR 14 million per year in 2027, rising to EUR 21 million per year by 2036, requiring approximately three FTEs per Member State for policy coordination, reporting, and enforcement activities.

For the strategic and high-impact project frameworks, steady-state staffing requirements for single points of contact range from 0.3 to 0.9 FTEs per Member State under low uptake, 0.7 to 1.8 FTEs under medium uptake, and 1.1 to 3.0 FTEs under high uptake. These are incremental rather than structural costs: in most Member States, existing authorities are expected to be designated rather than new structures created, with the primary burden concentrated in front-loaded process design and workload reallocation.

SoHO sandbox supervision increases NCA workload materially on a per-case basis, with medium-risk sandbox cases requiring 75 to 94 person-days per case (EUR 22,575 to EUR 28,294, a 57 to 114% increase over standard authorisation) and high-risk cases 98 to 149 person-days (EUR 29,498 to EUR 44,849, a 10 to 63% increase). Cross-Member State learning is assumed to offset these elevated unit costs over the medium term. For organ

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processing, per-assessment costs are estimated at EUR 7,000 to EUR 10,000, with aggregate EU27 transition-phase assessment costs of EUR 420,000 to EUR 1,450,000 over 2029 to 2031, declining to EUR 60,000 to EUR 85,000 per year in steady state. Monitoring oversight for Track 2 conditional authorisations adds EUR 63,000 to EUR 216,000 per year during transition.

Finally, participation in the European Health Biotechnology Steering Group requires approximately two FTEs per Member State per year, and strategic ecosystem mapping data provision approximately 0.25 FTEs per year. These governance obligations are ongoing but modest relative to the biosecurity and sandbox functions.

European Commission

The Commission's recurring fiscal commitment under the Act is dominated by the biodefence and biosecurity components. Total annual operational costs of the combined biodefence surveillance system and biosecurity screening oversight are estimated at EUR 86 to 190 million per year across Union and Member State budgets, with the biodefence component alone accounting for EUR 46 million per year under Scenario 1 and EUR 110 million per year under Scenario 2. EU-level biosecurity coordination and oversight specifically is estimated at EUR 1.3 million per year in 2027 rising to EUR 1.9 million in the long term, corresponding to approximately 11 FTEs. These commitments should be read against EUR 2.9 to 5.5 billion in annual prevention benefits the two instruments are jointly expected to deliver.

Beyond biosecurity, Commission-level costs are more modest. Operating the Steering Group secretariat, conducting strategic mapping, and coordinating the Support Network requires approximately EUR 2.6 million annually, equivalent to EUR 18.4 million over the MFF period. EU-level supervision of high-impact strategic projects requires 1 to 3 FTEs under low uptake, 2.5 to 8 FTEs under medium uptake, and 5 to 15 FTEs under high uptake. Sandbox establishment under clinical trials and novel health products each require approximately EUR 4.3 million over approximately three years as an order-of-magnitude reference, with adopting implementing acts for VMP sandboxes representing an additional unquantified legislative workload over 2026 to 2040.

Citizens, patients, and consumers

Earlier access to medicines

The acceleration of clinical trial authorisation procedures and the removal of the biosimilar CES requirement are expected to result in approximately 100 products reaching the market up to six months earlier than under the baseline, applying an approximate 8% average launch rate to the 2,500 to 3,000 products tested annually in EU trials. ATMP procedural reforms are expected to accelerate access in high unmet-need areas, though patient-level quantification is not yet available.

Organ transplantation

On the regulatory changes proposed to organ processing, the moderate-scenario projection of 1,435 additional transplants per year by 2035 translates into 57 to 72 fewer waiting-list

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deaths annually, or 248 to 311 cumulative deaths averted over 2028 to 2035, valued at EUR 285 to 537 million. A further EUR 158 million in cumulative dialysis cost avoidance is attributable to approximately 3,295 additional patients living with a functioning transplant by 2035 who would otherwise have remained on dialysis.

Patient access and the SPC extension trade-off

The SPC extension entails a direct and quantifiable cost on patients and payers. The additional year of originator exclusivity delays biosimilar competition, resulting in a combined social cost of approximately EUR 205 million per qualifying medicine (range EUR 140 to 290 million), comprising EUR 135 million in delayed patient access value and EUR 70 million in direct payer expenditure. At three medicines per year, aggregate annual social costs amount to approximately EUR 615 million. The cost is driven primarily by the delay in the expansion of patient coverage rather than by direct price effects: coverage expands upon loss of protection, and the main social cost of the extension therefore consists in the temporary postponement of this expansion.

Biosecurity and public safety

RAND (2025) estimates that mandatory NA synthesis screening prevents 35% of deliberate bioattacks and 86% of accidental release events, generating expected annual prevention benefits of EUR 2.9 billion in 2027 rising to EUR 5.5 billion by 2036. A further EUR 10 billion in future research value is preserved by averting the regulatory backlash that would follow a major biosecurity incident.

Consumer and environmental interests

Consumers benefit indirectly from the long-term competitive effects of a stronger EU biosimilar market supporting pricing pressure at patent expiry, and from sustainable food production technologies enabled through the food law sandbox. Environmental gains materialise through GMM applications in biofertilisation, biocontrol, and bioremediation, and through expanded veterinary biotech vaccine uptake supporting antimicrobial resistance reduction targets. A 10 % reduction in livestock disease levels is empirically associated with an 800 million tonne reduction in GHG emissions, equivalent to the annual emissions of 117 million Europeans. No direct costs are anticipated for ordinary consumers beyond the payer-side cost of the SPC extension, which manifests primarily through public health system expenditure.

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2. Summary of costs and benefits

I. Overview of Benefits (total for all provisions)		
Description	***Amount***	***Comments***
Direct benefits		
Elimination/reduction of duplicative regulatory obligations across intersecting/overlapping legal frameworks	EUR 5.2–5.5 billion/year Combined annual savings (clinical trials + biosimilars) EUR 2,700–4,500 Per multinational trial (SCM; admin costs only) ~EUR 2.8–4.7 million/year aggregate (derived: ~1,050 multinational trials/year × per-trial saving)	The EUR 5.2–5.5 billion/year figure covers these annualised streams: • clinical trial reform (EUR 1.5–3.1 billion/year in direct sponsor savings, ~5%; aggregate indirect savings raise the total to >EUR 5 billion/year) • the VMP single GMO pathway removes EUR 5–14.5 million in cumulative administrative costs to 2040 • biosimilar CES rationalisation (EUR 222–467 million/year across 12–18 MAAs/year) • electronic submission and digitalisation measures yield EUR 112–225 million cumulatively over 15 years (~EUR 7.5–15 million/year annualised. Three further components are additional to this figure but presented on different units: • the SCM-derived per-trial saving of EUR 2,700–4,500 (15–25% reduction in sponsor administrative costs per multinational trial through reduced staff time). • ATMP reforms additionally remove 0.15–0.3 FTE-years per CTA.
Reduction of regulatory fragmentation across Member States	Qualitative	Harmonised templates, single GMO pathways for VMPs, shared infrastructure, and the EU Support Network reduce Member State divergence in risk classification, product categorisation, and procedural interpretation.
Enhanced predictability and legal certainty in permitting and project development	EUR 265 million – 1.16 billion Combined avoided delay costs (medium uptake, to 2038) ~EUR 22–97 million /year simple annual average[21]	Strategic project recognition (60–70 projects, medium uptake) and high-impact flagship tier (12–15 projects) together yield EUR 265 million – 1.16 billion in avoided permitting delay costs by 2038. Converts an opaque, variable permitting landscape into a bounded, time-limited pathway, directly improving the bankability of industrial-scale deployments and creates a structured "investability" channel that previously did not exist.

[21] The annualised figure should be interpreted as a simple average over the implementation period; actual annual benefits are back-loaded, materialising primarily as projects reach permit-granting maturity in the 2030–2038 window.

Streamlined authorisation procedures and compressed timelines in clinical development	106 → 75 days (47 without RFI) EUR 1.5–3.1 billion/year direct sponsor savings (~5%) Aggregate savings potentially exceeding EUR 5 billion/year	Clinical trial authorisation timeline compressed from 106 to 75 days (47 without RFI), with harmonised templates and parallel modification submissions. Direct cost savings of ~5% of annual EU sponsor expenditure yield EUR 1.5–3.1 billion/year; indirect savings through faster technical execution raise the aggregate to potentially above EUR 5 bn/year. Electronic submission saves EUR 112–225 million over 15 years.
Streamlined risk assessment processes	12–24 months shorter per product (biosimilars) (monetised annual figure already accounted for under the first benefit) 50-day assessment period eliminated; modification timelines cut from 96 to 47 days (ATMPs) 0.15–0.3 FTE-years per CTA removed (ATMPs) 30–90 days per CTA removed (VMPs) EUR 22.5 million PV savings, central estimate (EUR 15–30 million range) (VMP variations, to 2040). The central annual saving in the base year is approximately EUR 1.46 million/year rising to EUR 3.07 million/year by 2040.	Biosimilar CES removal shortens development by 12–24 months and removes EUR 19–26 m in direct trial costs per product (representing 20–50% of total development expenditure depending on molecule complexity), with the timeline reduction enabling developers to start later in the originator's market protection period and reducing commercial risk. For ATMPs, the elimination of the additional 50-day assessment period and the reduction of substantial modification timelines from 96 to 47 days are the principal procedural gains; ERA exemptions for qualifying GMO-ATMPs additionally remove 0.15–0.3 FTE-years per CTA in administrative burden, concentrated in regulatory affairs and project management functions, with benefits disproportionately accruing to the SME-dominated developer base. For VMPs containing GMOs, the single regulatory pathway removes 30–90 days per CTA (240–1,350 product-days of delay eliminated annually at current pipeline volumes; EUR 5–14.5 million in cumulative administrative cost savings to 2040). The uniform handling regime for VMP variations not requiring assessment yields a further EUR 22.5 million in present-value savings to 2040 (range EUR 15–30 million), derived from a 10–20% efficiency gain on VNRA processing workload applied across the sector.
Anchoring late-stage investment and scale-up activity in the EU	EUR 19–40 billion Total investment mobilised by 2038 (project frameworks) ~EUR 1.6–3.3 billion/year annual average[22]	Investment mobilised: • Strategic project framework: EUR 15–28 billion (medium uptake, 60–70 projects). • High-impact flagships: EUR 4–12 billion (medium uptake, 12–15 projects).

[22] Cumulative EUR 19–40 billion ÷ 12 years; not uniform, because investment mobilisation is ramp-up dependent with bulk of activity concentrated in 2030–2038 as project pipeline matures.

	EUR 10 billion mobilised in 2026–2027 (BioTechEU / InvestEU) EUR 230 million/year additional originator gross profit per qualifying SPC medicine	• Combined EUR 19–40 billion by 2038. Pending full establishment, the BioTechEU initiative under the current MFF and InvestEU programme will mobilise up to EUR 10 bn in biotechnology investments in 2026–2027. Additionally, the SPC extension, operating via a distinct IP protection mechanism rather than project recognition or financing instruments, generates: • an estimated EUR 230 million in additional originator gross profit per medicine benefitting from the incentive per year (sensitivity range EUR 140–290 million), • corresponding to approximately EUR 690 million/year in aggregate at an average of three medicines per year. • the associated combined payer expenditure and monetised cost of delayed patient access amounts to approximately EUR 205 million per medicine (EUR 615 million/year in aggregate at three medicines). • if developer behaviour changes in response to the incentive, up to five products per year could benefit from the incentive rather than up to 3.
Strengthening the EU's global competitive position in biosimilars	45–55% EU-based share of biosimilar MAs maintained (vs projected 40–50% without intervention) 12–24 months faster market entry per product	Without intervention, the EU-based share of biosimilar MAs is projected to fall from 49% (2025) to 40–50% as manufacturing migrates to Asia and competitor jurisdictions accelerate their own regulatory streamlining. CES removal would arrest this decline by reducing the cost threshold for EU-based biosimilar development, accelerating market entry by 12–24 months per product and enabling EU developers to respond more quickly to patent expires. Strategic project eligibility for biosimilar manufacturing reinforces this effect on the supply side by improving the bankability of EU-based biomanufacturing deployments. Together these measures can contribute to stabilise the EU-based company share at 45–55%
Improving the EU's attractiveness as a location for commercial clinical research	350–700 additional trials over 3–4 years (domestic scenario; 4–8% increase)	If the Act enters into force swiftly, a one-off domestic increase of 4–8% over 3–4 years is considered feasible, yielding 350–700 additional trials; The average economic activity

	Up to 700–1,400 additional trials (relocation scenario; 6–16% increase) 14 products from 2016-2025 identified as marginal cases for conducting multi country clinical trials in Europe (SPC extension conditional incentive)	value associated with this scenario is EUR 40–80 million/year and broader economic spillovers are estimated at EUR 316–695 million/year. If relocation effects also materialise, total additional trials could reach 700–1,400, though this depends on factors beyond regulation including HTA and reimbursement conditions. The average economic activity value associated with this scenario is EUR 80–160 million/year and broader economic spillovers are estimated at EUR 630–1,400 million/year. Additionally, the SPC extension is expected to influence trial location at the margin: between 2016-2025, of 100 products within scope of the eligibility incentive, 14 met all conditions except the multi-Member State trial requirement, representing the marginal case for developers to modify their behaviour in response to the incentive and conduct part of their clinical trials for marketing authorisation in more than 2 EU MS.
Enabling innovation and supporting new market entrants through regulatory sandboxes	6–40 SOHO sandboxes established per year (90–250 eligible cases/year; 7–16% acceptance rate) 40% shorter time from regulator engagement to market authorisation	For SOHO, sandbox-eligible cases are estimated to represent 5–10% of overall SOHO activities, corresponding to 90–250 eligible cases per year; given observed acceptance rates of 7–16% in comparable sandbox regimes, between 6 and 40 sandboxes are expected to be established per year. Evidence from FinTech sandboxes indicates participants achieve on average 40% shorter time from engagement with the regulator to market authorisation than comparable firms using standard processes; analogous gains are expected in SOHO though not yet quantifiable against a baseline given the absence of comparable EU precedent. For VMPs, the baseline is zero as no EU-level veterinary sandbox currently exists; the measure therefore creates an entirely new pathway rather than improving an existing one.
Accelerating the translation of research into clinical and commercial development	4–40 additional CTAs/year (low to high uptake via high-impact infrastructure) 60–600 firms served annually (low to high uptake via high-impact infrastructure)	High-impact infrastructure uptake scenarios assume 2 projects with shared late-stage translation capability under low uptake, 4–6 under medium, and 8–10 under high, driving the CTA and firms-served ranges proportionally. The 60% SME share is consistent across all uptake scenarios. The 24-product SPC manufacturing effect reflects products meeting all other eligibility conditions except an EU-based manufacturing step at time of approval; the incentive is

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	24 products from 2016 -2025 identified as marginal cases for EU manufacturing step inclusion (SPC extension conditional incentive)	expected to influence incremental production network decisions at the margin, not drive fundamental manufacturing relocation.
Building the enabling infrastructure for AI-driven biotechnology innovation	EUR 89,000 per EMA qualification request replaced by free public guidance; 160–250 days saved per interaction (Article 31) 120–495 companies and data users/year (low uptake); 1,100–3,400/year (medium uptake); 4,250–12,600/year (high uptake) (Articles 32 and 33) EUR 85–205 million cumulative CAPEX (low); EUR 650 million – 1.3 billion (medium); EUR 2.4–7.2 billion (high) over 5–15-year build-out period. Annualised CAPEX during build-out: EUR 17–41 million/year (low); EUR 65–130 million/year (medium); EUR 160–480 million/year (high)[23]	Article 31 harmonised AI guidance replaces costly one-off bilateral EMA interactions (currently EUR 89,000 per qualification request and 160–250 days per interaction) with a single publicly accessible reference point, disproportionately benefiting SMEs and academic developers. Articles 32 and 33 establish shared testing environments and data quality accelerators across three uptake scenarios, serving: • 120–495 companies and data users/year (low; 2–3 environments and 2–3 accelerators), • 1,100–3,400/year (medium; 5–8 each), and • 4,250–12,600/year (high; 10–15 each). Total CAPEX ranges from EUR 85–205 million (low) to EUR 650 million – 1.3 billion (medium) to EUR 2.4–7.2 billion (high) over the project build-out period. Direct employment: 160–420 FTE (low) to 1,000–2,640 FTE (medium) to 3,300–7,500 FTE (high).
Mitigating biosecurity risks arising from the wider accessibility of biotechnologies	EUR 2.9 billion expected benefits (2027): EUR 1.8 billion attack prevention + EUR 1.2 billion accident prevention EUR 5.5 billion by 2036: EUR 2.9 billion attack prevention + EUR 2.7 billion accident prevention 35% deliberate attacks prevented; 86% accidental releases prevented EUR 10 billion avoided future research value	Benefits split: EUR 1.8 billion (attack prevention) + EUR 1.2 billion (accident prevention) = EUR 2.9 billion in 2027; rising to EUR 2.9 billion + EUR 2.7 billion = EUR 5.5 billion in 2036, reflecting increased screening coverage over time. The 35% attack prevention rate reflects that malicious actors can still order through non-EU suppliers; the 86% accident prevention rate reflects near-complete coverage of accidental misuse pathways. –

[23] Annualised CAPEX assumes 5-year build-out under low uptake, 10-year under medium, and 15-year under high.

		The EUR 10 billion avoided research value represents RAND's estimate of lost future research value from a regulatory backlash following a major biosecurity event.
Indirect benefits		
Earlier and broader patient access to biotechnology-derived treatments	~100 products reaching market up to 6 months earlier 1,435 additional transplants/year by 2035 57–72 waiting-list deaths averted/year by 2035; 248–311 cumulatively (2028–2035); valued at EUR 285–537 million EUR 158 million cumulative dialysis cost avoidance (2028–2035) ; ; EUR 19.75 million/year average. EUR 443–695 million total monetised benefit (EUR 285–537 million + EUR 158 million); EUR 55 – 87 million/year average.	Clinical trials reform: ~8% average launch rate applied to 2,500–3,000 products tested annually yields ~100 products potentially reaching market up to 6 months earlier. ATMP reforms expected to accelerate access in high-unmet-need areas, however not quantified. Organ processing: 1,435 additional transplants/year by 2035 (approximately 847 kidney, 357 liver, 99 lung) derived from a moderate-scenario 1.5–2.5 percentage point reduction in the all-organ discard rate; set against a baseline waiting list of 52,488 patients and 3,366 waiting-list deaths annually (6.4% annual mortality rate). 570–945 fewer organ discards/year by 2035. Deaths averted: 57–72/year applying a conservative 4–5% marginal mortality rate to marginal transplant recipients; 248–311 cumulative over 2028–2035, valued at EUR 285–537 million. Dialysis cost avoidance: EUR 158 million cumulative (2028–2035), based on ~3,295 additional patients living with a functioning transplant by 2035.
Strengthening supply chain resilience for essential biotechnology medicines	8–60 capacity-relevant EU biomanufacturing deployments by 2038 (low: 8–15; medium: 18–35; high: 30–60) Of which 1–10 biosimilar-specific manufacturing deployments (low: 1–2; medium: 3–5; high: 5–10)	Strategic project framework delivers 8–15 (low), 18–35 (medium), and 30–60 (high) capacity-relevant EU-based biomanufacturing deployments by 2038, assuming approximately 30–50% of recognised projects translate into capacity-relevant outputs. Biosimilar manufacturing constitutes a distinct subset: 1–2 (low), 3–5 (medium), and 5–10 (high) capacity-relevant biosimilar deployments, mobilising EUR 0.9–7.6 billion in cumulative investment by 2038.

	EUR 0.9–7.6 billion cumulative investment in biosimilar manufacturing by 2038 (low to high uptake); on average EUR 75 – 633 million/year.	
Environmental and sustainability benefits	EUR 29.1 billion+ combined microbial market across biofertilisation, biocontrol, bioremediation, bioleaching (9–14%/year growth; GMM-specific share not separately quantified; currently zero EU authorisations for GMM deliberate release) 800 million tonnes potential GHG reduction (10% livestock disease reduction via biotech vaccines). Equivalent to annual emissions of 117 million Europeans	GMM regulatory reform unlocks market access across four application sectors: biofertilisation (USD 1.38–3.1 billion; 10.9–12.8% CAGR), biocontrol (USD 6.5 billion; 14.3% CAGR), bioremediation (USD 16.45–18.08 bn; 9.93–13.0% CAGR), and bioleaching (USD 10.14–11.19 billion; 8.9–9.06% CAGR) - combined USD 34–39 billion. The EU currently has zero authorised GMMs for deliberate release. Veterinary biotech vaccine uptake enabled by VMP reform supports the EU's target of halving antimicrobial sales by 2030. 10% reduction in livestock disease levels is empirically associated with an 800 m tonne GHG decrease, equivalent to the annual emissions of 117 million Europeans. Food chain sandbox creates structured pathways for pre-market testing of sustainable food production technologies across all stages of production, processing and distribution, food contact materials, and GMO-containing products.
Ecosystem-level coordination and connectivity infrastructure	Qualitative; functions as a cross-cutting enabler of all other interventions 14 pp higher knowledge sharing and collaboration capability for firms receiving network support vs unsupported firms	Four interconnected mechanisms underpin uptake of all substantive reforms: • The EU Health Biotechnology Support Network is a single entry point for SMEs and start-ups to navigate regulatory pathways, access funding and scaling-up resources, and connect with investors across EU27; • Networks of health biotechnology clusters for cross-border collaboration, infrastructure access, and knowledge transfer; • The European Health Biotechnology Steering Group for strategic coordination between Member States and the Commission; and • strategic mapping of the Union's biotechnology ecosystem for evidence base covering industrial capacity, infrastructure, capital access, and skills gaps informing all other measures.

		EEN benchmark: firms receiving network support report 14 pp higher knowledge sharing and collaboration capability than unsupported firms (69% vs 55%).

I. Overview of Benefits (Totals)		
Amount	***Components***	***Comments***
	Direct benefits	
~EUR 8.3–11.3 billion/year	Duplication removal savings: EUR 5.2–5.5 billion/year VMP procedural savings: ~EUR 1.5–3.1 million/year Permitting predictability: ~EUR 22–97 million/year Biosecurity screening: EUR 2.9–5.5 billion/year	Sum of directly quantified annual benefit figures drawn from intervention-level assessment of impacts. . The EUR 10 billion biosecurity avoided research value is also excluded from the annual total as it represents a one-off expected loss avoided rather than an annual flow, and is therefore not additive to annual benefit figures. All figures are subject to uptake, implementation, and market conditions as described in the benefits table above.
	Indirect benefits	
~EUR 55–87 million/year	Patient access monetised benefits: EUR 55–87 million/year average (EUR 443–695 million cumulative 2028–2035)	Covers organ processing reforms only (VSL valuation of deaths averted + dialysis cost avoidance). Clinical trial and ATMP patient access effects are not separately monetised. Supply chain resilience benefits are not directly monetised as deployment counts and investment figures serve as proxies only. Environmental and ecosystem benefits are qualitative.

II. Overview of costs								
		Citizens/Consumers		Businesses		Administrations		
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent	
Action (a)	Direct adjustment costs	n/a.		**Clinical trials:** - Initial investment in harmonised standard operating procedures to meet enforcement expectations across National Competent Authorities and ethics committees. Not quantified - low. **Substances of Human Origin:** - One-off costs of adjusting to the sandbox route for SoHO entities. Not quantified – low. **Responsible use of AI and data management:** - Adaptation of internal governance, validation procedures and documentation to comply with new EMA lifecycle guidance on AI. Not quantified – medium.	**Substances of Human Origin:** - Evidence generation within sandbox route: total additional cost to SoHO entities EUR 718,500/year (low estimate, 6 sandboxes per year) to EUR 4,790,000/year (high estimate, 40 sandboxes per year). - Sandbox costs comparable to high-risk SoHO authorisations (50-100 patients, EUR 1,200–6,000 per patient), assuming half medium-risk and half high-risk cases. If medium-risk cases use the sandbox route, direct cost per case increases relative to the standard SPA route. **Organ processing:** - Ongoing data collection, analysis and reporting under mandatory clinical-outcome monitoring plans, estimated at approximately EUR 9,000 per monitoring plan per year. Aggregate across EU-27 during the transition phase (approximately 15–36 active monitoring plans): EUR 405,000–980,000 over three years (2029–2031), or circa EUR 135,000–327,000/year.	**Biotech ecosystem:** - Designation of single points of contact for health biotechnology; source notes this is a scope extension of structures already established under the Net-Zero Industry Act and Critical Raw Materials Act, resulting in marginally lower set-up costs than those benchmarks; not quantified – low. **Biosimilars:** - Article 28: finalising the Draft Reflection Paper into adopted guidance; estimated at 0.5–1.0 full-time equivalent-year at EMA. Cost can be considered negligible. **Novel health biotechnology products:** - Setting up the regulatory sandbox and establishing the foresight panel; borne by the Commission only. Approximately EUR 4.3 million over approximately 3 years is an order-of-magnitude reference. Or approximately EUR 1.4 million/year over the	**Biotech ecosystem:** Member State level: - Steering Group participation: approximately 2 full-time equivalents per Member State per year; - Facilitation of Support Network tasks (Article 19(7)): not separately quantified - low. Commission level: - Operating Steering Group secretariat, conducting strategic mapping and coordinating Support Network: approximately EUR 2.6 million annually (EUR 18.4 million over the MFF period). **Biosimilars:** - Article 28: ongoing maintenance of tailored biosimilar guidance and handling of tailored scientific advice requests; estimated at 0.2–0.5 full-time equivalent-year at EMA. **Novel health biotechnology products:** - Operating the regulatory sandbox and running the foresight panel (Commission); not quantified – low to medium. **General food law reform:** - Additional staff and coordination effort in EFSA for expanded scope of pre-submission advice. The costs are expected to be offset by efficiency gains from fewer stop-the-clock procedures and less remedial work on poor-quality dossiers. Not quantified - low. - Member State national competent authorities: establishing and supervising regulatory sandboxes and submitting annual reports to the Commission on sandbox results. Not quantified - low. **Access to funding:** - Monitoring and reporting of the Pilot, evaluation of leverage and additionality across instruments.

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						initial three-year setup period. **Clinical trials:** - Setting up sandbox ecosystem infrastructure approximately EUR 4.3 million over approximately 3 years as an order-of-magnitude analogy. Or approximately EUR 1.4 million/year over the initial three-year setup period. - Separate sandbox from Novel health biotechnology products, but similar cost expected. **ATMP:** - Commission preparation of delegated acts to update the tissue engineered product definition, including consultations with EMA and the Substances of Human Origin Coordination Board. Not quantified - negligible. **VMP:** - EMA: one-off development of SPC eligibility assessment guidance and criteria. Not quantified - negligible. - Commission: adopting implementing act(s) establishing the regulatory sandbox rules and limits; one per sandbox established; approximately 2–3 over 2026–2040. Not quantified - negligible.	Not quantified - negligible (largely absorbed within existing EIB structures). **Responsible use of AI and data management:** - Arts. 32 & 33: continuous technology refresh to maintain state-of-the-art status for recognised testing environments and data quality accelerators: 15–20% of initial capital expenditure annually; 30–40% of software stacks require major replacement or updates every 18–24 months. - Article 33: accelerator-grade data curation uplift beyond EHDS baseline obligations - approximately 15% added to experimentation costs for AI-readiness; EUR 100,000–500,000 per project for accelerator-grade data provision. **Biodefence:** Sampling and collection costs (NWSS municipal sites plus transport gateway sampling): - EU Scenario 1 approximately €23 million per year total collection; EU Scenario 2 approximately €8 million per year total collection (no nasal swabs). Metagenomic sequencing, processing and bioinformatics analysis (BIORADAR component): EU Scenario 1 approximately €23 million per year; EU Scenario 2 approximately €102 million per year. - Total annual operational costs including overhead: approximately €46 million per year (EU Scenario 1) to approximately €110 million per year (EU Scenario 2). **Biosecurity:** - Total direct compliance costs for providers implementing mandatory sequence and legitimacy screening. o Lower-bound estimate: approximately EUR 7.3 million per year. o Upper-bound estimate: 22.2 million - Only legitimacy screening: estimated EUR 19 million in 2027 rising to EUR 34 million in 2036; - Only sequence screening: EUR 1.6 million rising to EUR 2.8 million in 2036

						- EMA: adapting the Union Product Database to remove the approve/reject functionality for National Competent Authorities. Estimated at EUR 150–300K (3–6 months, one IT team). **Substances of Human Origin:** - NCA upfront sandbox capability setup; Not estimated – low to medium. - Commission costs for hosting EU SoHO Platform and SCB engagement. Not estimated – low. **Organ processing:** - National competent authority capacity building, comprising recruitment or training of multidisciplinary assessment staff, establishment of cooperation channels with pharmaceutical, medical device, and SoHO authorities, and development of internal procedures and assessment templates. Not quantified – low to medium. - Commission: adopting implementing acts to establish the detailed authorisation procedure (Article 6a(12)). Not quantified - negligible. **Access to funding:**	- Only costs for procedure introduction and regulatory adjustment: EUR 1.7 million in 2027 rising to EUR 2.5 million in 2036.

						- Design and establishment of the Investment Pilot by end-2026, including instrument structuring, biotech tagging and KPI comparability arrangements across instruments. Costs moderate. Not quantified - low. **Responsible use of AI and data management:** - Developing lifecycle-wide AI guidance across the medicinal product lifecycle; capacity-building and training costs borne at both Union and national levels. Not quantified – low to medium. **Biodefence:** - Expansion of collection infrastructure to strategic locations (airports, train stations, schools, hospitals) beyond existing wastewater treatment sites. - **Cost minimal** as it would rely on existing wastewater plants where available.	
	Direct administrative costs	n/a.	- n/a.	**Strategic projects & High impact strategic projects (including Biosimilars and AI):** - Preparation and submission of the recognition for (high impact) strategic project application: staff time, external consultancy and legal fees, reporting and administrative tasks.	**ATMP:** - Submission of a simplified declaration per clinical trial application explaining the applicable negligible-risk categorisation, in lieu of a full ERA dossier. New information obligation; net direction relative to baseline is a	**Strategic projects & High impact strategic projects:** - Front-loaded setup: process design, workload reallocation and service standards to establish and operate single points of contact. In many Member States, existing authorities may be designated rather	**Strategic projects & High impact strategic projects & Biosimilars:** - Reporting on recognised project pipeline to Commission under updated Strategic Technologies for Europe Platform information flows. Not quantified - negligible. **Biotech ecosystem:** Member State level

				- Central estimate: 1–2 full-time equivalents per project per year, corresponding to approximately 1–2% of total project value (upper bound: 1–3 full-time equivalents where State-aid-intensive governance applies). Worst-case participation cost: EUR 700,000–800,000 per firm (upper bound only; source explicitly states this is not representative of the Act's default recognition-and-coordination pathway). - **This is a voluntary cost**. **Clinical trials:** - initial upfront planning and reporting effort for sandbox participation. This "initial overhead"; net direction over the product lifecycle is expected to be a reduction[24]. Not quantified - low. **Organ processing:** - Full authorisation, Article 6a(2): approximately EUR 11,500 per application. - Conditional authorisation with clinical-outcome monitoring, Article 6a(3)): approximately EUR 16,750 per application.	reduction. Not quantified – negligible. **Organ processing:** - Steady-state from approximately 2032 onwards: approximately 7–10 new applications per year EU-27 at ~EUR 12,800 each: EUR 90,000–128,000 per year; - Recurrent monitoring reporting costs EUR 16,000–22,500 per year; - Total steady-state approximately EUR 106,000–150,500 per year. **Access to funding:** - Marginal compliance and reporting costs associated with participation in supported instruments. Source explicitly characterises these as the only business-side effect and the overall administrative cost impact as neutral. Not quantified. **SPC extension:** - Demonstrating eligibility for the SPC extension to EMA per application. **Negligible cost**; EMA assessment relies largely on regulatory information	than new structures created. Not quantified – low to medium.	- Data provision for strategic mapping on Commission request: approximately 0.25 full-time equivalents per Member State per year. **Novel health biotechnology products:** - Maintaining the regulatory status repository (Commission information system); not quantified - low. **Organ processing:** - Commission: maintaining publicly accessible list of authorised processing operations (Article 6a(11)); - facilitating exchange of clinical outcome data between competent authorities (Article 8, as amended). Not quantified – negligible.

[24] Initial overhead for the limited number of available sandboxes may increase upfront planning and reporting effort, but net administrative burden over the product lifecycle is expected to fall—primarily through implementation of tested innovative approaches by SMEs, avoiding failed submissions and protocol overhauls while mitigating high consultancy and learning costs. Initial overhead for sandbox participation may increase upfront planning and reporting effort, but net administrative burden over the product lifecycle is expected to fall where sandboxes avoid failed or heavily delayed applications-submissions and protocol overhauls for SMEs, which currently face high consultancy and learning costs. Initial overhead for sandbox participation may increase up-front planning and reporting effort, but net administrative burden over the product lifecycle is expected to fall where sandboxes avoid failed or heavily delayed applications.

				- Weighted average during transition (~75% Track 1 / ~25% Track 2): approximately EUR 12,800. - Total transition-phase burden EU-27 (~60–145 applications, 2029–2031; central estimate ~100): EUR 768,000–1,856,000. - Cumulative burden 2029–2035: approximately EUR 2.5 million. approximately EUR 256,000–619,000/year during the transition phase (2029–2031).	already available to the Agency. **Biosecurity:** Compliance costs for customers and researchers (documentation, procurement adjustments, internal compliance procedures, per-order verification): approximately EUR 16.4 million per year.		
	Direct regulatory fees and charges	n/a.	n/a.	n/a.	n/a.	n/a.	n/a.
	Direct enforcement costs	n/a.					**Strategic projects including Biosimilars:** - Single points of contact dealing with recognition applications, queries, permitting coordination and dispute-settlement information. Indicative steady-state staffing needs (caveat: figures illustrate scale, not a precise prediction): o low uptake (25–30 projects by 2038): 0.3–0.9 full-time equivalents per Member State; o medium uptake (60–70 projects): 0.7–1.8 full-time equivalents per Member State; o high uptake (100–120 projects): 1.1–3.0 full-time equivalents per Member State. **High Impact strategic projects (including AI):** - EU-level supervision of recognised high-impact strategic projects: recognition, monitoring, compliance verification and cross-border coordination. 0.3–0.5 full-time equivalents per single-country project per year; 0.5–1 full-time equivalent per multi-country project: o 1–3 full-time equivalents under low uptake (2–3 projects); o 2.5–8 full-time equivalents under medium uptake (5–8 projects); o 5–15 full-time equivalents under high uptake (10–15 projects). **General food law reform:**

							Member State national competent authorities - Ongoing supervision and enforcement of established sandboxes; ensuring sandbox activities remain within defined parameters and do not jeopardise public health. Not quantified – low to medium. **ATMP:** - CHMP verification of sponsor declarations submitted in place of full ERA dossiers, as part of the centralised clinical trial and marketing authorisation procedure. Not quantified - negligible (verification of simplified declarations is incremental to the existing CHMP centralised procedure; no new assessment infrastructure required). - . **VMP:** EMA/Commission - Application assessment, scientific advice, risk-benefit assessment, and two-year assessment report per established sandbox. Not quantified – negligible (2–3 assessments over 14 years). **Substances of Human Origin:** - Additional NCA workload per sandbox case relative to standard SoHO preparation authorisation, at EUR 301/person-day: medium-risk sandbox case 75–94 person-days total (EUR 22,575–28,294), a 57–114% cost increase over standard authorisation; high-risk sandbox case 98–149 person-days total (EUR 29,498–44,849), a 10–63% cost increase. - Alternatively, approximately EUR 156,000–219,000/year under low uptake (6 sandboxes); approximately EUR 1.04–1.46M/year under high uptake (40 sandboxes). - Learning-by-doing costs and medium-term efficiency gains from cross-Member State learning are assumed to cancel out. **Organ processing:** - National competent authority assessment of applications. Per-assessment cost approximately

							EUR 7,000–10,000 (central estimate ~EUR 8,500), comprising: internal assessment staff 15 working days at EUR 350–450 per day (EUR 5,250–6,750); external expert consultation 3–5 days at EUR 400–500 per day (EUR 1,200–2,500); administrative overhead EUR 500–750. - Transition phase (2029–2031): aggregate EU-27 approximately EUR 420,000–1,450,000 over three years (central estimate ~EUR 850,000, approximately EUR 280,000 per year). - Steady state (from approximately 2032): approximately EUR 60,000–85,000 per year EU-27. - Ongoing monitoring oversight for Track 2 authorisations: approximately 12–20 working days per active monitoring plan per year (3–5 days per quarterly reporting cycle); aggregate approximately EUR 63,000–216,000 per year during transition, declining in steady state. - Alternatively, annually: Transition phase (2029–2031): approximately EUR 140,000–483,000/year EU-27 (central estimate ~EUR 280,000/year). Steady state (from approximately 2032): approximately EUR 60,000–85,000/year EU-27. Ongoing Track 2 monitoring oversight: approximately EUR 63,000–216,000/year during transition, declining in steady state. **SPC extension:** EMA: - Eligibility verification per application, estimated at approximately 1 full-time equivalent working day per application. Given that between 15 and 28 biotech products are authorised annually (not all would qualify), the maximum annual workload is estimated at approximately 28–30 working days per year EU-wide. **Biosecurity:** Member State level: - Approximately EUR 14 million per year in 2027, rising to approximately EUR 21 million per year in 2036. - Estimated staffing requirement: approximately 3 full-time equivalents per Member State for policy

							coordination, reporting, and enforcement activities including inspections. EU level: - Approximately EUR 1.3 million per year in 2027, rising to EUR 1.9 million per year in the long term; - corresponding to approximately 11 full-time equivalents for the lead Directorate-General plus supporting coordination and technical functions.
	Indirect costs	n/a.	**SPC extension:** - Delayed access to biosimilar/competition during the additional protection year. Estimated combined social cost of approximately EUR 205 million per medicine (EUR 615M annually at 3 qualifying medicines per year); - Delayed patient access: ~EUR 135 million per medicine (~EUR 405 million annually at aggregate level); - Direct payer expenditure: ~EUR 70 million per medicine (~EUR 210 million annually)		**Biosecurity:** - Research loss from chilling effect (researchers abandoning or deferring projects due to concerns about order delays or rejections) - Approximately 10% of researchers may shift to in-house synthesis at substantially higher per-order costs. - Indirect productivity loss to providers from regulatory compliance intensity: EUR 8.6 million per year to EUR 24.8 million per year.		

II. Overview of costs (Totals)							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off[25]	Recurrent	One-off	Recurrent
Action (a)	Direct adjustment costs	n/a.	n/a.	- Not quantifiable; qualitatively low to medium	- **EUR 8.16–27.32 million/year** (SoHO EUR 0.72–4.79 million + organ processing EUR 0.14–0.33 million + biosecurity providers EUR 7.3–22.2 million); - AI recurrent maintenance not monetised, qualitatively assessed as medium.	- **EUR 8.75–8.9 million monetised** (Novel health products sandbox EUR 4.3 million + clinical trials sandbox EUR 4.3 million + VMP UPD EUR 0.15–0.3 million ; each spread over approximately 3 years); - Remainder qualitatively negligible to low to medium.	- **EUR 48.6–112.6** million **/year monetised** (Biodefence EUR 46–110 million + Biotech ecosystem Commission EUR 2.6 million); - AI technology refresh and curation uplift not monetised; qualitatively assessed as medium to high.
	Direct administrative costs	n/a.	n/a.	- **EUR 0.77–1.86** million monetised (organ processing transition applications 2029–2031); - Strategic project recognition applications not monetised as	- **EUR 16.51–16.55 million/year** monetised (Biosecurity customers EUR 16.4 million + organ processing steady-state EUR 0.11–0.15 million); - ATMP declaration, access to funding,	- Not monetised; qualitatively low to medium (strategic projects SPC front-loaded setup)	- Not monetised in EUR; qualitatively negligible to low (Biotech ecosystem 0.25 FTE/MS data provision; STEP reporting; repository maintenance; organ processing Commission list)

[25] One off costs were left not annualised, because they occur once, so by design they do not repeat throughout the years.

				aggregate; voluntary cost	SPC eligibility: negligible		
	Direct regulatory fees and charges	n/a.	n/a.	n/a.	n/a.	n/a.	n/a.
	Direct enforcement costs	n/a.	n/a.	n/a.	n/a.	n/a.	- **EUR 15.52–25.06** million/**year** (Biosecurity MS EUR 14–21 million + Biosecurity EU EUR 1.3–1.9 million + SoHO NCA EUR 0.16–1.46 million + organ processing NCA EUR 0.06–0.70 million , higher during transition 2029–2031, declining from 2032); - Strategic projects FTEs and AI EU supervision not monetised; qualitatively assessed as low to medium.
	Indirect costs	n/a.	- **EUR 615** million/**year** (SPC extension combined social cost at 3 qualifying medicines/year; comprising delayed patient access EUR 405 million /year + direct payer expenditure EUR 210 million /year)	n/a.	- n/a.	n/a.	- **EUR 105.6–194.8** million /**year** (Biosecurity chilling effect EUR 97–170 million /year + productivity loss EUR 8.6–24.8 million /year)
	Grand Total (monetised costs only)	**n/a.**	**EUR 615** million/**year**	**EUR 0.77 – 1.86** million	**EUR 24.7 – 43.87** million/**year**	**EUR 8.75 – 8.9** million	**EUR 169.7 – 332.5** million /**year**

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III. Contribution to the administrative burden reduction targets					
Administrative costs [EUR million]	**New recurrent costs (INs)** (nominal values per year)	**Removed recurrent costs (OUTs)** (nominal values per year)	**Net cost(INs – OUTs)** (nominal values per year)	**New one-off costs (INs)** (annualised total net present value over the relevant period)	**Removed one-off costs (OUTs)** (annualised total net present value over the relevant period)
All businesses	(Organ processing) Authorisation application per processing technique (steady state from ~2032): ~7–10 applications/year EU-27 at ~EUR 12,800 each; annual value: ~EUR 0.09–0.13 million/year. (Biosecurity) Per-order verification, documentation and procurement compliance: EUR 16.4 million/year (EUR 3.56 million gene orders +	(ATMP) Full ERA dossier and parallel national GMO submission obligations replaced by a simplified declaration per CTA. Saving: ~0.15–0.3 FTE-year per CTA application. GMO-specific workload of ~0.3–0.5 FTE-year per CTA is reduced by 50–70%. At ~8–15 CTAs/year subject to dual-track burden, and an indicative EU regulatory affairs cost approx. EUR 16,800–33,600 per CTA. Annual value: ~EUR 0.13–0.50 million/year (VMP) VNRA batching: 45–55% reduction in submission events for ~31,875 non-SPC VNRAs/year. Staff time saving: 14,930–29,859 hours/year saved sector-wide at ~EUR 65/hour. Annual value: ~EUR 0.97–1.94 million/year (central: ~EUR 1.46 million/year)	~ + **EUR 6.9–11.4M/year** (net increase, driven primarily by Action 17 biosecurity customer compliance at EUR 16.4 million/year)	(Organ processing) Authorisation applications for organ processing techniques during transition phase (2029–2031): total EUR 0.77–1.86 million (approx. 60–145 applications EU-27 at weighted average EUR 12,800 each); annualised NPV over 11-year assessment period (2028–2038): **approximately EUR 0.08–0.20 million.**	None

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	EUR 12.85 million oligo orders) (multiple) Ongoing reporting, knowledge-sharing and participation compliance obligations; recognised strategic project applications; SPC eligibility demonstrations; clinical trial sandbox reporting. Not quantified. **Approx. EUR 16.5 million/year**	(VMP GMO exemption) Elimination of requirement to compile Annex III GMO documentation under Directive 2001/18/EC for GMO-containing VMP marketing authorisation applications. Saving: approximately EUR 7,000 per MA dossier. At approximately 5–10 GMO-VMP MA applications per year: annual aggregate value approximately EUR 0.035–0.070 million/year. (Biosimilars) Reduced MAA dossier preparation burden where CES is eliminated: ~75 person-days saved (EUR 30K–45K) per eligible MAA. At ~12–18 MAAs/year qualifying during 2025–2030. Annual aggregate value: ~EUR 0.36–0.81 million/year (12–18 MAAs × EUR 30–45 thousand). (GMMs) Reduced standard GMO dossier requirements for low-risk pathway applications: source explicitly estimates ~1% reduction per application (589 vs 593 working days NCA burden). Near-zero applications currently (no authorised non-food GMMs under current framework); net saving negligible at present (Clinical trials) Reduced administrative FTE time per multinational clinical trial application through streamlined authorisation procedures: approximately EUR 2,714–4,496 per application (Standard Cost Model; 15–25% reduction in time spent with regulators).			

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		At approximately 1,050 multinational trials/year: approximately EUR 2.8–4.7 million/year. (Clinical trials) Elimination of duplicate parallel submissions for combined studies (medicinal products and medical devices/diagnostics). Coordinated assessment reduces excess submissions by approximately 30%; 381–748 excess submissions eliminated per year at EUR 2,239 processing cost per Member State. Annual value: approximately EUR 0.8–1.6 million/year. **Approx. EUR 5.1–9.6 million/year**			
- in which SMEs					
Public administrations	**Not monetised; qualitatively negligible to low:** Biotech ecosystem: data provision for strategic mapping on Commission request (~0.25 FTE/MS/year) Strategic projects and biosimilars: reporting on recognised project pipeline under STEP information flows	(Biotech ecosystem) Maintaining and updating strategic mapping outputs and reporting on recognised project pipeline under STEP information flows. Cost absorbed within EUR 2.6 million/year Commission coordination appropriation reported under adjustment costs; not separately quantified to avoid double-counting.	Negligible (qualitatively assessed)	(Strategic projects and high-impact strategic projects) Front-loaded setup of single points of contact: process design, workload reallocation and establishment of service standards. Not quantified, assessed qualitatively as low to medium.	None

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	Novel health products: maintaining the regulatory status repository Organ processing (Commission): maintaining publicly accessible list of authorised processing operations; facilitating exchange of clinical outcome data between competent authorities				
Citizens	None	None		None	None

3. Relevant sustainable development goals

IV. Overview of relevant Sustainable Development Goals		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG 3 'Good health and well-being: Ensure healthy lives and promote well-being for all at all ages'	Expected increase of patients' access to clinical trials in the EU and innovative products on the single market, including rare diseases.	
SDG 9 'Industry, innovation and infrastructure: Build resilient infrastructure, promote inclusive and sustainable industrialisation and foster innovation'	Increased access of biotechnology companies to capital through the different stages of their development; EU's capabilities in research, development and production are reinforced.	
SDG 12 'Responsible consumption and production: Ensure sustainable consumption and production patterns'	Biotechnology products placed on the market (such as microbial biocontrol and microbial fertilisers) will have the potential to replace products potentially harmful for the environment.	

ANNEX 4: ANALYTICAL METHODS

Overarching analytical framework

This section describes the overarching analytical framework applied across the **17 policy intervention assessments** that together constitute the evidence base for the analysis[26]. While each intervention-specific analysis was tailored to its thematic context, regulatory domain, and relevant data, all assessments followed a common methodological architecture.

1. Alignment with the EU Better Regulation framework

The **baseline** is constructed as a counterfactual scenario depicting how identified challenges would evolve absent the proposed intervention, rather than a static description of current conditions. The **analysis of impacts** is a standardised set of impact dimensions derived from the Better Regulation Toolbox's analytical categories, and the depth of analysis is calibrated to the significance of each intervention and the availability of evidence. The analytical phases follow the **following sequence**: policy mapping (translating the legislative text into structured analytical units), baseline development (establishing the counterfactual), assessment of impacts (evaluating costs, benefits, and broader effects against the baseline), and compilation of findings (including cumulative impacts).

2. The policy intervention as the unit of analysis

The policy intervention was defined as the primary unit of analysis, translating the articles of the proposed Regulation and of the proposed Directive into **17 policy interventions**, each encompassing one or more underlying policy measures that share common policy objectives, target stakeholders, and implementation mechanisms. The mapping operated at three hierarchical levels: broader policy areas corresponding to the structure of the proposed European Biotech Act, policy interventions representing the intended aims of the proposed initiatives, and policy measures detailing the specific legislative changes. For the purpose of the SWD, the impacts of interventions n°9, 10 and 11 are presented together in the main report.

The 17 policy interventions span **six thematic areas**: strategic projects and clusters (including biosimilars), time-to-market regulatory proposed changes, access to capital, intellectual property, AI and data, and biodefence and biosecurity. This grouping ensured coherence by combining related policy measures under unified assessment frameworks while maintaining sufficient granularity to capture intervention-specific dynamics. For each policy intervention, a dedicated baseline was established, a thorough assessment of the impacts of the proposed measures was conducted.

3. Impact framework development

The assessment of each intervention is anchored in an **intervention-specific impact framework** that sets out the logic chain linking the proposed policy measures to their expected effects, the indicators selected to track those effects, the expected direction of

[26] Rapid Assessment Scenarios study (forthcoming).

change, and the data sources available for baseline calibration and impact estimation. The impact framework serves as the analytical blueprint for the entire assessment, ensuring that the subsequent baseline and impact analysis are focused on the channels through which the intervention is expected to operate.

Seven standardised impact dimensions were applied across all 17 assessments, providing a common analytical structure:

- Conduct of business.
- Administrative costs on businesses, including SMEs.
- Competitiveness, trade and investment flows.
- Functioning of the internal market and competition.
- Innovation and research.
- Administrative costs to public authorities.
- Public health and safety.

All dimensions were screened for relevance for each intervention, with the analysis emphasising the most pertinent dimensions for each case while maintaining a minimum level of coverage across all seven to ensure comparability for the cumulative assessment. This standardised structure enables the cumulative impact analysis to aggregate findings by impact dimension across interventions and to identify synergies, trade-offs, and emergent systemic effects.

For each impact dimension, the framework specifies **indicators** that are, to the extent possible, quantitative and measurable, together with the data sources used for baseline calibration. Where **quantitative indicators** could not be established due to data constraints (a frequent occurrence, particularly for novel instruments such as regulatory sandboxes, the biothreat radar, and the foresight panel), **qualitative indicators** based on directional assessments were used. This approach ensured that the absence of quantitative data did not result in the exclusion of important impact channels from the analysis.

4. Baseline construction

Consistent with the Better Regulation Toolbox (Tool #60), the baseline for each intervention describes the **counterfactual scenario**: how identified problems and current conditions would evolve in the absence of the proposed policy intervention (see Annex 7). The baseline is a dynamic projection that takes account of existing trends, recent Commission proposals, autonomous market developments, and foreseeable changes in the regulatory or technological environment. This dynamic character is essential because it establishes the reference point against which incremental impacts of the proposed intervention are measured.

Across the 17 assessments, a common baseline architecture was applied. **Discussion of the time horizons** adopted for baseline and assessment of impacts is provided below**.**

Across all interventions, the baseline is also based on explicit **assumptions,** which are presented into details in the supporting study (Rapid Assessment Scenario Study).

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5. Evidence base and data collection methods

The assessments draw on a multi-layered evidence base assembled through three complementary data collection methods: desk research, targeted stakeholder consultations, and analysis of the public consultation and call for evidence responses.

6. Proportionality and analytical transparency

While the overarching framework is common, its application was adapted to the thematic and context of each intervention. This adaptation reflects the **proportionality principle**: the depth and method of analysis were calibrated to the significance of the intervention, the novelty of the proposed measures, and the availability and quality of evidence.

The adaptations occurred for example, on the **degree of measure-level disaggregation.** These varies across interventions. Interventions encompassing multiple distinct policy measures with separable effects, such as the VMPs intervention (four distinct measures: GMO exemption, SPC extension for zoonotic products, regulatory sandbox, and VNRA burden reduction) or the general food law intervention (EFSA procedural revision and food chain sandboxes), conduct assessments at both the measure level and the intervention level, enabling the identification of measure-specific effects. Interventions consisting of a single unified measure or a tightly integrated package (such as the SPC extension or the biosecurity framework) are assessed primarily at the intervention level.

The **use of scenario analysis and comparator evidence** was also deployed selectively. Where the intervention creates new instruments without direct EU precedent (such as regulatory sandboxes, strategic project recognition, or the biothreat radar), the analysis draw on comparator evidence from analogous frameworks in other jurisdictions (e.g., the UK FCA sandbox, the US Nucleic Acid Observatory, the Net-Zero Industry Act) or from other policy domains (e.g., InvestEU) to calibrate assumptions and bracket plausible ranges. Where the intervention amends existing procedures with observable cost parameters, the analysis relies more directly on existing regulatory data and stakeholder-validated estimates.

Finally, a principle of **analytical transparency** was applied throughout. Each analysis explicitly identifies data limitations, evidentiary gaps, and areas of uncertainty (see the Rapid Assessment Scenario study for more information). Where assumptions cannot be empirically validated, they are flagged as such. Where quantitative estimates are derived from proxy data or comparator evidence, the degree of approximation is stated.

7. Time horizon for baseline and assessment of impacts

A **default temporal framework** structured around two projection periods was adopted: a **near-term horizon of 2025-2030** and a **medium-term horizon of 2030-2038**, with 2025 serving as the base year (T0). The selection of 2038 as the default medium-term endpoint reflects two reinforcing considerations: alignment with the EU Multiannual Financial Framework (MFF) programming cycle, which provides the institutional and budgetary context within which the proposed European Biotech Act's instruments will operate, and the expectation that a period of **approximately ten years from the expected regulatory transposition** at EU and national levels date (likely by 2028) represents a reasonable timeframe for the proposed policy measures to produce observable impacts across the

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majority of intervention areas (also accounting for institutional establishment, stakeholder adaptation, and the initial materialisation of structural effects).

Within this common framework, a principle of **intervention-specific temporal calibration was applied**, whereby the precise time horizons were adapted to the causal logic, sectoral dynamics, and primary evidence base of each intervention. This approach reflects a deliberate methodological choice to prioritise analytical coherence and evidential integrity within each assessment over rigid temporal uniformity across the portfolio. Three categories of adaptation were applied.

- First, **two assessments** extended the baseline projection horizon **to 2040**: the **veterinary medicinal products framework and the organ processing directive**. In both cases, the extension was driven by the sector-specific product development and adoption cycles that define the relevant causal pathways. The veterinary sector is characterised by lengthy product development pipelines and a small, commercially constrained market in which effects of the proposed regulatory changes on innovation throughput require longer observation windows to materialise in measurable form. The organ processing assessment relies on compound annual growth rate (CAGR) projections of transplant volumes in a sector where substantial shifts in supply-demand dynamics are unlikely. However, when it came to the cumulative impacts, a more conservative time horizon (until 2035) was adopted since the proposed measures are highly contentious on the pace of technological development in organ processing and the ability of the legal/regulatory environment to cope with such technological shifts.
- Second, the biosecurity framework assessment employed a **distinct set of temporal milestones**: short term (~2027), medium term (~2031), and long term (~2036).
- Third, five assessments: the biotech ecosystem, general food law, SoHO sandbox, AI and data guidance, and biodefence, employ **qualitative temporal descriptors** (short-term, medium-term, longer-term) without specifying year ranges. These interventions share a common feature: they establish enabling institutional frameworks, coordination structures, or guidance mechanisms whose effects are inherently structural and emergent rather than discrete and time-phased.

This differentiated approach to temporal framing remains consistent with the **proportionality principle** that governs the overarching methodology.

8. Impact estimation and modelling approaches

The 17 intervention-specific assessments employed a differentiated set of approaches to impact estimation, reflecting the heterogeneous nature of the interventions, the maturity and availability of evidence, and the directness of the causal chains linking proposed measures to observable outcomes.

Spectrum of quantification approaches

No single modelling framework was imposed across all 17 assessments. The overarching analytical framework prescribed a common architecture of impact dimensions, baseline construction, and qualitative summary ratings, but left the choice of estimation technique to the intervention-specific context. Five broad categories of estimation approach can be

identified, arranged along a spectrum from formal quantitative modelling to qualitative directional assessment.

Category A: Formal quantitative modelling

The analysis of three interventions employed dedicated quantitative modelling frameworks. For the **biosecurity assessment,** its core cost-benefit analysis draws directly on an external quantitative model developed by RAND Europe, itself adapted from the Centre for Long-Term Resilience (CLTR) framework for the United Kingdom. The RAND model estimates costs (provider screening costs, customer compliance costs, research productivity losses, public enforcement costs) and benefits (attack-prevention and accident-prevention value, derived from probabilistic risk modelling) over a ten-year horizon, producing monetised net benefit estimates at defined temporal milestones (short-term ~2027, medium-term ~2031, long-term ~2036).

The **organ processing assessment** deployed a modelling framework constructed in the context of the supporting study. It uses a triangulated estimation approach combining three analytical pillars: CAGR-proxy logic (deriving an incremental policy acceleration effect of +0.95 percentage points per annum from observed pre- and post-Directive transplant growth rates), programme-level adoption modelling (projecting the share of EU transplant programmes adopting processing technologies under three scenarios at 25%, 50%, and 100% of the gap between baseline plateau and clinical ceiling), and organ-level intensity logic (estimating the shift from selective to systematic processing within adopting programmes). Baseline projections to 2040 used compound annual growth rates anchored to EDQM trend data, and impact estimation applied scaling factors to the identified adoption headroom. This three-pillar approach was necessitated by the absence of a directly comparable historical precedent for the proposed regulatory intervention.

The **VMPs assessment** employed bottom-up process-level cost estimation, calculating per-unit administrative savings (FTE-equivalents, person-days, cost per regulatory action) for each of its four policy measures and aggregating these over a 15-year horizon (2025-2040) with a 3% social discount rate to produce cumulative present-value estimates. It quantified product-day delays eliminated, VNRA redistribution effects across the sector, and staff-time savings using stakeholder-validated parameters.

Category B: Market-level quantification

The impacts of two interventions were quantified by scaling product-level or firm-level data to the sector, without deploying formal multi-year projection models with discount rates. The **biosimilars assessment** estimated per-product development cost savings from CES elimination and scaled these to sector-level annual aggregate savings using observed MAA submission volumes and transition-rate assumptions. It drew on published cumulative healthcare savings data, published IQVIA market data on therapeutic-area price reductions, and EMA pipeline activity trends to construct a quantified baseline against which incremental effects were assessed. The **SPC extension assessment** used revenue-profile analysis drawing on the European Commission modelling based on a cohort of 198 innovative medicines for which data on the value and volume of sales were drawn from IQVIA MIDAS, last layer of protection was determined through IQVIA Patent Intelligence and product eligibility though EMA data, manufacturing footprint analysis using EudraGMDP data (624 manufacturing and import authorisations, 2012–2025), and clinical trial location data from EMA databases to construct a quantified baseline of the

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IP-protection landscape. Impact estimation combined these empirical baselines with published evidence on loss-of-exclusivity revenue dynamics and patenting trends.

Category C: Scenario-based order-of-magnitude estimation

The analysis of three interventions employed scenario-based approaches to generate illustrative order-of-magnitude ranges, without claiming the precision of formal modelling. The **strategic projects and high-impact projects assessments** used a common estimation architecture: three uptake scenarios (low, medium, high) defined in terms of project numbers by 2038, combined with monetisation calibrations for avoided delay costs (using an illustrative project value range and a 34% cost-overrun assumption for delays exceeding 12 months) and investment mobilisation ranges (using observed leverage multipliers from EU financial instruments, e.g. ~1.3x for loans, ~4.8x for guarantees). These produced cumulative order-of-magnitude ranges (e.g. millions in avoided delay costs for strategic projects under different uptake scenarios). The **access to funding assessment** similarly used published financial benchmarks (VC round sizes, EIB mobilisation data, institutional capital estimates) to calibrate plausible impact ranges, while noting that attribution of incremental effects to the specific policy measures remains sensitive to the broader financing environment.

Category D: Benchmark-anchored partial quantification

The analysis of two interventions embedded specific quantified parameters within predominantly qualitative frameworks. The **clinical trials assessment** drew on published cost-modelling evidence to anchor key parameters: administrative expenses accounting for 11-29% of total clinical trial costs, an indicative net present value return of approximately five times the investment for phase II decentralised trials and approximately thirteen times for phase III, and time savings of 1-3 months from decentralised elements. However, it did not construct a cumulative cost-benefit model, instead using these benchmarks as illustrative reference points within a qualitative assessment of each policy measure. The **novel health products assessment** adopted a similar approach, using comparator evidence from analogous frameworks (notably the UK FCA regulatory sandbox) to calibrate expectations, while acknowledging the absence of directly comparable EU-level precedent for the proposed instruments.

Category E: Qualitative directional assessment

The analysis of sever interventions relied predominantly on qualitative assessment. These cover the biotech ecosystem, general food law, ATMPs, SoHO sandbox, GMMs, data and AI, and biodefence. Their interventions either create entirely new institutional structures without quantifiable precedent (the biothreat radar, the SoHO sandbox, the foresight panel), establish enabling or coordination frameworks whose value is inherently structural and emergent (the biotech ecosystem support network, the AI guidance mandate), or operate in regulatory domains where the primary effects are qualitative changes in regulatory coherence, clarity, or flexibility rather than directly monetisable cost or revenue changes (ATMP classification proposed changes, GMM-specific risk assessment criteria, EFSA procedural proposed changes). The analysis relied on causal-chain reasoning grounded in intervention logic, comparator evidence from analogous frameworks in other jurisdictions or policy domains, stakeholder-validated assumptions, and the standardised qualitative rating scale (strongly negative to strongly positive) applied across all seven impact dimensions.

Cross-cutting methodological features

Several methodological features cut across the categories described above and merit specific note.

First, all 17 analyses applied the **same qualitative summary rating** (from ++ to - -) across the seven impact dimensions. This ensures that the cumulative impact analysis can draw on a consistent set of structured qualitative judgements even where quantified estimates are unavailable.

Second, where scenario analysis was employed (Categories A-C), the **scenarios were explicitly labelled** as illustrative and designed to bracket plausible ranges under different assumptions about uptake, implementation pace, and market response, rather than as probabilistic forecasts.

Third, the **use of comparator evidence** from analogous frameworks, whether from other EU instruments or from other jurisdictions, was deployed selectively across the spectrum: as calibration input for quantitative models in Categories A-B, as anchor points for scenario ranges in Category C, and as the primary basis for directional assessment in Categories D-E.

Fourth, **assumptions** are explicitly stated (see the supporting study), with each impact dimension within each analysis opening with a clearly delineated assumptions box.

Approach to cumulative impact

1. *Outline of the overall approach*

The analysis was organised in terms of the impact areas that are reflected in the 17 analyses:

- Conduct of business
- Administrative costs on businesses, including SMEs
- Competitiveness, trade and investment flows
- Functioning of the internal market and competition
- Innovation and research
- Administrative costs to public authorities
- Public health and safety

In each impact area, the following question was asked: **through what distinct mechanism does the proposed European Biotech Act change this dimension?** Each mechanism is driven by a specific combination of interventions, some of which are direct movers, some as conditions or amplifiers.

To prepare the analysis the following steps were followed:

Step 1. Identification of the mechanisms operative in this impact area:

Each impact area has 2-3 distinct mechanisms. These are distinct processes, driven by different combinations of interventions, producing different types of competitive effect.

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Step 2. For each mechanism, identification of the intervention combination that drives it:

Each mechanism identified in Step 1 is driven by a combination of multiple interventions. This is where multiplier effects become visible from the interventions that do not lead to impacts themselves but enable other interventions.

Step 3. Assessment of the cumulative effects mechanism by mechanism:

This step involves combining the analyses from the individual intervention and arriving at a comprehensive narrative. For each mechanism relevant information corresponding to impact area was identified. For example, when working on "Reduction of overlapping regulatory obligations across frameworks", the analyses under Conduct of business for the proposed ATMP revision, Vet medicinal product proposed amendments, proposed clinical trial coordinated assessment for combined studies, and the proposed EU Health Biotechnology Support Network were used.

In the cumulative assessment, impacts are analysed indicator by indicator. This is necessary because the interventions generate heterogeneous types of impacts and indicators, which cannot be combined using a single quantitative methodology. Several mechanisms may affect the same indicator (e.g. administrative costs to authorities, clinical trial timelines, investment levels). In such cases, impacts are combined only where they arise from distinct regulatory drivers.

Double counting is avoided by distinguishing between:

- Independent policy drivers, where different interventions create separate cost or benefit effects affecting the same indicator. In such cases, the impacts are treated as additive (for example, administrative workload generated by AI-related regulatory guidance and workload generated by SPC-related measures affecting the same authority).
- Shared administrative or regulatory processes, where several measures rely on the same underlying procedure or institutional activity. In these cases, the impact is counted once, even if multiple policy measures refer to that process (for example, different categories of strategic project designation relying on the same workflow).

This distinction ensures that cumulative impacts reflect the true incremental effects of policy measures, while avoiding artificial inflation of costs or benefits where measures operate through the same administrative mechanism.

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2. Mapping of the mechanisms of change and interventions

Causal chain for each of the impact area and mechanisms is presented into details in the supporting study (Rapid Assessment Scenario Study), together with a precise narrative, assumptions, and implications.

Conduct of Business

Change mechanism 1: Reduction of overlapping regulatory obligations across frameworks

Biotech companies developing products that span multiple regulatory regimes (ATMPs with GMO components, organ-derived products, combination products involving devices and diagnostics, veterinary medicinal products with GMO elements) currently face parallel and often duplicative assessments under separate legal frameworks. The proposed Act aim at addressing this through five distinct regulatory channels. The changes in the ATMP framework eliminates procedural duplication in the relationship between the ATMP and general medicinal product frameworks. The proposed clinical trial framework introduces a coordinated assessment pathway for combined studies that span the CTR and IVD/MDR frameworks simultaneously. The proposed intervention on VMPs creates a single 'one-stop-shop' pathway for GMO veterinary medicinal products, eliminating the need for a separate GMO environmental risk assessment alongside the marketing authorisation procedure. The intervention on organ transplantation expands the scope of the transplantation directive to cover organ processing and establishes a clear authorisation regime for processing techniques, resolving a currently unaddressed overlap with tissue and cellular frameworks. The regulatory status repository addresses a foundational source of framework overlap: uncertainty about which legal regime governs a given product, which currently forces companies to engage with multiple frameworks simultaneously as a precautionary measure.

Each proposed intervention reduces a specific source of overlap; together they address the full landscape of cross-framework friction. The EU Health Biotechnology Support Network and AI guidance framework amplify the proposed measures by reducing the navigation costs that persist even after formal regulatory overlap has been removed.

Emergent effect: Firms developing complex biotech products face a qualitatively more coherent regulatory environment, not just an incrementally less burdensome one.

Risk: Proposed interventions are enacted under different frameworks at different speeds; residual fragmentation may persist where one intervention advances and another stalls.

Change mechanism 2: Predictability and certainty in permitting and project development

Regulatory uncertainty operates as a material business risk when firms cannot form reliable expectations about the timeline, applicable pathway, or outcome of their regulatory interactions. The proposal addresses this across several distinct dimensions. Strategic project recognition introduces mandatory timelines, single points of contact, tacit approval provisions, and highest national significance status, converting a previously discretionary and variable permitting process into a structured, time-bounded one. The regulatory status repository and Foresight Panel reduce a further category of uncertainty: firms developing genuinely novel products currently face extended pre-application periods of regulatory

status ambiguity, during which they cannot reliably plan development timelines. By establishing clear classification procedures and expert horizon-scanning, this mechanism resolves pathway uncertainty before the formal application process begins. In the area of organ transplantation, the proposed organ processing authorisation regime provides legal certainty and a clear regulatory pathway for transplantation centres and national authorities, replacing ad hoc national practices with a structured authorisation procedure.

Recognition must be granted and classification must be completed before the predictability benefits materialise; the quality of Member State implementation determines the actual gain.

Emergent effect: Firms can make capital allocation decisions based on a known permitting and pathway horizon rather than an open-ended one, materially changing project feasibility assessments.

Risk: Dependent on Member State implementation quality; tacit approval provisions may create legal uncertainty in some jurisdictions.

Change mechanism 3: Reduced friction for SMEs, start-ups and scale-ups in accessing regulatory and market pathways

SMEs and start-ups face disproportionate burdens from regulatory complexity because they lack the in-house capacity that large firms use to navigate it. The proposal creates dedicated support through three direct mechanisms: strategic project recognition includes mandatory dedicated communication channels and personalised administrative support for smaller firms; high-impact project recognition maintains and extends these provisions with particular attention to scale-ups and biotechnology development accelerators; and the EU Health Biotechnology Support Network provides regulatory navigation, IP support, investor connection, and AI integration assistance targeted specifically at developers who lack these capabilities in-house.

Four further interventions amplify these direct measures by reducing the underlying complexity that smaller firms must navigate: the regulatory status repository reduces the cost of pathway determination; the changes in the ATMP framework simplify a product category where SMEs are disproportionately represented as innovators; the proposed clinical trial framework reduces the variable costs of multinational trial applications; and AI tools under the AI and data guidance framework provide technology-enabled efficiencies that partially substitute for human regulatory capacity.

Emergent effect: Smaller firms can access the same regulatory pathways and support infrastructure that were previously accessible mainly to large, well-resourced companies.

Risk: Effectiveness depends on the Network's actual operational quality and coverage, which is difficult to guarantee at design stage.

Administrative Costs on Businesses, including SMEs

Change mechanism 1: Direct reduction of procedural steps and timelines in clinical development

The changes in the ATMP and clinical trial frameworks each reduce direct administrative costs in clinical development through distinct but complementary procedural interventions.

The revised ATMP framework eliminates the additional 50-day ATMP assessment period that currently applies to advanced therapy products within the clinical trial procedure, removing a time and cost burden specific to this product category. The proposed clinical trial framework delivers broader reductions across all multinational trials: authorisation timelines fall from 106 to 75 days (47 days without a request for information), substantial modifications from 96 to 47 days; harmonised templates for Part II applications reduce drafting costs; parallel submission of distinct modifications eliminates sequential procedural bottlenecks; and the investigational medicinal product core dossier enables reuse of validated documentation across multiple trials.

These direct procedural reductions are amplified by three enabling conditions. The EU Health Biotechnology Support Network reduces the cost of inadequate dossier preparation by providing early navigation support and connecting developers to relevant expertise. The regulatory status repository reduces pre-application uncertainty costs by ensuring developers enter the formal procedure with a confirmed regulatory classification. AI tools under the AI and data guidance framework enable technology-assisted dossier preparation and submission management, reducing the variable cost per application. Each procedural intervention reduces a distinct category of administrative cost independently.

Emergent effect: The cumulative reduction across a full clinical development programme is substantially larger than any single timeline saving, as the savings compound across multiple applications, modifications, and Member States.

Risk: Realisation depends on consistent implementation across all Member States; variable quality of reporting Member State performance could erode the gains.

Change mechanism 2: Streamlined/improved risk assessment processes for GMMs, food, feed and food chain inputs and promotion of innovation in the food chain

EFSA's general pre-submission advice to applicants upon request is expanded to cover study design and testing strategies, replacing also the existing renewal pre-submission advice, reducing the cost of inadequate study design at the application stage. The procedural delay for non-compliance at pre-submission phase (study notification requirement) is shortened from six months to three months. The governance of EFSA's Scientific Panels and Scientific Committee is adapted (EFSA staff chairing with no voting rights) to strengthen the coherence of risk assessment while EFSA's mandate on nutrition matters is expanded to cover all nutrition matters. A harmonised framework for the set-up of regulatory sandboxes is also introduced to test products and technologies as well as data and alternative regulatory requirements for food (except novel foods), feed, all GMO uses, and food contact materials (except recycled plastics).

For companies developing biotech products pertaining to the food chain, the cumulative effect of these targeted amendments is expected to reduce both direct assessment costs and the indirect costs of prolonged authorisation procedures, as well as the costs of testing innovative technologies and products. Regulatory sandboxes allow risk assessors and risk managers to harvest useful evidence from testing data and alternative regulatory requirements, contributing to their faster adaptation. In the area of GMMs in products for deliberate release into the environment, the authorisation procedure is adapted to better suit micro-organisms, to reduce some disproportionate burden, and to accelerate and streamline the procedure for some low-risk products, without lowering the level of safety.

Emergent effect: The combination of expanded pre-submission guidance, shorter procedural delays, and governance proposed changes to Scientific Panels could reduce the total cost of a food/feed biotech application (especially for SMEs) more than either intervention alone, while ensuring the coherence of risk assessment.

Risk: EFSA capacity to absorb expanded pre-submission advice tasks is a constraint and should not be detrimental to its core business (risk assessment tasks).

Competitiveness, Trade and Investment Flows

Change mechanism 1: Shifting late-stage investment and scale-up decisions towards the EU

The EU currently loses late-stage investment to the US and other regions primarily because the risk-adjusted return on EU-domiciled scale-up is inferior: regulatory timelines are longer, permitting is unpredictable, capital is scarcer, and the return horizon is shorter. The proposal addresses all four dimensions simultaneously through four direct mechanisms. Strategic project recognition directly changes the investment calculus by de-risking the permitting pathway that investors price into their return expectations: mandatory timelines, single points of contact, and priority status convert a variable and opaque process into a bounded and transparent one. High-impact project recognition extends and enhances these effects, adding Commission-level recognition and Union-level financial support mechanisms. The changes to the clinical trial framework shorten the development timeline, directly improving time-to-market projections. The investment pilot and late-stage capital booster address the capital availability dimension, providing financial instruments specifically designed for the scale-up phase where EU funding gaps are most acute.

The proposed SPC extension amplifies the returns generated by all four direct mechanisms by extending the period of protected commercialisation, making the full investment package more financially attractive. No single instrument shifts the investment calculus; the combination does. Emergent effect: A fundamentally different risk-adjusted return profile for EU-domiciled biotech investment, sufficient to change location decisions at the margin for a non-trivial number of companies.

Change mechanism 2: Strengthening the EU's global competitive position in biosimilars

The EU has strong existing expertise in biosimilars but has not converted that expertise into dominant manufacturing capacity. The biosimilars competitiveness framework is the direct driver of this mechanism, operating across three dimensions: EMA guidance on tailored regulatory approaches potentially reduces clinical data requirements; a dedicated strategic project track for biosimilars manufacturing provides the full administrative and financial support package available to strategic projects, focused specifically on the biosimilars category; and international partnership provisions encouraging partnership among economic operators. This addresses both the regulatory cost competitiveness of EU biosimilars development and the strategic visibility of the EU as a biosimilars manufacturing hub.

Change mechanism 3: Improving EU attractiveness for commercial clinical research

The EU's share of global commercial clinical trials has fallen from 22% to 12% in a decade. This is primarily a competitiveness problem: sponsors locate trials where authorisation is

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fastest, most predictable, and most administratively manageable. The changes to the clinical trial framework are the direct driver, addressing the principal factors sponsors use to make trial location decisions: multinational authorisation timelines, administrative harmonisation, digital infrastructure for trial management, and operational flexibility through parallel modifications and electronic consent.

Four interventions amplify the competitiveness effect of the proposed clinical trial framework by improving associated conditions. Changes to the ATMP framework make EU clinical development for advanced therapies more operationally attractive, addressing a category where sponsors currently face additional procedural burden relative to other jurisdictions. Financing instruments improve the financial attractiveness of EU-domiciled trial investment by providing capital instruments oriented toward the biotech development stage at which sponsors make location decisions. SPC extension increases the commercial value of products developed through EU clinical programmes, strengthening the financial case for EU-based development. AI guidance reduces the operational cost of trial management, an increasingly important factor in sponsor location decisions. Emergent effect: The EU becomes competitive on the factors sponsors actually use to make trial location decisions, reversing a decade-long structural decline.

Functioning of the Internal Market and Competition

Change mechanism 1: Reducing regulatory fragmentation across Member States

The internal market for biotech products is currently impaired by divergent national implementation across multiple regulatory domains. The proposal introduces harmonisation through four direct regulatory interventions, each targeting a distinct layer of fragmentation. The proposed clinical trial framework introduces mandatory harmonised templates, strengthened reporting Member State roles, and mutual trust and reliance principles, directly reducing the degree to which clinical trial authorisation operates as 27 separate systems under a nominal common framework. The changes to the veterinary medicinal products framework create a single 'one-stop-shop' regulatory pathway for GMO veterinary medicinal products, eliminating the divergent dual-track national procedures that currently apply. The changes to the General Food Law harmonise EFSA procedures and governance, reducing divergent national approaches to food and feed biotech risk assessment. The biosecurity framework establishes common screening, verification, and reporting rules for biotechnology products of concern, replacing the patchwork of divergent or absent national rules that currently creates an uneven regulatory environment across Member States.

Four further interventions amplify the fragmentation-reduction effect. The regulatory status repository provides a shared reference point that reduces divergent national interpretations of applicable frameworks. SoHO regulatory status coordination extends coherence to the substances of human origin domain. The changes to the organ transplantation EU rules reduce fragmentation in organ processing authorisation practices across Member States. The biodefence framework adds a cross-Member State intelligence-sharing dimension that reinforces the common biosecurity rules.

Emergent effect: A meaningfully more integrated regulatory space across multiple biotech product categories, reducing the effective cost of operating simultaneously across multiple Member States.

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Change mechanism 2: Levelling the competitive playing field through common biosecurity rules

Currently, divergent or absent national rules on screening biotechnology products of concern create an uneven competitive environment: companies in jurisdictions with stricter national rules face higher compliance costs than those in jurisdictions with weaker rules, without any corresponding public safety justification. The proposed Act harmonises these rules at Union level, establishing common screening, verification, and reporting obligations applicable to all economic operators across all Member States.

The EU Biothreat Radar amplifies the level-playing-field effect by providing the ongoing intelligence and monitoring infrastructure that enables consistent updating of the products-of-concern list across Member States, ensuring that the common rules remain current and are not systematically circumvented through product redesign.

Emergent effect: A genuinely common competitive environment for the handling of dual-use biotech products, replacing a patchwork of national regimes that currently distorts competition and compliance costs.

Change mechanism 3: Enabling/supporting new market entrants through regulatory sandboxes and clarified pathways

Novel biotech products that do not fit existing regulatory categories face a structural market access barrier: the absence of a clear pathway either prevents market entry or forces products into ill-fitting categories that impose disproportionate requirements. The proposal creates structured routes to market through four direct mechanisms. The novel health biotechnology framework establishes a Commission-led sandbox for health biotech products not falling under other existing sandbox regimes and provides the regulatory status repository and Foresight Panel that reduce classification uncertainty across all categories. The revision of the General Food Law introduces a harmonised sandbox framework covering food (except novel foods), feed, all GMO uses, and food contact materials (except recycled plastics). The proposed veterinary medicinal products framework establishes a sandbox for innovative technologies, methods, or products related to animal health. The proposed SoHO framework introduces a regulatory sandbox framework for substances of human origin.

Three interventions amplify market entry enablement without operating dedicated sandbox frameworks of their own. The EU Health Biotechnology Support Network helps developers identify, access, and navigate sandbox procedures and clarified pathways. The changes in the ATMP framework reduce the cost of accessing the advanced therapy pathway, lowering the threshold for products approaching but not yet qualifying for ATMP classification. The GMM framework provides an accelerated low-risk pathway that functions analogously to a sandbox for a specific product category. The cross-framework sandbox coordination mechanism ensures that the four sandbox regimes do not create regulatory arbitrage opportunities between themselves.

Emergent effect: A structured route to market for product categories that currently have no viable pathway, increasing competitive diversity in the biotech market.

Risk: Sandboxes create temporary regulatory accommodations that may advantage sandbox participants over non-participants, raising competition concerns within the transition period.

Innovation and Research

Change mechanism 1: Accelerating the translation of research into clinical development

The EU's core innovation problem is not insufficient scientific output but insufficient translation of that output into clinical and commercial development. The proposal addresses the translation gap through three simultaneous direct levers. The regulatory status repository and Foresight Panel reduce the regulatory pathway uncertainty that currently delays translation decisions: developers currently face extended periods of ambiguity about which framework governs their product and what evidence requirements apply, before they can plan a development programme. By resolving classification and establishing forward-looking pathway guidance, this mechanism removes a structural pre-application barrier that currently delays translation even before costs are formally incurred. The changes in the ATMP framework directly reduce the regulatory distance between research-stage advanced therapy products and clinical entry, eliminating duplicative procedural steps for a product category where the translation gap is most acute. The changes in the clinical trial framework reduces the cost and time of the clinical entry point itself, lowering the threshold at which a translation decision becomes financially viable for developers.

Three amplifying interventions improve the conditions under which the direct mechanisms operate. High-impact project support provides resources, priority access, and administrative support specifically for projects in the translation phase, accelerating progress without shortening the formal regulatory pathway. Financing instruments reduce the capital constraints that prevent translation decisions from being taken even when the regulatory pathway is clear. AI tools accelerate evidence generation, reducing the time between the translation decision and the first regulatory submission.

Emergent effect: The translation gap narrows structurally, not just for products that happen to fit existing pathways but also for genuinely novel products that currently have no viable translation route.

Risk: The Foresight Panel's effectiveness depends on the quality and independence of its expert composition; a poorly functioning Panel could increase rather than reduce pathway uncertainty.

Change mechanism 2: Building the infrastructure for AI-enabled biotechnology innovation

AI has transformative potential for biotech R&D across functions such as target identification, molecule design, clinical trial optimisation and manufacturing process development, but its application is currently constrained by fragmented data, limited testing environments, and unclear governance. The proposed Act establishes three direct infrastructure components through the AI and data guidance framework: EMA guidance on AI deployment across the medicinal product lifecycle, which resolves the regulatory acceptance uncertainty that currently limits use of AI-generated evidence in submissions; biotechnology testing environments, which provide the controlled infrastructure needed to develop and validate AI tools for biotech applications; and a data quality accelerator, which addresses the data fragmentation and quality constraints that currently limit AI model development and training.

Three interventions amplify this infrastructure by creating demand-side conditions for its use. High-impact project recognition includes AI integration as a qualifying criterion, creating institutional incentives for AI adoption among project promoters. The Foresight Panel explicitly addresses AI-biotech convergence in its horizon-scanning mandate, ensuring that emerging AI-biotech applications are mapped to regulatory pathways before they reach market-ready stage. The clinical trial framework introduces AI-specific provisions including AI use in trial design and electronic consent, creating a regulated application domain within which AI tools can be deployed and validated against real regulatory requirements.

Emergent effect: A functioning infrastructure for AI-enabled biotech research that does not currently exist in a coherent form, enabling a category of research acceleration that is otherwise blocked by infrastructure and governance gaps.

Administrative Costs to Public Authorities

Change mechanism 1: Increased administrative burden from new coordination and governance obligations

The proposal creates substantial new institutional infrastructure across four direct sources of burden on public authorities. Strategic project recognition frameworks require each Member State to designate competent authorities, establish single points of contact, process recognition applications, manage priority status grants, coordinate with the European Health Biotechnology Steering Group, and provide ongoing administrative support to recognised projects (including dedicated channels for SMEs and start-ups). High-impact project recognition extends these obligations and adds Commission-level recognition processes, coordination with EU-level financial instruments, and additional reporting requirements. The proposed clinical trial governance and enforcement framework expands the mandate of the CTAG, requires Member States to designate national contact points, strengthens ethics committee coordination obligations, introduces new inspection and Union control provisions, and creates the operational requirements for the expanded EU Portal. The biosecurity enforcement framework requires Member States to designate national inspection authorities for products of concern, implement verification of legitimate need procedures, establish benchtop equipment screening obligations, create suspicious transaction reporting systems, and participate in Commission-coordinated enforcement and audit activities.

Three further interventions amplify the aggregate administrative load without independently generating major new institutional structures. The veterinary framework adds coordination obligations for the single GMO/VMP pathway and sandbox administration. AI guidance creates new EMA obligations for guidance production and ongoing revision as technology evolves. The biodefence framework adds monitoring and intelligence-sharing obligations that build on but exceed the structures established by the biosecurity enforcement framework.

Emergent effect: A significantly expanded public sector role in biotech governance, requiring new capacities in regulatory coordination, scientific expertise, investment facilitation, and biosecurity enforcement simultaneously.

Risk: Member States vary substantially in their existing administrative capacity; the proposed Act's obligations may be feasible for large Member States and seriously burdensome for smaller ones, creating implementation asymmetry.

Change mechanism 2: Enhanced coordination capacity and reduced duplication through common platforms and tools

Against the burden generated by Mechanism 1, the proposed Act also creates tools that reduce the unit cost of coordination between authorities. Three direct infrastructure elements provide the core shared platforms. The EU Health Biotechnology Support Network and cluster framework creates structured coordination channels between national authorities, the Commission, and ecosystem actors, reducing the transaction costs of multi-authority interactions and providing a shared operational layer for implementation. The regulatory status repository and Foresight Panel serve as shared reference points that reduce the need for each authority to develop independent interpretive positions on novel product classifications, reducing duplication of analytical effort across Member States. The EU Portal development plan and expanded CTAG mandate provide the digital infrastructure and governance forum that reduce the cost of multi-Member State clinical trial administration.

Four interventions amplify coordination capacity without themselves constituting primary shared infrastructure. Strategic project support and high-impact project support generate structured coordination needs that the shared platforms are designed to address, creating demand for the infrastructure while also feeding it with standardised information from recognised projects. The veterinary single pathway reduces coordination friction between marketing authorisation and environmental risk assessment authorities. AI tools enable technology-assisted coordination functions across the shared platforms.

Emergent effect: Over time, the coordination tools reduce the marginal cost of managing an increasingly complex regulatory environment, partially offsetting the burden from Mechanism 1.

Risk: The offset is likely to be partial and delayed; in the short term, building new institutions and tools imposes costs before they generate savings.

Public Health and Safety

Change mechanism 1: Earlier and broader patient access to innovative biotech therapies

Two direct mechanisms drive earlier patient access. High-impact strategic project support accelerates access along two pathways: the 'centres of excellence for advanced therapies' designation creates specialised infrastructure that brings cutting-edge therapies to patients in settings that currently lack access, while the high-impact recognition criteria explicitly include therapies addressing unmet medical needs, ensuring that the full administrative and financial support package is directed toward the products where access delay has the greatest clinical consequence. The clinical trial framework reduces the time between a therapy's first clinical evidence and its availability to patients by shortening authorisation timelines, eliminating duplicative assessments, enabling faster evidence generation through combined studies, and introducing digital innovations that reduce trial setup and operational burden.

Three amplifying mechanisms extend the breadth and sustainability of patient access improvements. The novel health biotechnology sandbox creates pathways for therapies that currently have no viable route to patients because they do not fit existing regulatory categories, thereby expanding the range of products that can reach clinical and ultimately

market-ready stage. Financing instruments sustain investment in therapeutic categories where commercial incentives are weakest, including rare diseases, advanced therapies and precision medicine, and access delays are greatest. SPC extension maintains the commercial incentives to bring innovative therapies to EU patients, rather than prioritising markets where protected return periods are longer.

Emergent effect: A structurally faster and more inclusive pathway to patient access, particularly for the advanced therapy categories where the EU currently has the greatest access delays relative to other jurisdictions.

Change mechanism 2: Strengthening supply resilience for critical biotech medicines

Strategic project recognition explicitly includes supply resilience as a qualifying criterion for both standard and high-impact strategic projects, ensuring that manufacturing capacity and supply chain security are weighed alongside scientific and clinical merit in project support decisions. The biosimilars competitiveness framework strengthens EU manufacturing capacity in a product category where supply concentration creates structural vulnerability: a more competitive EU biosimilars market directly reduces dependence on a small number of dominant external suppliers.

Financing instruments amplify by supporting the scale-up of domestic manufacturing capacity for projects meeting the resilience criterion. The EU Biothreat Radar and biodefence framework address the specific resilience gap in medical countermeasures against biological threats, representing the extreme tail of supply risk where commercial market mechanisms cannot be relied upon. Strategic project support builds general manufacturing resilience; the biosimilars framework addresses a specific product category where EU capacity is underutilised; biodefence projects address the emergency scenario.

Emergent effect: A more resilient EU supply base for biotech medicines across normal market conditions and emergency scenarios, reducing dependence on external suppliers in both contexts.

Risk: Supply resilience measures may increase costs for healthcare systems that currently benefit from lower-cost external supply; the public health gain in resilience may come at a cost to healthcare budget efficiency.

Change mechanism 3: Mitigating biosecurity risks from the wider accessibility of biotechnologies

As biotechnology tools become more accessible and AI lowers barriers to misuse, the public health risk from deliberate or accidental release of dangerous biological materials increases. The proposed Act's biosecurity framework addresses this through a comprehensive suite of direct regulatory tools: product-of-concern regulation establishing common definitions and obligations, benchtop device screening requirements, transaction verification and verification of legitimate need, suspicious transaction reporting obligations, national inspection authorities with enforcement powers, penalties, and AI model monitoring provisions for biological applications.

The EU Biothreat Radar amplifies the framework established by the intervention n°17 by providing the ongoing intelligence and monitoring infrastructure that keeps the regulatory response current: the Biothreat Radar identifies emerging threats and technologies that should be added to the products-of-concern list before they reach widespread availability,

enabling the biosecurity framework to operate proactively rather than reactively. The Advisory Group on Biosecurity and the Commission guidance on legitimate need assessment ensure that the common rules are interpreted and applied consistently across Member States.

Emergent effect: A proactive rather than reactive biosecurity governance system, capable of responding to technological change rather than only to known threats.

Risk: The effectiveness of the framework depends heavily on keeping the products-of-concern list current; a static list rapidly becomes obsolete in a fast-moving technological landscape. The AI monitoring provisions are novel and their practical implementation is untested.

Additional methodological information on specific measures:

1. *Intervention n°13: SPC extension for biotechnology medicines*

While in line with the overall methodology used for impact quantification of the other measures on the Biotech Act proposal, the methodology to assess the SPC extension also draws from the model used for the impact assessment of the pharmaceutical legislation. To provide a more complete overview and comprehensive background to the approach utilised, we provide further details in this dedicated section.

The assessment of the proposed 12-month extension of the Supplementary Protection Certificate (SPC) for biotechnology medicines is based on a structured analytical framework combining quantitative modelling, empirical data analysis and supporting qualitative evidence. The objective of the methodology is to estimate the economic, budgetary and public health impacts associated with extending the effective period of protection for a defined subset of innovative biotechnology-derived medicinal products.

The modelling undertaken draws on a cohort of 198 innovative medicines (other than vaccines) that lost patent or regulatory protection between 2016 and 2024 and that have since remained on the market. Within this broader sample, a sub-sample of 31 biological medicines was identified, of which 12[27] products rely on the SPC as the last form of protection to expire.

The policy scenario introduces a one-year extension of SPC protection for eligible products. The modelling is carried out over a 20-year product lifecycle horizon. In the baseline, the twenty years began fifteen years before loss of exclusivity (most SPC-reliant medicines lose exclusivity after fifteen years) to four years after loss of exclusivity, i.e. five years of contested sales including year zero. In the policy scenario, this timeline is adjusted to incorporate one additional year of uncontested sales, during which revenues and volumes are assumed to remain at the level observed in the final year prior to expiry. At the same time, the period of post-expiry competition is reduced by one year.

Data on the value and volume of sales of the products used for the sample products were drawn from IQVIA MIDAS for the years 2008 to 2024, while to determine the last layer

[27] One of the products with particularly outlier characteristic was removed from the sample for the purpose of the cost calculation, however factored into the sensitivity analysis set out in Annex 7 to give a range of possible impacts.

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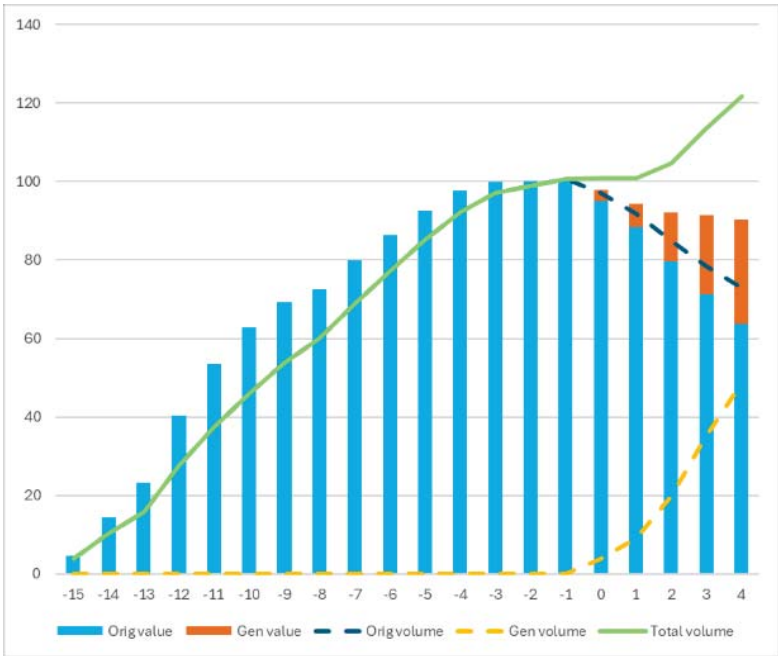
of protection, data were drawn from IQVIA Patent Intelligence.[28] The twelve medicines considered were authorised between 2003 and 2009 with loss of protection correspondingly between 2017 and 2024. Thus, for all medicines, there were data available for the year preceding loss of protection (year -1). However, for a number of medicines that were used for the years -15 to -1, the years after loss of protection were not available. Conversely, for some of those used for years 1 to 4, only a few years were available before loss of protection. Thus, the model is, by necessity, based on a 'moving cohort'. Nonetheless, the data for the different years are comparable because for each medicine, the data are normalised, i.e. expressed as a percentage of the value/volume in year -1, the year before loss of protection. It was then possible to take the average of these normalised quantities.

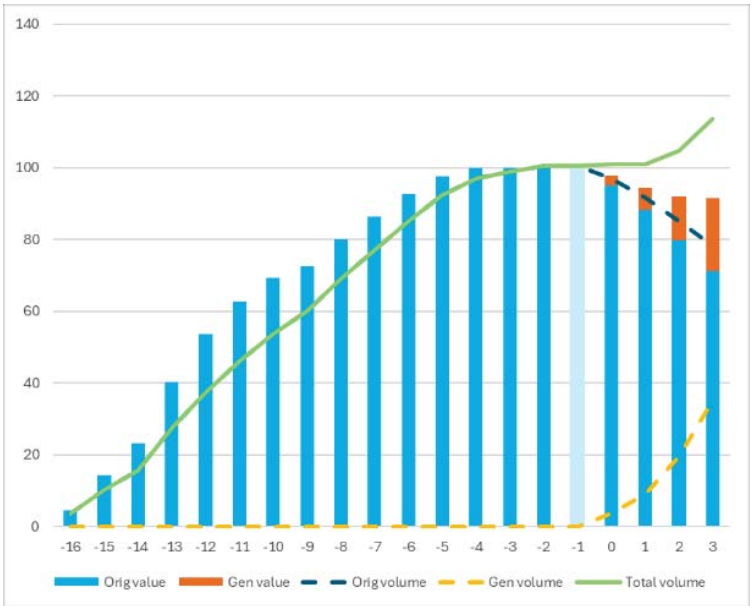
The results are presented in the graphs below. A full table of results are presented at the end of this Annex for both scenarios.

Figure 1. Normalised sales and volume for SPC-reliant biological medicines with current duration of SPC



[28] Internal analysis by the authors using IQVIA MIDAS® quarterly sales data 2008-2024. Geographical coverage: EU27 without Cyprus, Malta and Denmark. which were obtained under license from IQVIA and reflect estimates of real-world activity. Copyright IQVIA. All rights reserved. The statements, findings, conclusions, views, and opinions contained and expressed herein are not necessarily those of IQVIA.

Figure 2. Normalised sales and volume for SPC-reliant biological medicines with a 12-month SPC extension



For the purposes of calculating profits, unit manufacturing, marketing and distribution costs were assumed to be equal to 20% of the price in the year before expiry for originators and 33% of that price for biosimilars.

Spending by payers in the SPC extension scenario is compared to spending in the baseline. In addition to this direct cost to payers, the increase in price results in fewer doses being bought by payers and consequently fewer patients being treated. To quantify the cost to patients resulting from this lower coverage, we calculate the additional spending that would be required to achieve the volume that is reached at the lower prices seen in the baseline.

The impacts in normalised amounts, i.e. set out as a multiple of the value in the year preceding loss of protection, are presented in the table below. The change is multiplied by average sales in year -1 for SPC-reliant biological medicines (e.g. for the impact on originator sales, we take 36% of average sales in year -1).

Table 1. Comparison of key indicators in the two scenarios summed over the 20-year reference and expressed in terms of revenues in the year before loss of protection (revenues in y-1=100)

	Baseline	SPC+1	Change	% change
Originator sales	1395 m	1432 m	36 m	2.6%
Originator gross profit	1135 m	1166 m	31 m	2.7%
Biosimilar sales	68 m	41 m	-27 m	-39.2%
Biosimilar gross profit	30 m	19 m	-11 m	-35.9%
Cost to public payer	1463 m	1473 m	10 m	0.7%
Volume (patients treated)	1416	1395	-21 m	-1.5%
Patients + payer monetised gain/loss (cost of baseline volume)	1463 m	1491 m	28 m	1.9%

***Source**: author analysis based on IQVIA MIDAS*

When applied to an average sales value for an SPC-reliant biological medicine in the year prior to expiry of EUR 740 million, these proportions give the following results in euro terms:

Table 2. Impact of change of +1 SPC extension for biotechnology medicines

1 year increase in protection	Per med	Annual (3 meds)
Originator gross profit	**230 m**	**690 m**
Biosimilar gross profit	-80 m	-240 m
Cost to public payer	70 m	210 m
Patients monetised gains/losses	135 m	405 m
Patients + payer monetised gain/loss	**205 m**	**615 m**

***Source**: author analysis based on IQVIA MIDAS*

To assess whether behavioural changes would be expected on the part of developers in response to the measure, we analysed EMA data on products authorised between 2016 and 2025 to determine which of them would have fulfilled the criteria for being awarded the SPC extension. The information on these products is derived from the Agency's European public assessment reports (EPAR) for each product, the Agency's internal databases and own analysis.

The results of this assessment were as follows: According to EMA data from 2016 to 2025, in addition to the 5-6 products that would have met all the criteria each year, a further five products would have met all the criteria except the "geographic" ones, i.e. conducting trials in more than two EU Member States and having part of their manufacturing in the EU. We assume again that about 40% of the products are SPC-reliant. Thus, the SPC extension could potentially be awarded to 4-5 products annually (rather than 2-3) if developers changed their behaviour in response to the incentive.

The modelling framework is subject to a number of assumptions and limitations. The use of list prices rather than net transaction prices implies that cost estimates may be overstated, as they do not capture confidential discounts and rebate mechanisms applied at national level. In addition, the distribution of revenues among pharmaceutical products is highly skewed, implying limitations on inferences that can be drawn from averages. Further limitations arise from the small sample size and the need to simplify complex real-world behaviours, including firm investment decisions, clinical trial location choices and manufacturing strategies.

These limitations are mitigated through the use of multiple data sources (EMA databases, IQVIA datasets) and consistency checks with the broader literature and European

Commission previous evaluations[29] and studies touching upon SPC and other types of regulatory and patent protection[30].

[29] These include European Commission, *Inception Impact Assessment on Supplementary Protection Certificates*, 2017 (roadmap for SPC reform and evaluation); *Impact Assessment accompanying the revision of the EU pharmaceutical legislation (pharma package)*, 2023 (including analysis of SPC-related incentives and their effectiveness); *Legislative proposals on the Unitary Supplementary Protection Certificate and centralised SPC procedure*, 2023.

[30] These includes: Technopolis Group (2018) Effects of supplementary protection mechanisms for pharmaceutical products. Final report, May 2018. Amsterdam/Vienna: Technopolis Group, European Parliament. (2023). The potential impact of the unitary Supplementary Protection Certificate on access to health technologies (PE 753.104). Policy Department for Citizens' Rights and Constitutional Affairs, Directorate-General for Internal Policies of the Union, European Commission (2018) "Study on the economic impact of supplementary protection certificates (SPCs), pharmaceutical incentives and rewards in Europe" (Copenhagen Economics) and *Study on the legal aspects of supplementary protection certificates in the EU*, European Commission (Max Planck Institute for Innovation and Competition), 2018.

Table 3. Normalised values for the baseline[31]

Year from expiry	-15	-14	-13	-12	-11	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	0	1	2	3	4
Originator sales	5	14	23	40	54	63	69	73	80	86	93	98	100	100	100	95	88	80	71	64
Biosimilar sales	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	6	12	20	27
Total sales	**5**	**14**	**23**	**40**	**54**	**63**	**69**	**73**	**80**	**86**	**93**	**98**	**100**	**100**	**100**	**98**	**94**	**92**	**91**	**90**
Originator volume	4	10	16	28	37	46	54	60	69	77	85	92	97	99	101	97	92	85	78	73
Biosimilar volume	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	9	20	35	49
Total volume	**4**	**10**	**16**	**28**	**37**	**46**	**54**	**60**	**69**	**77**	**85**	**92**	**97**	**99**	**101**	**101**	**101**	**105**	**114**	**122**
Originator profit	4	12	20	35	46	54	59	61	66	71	76	79	81	80	80	76	70	63	56	49
Biosimilar profit	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	3	6	9	11
Total profit	**4**	**12**	**20**	**35**	**46**	**54**	**59**	**61**	**66**	**71**	**76**	**79**	**81**	**80**	**80**	**77**	**73**	**68**	**64**	**60**
Originator price	1.18	1.40	1.48	1.46	1.43	1.37	1.29	1.21	1.16	1.12	1.09	1.06	1.03	1.01	0.99	0.98	0.96	0.94	0.91	0.87
Biosimilar price																0.72	0.67	0.62	0.58	0.55
Average price	**1.18**	**1.40**	**1.48**	**1.46**	**1.43**	**1.37**	**1.29**	**1.21**	**1.16**	**1.12**	**1.09**	**1.06**	**1.03**	**1.01**	**0.99**	**0.97**	**0.94**	**0.88**	**0.81**	**0.74**

[31] Four-year moving average.

Table 4. Normalised values for the policy scenario[32]

Year from expiry	-16	-15	-14	-13	-12	-11	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	0	1	2	3
Originator sales	5	14	23	40	54	63	69	73	80	86	93	98	100	100	100	100	95	88	80	71
Biosimilar sales	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	6	12	20
Total sales	**5**	**14**	**23**	**40**	**54**	**63**	**69**	**73**	**80**	**86**	**93**	**98**	**100**	**100**	**100**	**100**	**98**	**94**	**92**	**91**
Originator volume	4	10	16	28	37	46	54	60	69	77	85	92	97	99	101	101	97	92	85	78
Biosimilar volume	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	9	20	35
Total volume	**4**	**10**	**16**	**28**	**37**	**46**	**54**	**60**	**69**	**77**	**85**	**92**	**97**	**99**	**101**	**101**	**101**	**101**	**105**	**114**
Originator profit	4	12	20	35	46	54	59	61	66	71	76	79	81	80	80	**80**	76	70	63	56
Biosimilar profit	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**	1	3	6	9
Total profit	**4**	**12**	**20**	**35**	**46**	**54**	**59**	**61**	**66**	**71**	**76**	**79**	**81**	**80**	**80**	**80**	**77**	**73**	**68**	**64**
Originator price	1.18	1.40	1.48	1.46	1.43	1.37	1.29	1.21	1.16	1.12	1.09	1.06	1.03	1.01	0.99	0.99	0.98	0.96	0.94	0.91
Biosimilar price																	0.72	0.67	0.62	0.58
Average price	**1.18**	**1.40**	**1.48**	**1.46**	**1.43**	**1.37**	1.29	1.21	1.16	1.12	1.09	1.06	1.03	1.01	0.99	0.99	0.97	0.94	0.88	0.81
Cost of baseline volume	5	14	23	40	54	63	69	73	80	86	93	98	100	100	100	100	98	98	100	98

[32] Four-year moving average.

2. *Intervention n°16: Prevention of biotechnology misuse*

Costs for providers

Two approaches are used to estimate costs for providers. The first provides a lower-bound estimate, capturing the additional cost for non-screening providers of one full-time equivalent (FTE), based on industry interview evidence. The second applies a more complex calculation, incorporating both direct and indirect costs for providers. The latter is based on the RAND Europe (2025)[33] model but adjusted to the custom nucleic acid synthesis market and EU labour costs. It provides an upper-bound estimate as it doesn't account for companies that are already screening.

Concerning the first approach, the estimation of compliance costs for non-screening providers is based on assumptions derived from industry evidence and existing models. First, evidence collected through industry interviews indicates that biosecurity screening activities can be integrated into routine operations with relatively limited resource requirements. In particular, SMEs with approximately 40–50 employees that already apply biosecurity screening typically allocate around 1 one full-time equivalent (FTE) to screening-related tasks. This benchmark is used as the standard unit of labour input for providers that currently do not perform screening.

Based on IBBIS data, the total number of EU custom NA synthesis providers is 110 (66 custom providers, 40 third party providers, and 4 benchtop manufacturers). Based on available evidence, an average of 70% of these providers are assumed not to conduct biosecurity screening at present.[34]

For each of the 70% of providers, one FTE is allocated to screening activities. This FTE is modelled as a composite of two occupational profiles: 50% managerial staff (ISCO-1) and 50% research staff (ISCO-2). The corresponding hourly labour costs are estimated at EUR 54.9 for managerial staff and EUR 40.5 for research staff.[35] Assuming a standard annual workload of 2,000 hours, the annual labour cost per provider is estimated at EUR 95,400.

Aggregating across all non-screening providers, total direct compliance costs are calculated as:

110 × 0.7 × 1 FTE × EUR 95,400 ≈ EUR 7.3 million per year.

In addition to direct labour costs, indirect costs due to productivity loss are incorporated following the methodology applied in the RAND analysis. Indirect costs are estimated using a multiplier of 1.17 applied to direct costs. Therefore, indirect costs are estimated as:

EUR 7.3 million × 1.17 ≈ 7.3 million × 1.17 ≈ 7.3 million × 1.17 ≈ EUR 8.6 million per year.

[33] Zakaria, S. et al. (2026). Cost–benefit analysis for synthetic nucleic acid screening in the European Union. Santa Monica, CA: RAND Corporation, 2026. https://www.rand.org/pubs/research_reports/RRA4805-1.html.
[34] Estimation based on the average between minimum (15%) and maximum (45%) estimates in the RAND analysis (2026) of the proportion of EU gene companies that voluntarily screen currently.
[35] Source: Eurostat Structure of earnings survey, Labour Force Survey data for Non-Wage Labour Costs.

Concerning the second approach, the RAND model[36] was adapted to better cover the actual targeted companies by the biosecurity provisions in the proposed EU Biotech Act. The RAND model takes into account companies of the NA synthesis market, without distinguishing between custom and non-custom providers. The biosecurity provisions in the proposed EU Biotech Act target only the custom DNA synthesis market, i.e. orders of NA fragments which could be assembled into dangerous pathogens synthesised without templates.[37]

To adapt the model and estimations accordingly, the following corrections were applied based on the outlined assumption:

- Since the costs are calculated based on the expected increase in orders, it is assumed that the share of these orders belonging to the custom NA synthesis market is 51%. This assumption is based on the share of the custom NA synthesis companies in the EU, 110, over the total number of NA synthesis providers in the EU, which is 215, based on IBBIS data.[38] This entails multiplying orders in the cost's calculations by 0.51.
- Therefore, the number of companies involved in the model (between 66 and 126) is also changed with the minimum number corresponding to only custom NA synthesis providers, and 126 corresponding to synthesis providers identified on the IBBIS map in Europe (for which we have sure information on 110, but as maximum number we keep 126).
- To have comparable estimations, the labour costs are adapted to the European averages, allocating the time to senior staff (ISCO 1-managers and ISCO 2-professionals, as upper and lower bound), and non-senior staff corresponding to ISCO 3, as technicians and associate professionals.[39]

Costs for customers

The cost estimation for customers (research organisations, private companies, and individual researchers) follows a labour-cost-based approach derived from the CLTR model.[40] The methodology captures both fixed compliance costs (learning, training, documentation) and variable costs (per-order verification).

The initial compliance cost is defined as the time required to learn and implement the screening procedure. This is allocated across two staff categories: senior staff (ISCO 2) and junior staff (ISCO 3). Senior staff account for 1.5 hours and junior staff for 2 hours, with respective hourly labour costs of EUR 40.5 and EUR 32.7.[41] This results in a one-off initial cost of EUR 126.15 per customer. To reflect ongoing compliance, an annual

[36] Zakaria, S. et al. (2026). Cost–benefit analysis for synthetic nucleic acid screening in the European Union. Santa Monica, CA: RAND Corporation, 2026. https://www.rand.org/pubs/research_reports/RRA4805-1.html.
[37] i.e. "Molecules of polymeric nucleic acids that have been synthesized *de novo* (without template), Annex 1 of the Biotech Act.
[38] IBBIS (2026), Global DNA Synthesis Map. https://globalsynthesismap.bio/
[39] Source: Eurostat Structure of earnings survey, Labour Force Survey data for Non-Wage Labour Costs.
[40] Fady, P. et al. (2025). Cost-Benefit Analysis of Synthetic Nucleic Acid Screening for the UK. The Centre for Long-Term Resilience. doi.org/10.71172/kyey-h0ya. Calculations based on the Customer TAB https://docs.google.com/spreadsheets/d/1oBzXTGxIRHLTF9CSiLRV6kk7EyetcX-xF1Y4ekWn5Z0/edit?gid=428955976#gid=428955976
[41] Source: Eurostat Structure of earnings survey, Labour Force Survey data for Non-Wage Labour Costs.

"refresh" cost is included, consisting of 0.5 hours of senior staff time and 1 hour of junior staff time, amounting to EUR 52.95 per year. The total compliance cost is then annualised over a 10-year period, leading to an annual labour cost of EUR 65.57 per customer. In addition, a marginal cost per order is included to capture the time required to verify suppliers. This is estimated at 3 minutes (0.05 hours) of junior staff time per sequence, corresponding to an additional EUR 1.635 per order.

These costs are then allocated across different types of orders using CLTR estimates of average ordering behaviour. For gene sequences, each customer is assumed to place 20 orders per year. The annualised fixed cost (EUR 65.57) is distributed across these orders, resulting in a fixed cost of EUR 3.28 per sequence. Adding the per-order verification cost (EUR 1.635) yields a total cost of EUR 4.91 per sequence for customers not already compliant. Indeed, to account for existing practices, an adjustment is introduced: 60% of customers are assumed to already follow compliance procedures and therefore incur only 10% of the full cost. This leads to an expected cost of EUR 2.26 per gene sequence.

For long oligonucleotides, the same structure is applied but with 1,000 annual orders per customer. This results in a much lower fixed cost per sequence (EUR 0.0197), and a total cost of EUR 1.65 per sequence for non-compliant customers. After applying the same compliance adjustment (with an additional correction that 70% of oligo customers already order genes and thus partially internalise compliance costs), the expected cost per oligo sequence is EUR 0.76.

Aggregating these per-sequence costs across total estimated order volumes yields total annual customer costs of approximately EUR 3.56 million for gene orders and EUR 12.85 million for oligo orders. The combined total cost for customers is therefore estimated at EUR 16.41 million per year. To have comparable and consistent numbers across the report, we use the order volumes based on the RAND model but still adapted to 51% to only account for custom NA synthesis market.

3. *Intervention n°17: Biodefence*

The surveillance cost estimates adapt a 2025 model by SecureBio Detection[42] for scaling US pathogen detection to the EU context. The US model combines three sampling streams: aircraft wastewater via triturator sampling at major airports, passenger nasal swabs at airports, and municipal wastewater sampling through the National Wastewater Surveillance System (NWSS).

EU Scenario 1 (proportional scaling). Scales the US model to European transport and wastewater infrastructure while maintaining comparable coverage. Based on 2024 European airport passenger volumes (~1 billion/year, ~2 million movements/day), approximately 6 major airports plus 10 additional airports are needed to match US coverage. For wastewater, 5–10 large urban treatment plant catchments replicate the US NWSS coverage of ~2.5 million individuals. Triturator-based aircraft wastewater sampling, currently in limited European pilots only, would require new deployment.

[42] SecureBio Detection (2025), Scaling US Pathogen Detection.

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EU Scenario 2 (expanded environmental sampling). Discontinues passenger swabbing and expands triturator-based sampling to 20 major airports with increased processing capacity. Significantly scales up sequencing and bioinformatics infrastructure (EUR 102 million for this component alone vs. EUR 23 million in Scenario 1), resulting in higher overall costs.

Cost adjustments. Salaries for laboratory managers, analysts, technicians and bioinformaticians are adapted to EU standards using Eurostat average values for ISCO-1, ISCO-2 and ISCO-3 professional profiles. Equipment and processing costs are assumed internationally comparable and converted from USD to EUR at the applicable exchange rate.

Benefits estimation. Public health benefits draw on Nascimento de Lima *et al.* (2024), which models the first year of a COVID-19-type pandemic under varying early-warning lead times. The model estimates mortality, illness costs and lockdown duration across scenarios of 0 to 10 days of advance detection. The five-day scenario is used as the central reference, consistent with empirical findings of 5–19 day lead times from European wastewater surveillance.

Table 5. Inputs adapted from the US model

Inputs	US model	EU 1st scenario	EU 2nd scenario
NWSS			
Number of municipal sites in mature system	5	5	10
TGS			
SWABS			
Number of swab airports	13	16	20
Daily swabs per airport	400	400	0
TRITURATORS			
Number of total triturator airports	13	16	20
Of these, number of new triturator airports	10	16	20
Individuals contributing to each triturator	7,500	7,500	7,500
INDIVIDUAL PLANES			

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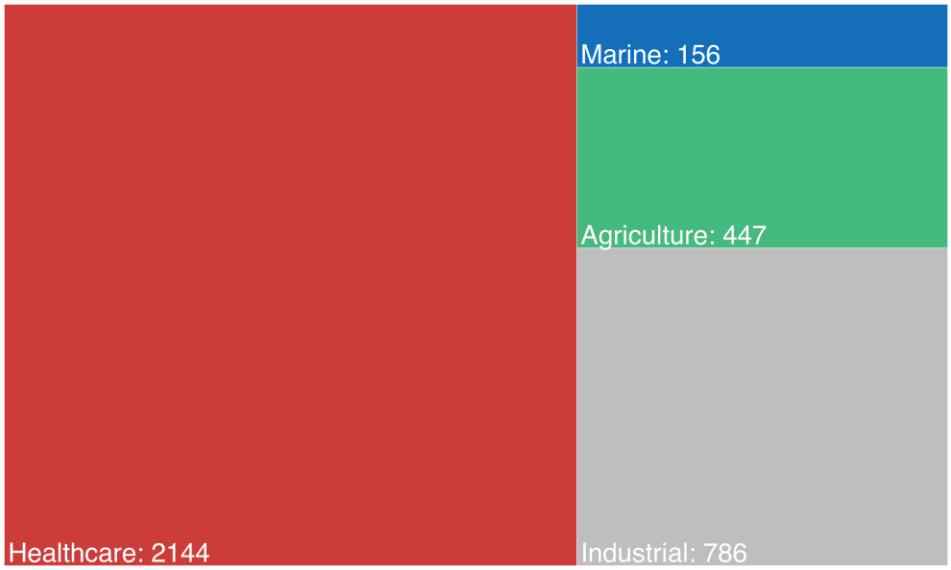
Number of individual plane airports	2	2	2
Daily individual planes sampled per site	25	25	25
PROCESSING			
Number of sites	2	2	15

Source: https://securebio.org/blog/biothreat_radar/ ; https://docs.google.com/spreadsheets/d/1ay2cFWjGjjnPOTBXqD-X2Kh32R4hAW4GHMUSxZxG_8g/edit?gid=1660342520#gid=1660342520

ANNEX 5: ADDITIONAL INFORMATION ON BACKGROUND ON THE SECTOR AND PROBLEM DEFINITION

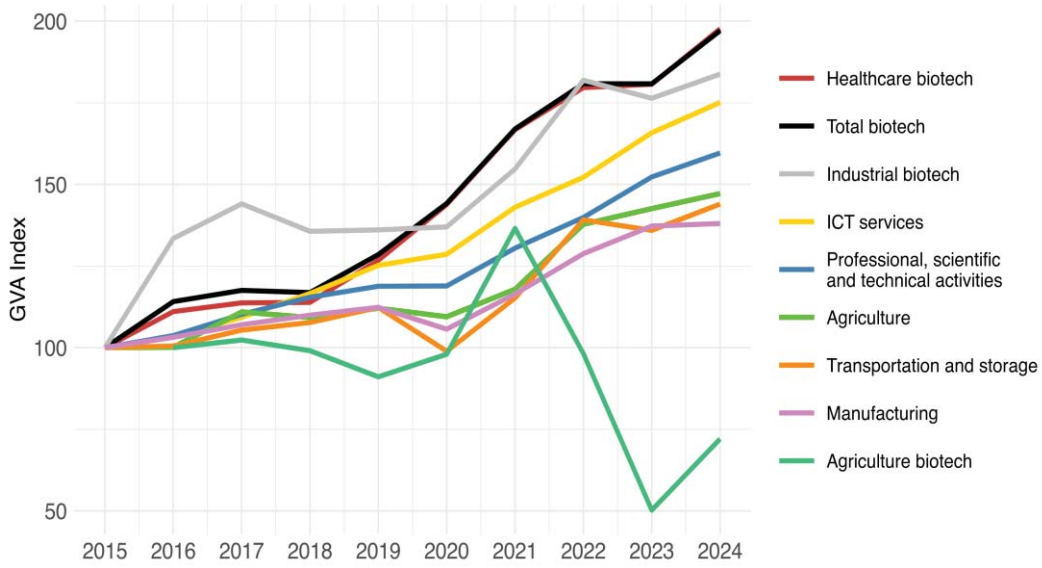
1 BACKGROUND ON THE SECTOR

Figure 1. Distribution of EU biotech startups across biotechnology domains (founding year ≥2015; active in 2025)



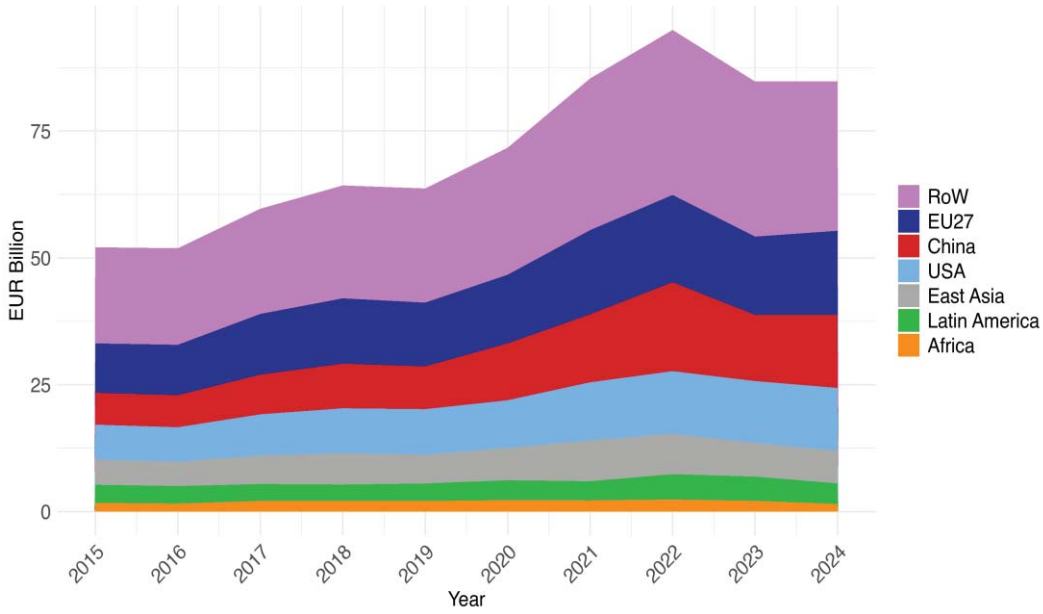
***Source**: Technopolis Group based on Crunchbase (Landscape analysis study).*

Figure 2. Sector GVA comparison (index = 100 in 2015)



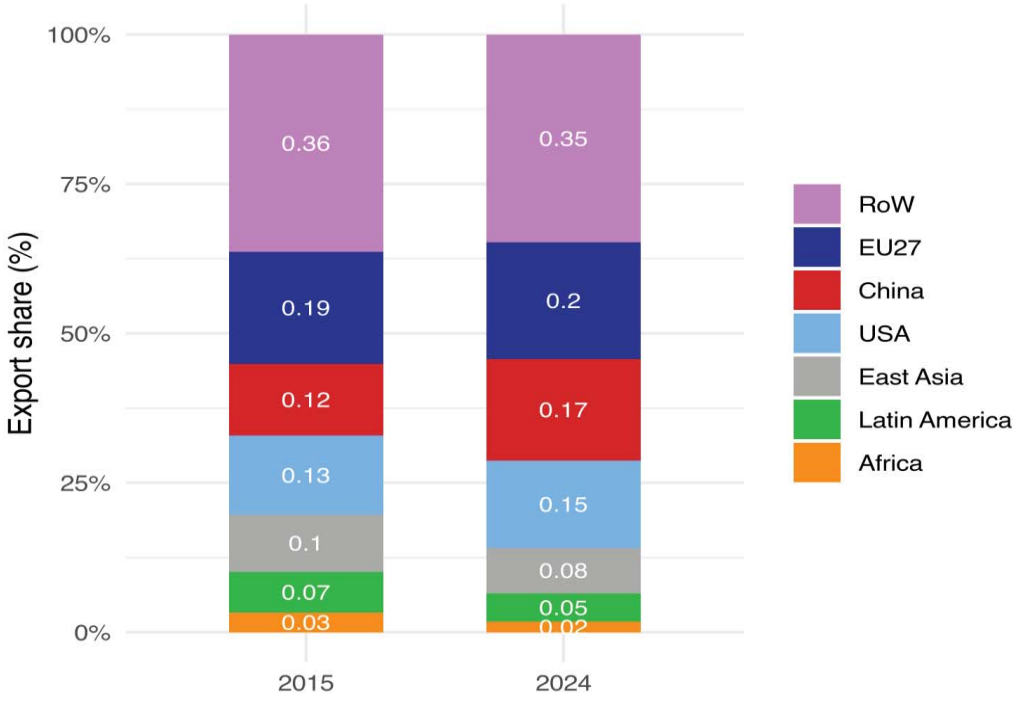
***Source**: Technopolis Group based on Prodcom; Eurostat (Landscape analysis study).*

Figure 3. Global biotechnology exports (billion EUR)



***Source**: UN Comtrade (Landscape analysis study); Note: East Asia does not include China.*

Figure 4. Biotechnology export share



***Source**: UN Comtrade (Landscape analysis study).*

Focusing on the relative technological specialization in biotechnology within the EU, the study conducted by the JRC "Exploring the global landscape of biotech Innovation: preliminary insights from patent analysis", points out a few statements.

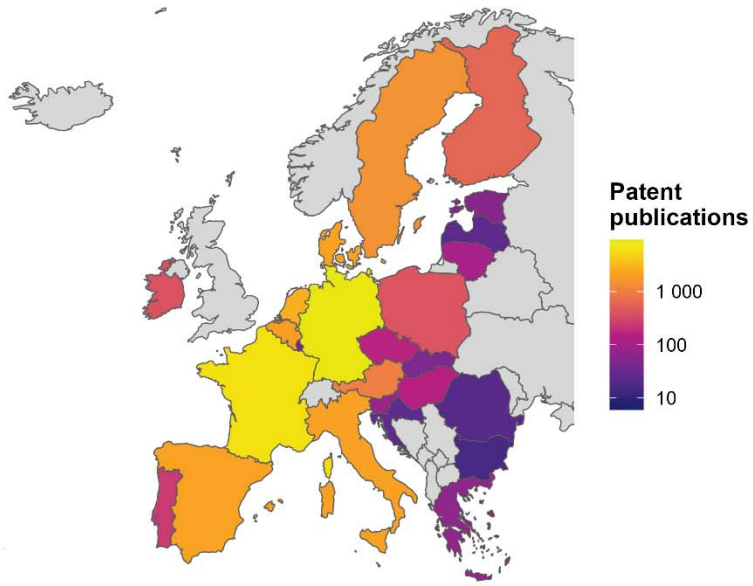
Firstly, Germany, France, The Netherlands, Denmark and Italy are the five Member States with the highest share of biotechnology patents during the study period (from 2001 to 2020), which accounted for 74.9% of the total EU biotechnology patents (see Figure 5).

Secondly, the number of white and red biotechnology patents represents the majority of all biotechnology patents, whereas the number of green biotechnology patents is extremely low.

Thirdly, Germany and France are the Member States that account for the highest number of biotechnology patent applicants. In fact, the two countries represent more than 50% of all EU biotechnology patents (see Figure 5).

Lastly, it is also important to note that The Netherlands is the only country that shows clear specialisation in green biotechnology. Italy has the highest specialisation index in red biotechnology and Denmark has the highest index values for white biotechnology.

Figure 5. Geographic distribution of applicants within the EU-27

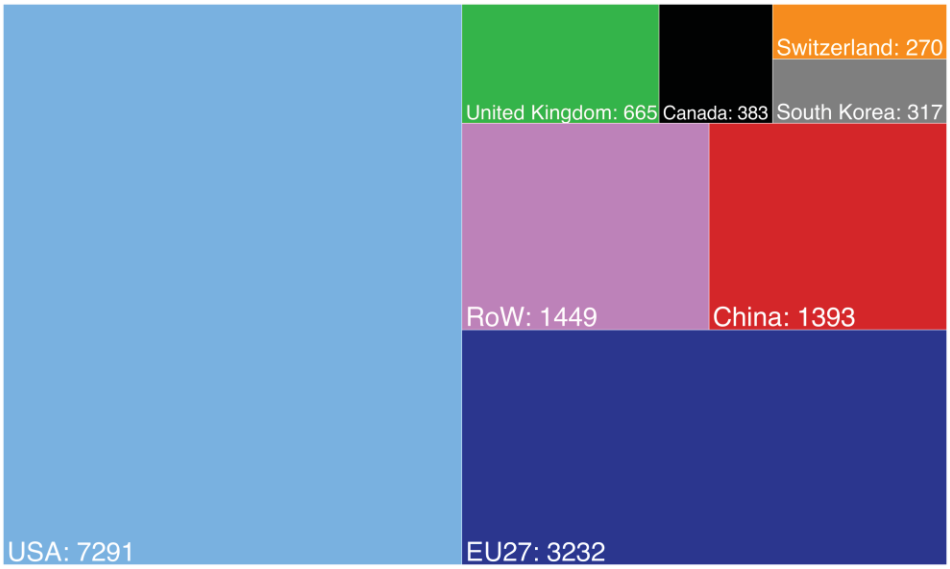


***Source**: Orbis IP, calculation: Technopolis Group (Landscape analysis study) Note: the number of distinct patent publications are represented with a log scale to account for strong disparities across countries. The geographical dimension is analysed based on the inventors' location.*

2 PROBLEM DEFINITION - SUPPORTING EVIDENCE TO AND DETAILED EXPLANATIONS OF THE PROBLEM AND DRIVERS

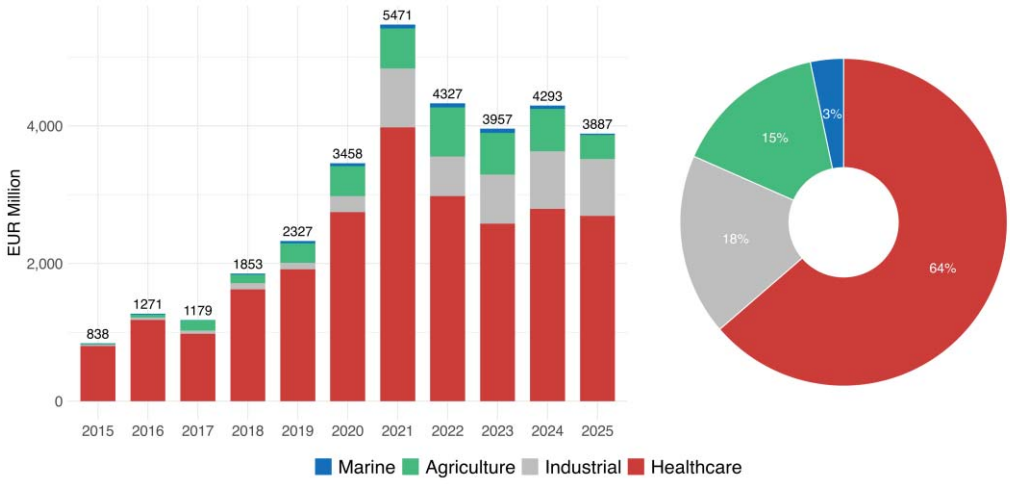
2.1 Supporting evidence to the overall problem

Figure 6. Global distribution of biotechnology startups founded since 2015



***Source**: Technopolis Group based on Crunchbase (Landscape analysis study).*

Figure 7. VC investment per biotechnology area in the EU, 2015 – 2025



***Source**: Technopolis Group based on Crunchbase (Landscape analysis study).*

2.2 Supporting evidence on the problem and drivers across selected health and food biotechnology sectors

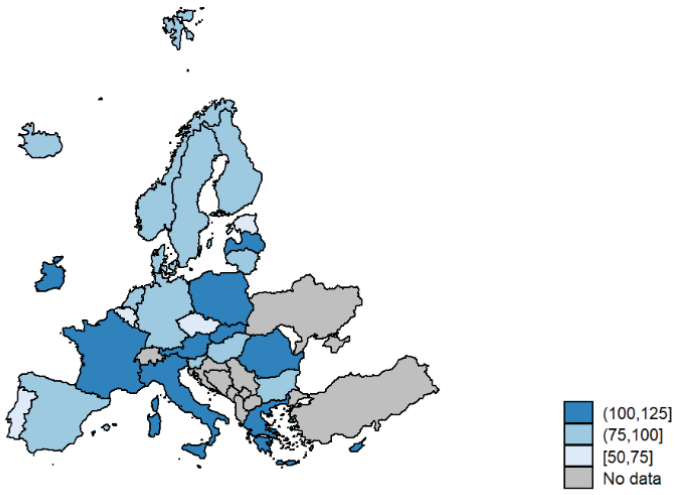
2.2.1 Authorisation of clinical trials

Europe faces growing challenges in maintaining its competitive edge due to lengthy regulatory timelines and higher administrative requirements compared to other regions. As a result, sponsors[43] increasingly favour jurisdictions that offer faster regulatory timelines, simpler and more streamlined approval processes, and improved access for the recruitment of patient populations, contributing to a widening in the competitive gap.

(i) Longer timelines for the authorisation of clinical trials in EU/EEA compared to other regions

The average time from submission to decision for the authorisation of Part I of multinational clinical trials in the EU/EEA is 117 days, with relatively little variation across Member States (Standard Deviation= 6 days). In contrast, mono-national clinical trials are generally authorised more quickly, with an average duration of 91 days, but this varies substantially across Member States (Standard Deviation= 19). Approval times range from approximately 60 days in Belgium, the Czech Republic, and Portugal to around 120 days in Slovakia, Ireland, and Poland (see Figure 8). Additionally, the low share of ATMP trials in the EU/EEA (~3.8% of the applications) may be attributed to long and complex approval timelines.

Figure 8. Duration in days from submission to decision for mono-national clinical trials in the EU/EEA[44]



Note: *The Figure illustrates the average duration in days from submission to decision for mono-national trials between January 2022 and May 2025.*

Overall approval timelines appear to be systematically longer in the EU/EEA compared to the USA, Australia, and Canada across various therapeutic areas. In the USA, authorisation typically takes approximately 1–3 months, accounting for the Food and Drug Administration's 30-day Investigational

[43] Sponsors are the individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial.
[44] Calculations done by the European Commission based on data from CTIS.

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New Drug review period and parallel Institutional Review Board approval.[45] China has progressively streamlined its clinical trial approval procedures, and recent 2025 reforms establish an expedited 30-working-day review pathway for eligible Class I innovative drugs, representing a significant acceleration relative to the standard 60-working-day implicit approval timeline introduced around 2018–2019 under China's silent approval mechanism.[46] In the EU/EEA, these longer timelines are driven by several factors, including the Member State with the longest assessment period, limited reliance on existing assessments, and duplication of assessment by the Reference Member State (RMS) and Member States concerned (MSC).

Beyond, in situation of public health emergencies, multi-national clinical trials offer the advantage of involving large groups of investigators across different regions, facilitating the achievement of required sample sizes within a shorter timeframe and mitigating the impact of regional or local variations in participant eligibility. However, experience during the COVID-19 pandemic has demonstrated that slow assessment and authorisation of clinical trial applications in the EU/EEA have hindered the rapid setup of multinational clinical trials, where timely and scientifically sound decisions are crucial.

(ii) Comparatively higher administrative burdens/costs associated with the clinical trials authorisation process and conduct in clinical trials in the EU/EEA due to a fragmented clinical trial environment and regulatory complexity.

Within the EU regulatory framework, diverse national systems and intricate administrative requirements add layers of complexity for sponsors, possibly impacting the EU's ability to remain competitive in the rapidly advancing global pharmaceutical sector.[47] In contrast to the centralised regulatory framework in the US, China, or Australia, the authorisation procedure for multinational clinical trials in the EU requires close coordination and cooperation across multiple Member States. Sponsors for multinational clinical trials currently face increased administrative burden associated with diverging national requirements and approaches, insufficient reliance across Member States in the scientific and ethics reviews contributing to duplicative and complex documentary submission requirements, unpredictable timelines, language translation requirements, and a lack of harmonised personal data protection requirements[48]. Additionally, current regulatory authorisation requirements for postmarketing trials, such as treatment optimisation trials, may impose disproportionate obligations on sponsors, often academics, and thus, hinder trial conduct in the EU, despite the potential for these trials to reduce costs of the public health system. Compared to the EU, other jurisdictions, such as the US and China, show a

[45] EFPIA (2024) assessing-the-clinical-trial-ecosystem-in-europe.pdf; Start-Up Timelines Across Global Regions in Clinical Trials – Clinical Research Made Simple

[46] Tan et al (2025) Current landscape of innovative drug development and regulatory support in China | Signal Transduction and Targeted Therapy

[47] Tan et al. (2025) Current landscape of innovative drug development and regulatory support in China | Signal Transduction and Targeted Therapy

[48] It is to note that there is only limited data available on the cost structures across comparative regions. However, feedback from sponsors indicates that diverging costs are driving the sponsor's choice of the location for conducting clinical trials.

higher emphasis on earlier-stage development, reflected in its relatively high share of Phase 1 trials, underscoring its central role in early clinical innovation[49].

This regulatory fragmentation is also evident in the uneven distribution of annual clinical trial applications across Member States. Although the majority of clinical trials take place in large-population countries such as France, Germany, Italy, and Poland (see Figure 9a), per-capita figures reveal that some medium-size Member States—including Belgium, Denmark, the Czech Republic, and Austria—exhibit comparatively higher clinical trial activity (Figure 9b). This uneven distribution points to structural, regulatory inefficiencies and may lead to the underutilisation of population potential for clinical trials in several Member States, highlighting the need for more coordinated policy approaches at EU level.

Figure 9. Number of clinical trials applications in 2024[50]

Figure 9a. *Total number of clinical trials in 2024*

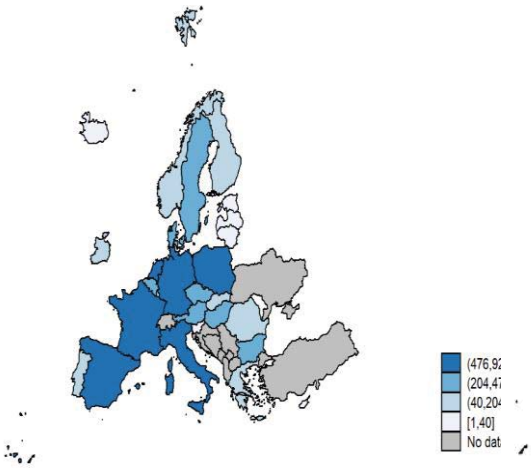
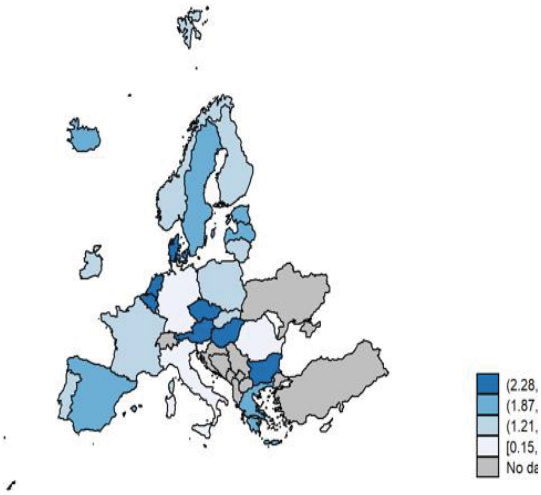


Figure 9b. *Number of clinical trial applications per 100,000 inhabitants in 2024*



2.2.2 Advanced Therapeutical Medicinal Products (ATMPs)

Dual regulatory burden for investigational GMO-ATMPs

Clinical trials involving investigational ATMPs containing GMOs are currently regulated under both Regulation (EU) No 536/2014 and the GMO legislation, creating a dual regulatory burden. Sponsors must submit both a clinical trial authorisation application and a separate GMO submission, leading to administrative complexity, delays, and increased

[49] Fast-track landscape analyses to assess the regulatory clinical trial eco-system in the EU/EEA and in other relevant regions (forthcoming)
[50] Calculations done by the European Commission based on data from CTIS.

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costs due to varying national GMO dossier requirements across Member States. This fragmented system undermines the competitiveness of EU-based ATMP developers compared to US and Asian markets and makes the EU a less attractive location for clinical trials and investments for foreign sponsors.

Recent progress under the revision of the EU pharmaceutical legislation

The recently agreed revision of the EU pharmaceutical legislation introduces a centralised EU-wide procedure for GMO submissions. It transfers authorisation requirements, including Environmental Risk Assessments (ERAs), from GMO authorities to the EMA and its Committee for Medicinal Products for Human Use (CHMP). However, the revision does not provide for risk-based derogations from GMO requirements for specific categories of investigational ATMPs, particularly where EU experience demonstrates negligible environmental risk.

Outdated definitions hamper innovation

Definitions in the ATMP Regulation (Regulation (EC) No 1394/2007) encompass gene therapy medicinal products, somatic cell therapy medicinal products, and tissue-engineered products (TIEPs). However, scientific and technological advances are outpacing this framework, driving the development of new ATMPs that may challenge existing definitions. The current definition of TIEPs is outdated and fails to capture emerging modalities such as in vivo tissue generation, acellular therapies, and bio-synthetic hybrids.

This leads to regulatory gaps and classification uncertainty, placing EU ATMP developers at a disadvantage compared to jurisdictions with more adaptable regulatory frameworks.

Prolonged assessment timelines

Under the Clinical Trials Regulation, ATMPs are subject to additional assessment time beyond that for conventional medicinal products. The current rules allow up to 50 extra days for ATMP clinical trial application assessments, with further extensions for substantial modifications. These prolonged and less predictable timelines undermine global competitiveness, as developers in other regions, such as the US, often face shorter assessment periods and can secure earlier market access. Extended timelines also increase development costs for EU-based companies and delay patient access to potentially curative therapies.

Consequences of inaction

Without intervention the EU risks falling further behind global competitors in ATMP development, compromising its leadership in this critical sector. This regulatory lag could lead to poorer patient outcomes, increased healthcare costs, and limited access to effective treatments across Europe.

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2.2.3 Veterinary medicine products

(i) Duplicative, not-fit-for purpose regulatory framework applicable to veterinary medicinal products that contain or consists of GMOs

Veterinary medicinal products that contain or consist of GMOs, developers are not only required to comply with the Regulation (EU) 2019/6, which ensures the safety of veterinary medicinal products as regards the treated animal, the user of the veterinary medicinal product, the consumer (in case of food-producing animals) and the environment but also with Union GMO legislation[51], which also aims at ensuring the protection of human and animal health and the environment. Challenges on the application of the GMO legislation to medicinal products has been consistently identified as a hurdle for the development of novel medicinal products[52]. Actions to address this have focused on human medicinal products, leaving veterinary products unaddressed.

Clinical trials with veterinary medicinal products containing or consisting of GMOs are subject to a **double authorisation procedure:** approval by competent authorities responsible for veterinary medicines in accordance with applicable national laws and Good Clinical Practice which includes the protection of the environment, and also compliance with the Union GMO legislation. The latter has not been designed for veterinary medicinal products, **resulting in complex compliance requirements and delays**. Additionally**, the GMO legislation is not applied in a harmonised way throughout the Union,** leading to an **unequal level playing field** for operators across the EU and **increased costs and time** for multinational trials.

For **marketing authorisation** of such products, applicants must include technical documentation and an environmental risk assessment in accordance with Directive 2001/18/EC. The content of this technical file does not account for the specific characteristics of veterinary medicinal products and overlaps with other parts of the marketing authorisation application. Moreover, competent authorities under Regulation (EU) 2019/6 are required to hold consultations with competent authorities under Directive 2001/18/EC. Experience shows that these consultations increase burden for the assessors of marketing authorisation applications and can be challenging in case of accelerated procedures.

Additionally, the **lack of legal certainty on the status of animals that are treated with certain novel biological veterinary medicinal products** can deter the use thereof. While the GMO legislation specifically excludes that humans treated with medicinal products are regarded as GMOs, clarification as regards the legal status of animals that are administered medicinal products does not currently exist in Union legislation.

(ii) Disproportionate administrative burden of the handling of variations non requiring assessment

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[51] Directive 2001/18/EC, OJ L 106, 17.4.2001, pp. 1–39. ELI: http://data.europa.eu/eli/dir/2001/18/oj and Directive 2009/41/EC, OJ L 125, 21.5.2009, p. 75-97. ELI: http://data.europa.eu/eli/dir/2009/41/oj

[52] See for example, the Explanatory Memorandum to Regulation (EU) 2020/1043 [COM(2020) 261 final] or the Pharmaceutical Strategy for Europe [COM(2020) 761 final].

Variations to the marketing authorisation happen routinely during the life-cycle of any medicinal product; the number of variations being typically higher for biological veterinary medicinal products. Regulation (EU) 2019/6 created the category of variations not requiring assessment. This category of variations was established with a view to reduce administrative burden, allowing notification of changes without formal procedure or cost.

Experience with the implementation of the Regulation shows that this objective has not been achieved. The obligation to **notify** all variations non requiring assessment within 30 days has led to an overall increase in the number of notifications by marketing authorisation holders, thus **increasing administrative burden for operators**. The obligation for competent authorities to record the rejection or approval of the variation resulted in the **assessment** by competent authorities of the submission, leading to **administrative burden also for public authorities**. In some Member States the confirmation by the authority is associated with **a fee**, further increasing for operators.

(iii) Future innovation

Regulatory uncertainty represents a serious hurdle to the marketing or use of novel technologies, methods or products. While advances in biotechnology enable the development of novel concepts, this innovation may never reach the market due to the lack a clear regulatory framework which secures access to the Union market. While regulatory sandboxes have been proposed for human medicine and in other areas, no such framework exists for animal healthcare, which would deter the development of new technologies, methods or products in the EU.

(iv) Regulatory protection

The regulatory protection for biological VMPs comprises two strong distinct and interacting approaches: regulatory data protection (Articles 39-40 of Regulation 2019/6) and intellectual property (IP) protection (patents and Supplementary Protection Certificates (SPCs) under Regulation (EC) No 469/2009).

Nevertheless, the veterinary pharmaceutical market presents distinctive challenges for innovation, such as fragmented species-specific markets, low prices, a small overall market size.

In this context, there is a need for enhanced incentives as a way of supporting the development of biotech VMPs to diagnose, treat or prevent zoonotic diseases.

2.2.4 Novel health biotechnologies

(i) Union legislative frameworks not adapted to complex and hybrid emerging health biotechnology products

While existing EU regulatory frameworks in the health area (including recent or forthcoming revisions) ensure a high level of health and safety protection, these frameworks operate largely in silos, each addressing specific product categories with insufficient flexibility. In practice developers of complex and hybrid emerging novel health biotechnology products must navigate several regulatory frameworks, including their specific differing logic, evidence requirements and language. This is a particular

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challenge for smaller companies, often start-ups working on a breakthrough product, as they lack the regulatory expertise and resources to optimally navigate regulatory options. **Current mechanisms for addressing complexities related to the novelty of health biotechnology products focus on individual products on a case-by-case basis, without structural cross-framework dialogue on emerging innovation**. This reactive, product-specific approach lacks systematic coordination across Union legislative frameworks and prevents regulators from identifying patterns, preparing for emerging innovations, and developing consistent approaches. Without horizontal foresight and structured horizon-scanning activities, regulators remain perpetually reactive rather than proactive, and therefore less efficient than they could be.

It is also cannot be excluded that in the future innovative health biotech products may not find fully suitable regulatory pathways in the existing EU legal frameworks, including the regulatory sandboxes foreseen in those frameworks, resulting in products getting 'stuck' in the system.

Taken together, these elements lower the perceived innovation-friendliness of the EU regulatory system, making the EU less attractive for cutting edge research, investments in breakthrough innovation, and as an early launch market for complex but clinically impactful products.

(ii) Lack of legal certainty on products classification and evaluation

Developers, particularly smaller entities, also lack easy access to consolidated information about available regulatory options and guidance, and on how similar products have been classified and evaluated under various frameworks. While opinions, recommendations, and decisions exist, they are not systematically compiled or made accessible in a way that enables developers and authorities to learn from precedents and ensure consistency. Especially for SMEs, start-ups, and scale-ups, there is a significant gap in regulatory expertise. These entities often cannot afford dedicated regulatory affairs specialists and struggle to understand which frameworks apply, what adaptations might be needed, and how to efficiently navigate procedures.

2.2.5 Biosimilars

The current EU regulatory framework for biosimilars can include unnecessary, lengthy and costly multi-country clinical trials. A tailored development approach, where robust analytical and in vitro characterisation reduce clinical data requirements without compromising quality, safety, or efficacy—could accelerate approvals, as also being considered by the U.S. Food and Drug Administration.

Biosimilar development currently entails costs of approximately EUR 85.5–256 million and timelines of 6–9 years[53, 54] Europe is the leading region for biosimilar clinical trials

[53] IQVIA, The Impact of Biosimilar Competition in Europe, 2026, iqvia-the-impact-of-biosimilar-competition-in-europe-2026-01-26-forweb.pdf

[54] Medicines for Europe, European Biosimilar Medicines Sector: Delivering Impact Beyond Health – Economic, Scientific & Strategic Contribution, Biotech Act Factsheet Series, March 2026, Pillar 1-2-3-4-FOOTPRINT-SPC-Biotech-Act-facsheets-ppt.cdr

with 83 trials conducted between 2020–202 and roughly EUR 0.7 billion with 71% allocated to comparative efficacy studies (CES).

Regulatory practice has already begun to evolve toward a risk-based approach. For well-characterised, simpler products with accepted pharmacodynamic biomarkers the EMA has accepted PK/PD-based clinical packages without Phase III CES for many years. From the EMA Medicines Database, 41 of 151 authorised biosimilars (27.2%) are simple biologics in this category, but in the past 3 years, their share fell to below 10%.[55]. For monoclonal antibodies and fusion proteins, Phase III CES with clinical efficacy endpoints was included in 100% of the 36 MAAs evaluated by EMA between July 2012 and November 2022[56]. However, evidence shows that negative regulatory outcomes were linked to quality deficiencies rather than clinical efficacy results, indicating that CES has had limited regulatory impact in determining approval outcomes[57].

Table 1. The EMA Medicines Database records the following biosimilar CHMP opinions per year, disaggregated by molecule type:

	2018	2019	2020	2021	2022	2023	2024	2025	Cum. Total
Total opinions	13	4	9	6	7	8	25	40	**151**
Simple biologics	5	2	4	0	4	0	1	3	41
mAb / fusion proteins	8	2	5	6	3	8	24	37	**110**
% mAb/FP	62%	50%	56%	100%	43%	100%	96%	93%	72.8%

***Source**: The EMA Medicines Database (extracted 2 March 2026) records 151 authorised biosimilars in the EU (over 160 including subsequent approvals through Q3 2025; IQVIA, 2026; Medicines for Europe, 2025).*

Table 2. Biosimilar Authorisation Activity in the EU

	2018	2019	2020	2021	2022	2023	2024	2025	Cum. Total	Trend
Opinions	13	4	9	6	7	8	25	40	151	↑↑
New ref. products	1	0	1	1	1	5	3	2	27	↑

***Source**: EMA Medicines Database (extracted 2 March 2026). "New ref. products" = active substances receiving their first EU biosimilar authorisation in that year. 2025 data includes CHMP opinions to date.*

The acceleration from 8 opinions in 2023 to 25 in 2024 and 40 in 2025 is the most significant volume increase in EMA biosimilar history. The 2024–2025 period is dominated by mAb/fusion protein classes (93–96%), driven by the denosumab (29), aflibercept (12), and ustekinumab (12) cohorts. **Nine new reference** product classes entered the biosimilar market after 2022, compared with 18 in the preceding 19 years -

[55] European Medicines Agency. (2026). Medicines output report [dataset]. Retrieved 2 March 2026 from https://www.ema.europa.eu/en/medicines/download-medicine-data

[56] Kirsch-Stefan, N., Guillen, E., Ekman, N., Barry, S., Knippel, V., Killalea, S., Weise, M., & Wolff-Holz, E. (2023). Do the outcomes of clinical efficacy trials matter in regulatory decision-making for biosimilars? BioDrugs, 37(6), 855–871. https://doi.org/10.1007/s40259-023-00631-4

[57] Kirsch-Stefan, N., Guillen, E., Ekman, N., Barry, S., Knippel, V., Killalea, S., Weise, M., & Wolff-Holz, E. (2023). Do the outcomes of clinical efficacy trials matter in regulatory decision-making for biosimilars? BioDrugs, 37(6), 855–871. https://doi.org/10.1007/s40259-023-00631-4

indicating a broadening of the biosimilar pipeline including into new therapeutic areas. The denosumab cohort (29 products) is the largest single-reference-product biosimilar wave in EU history.

The EMA published a Reflection Paper on a Tailored Clinical Approach in Biosimilar Development (2026) concluding that "Based on the advancements in analytical technology and the regulatory experience gained, a tailored approach for clinical development of biosimilar candidates is possible. CES are no longer expected to be required for approval of biosimilars that can be thoroughly characterised using state-of-the-art analytical methods and have demonstrated similarity in physicochemical and functional properties. Comparative clinical PK studies are still essential elements in biosimilar development and can provide supportive safety and immunogenicity data. This tailored clinical approach is expected to be applicable for the majority of biosimilar candidates. A regulatory option that, under certain conditions, allows authorisation of biosimilars based on demonstrated comparability at the analytical level with a limited clinical data package streamlines the development process without compromising efficacy and safety."[58] Building on this conclusion, the revised guidance for biosimilars is expected to set out the conditions and provide for more tailored approach for CES requirements for complex biosimilar products. This is particularly relevant in light of recent regulatory trends. Over the past three years, applications concerning monoclonal antibodies and fusion proteins have represented more than 90% of all biosimilar marketing authorisation applications (see Annex). The revised approach is therefore expected to have a broad practical impact, as it applies to the majority of current and future biosimilar development programmes. The finalised Reflection Paper supports rapid advancement already in the interim, currently several scientific advices as well as 2 marketing authorisation application assessments are ongoing, which propose tailored CES approach.

This risk-based approach aligns with international regulatory convergence. The U.S. Food and Drug Administration has removed switching study requirements and expanded flexibility in clinical evidence (2024–2025)[59], while Canada is consulting on CES elimination for most biosimilars[60]. South Korea already applies CES waivers in practice[61], and Japan is expected to adopt similar flexibility by 2028. In this context, the EMA plays an active role in international regulatory dialogue and outreach. Ensuring that the EU approach is effectively promoted at global level will be important to support convergence towards a harmonised, tailored and streamlined approach to biosimilar development, in particular with regard to the reduced reliance on Comparative Efficacy Studies.[62, 63]

Under the baseline, the EMA is expected to continue a gradual shift toward tailored, risk-based approaches without the revision of the current biosimilar guidance portfolio for a more systematic and predictable procedure for unnecessary CES elimination, as

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[58] Reflection paper on a tailored clinical approach in biosimilar development
[59] U.S. Food and Drug Administration. (2024). Considerations in demonstrating interchangeability with a reference product: Update (draft guidance). Silver Spring, MD: FDA.
[60] Smart & Biggar. (2025, July 4). Update on biosimilars in Canada – June 2025. https://www.smartbiggar.ca/insights/publication/update-on-biosimilars-in-canada-june-2025
[61] Kang, H. N., Thorpe, R., Knezevic, I., et al. (2020). The regulatory landscape of biosimilars: WHO efforts and progress made from 2009 to 2019. Biologicals, 65, 1–9. https://doi.org/10.1016/j.biologicals.2020.02.005
[62] ICH_M18_Final_Concept_Paper_MCEndorsed_2025_1119.pdf
[63] IPRP_BWG_Final IPRP Scientific Workshop Summary Report_2024_0506.pdf

appropriate. The formal regulatory standards for safety, quality, or efficacy are and will remain maintained. At the same time, global competitors streamline evidentiary requirements more rapidly. As a result, EU competitiveness in biosimilar development is expected to weaken, with developers prioritising earlier submissions in jurisdictions with lighter requirements, potentially delaying EU market entry.

The EU and the United States combined hold the vast majority of the global biosimilar market by revenue. However, the EU's relative share is declining as the US market expands rapidly. The US biosimilar market grew from EUR 6.07 billion in 2020 to an estimated EUR 10.1 billion in 2024, while the Asia-Pacific region - driven primarily by China - grew from EUR 1.54 billion to approximately EUR 4.53 billion over the same period[64]. The EU biosimilar market projected to grow at a compound annual growth rate (CAGR) of approximately 17%, increasing from EUR 13.2 billion in 2025 to EUR 62.9 billion by 2035[65] driven primarily by patent expiries and expanding therapeutic applications. The estimated cumulative savings of EUR 75 billion from biosimilar competition since 2006 with EUR 13 billion in 2024 continues to grow. Advances in analytical sciences are expected to further strengthen the scientific consensus that Phase III CES provides limited additional value for well-characterised biosimilars. However, as development shifts toward more complex products (e.g. monoclonal antibodies, bispecific antibodies, antibody–drug conjugates), a proportion of applications will continue to require clinical data, particularly for immunogenicity assessment.

Table 3. Biosimilar MAA pipeline efficiency: submission-to-authorisation outcomes in the EU centralised procedure, 2003–2026 (EMA Medicines Database, extracted 2 March 2026; EMA Annual Report 2024).

	VALUE	SOURCE
Total biosimilar MAAs (2003–2026)	173	EPAR Database
Authorised	151 (87.3%)	EPAR Database
Withdrawn/Refused	22 (12.7%)	EPAR Database
Success rate 2020–2026	92.7% (101/109)	EPAR Database
2024 biosimilar MAAs resolved	27 (25 auth + 2 W/R)	EPAR Database
EMA scientific advice requests 2024	635 (all products)	EMA Annual Report 2024

2.2.6 12-month extension of Supplementary Protection Certificates (SPC) for biotechnology medicine

The EU faces increasing global competition in the field of biotechnology. Patent data, geographic distribution of clinical trials and biologic manufacturing reflect this reality and support the need for urgent action to boost Europe's competitiveness in health biotech through a combined set of regulatory and industrial policy measures. These include the 12-

[64] Precedence Research. (2025, August 13). Biosimilars market size to hit USD 175.99 billion by 2034. https://www.precedenceresearch.com/biosimilars-market

[65] Precedence Research. (11 Mar 2026). Biosimilars Market Size, Share and Trends 2026 to 2035. https://www.precedenceresearch.com/biosimilars-market

month SPC extension, a very attractive and effective patent incentive that extends the IP's effect, thereby providing a very robust shield from competition for the relevant molecule[66].

First, table 4 below shows that the EU accounts for a limited share of global earliest biotech patent filings between 2012–2024, representing around 4% of patent families worldwide. When restricting the analysis to patent families owned by European companies, however, the EU appears more prominent as an early filing location, accounting for around 33% of earliest filings over 2012–2024, while multiple-jurisdiction filings including the EU represent around 39%.

Table 4. Biotech patents in 2012-2024

	All PATSTAT patents	Patents filed by EU-based companies
EU	4%	33%
Multiple (incl. EU)	11%	39%
US	7%	6%
China	60%	3%
All other	17%	20%

***Source**: PATSTAT data, compiled by PPMI group*

Second, the geographical distribution of clinical trials has shifted, with the EU losing ground relative to other regions such as the United States and China. The EU/EEA's share of commercially sponsored clinical trials fell from 22% in 2013 to 12% in 2023, with absolute Phase III commercial trial in the EEA declining from 439 in 2018 to 327 in 2023[67]. This decline is prominent in the biotech segment as well, where, for instance, Europe's share of cell and gene therapy trials went from 25% in 2013 to 10% in 2023 (see problem driver 2.2 for further context).

Third, manufacturing capacity within the EU has expanded over time, as illustrated by the increasing number of manufacturing authorisations and sites recorded in EudraGMDP data[68]. The table below shows a marked increase in manufacturing authorisations, particularly in recent years, with strong growth in both the number of sites and the number of organisations involved.

Table 5. Annual authorised biological manufacturing footprint in the EU (2012-2025)

Year	New MIAs (flow)	New sites (LOC IDs)	New organisations (ORG IDs)
2012	6	6	6
2013	6	4	4
2014	16	10	10
2015	14	8	7

[66] Max Planck Institute for Innovation and Competition (2018), Study on the Legal Aspects of Supplementary Protection Certificates in the EU.

[67] IQVIA. (2024). Assessing the clinical trial ecosystem in Europe: Final report. European Federation of Pharmaceutical Industries and Associations (EFPIA) & Vaccines Europe. https://www.efpia.eu/media/3edpooqp/assessing-the-clinical-trial-ecosystem-in-europe.pdf

[68] Manufacturing investment proxied by regulatory data: Manufacturing and import authorisations (MIAs, i.e. regulatory authorisations issued by national competent authorities allowing the manufacture or import of medicinal products or active substances in the EU) and biological manufacturing sites, as recorded in the EudraGMDP database for biological medicinal products, are used as proxies for manufacturing footprint in the EU. These indicators capture the presence and location of investment but not production volumes or economic value, within globally integrated value chains.

2016	18	11	11
2017	10	4	4
2018	13	5	5
2019	17	10	10
2020	15	9	9
2021	30	19	18
2022	55	43	42
2023	77	70	64
2024	158	138	128
2025	192	174	148
Total	624	511	466

***Source**: EudraGMDP data; compiled by PPMI group*

While such data point at a positive trend for manufacturing in the EU, it is key to consider the evolving global context. Asia is emerging as a major competitor not only in the production of generics and active pharmaceutical ingredients, but also in the manufacturing of complex biologics and innovative biotechnology products. A recent study by McKinsey describes Asia as "the emerging epicentre" of global biopharmaceutical activity, noting that the region has expanded its share of the global innovative medicines pipeline from 28% to 43% within five years, surpassing both Europe and the United States.[69]

Given the current competitive international environment in which various jurisdictions are actively enhancing their appeal to innovators—it is essential that the EU provides a clear signal of its commitment to support innovation and attract health biotech investments in research, development and manufacturing.

2.2.7 Food and feed products and other food chain inputs

Union law requires pre-market authorisations/approvals for several categories of food and feed products and related food chain inputs – the so-called 'regulated products'[70]. In those cases, the European Food Safety Authority (EFSA) must conduct a scientific risk assessment under the applicable sectoral legislation before risk managers at EU and/or national level decide upon granting a pre-market authorisation/approval. To this end, applicants must comply with the specific procedural requirements set out in the relevant sectoral legislation and with certain general provisions set out in the General Food Law Regulation[71] (GFL) as regards the pre-submission and validation phases. Delays have been observed in both validation and risk assessment phases. Two main regulatory drivers have been identified for those delays:

(i) Dossier deficiencies and limited effectiveness of pre-submission advice

In the context of the risk assessment of regulated products, and when application dossiers are incomplete or insufficiently substantiated), EFSA requests additional information or data from applicants either in the context of the validation process or during the risk

[69]https://www.mckinsey.com/industries/life-sciences/our-insights/the-emerging-epicenter-asias-role-in-biopharmas-future?utm_source=chatgpt.com

[70] E.g. substances used in food and feed (such as additives, enzymes, flavourings, and nutrient sources), novel foods, food contact materials, genetically modified organisms, plant protection products etc.

[71] Regulation (EC) No 178/2002, OJ L 31, 1.2.2002, pp. 1–24. ELI: http://data.europa.eu/eli/reg/2002/178/oj.

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assessment process. These iterative exchanges interrupt the overall process and contribute to prolonged timelines before an authorisation is decided upon.

Although the General Pre-Submission Advice (GPSA) and Renewal Pre-Submission Advice (RPSA)[72] were introduced in 2021 to improve dossier quality, their uptake by applicants and their effectiveness have been limited. The scope of GPSA has been perceived as too narrow, as it cannot include advice on technical/scientific issues, *e.g.* on study design, to fulfil data requirements and/or testing strategies. GPSA is therefore less attractive for potential applicants, especially for SMEs and start-ups who request new authorisations, reducing the potential for improving the quality of the application dossiers. In a similar vein, the uptake of RPSA has been of limited use and value as applicants of renewals are largely familiar with the application process and do not particularly need support from EFSA at pre-submission phase. Moreover, the applicable pre-conditions for RPSA combined with the absence of any procedural penalties for the non-notification of intended studies, exacerbate the low uptake of RPSA.[73]

The uptake of pre-submission advice mechanisms has been limited and therefore their potential for reducing subsequent delays at validation and risk assessment phases by improving dossier quality has yet to materialise, contributing to persisting delays linked with subsequent requests for additional data and subsequently to delays to 'time to market'.[74] Long risk assessment periods reduce regulatory predictability in a sector characterised by rapid technological development and significant R&D investment. This may discourage investment especially for SMEs, delay scale-up and limit the commercialisation of biotechnology-based food and feed solutions and other related inputs within the Union.

(ii) Procedural consequences linked to study notification requirements

Since 2021, additional delays have arisen, following non-compliance with the obligation to notify commissioned studies during the pre-submission phase and the imposition of procedural consequences (Article 32b GFL), in which case applications are declared non-valid and resubmitted applications are subject to a six-month delay before validation.[75] Between 2021 and 2024, 47 applications were deemed non-valid on this basis, predominantly in the novel food sector.[76] In certain cases, the combination of extended

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[72] GPSA is provided by EFSA, upon request to all applicants (both for new authorisations/approvals and for renewals) at pre-submission phase; this advice is limited by law on the applicable legal framework and the content for an application. RPSA is only available to applicants for renewals of existing authorisations/approvals subject to a notification of intended studies to EFSA, including information on how such studies will be carried out to ensure compliance with regulatory requirements, and following a public consultation carried out by EFSA on the intended studies. This advice can also cover scientific aspects (e.g. studies design).

[73] Intellera, Ipsos, Tetra Tech, *Study supporting the Evaluation of the European Food Safety Authority 2017-2024*, pp. 51-5292, 154-155 (forthcoming).

[74] *Id.*

[75] Article 32b of GFL requires applicants of regulated products to notify EFSA during the pre-submission phase of any studies once they are commissioned, without delay, with a view to support a future application dossier. The purpose of this requirement is to ensure that EFSA is aware of all studies performed including those that may result in unfavourable outcomes. In case an unjustified non-compliance with the notification requirement is detected when an application is submitted, the application is considered non-valid; applicants can resubmit, but the validation process may only be initiated six months after the non-compliance is addressed.

[76] Intellera, Ipsos, Tetra Tech, *Study supporting the Evaluation of the European Food Safety Authority 2017-2024* (forthcoming)

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validation exchanges and the imposition of the procedural consequences have resulted in significant postponements in confirming application validity.

(iii) Governance constraints relating to Scientific Committee/Scientific Panels

The current configuration of EFSA's Panel-based governance model, consisting of eleven Panels and one Scientific Committee[77] and operating autonomously without reporting to EFSA's management, has ensured scientific independence and has leveraged dedicated experts to provide advice of high scientific excellence. Nevertheless, the lack of flexibility in the governance model (*e.g.* Panel chairs/vice chairs are reserved only for experts) constrained by provisions in the General Food Law and in other rules and procedures, restricts EFSA's ability to keep its risk assessment work both swift, coherent, timely and fit for purpose.[78]

(iv) Limited regulatory flexibility in a context of rapid technological advancement

The food and feed sector is experiencing rapid technological advancements, including in areas such as biotechnology, AI, smart farming techniques and circular economy practices promoting resource efficiency and waste reduction. Public consultation activities carried out in the context of the European Innovation Act[79] indicate broad, cross-sectoral support for the use of regulatory sandboxes as a tool to facilitate innovation while maintaining appropriate safeguards. In this context, there is a growing recognition among stakeholders and Member States of the potential added value of a more coordinated approach at Union level. In the absence of a coordinated framework, innovative solutions may face regulatory uncertainty and fragmentation when attempting to fit within existing authorisation procedures. This may lead to delays in innovative approaches to product development, particularly in areas characterised by rapid technological advancement. Furthermore, the current framework provides limited structured opportunities to test alternative data requirements, such as new methodological approaches instead of animal testing – and/or alternative regulatory requirements such as digital labelling instead of physical labelling affixed on food products.

Taken together, dossier deficiencies, limited effectiveness of existing pre-submission procedures, rigid procedural consequences relating to non-compliances at pre-submission phase, governance constraints and the limited availability of harmonised regulatory sandboxes create procedural complexity that slows the authorisation process and delays market entry of regulated food and feed products and other food chain inputs.

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[77] The members of the Panels/Scientific Committee are appointed for a fixed term and act in their personal capacity (experts). They are supported by EFSA staff, specialised Working Groups, and external contractors. The Scientific Committee, as the highest-ranking group compared with the Panels, promotes consistency and harmonisation in assessment methods across the Panels.

[78] Intellera, Ipsos, Tetra Tech, *Study supporting the Evaluation of the European Food Safety Authority 2017-2024* (forthcoming)

[79] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14593-European-Innovation-Act/public-consultation_en

Taken together, these patterns show that the EU's competitiveness gap in biotech is not primarily a science deficit, but a translation and scale-up deficit shaped by long, uncertain and capital-intensive pathways from research to market.

2.2.8 Organs[80]

The existing regulatory framework

Organ transplantation is among the highest-value therapeutic interventions available in modern medicine. For patients with end-stage organ failure, transplantation is frequently the only curative option. In the case of kidney failure, organ transplantation is also substantially more cost-effective in the long term than chronic dialysis. In 2024, over 32,000 organ transplants were performed across the EU, comprising 19,170 kidney transplants, 8,015 liver transplants, 2,416 heart transplants, 2,221 lung transplants, 525 pancreas transplants, and smaller numbers of small bowel and vascularised composite tissue (hand, face) procedures. Despite this activity, a persistent and widening gap between the supply of transplantable organs and clinical demand remains as of 31 December 2024, over 52,000 patients were registered on transplant waiting lists across the EU. [81]

Directive 2010/53/EU establishes common quality and safety standards for human organs intended for transplantation across the EU, setting minimum requirements applicable throughout the entire chain from donation to transplantation (i.e., donation, testing, characterisation, procurement, preservation, transport, and transplantation of organs). This framework is complemented by technical guidance from the European Directorate for the Quality of Medicines and HealthCare (EDQM) and by binding international principles (equitable access, the prohibition of financial gain from organs and tissues of human origin, and consent requirements for donation)[82], as well as EU rules on cross border information exchange (Directive 2012/25/EU[83]).

The technological transformation

Since the adoption of Directive 2010/53/EU, the field of organ transplantation has undergone a profound technological transformation that has altered the nature of what happens to an organ between its procurement from a donor and its transplantation into a recipient.

The traditional approach to organ handling, and the one implicitly assumed by the Directive when it was drafted, is static cold storage (SCS). Under this method, a procured organ is flushed with a cold preservation solution, packed in ice, and transported to the recipient hospital as quickly as possible. SCS slows cellular deterioration by cooling the organ to approximately 4°C, but it buys only limited time before ischaemia-reperfusion

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[80] Analysis largely based on Rapid Assessment Scenario Study - forthcoming

[81] SANTE-SoHO/D2 - European Commission. (2026). *Introducing "organ processing" into directive 2010/53/EU* [Unpublished slideshow].

[82] under the Council of Europe Convention on Human Rights and Biomedicine (ETS No. 164), with its Additional Protocol Concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186)

[83] European Commission. (2012). *Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation.* https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0025&from=EN

injury renders the organ unsuitable. These narrow time windows constrain the geographical reach of organ exchange, creating intense pressure on surgical teams. This means that organs from so-called “marginal” or “expanded criteria” donors (i.e., organs that are not in ideal condition but could still be clinically useful) are frequently discarded because there is insufficient time to assess or rehabilitate them.

Ex-vivo machine perfusion represents a different paradigm. Rather than passively preserving an organ on ice, ex-vivo machine perfusion places it on a device that continuously pumps an oxygenated, nutrient-rich perfusate through its vasculature, maintaining the organ in a metabolically active, near-physiological state outside the body. Machine perfusion can be performed under hypothermic conditions (1–8°C), subnormothermic conditions (typically 20-35°C), or normothermic conditions (34-38°C, essentially body temperature). The clinical consequence is transformative: ischaemia time constraints are dramatically relaxed, the organ’s function can be assessed in real time, and, for regulatory purposes, the extended ex-vivo window opens the possibility for active interventions on the organ.

These interventions go well beyond mere preservation. They include reconditioning damaged organs (e.g., reducing fat content in steatotic livers through defatting protocols during normothermic perfusion), administering pharmacological therapies directly to the organ (such as chemotherapy to treat cancer cells, antibiotics to clear infections, or anti-inflammatory agents to reduce ischaemia-reperfusion injury), performing surgical procedures on the organ while it is on the perfusion machine (e.g., ex-vivo tumour resection from a liver), and even delivering gene therapies via viral vectors in the perfusate. Taken together, these activities constitute what the proposed legislation terms “processing”: active operations designed to maintain or improve the functional status of an organ prior to transplantation. They transform the organ from a passively preserved specimen into one that is actively managed, assessed, and improved during the ex-vivo period.

The most established clinical application of EVMP is ex-vivo lung perfusion (EVLP), first introduced clinically in 2001 and now widely adopted in major transplantation centres across Europe and globally. Machine perfusion for kidneys, livers, and hearts has similarly progressed from experimental to routine or near-routine clinical use in leading centres. As a result, the global organ preservation market is expanding rapidly, driven by increasing adoption of perfusion machines.

Problem definition specific to this area of intervention

The central problem that the proposed amendments seek to address is that the regulatory framework established by the Directive has been overtaken by clinical and technological practice. The Directive was designed for an era in which the primary ex-vivo activity was preservation. Thus, it contains no provisions for authorising, overseeing, or ensuring the quality and safety of the active processing operations that are now being performed routinely in transplantation centres across the EU. This regulatory gap gives rise to a series of interconnected problems.

Legal uncertainty and absence of a dedicated authorisation framework

Directive 2010/53/EU, as currently in force, refers to "preservation" in its scope provision (Article 2(1)) and in its definitions (Article 3(l)), but it contains no reference to "processing." It has no framework for authorising processing operations, no mechanism for benefit-risk assessment of these interventions, and no provisions requiring transplantation centres to seek prior approval before applying a specific processing technique.

This absence of legal clarity generates uncertainty for all actors in the transplantation chain. Transplantation centres lack a clear legal framework for the processing activities they perform, making it difficult to establish uniform standards, allocate responsibilities, or demonstrate compliance. Competent authorities have no EU-level mandate or guidance for overseeing these operations. Pharmaceutical and medical device companies face regulatory ambiguity regarding the use of their products in the novel context of ex-vivo organ treatment, a context in which the patient (the organ recipient) is not the direct subject of the pharmacological intervention, but the organ is. The risk of different national regulatory approaches would bring a significant barrier for cross border exchange of organs, which is essential to optimize the donor/organ-recipient matching and the consequent transplant outcome.

Patient safety risks from unregulated processing

Organ processing, precisely because it involves active intervention on the organ, introduces new categories of risks that are not captured by the existing quality and safety framework. The administration of drugs to an organ during perfusion, the performance of surgery on an organ outside the body, or the use of biological agents in perfusates all carry the potential for adverse effects on the organ and, ultimately, on the transplant recipient. Without a systematic authorisation mechanism requiring benefit-risk assessment before processing operations are applied, there is no structured safeguard ensuring that these risks are identified, evaluated, and managed. The Directive's existing serious adverse event and reaction (SAE/SAR) reporting system (Article 11) was designed for the traditional donation-to-transplantation chain and does not specifically address risks attributable to processing operations.

Organ processing techniques also vary significantly in their maturity and evidentiary base, ranging from well-established hypothermic machine perfusion of kidneys to highly experimental ex-vivo gene therapy. The absence of a tiered regulatory approach, one that distinguishes between well-evidenced and novel processing techniques and calibrates oversight, accordingly, means that in practice both established and experimental interventions are, at the EU level, equally unregulated.

Fragmentation across Member States

In the absence of EU-level rules on organ processing, Member States have been left to develop their own approaches, or, in other cases, to not develop any specific framework at all. Some Member States have begun to address organ processing within their national transplant legislation or through administrative guidance from their competent authorities; others left processing activities to occur under the general authority of the transplantation

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centres themselves without specific regulatory oversight. This patchwork creates divergent standards across the EU, with direct implications for the need for cross-border exchange of organs that the Directive was originally adopted to facilitate.

When a processed organ crosses a national border, the receiving centre and competent authority currently have no common EU standard against which to assess the safety and quality of the processing that was performed. This could over time create *de facto* barriers to the cross-border exchange of organs within the EU. Over the last three years, the cross-border exchange rate of allocated organs fluctuated between 20-23%[84]. European organ exchange organisations such as Eurotransplant and Scandiatransplant, which coordinate allocation across multiple Member States, noted particular difficulties in the absence of harmonised processing standards.

Cross-framework coordination gaps

Organ processing is inherently a multi-regulatory-domain activity. A single processing operation may simultaneously involve a medical device (the perfusion machine, regulated under Regulation (EU) 2017/745), a medicinal product (a drug administered to the organ, regulated under Directive 2001/83/EC or Regulation (EC) No 726/2004), and a substance of human origin (blood products in the perfusate, regulated under Regulation (EU) 2024/1938). The current Directive 2010/53/EU contains no mechanism for coordination between the organ transplant competent authority and the competent authorities operating under these other legislative frameworks. As a result, valuable clinical outcome data generated from the use of medicinal products or devices in the novel context of ex-vivo organ treatment may be lost between regulatory silos. For instance, when a chemotherapy agent is used to treat cancer cells in a liver during perfusion, the outcome data is relevant both to the transplant authority (was the organ safe and effective?) and to the pharmaceutical authority (how did the drug perform in this unprecedented application?). Without a legal obligation to share and coordinate this data, neither authority has a complete picture. Furthermore, it necessarily to trial a medicinal product or medical device in the transplant setting, to have the engagement of the organ authorities with whom protocols are to be developed on which organs can and will be made subject to the trial, avoiding putting fully functional organs at risk while aiming to improve and recover less functional organs.

Furthermore, the recently adopted SoHO Regulation (EU) 2024/1938[85] has introduced a comprehensive SoHO Preparation Authorisation model based on benefit-risk assessment and clinical outcome monitoring. Solid organs are explicitly excluded from the scope of this Regulation. Yet the processing techniques being applied to organs are often analogous to those applied to tissues and cells and may involve the same types of products and substances. The absence of an equivalent authorisation mechanism within the organ Directive creates an asymmetry in the EU's regulatory architecture for substances of human origin, where tissues and cells are subject to a modern, risk-based authorisation

[84] See Rapid Assessment Scenario Study

[85] Consolidated text: Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC. ELI: http://data.europa.eu/eli/reg/2024/1938/2024-07-17

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system while organ processing remains entirely outside any EU-level authorisation framework.

Barriers to innovation uptake and equitable access

The regulatory vacuum does not only affect patients, but it also acts as a brake on innovation and contributes to inequitable access to advanced transplantation technologies. In the absence of a clear, harmonised EU framework for authorising organ processing, transplantation centres in Member States with less developed regulatory capacity, or in countries that have not established any national processing oversight regime, may be reluctant to adopt new processing technologies. This creates the risk of a two-tier system in which patients in some Member States benefit from organs improved through advanced processing while patients in others continue to rely on static cold storage alone.

The broader economic and competitive implications are also relevant. Many of the most advanced organ processing technologies are fundamentally biotechnological in nature: ex-vivo gene therapy delivered through machine perfusion, the use of bioengineered perfusates, and AI-driven perfusion assessment systems all sit at the intersection of biotechnology and transplantation. Many of the new technologies are developed by academia and spin-offs, while several SMEs are offering these processing technologies to transplant systems. Without regulatory clarity and a transparent authorisation pathway, developers or providers of these technologies face uncertain market conditions, which may deter investment and delay the clinical translation of innovations that could expand the pool of transplantable organs.

Problem drivers

The problems identified above share a common origin: the Directive was drafted and later adopted in 2010 on the basis of the then-prevailing clinical paradigm, in which the ex-vivo handling of organs was essentially limited to passive cold preservation. At that time, the legislative choice to include “preservation” but not “processing” in the Directive’s scope was reflecting the state of the art. Machine perfusion existed in experimental form, but its clinical deployment was limited and the prospect of routine ex-vivo organ treatment was still largely theoretical.

Over the subsequent fifteen years, the technology matured faster than the legislative framework evolved. Three principal drivers underpin the current regulatory gap. First, the **pace of clinical and technological innovation** in ex-vivo organ management has accelerated dramatically, with machine perfusion transitioning from experimental to routine or near-routine use in major centres across Europe. The technology has also shifted qualitatively, from simple hypothermic perfusion (which is functionally closer to preservation) to normothermic perfusion and active organ treatment (which are clearly beyond the concept of preservation). Second, the **original legislative design** chose a Directive as its instrument type, establishing minimum standards that Member States transpose into national law. While this approach provided flexibility, it also meant that the resulting national divergences in approach to transplantation and processing were not counterbalanced by common EU rules. Third, the **absence of a legislative review mechanism** capable of responding to technological change within the Directive itself meant that the framework could not self-correct. Unlike some other EU health legislation,

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Directive 2010/53/EU did not include a built-in mandate for periodic review or adaptation to scientific and technical progress, contributing to the widening gap between law and practice.

Furthermore, the GAPP Joint Action, which brought together competent authorities from 17 European countries to develop a common approach to the authorisation of preparation processes for substances of human origin. The organ processing authorisation model proposed in new Article 6a of the Directive 2010/53/EU is modelled on the SoHO Preparation Authorisation framework that emerged from this work and was subsequently codified in Regulation (EU) 2024/1938.[86] This lineage is significant: it means the proposed regulatory model is not an untested construction but rather an adaptation of a framework that has been developed, piloted, and validated through extensive multi-country collaboration in the closely related SoHO sector.

Scope of the problem

The regulatory gap identified above affects multiple categories of stakeholders. **Transplantation centres** are the primary operators of organ processing technologies and bear the most immediate consequences of the legal uncertainty, as they perform these activities without a clear EU-level legal or authorisation framework. **National competent authorities** designated under the Directive lack the EU mandate, tools, and in many cases the technical capacity to oversee processing activities, even as these activities become increasingly common within their jurisdictions. **Pharmaceutical and medical device companies** developing and marketing products and services for organ processing face an ambiguous market environment in which the regulatory pathway for their products in this novel application is unclear. **European organ exchange organisations** such as Eurotransplant and Scandiatransplant, which coordinate cross-border organ allocation, confront the practical challenge of managing organs that have been processed under divergent national regimes.

Ultimately, however, the most significant affected group is **patients**, both those on transplant waiting lists and those who receive transplants. The 52,488 patients on EU waiting lists at end-2024 stand to benefit from any regulatory intervention that safely expands the pool of transplantable organs by enabling the rehabilitation of marginal organs through processing. Conversely, they are at **risk from both the absence of processing oversight** (unregulated processing may introduce undetected safety risks) and **from the uneven uptake of processing technologies across Member States** (which may result in inequitable access to the benefits of organ processing depending on where a patient lives).

[86] See proposed Article 6a of the amended Directive 2010/53/EU, in COM(2025) 1031 final, Article 2.

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ANNEX 6: OVERVIEW OF THE PROPOSED MEASURES AND ARTICLES OF THE PROPOSED REGULATION AND DIRECTIVE

No.	Policy intervention	Policy measure(s)	Covered provision(s)	Simplifi-cation measure	New policy intervention
Strategic projects and clusters, incl. biosimilars					
1	**Recognition and support of strategic health biotechnology projects**	Support package for strategic health biotechnology projects	**Chapter II, Section 1:** Art. 3: Health biotechnology strategic projects ; Art. 7: Designation of competent authority ; Art. 8: Application for recognition ; Art. 9: Recognition by Member States **Chapter II, Section 2:** Art. 11: Single points of contact ; Art. 12: Priority status; Art. 13: Administrative support ; Art. 14: Financial and technical support **Chapter IX**: Art. 60: Amendments to Regulation (EU) 2024/795 (STEP) - projects deemed to contribute to STEP objectives **Recitals** (12)-(14), (27)-(30), (54)-(56)		X
2	**Recognition and support of high impact strategic health biotechnology projects**	Support package for high impact strategic health biotechnology projects, including for 'biotechnology development accelerators' and 'centres of excellence for advanced therapies'	**Chapter II, Section 1:** Art. 4: High impact health biotechnology strategic projects; Art. 5: Biotechnology development accelerators ;Art. 6: Centres of excellence for advanced therapies; Art. 7: Designation of competent authority; Art. 8: Application for recognition ; Art. 10: Recognition by the Commission **Chapter II, Section 2** : Art. 11: Single points of contact; Art. 12: Priority status; Art. 13: Administrative support ; Art. 14: Financial and technical support **Chapter IX** - Amendments: Art. 60: Amendments to Regulation (EU) 2024/795 (STEP) - projects deemed to contribute to STEP objectives **Recitals** (14)-(16), (24), (52)-(56)		X

3	**Health biotechnology ecosystem support framework**	Networks of health biotechnology clusters	**Chapter II, Section 2:** Art. 15: Networks of health biotechnology clusters **Recitals** (25)-(26)		X
		EU Health Biotechnology Support Network	**Chapter II, Section 4:** Art. 19: EU Health Biotechnology Support Network; Art. 20: European Health Biotechnology Steering Group **Chapter VII, Section 1**: Art. 34: Support to biotechnology developers **Recitals** (33)		X
4	**Biosimilars competitiveness framework**	Guidance on a tailored regulatory approach for the development of biosimilars	**Chapter V**: Art. 28: Guidance by the Agency on biosimilars **Recitals** (58)		X
		Support package for biotechnology health strategic projects for biosimilars	**Chapter V:** Art. 29: Biotechnology health strategic projects for biosimilars (specific criteria); Art. 30: International partnerships **Chapter II, Section 2** (Articles 11-14): Support measures apply **Recitals** (59)-(60)		X
Time-to-market					
5	**Regulation of novel health biotechnology products**	Union regulatory status repository and time limits	**Chapter VII, Section 1:** Art. 35: Union regulatory status repository; Art. 36: Time limits in the regulatory status process **Recitals** (72)-(74)	X	
		Foresight Panel for Emerging Health Innovation	**Chapter VII, Section 2:** Art. 37: Foresight Panel for Emerging Health Innovation (establishment, tasks, composition); Art. 38: Support to the Foresight Panel **Recitals** (75)-(78)		X

		Cross-framework coordination for regulatory sandboxes	**Chapter VII, Section 3:** Art. 39(1): Member State-level sandbox consultations; Art. 39(2): Union-level sandbox consultations; Art. 39(3): Combination products considerations; Art. 39(4): Swift contribution requirements Art. 39(5): Cross-framework knowledge sharing and regulatory learning **Recitals** (80)-(82)		X
		Regulatory sandboxes for novel health biotechnology products	**Chapter VII, Section 3**: Art. 40(1): Scope and eligibility criteria; Art. 40(2): Time-limited framework for evidence generation; Art. 40(3): Application requirements; Art. 40(4): Commission implementing act for establishment; Art. 40(5): Sandbox plan requirements; Art. 40(6): Consultations with Agency, SCB, Medical Devices Coordination Group, Foresight Panel ; Art. 40(7): Participant liability; Art. 40(8)-(9): Recommendations and lessons learned **Recitals** (83)-(87)		X
6	**Targeted regulatory reform of the General Food Law - (EC) No 178/2002**	Streamlined EFSA risk assessment processes	**Chapter IX**, Art. 56 (Amendments to Regulation (EC) No 178/2002): Art. 56(1): Art. 3 (new definitions – points 19-21); Art. 56(2): Art. 22(5)(a) (EFSA nutrition mandate); Art. 56(3): Art. 28(3), (6), (9) (Scientific Panel governance); Art. 56(4): Art. 32a(1) (enhanced pre-submission advice); Art. 56(5): Art. 32b(4), (5), (6) (shortened procedural timelines); Art. 56(6): Art. 32c(1) deletion (merger of consultation procedures) **Recitals** (107)-(112)	X	
		Regulatory sandboxes framework for food, feed and GMOs	**Chapter IX,** Art. 56(7) (insertion of new Chapter IIIA in Regulation (EC) No 178/2002): Art. 49a: General provisions on regulatory sandboxes; Art. 49b: Establishment of regulatory sandboxes; Art. 49c: Other responsibilities, monitoring and reporting obligations; **Recitals** (113)-(116)		X

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7	**Targeted regulatory reform of the Advanced Therapy Medicinal Products (ATMPs) framework - (EC) No 1394/2007**	Regulatory simplification and future-proofing of ATMPs	**Chapter IX,** Article 57: Amendment to Art. 2(1): Addition of point (e); Amendment to Art. 2: Addition of paragraph 6; New Art. 4a (paragraphs 1-5); Replacement of Art. 25a (paragraphs 1-6) **Recitals** (118)-(120)	X	
8	**Targeted regulatory reform of clinical trials - Regulation (EU) No 536/2014**	Accelerated and streamlined clinical trial authorisation procedures	**Chapter IX,** Art. 58: Art. 2: Definitions (points 3, 3a, 12, 13, 13a, 21, 36-43, 47) ; Art. 3: General principles Art. 4-5: Prior authorisation and submission ; Art. 5a-5b (new): RMS appointment and validation ; Art. 6-8: Assessment reports and decision (including translation adequacy assessment in Part II); Art. 14: Extension to additional Member States ; Art. 14a (new): Appointment of new RMS ; Art. 14b (new): Accelerated procedure for public health emergencies ; Art. 17-21: Substantial modifications ; Art. 25: Mandatory EU-templates for **Part II;** Art. 63a (new): Harmonised GDP for investigational medicinal products; Art. 28, 30-33, 41: Supporting provisions **Recitals** (123)-(139)	X	
		Clinical trial regulatory sandboxes	**Chapter IX**, Art. 58: Art. 2(45) (new): Definition of regulatory sandbox; Art. 27d (new): Clinical trial regulatory sandboxes; Art. 85(5)(i): CTAG task to provide sandbox recommendations **Recital** (149)		X

		Digital innovation and harmonised data governance for clinical trials	**Chapter IX,** Art. 58: Art. 2(44) (new): Definition of combined study ; Art. 2(46) (new): Definition of AI system Art. 14c (new): Combined studies (coordinated assessment) ; Art. 27e (new): Use of AI in clinical trials Art. 29: Informed consent (electronic provisions) ; Art. 81: EU database updates ; Art. 83a (new): Authority coordination ; Art. 85: CTAG (expanded mandate) ; Art. 93 (new): Data protection (harmonised GDPR basis) Art. 98a (new): EU Portal development plan ; Annex I amendments **Recitals** (140)-(148), (150)-(156)	X	
		Coordinated assessment for combined studies	**Chapter IX,** Art. 58: Art. 14c(1): Scope (clinical trials combined with IVD performance studies or medical device clinical investigations) ; Art. 14c(2): Single application submission; Art. 14c(3): EU Portal submission and coordinating sponsor designation; Art. 14c(4): Coordinated assessment under reporting Member State direction; Art. 14c(5): Assessment scope and permitted considerations; Art. 14c(6)-(7): Mutual recognition and grounds for disagreement; Art. 14c(8): Single decision by each Member State; Art. 14c(9)-(10): Commission delegated acts for streamlined procedures. **Recital** (135)	X	
		Governance and enforcement framework	**Chapter IX,** Art. 58: Art. 78(1): National competent authority inspections and supervision system; Art. 78(6): Inspection reports via EU Portal; Art. 78(8)-(9): Joint inspections and delegation of inspections; Art. 79: Commission Union controls; Art. 79a: Member State obligations regarding Union controls; Art. 83(1): National contact points for implementation; Art. 83(2): Powers, personnel, resources and expertise requirements; Art. 83a(1)-(2): Coordination between competent authorities and ethics committees within Member States. **Recitals** (147)-(148)	X	

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9	**Targeted regulatory reform of Veterinary Medicinal Products - Regulation (EU) 2019/6**	GMO exemption and single regulatory pathway for veterinary medicinal products	**Chapter IX**, Art. 59: Recitals (161)-(164) **Amendments to Regulation 2019/6:** Art. 3(3) (new): GMO exemption ('One-Stop-Shop'); Art. 4(46): Definitions (GMO VMPs); Art. 8(5): Deletion; Art. 9(2a) (new), (3), (4): Clinical trials ERA; Art. 28(2): MA examination consultations; Annex II: Technical amendments (as set out in Annex III of BTA)	X	
		Reduction of burden for the handling of variations not requiring assessment (VNRAs)	**Chapter IX,** Art. 59 **Recital** (160) **Amendments to Regulation 2019/6**: Art. 61: Variations procedure (replacement with new paras 1-4)	X	
		Targeted SPC extension for zoonotic biotechnology veterinary medicinal products	**Chapter IX**, Art. 59 **Recital** (166) **Amendments to Regulation 2019/6:** Art. 4(45): Definition; Art. 40a (new): SPC extension for zoonotic biotech VMPs	X	
		Regulatory sandbox for innovative technologies, methods or products related to animal health	**Chapter IX,** Art. 59 **Recitals** (167)-(170): **Amendments to Regulation 2019/6**: Art. 4(47): Definition (regulatory sandbox); Art. 136a (new Chapter IX): Regulatory sandbox		X

10	**Targeted regulatory reform of the substances of human origin (SoHO) framework - Regulation (EU) 2024/1938**	SoHO regulatory sandbox framework	**Chapter IX**, Article 61: Art. 61(1): Amendment to Art. 3 – Addition of definition (60) 'regulatory sandbox' Art. 61(4): New Art. 39a – SoHO regulatory sandboxes (paras 1-13) **Recitals** (171)-(173)		X
		Streamlined SoHO regulatory status consultation procedures	**Chapter IX,** Article 61: Art. 61(2): New Art. 13(3a); Art. 61(3): Amendment to Art. 69(2), first subparagraph **Recital** (171)	X	
11	**Targeted regulatory reform of Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation**	Scope expansion to include organ processing	Amendment to Art. 2(1): Scope expansion; New Art. 3(ka): Definition of 'processing'; Amendment to Art. 3(q): Definition of 'transplantation'	X	
		Organ processing authorisation regime	**New Art. 6a**: Organ processing authorisation (paras 1-12) **Amendment to Annex Part B:** 'Processing' data field	X	
		Cross-border and cross-framework regulatory coherence	**Art. 6a (4)-(8)**: Cross-framework coordination	X	
12	**Regulatory framework for genetically modified micro-organisms (GMMs) in non-food and non-feed**	Specific risk assessment criteria and targeted regulatory requirements for all GMMs	**Amendments to Directive 2001/18/EC:** Tailored GMM risk assessment requirements; Detection method modalities; Unlimited validity of market consents	X	
		Accelerated market authorisation	**Amendments to Directive 2001/18/EC**: Streamlined procedures for low-risk GMMs (delegated act); Low-risk status demonstration requirements (implementing act); PMEM exemption provisions	X	

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		pathway for low-risk GMMs			
Access to capital					
13	**Financing instruments for biotech companies and projects**	EU health biotechnology investment pilot	**Chapter III:** Art. 22: EU health biotechnology investment pilot **Recitals (44)-(49)**		X
		Support package for an EU biotechnology late-stage capital booster pilot projects	**Chapter III:** Art. 23: EU biotechnology late-stage capital booster pilot; Art. 24: Biotechnology as a strategic technology eligible for Union and national financial support; Art. 25: Funding for high impact health biotechnology strategic projects; Art. 26: Coordination of financing **Chapter II, Section 2 (Articles 11-14)**: Support measures apply via Article 4(1)(c) **Recitals** (50)-(56)		X
Intellectual property					
14	**SPC extension for biotechnology medicines**	Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines	**Chapter IV:** Art. 27: Extension of the supplementary protection certificate concerning best-in-class biotechnology medicines developed in the Union **Recital** (57)	X	
AI and data					
15	**AI and data guidance framework for**	EMA guidance on AI and advanced technologies in the medicinal	**Chapter VI**: Art. 31: Guidance on the deployment and use of systems based on advanced technologies, including AI, in the lifecycle of medicinal products **Recitals** (64)-(68)		X

	health biotechnology	product lifecycle (Article 31)			
		Biotechnology testing environments for advanced biotechnology innovations (Article 32)	**Chapter VI:** Art. 32: Biotechnology testing environments for advanced biotechnology innovations **Chapter II:** Art. 4(1)(d): High impact recognition criteria **Chapter II, Section 2 (Articles 11-14):** Support measures apply **Recitals** (69)-(70)		X
		Biotechnology data quality accelerator (Article 33)	**Chapter VI:** Art. 33: Biotechnology data quality accelerator **Chapter II:** Art. 4(1)(d): High impact recognition criteria **Chapter II, Section 2** (Articles 11-14): Support measures apply **Recitals** (69)-(71)		X
Biodefence and biosecurity					
16	**Control and monitoring framework for biotechnology products of concern**	Regulation of biotechnology products of concern	**Chapter VIII, Section 2**: Art. 43: Biotechnology products of concern; Art. 44: Verification of legitimate need Art. 45: Benchtop equipment; Art. 46: Prevention and reporting of biotechnology misuse **Annex I:** Biotechnology products of concern **Recitals** (88)-(100)		X
		Enforcement and monitoring mechanisms	**Chapter VIII, Section 2**: Art. 47: Training and awareness-raising ; Art. 48: National inspection authorities Art. 49: Commission enforcement support and monitoring; Art. 50: Audits; Art. 51: Penalties ; Art. 52: Advisory group on biosecurity ; Art. 53: Biological systemic risk ; Art. 54: Monitoring and guidance ; Art. 55: Coordination on biosecurity and biosafety **Recitals** (99)-(105)		X

17	**Recognition and support of high impact biodefence projects**	Support package for EU biothreat radar high impact health biotechnology strategic projects	**Chapter VIII, Section 1**: Art. 41: EU Biothreat Radar **Chapter II**: Art. 4(1)(e): High impact recognition criteria **Chapter II, Section 2** (Articles 11-14): Support measures apply **Recitals** (86)-(87)		X

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ANNEX 7: ADDITIONAL INFORMATION ON MEASURES AND EXPECTED IMPACTS

This annex provides additional analytical detail supporting the assessment of expected impacts of the interventions, drawing in particular on the *Study to support the rapid assessment of policy scenarios to strengthen innovation and competitiveness in the field of biotechnology in the EU*[87]. It complements the summary assessment in Section 5 of this staff working document by further elaborating on the design of the measures, the baseline, the impact transmission channels, the assumptions underpinning the assessment, potential caveats and limitations – as appropriate for each intervention area. It further provides the scientific and technical basis for the proposed measures in some areas.

More information is available in the support study (forthcoming), including the assumptions made.

1 INTERVENTION N°2: TARGETED REGULATORY REFORM OF THE GENERAL FOOD LAW

1.1 Baseline and counterfactual scenario

Conduct of business

Under the baseline, and in order to ensure a high level of protection of public health, animal health, plant health and – where relevant – the environment, **pre-market authorisations for certain categories of food, feed and inputs to the food chain will continue to apply** with the specific procedural requirements set out in the sectoral legislations and read together, where relevant, with the General Food Law. Authorisation procedures will continue to be based on the principle that it is for the applicants to prove that the subject matter of an application complies with EU requirements.[88]

In addition, EU **authorisations will continue to act as a 'regulatory passport'** to the market of third countries, facilitating market access in many non-EU regions (e.g., Latin America, Southeast Asia, Middle East). Third-country authorities often use the EU dossier as a reference or starting point; as such, the studies performed for EU risk assessment purposes and their stringent requirements are still considered by industry stakeholders as an advantage for other markets.[89]

Nevertheless, under the baseline, it is expected that the uptake of pre-submission advice mechanisms will remain limited and will thus not contribute to improve dossier quality.

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[87] Rapid Assessment Scenarios study, forthcoming.

[88] That principle is based on the premise that human health, animal health, plant health and, where relevant, the environment are better protected where the burden of proof is on the applicant since it has to prove that the subject matter of its application is safe prior to its placing on the market, instead of the public authorities having to prove that the subject matter is unsafe in order to be able to ban it from the market. Moreover, public money should not be used to commission costly studies (several thousand to several million Euros) that will eventually help the industry to place a product on the market. This principle remains valid.

[89] The Commission's 2024 evaluation of additives for use in animal nutrition indicates that third-country authorities in Chile, Canada and China reportedly use EU data as a reference in their procedures, and EU authorisation is described as helping to fast-track registrations in parts of Southeast Asia and Africa. See https://food.ec.europa.eu/document/download/e2029994-aa27-49f0-9ab6-18cfa81e29fe_en?filename=animal-feed_additives_eval-legis_reg-2003-429_swd_2024-46.pdf.

As a result, it is expected that delays linked with subsequent requests for additional data and delays to 'time to market' will persist.

Administrative costs on businesses, including SMEs

Based on these characteristics of the existing regulation, the baseline assumes that in the **future businesses will still have to incur certain administrative burdens in order to meet the regulatory requirements in the context of pre-market authorisations for certain categories of food, feed and other inputs to the food chain.** However, these administrative costs could be reduced to some extent if businesses would take advantage of the pre-submission advice mechanisms offered by EFSA under the existing legal framework and the prescribed limitations in terms of scope. Especially, SMEs would benefit from pre-submission advice as they would get a better understanding of the concrete requirements of the authorisation process under the general pre-submission advice. The exclusion of scientific matters from the scope of general pre-submission advice is a structural gap that is expected to continue to result in the low uptake of such advice and thus unnecessary administrative costs arising from poor quality application dossiers on scientific aspects cannot be avoided/minimised. Although both EFSAs[90] and the European Commission[91] has launched measures in recent years to support SMEs, SMEs would continue to be constrained in their efforts to be fully in compliance without incurring unnecessary administrative costs during the authorisation process. This might pose substantial market entry hurdles and result in unexploited innovation potential[92].

Competitiveness, trade and investment flows

Various studies that have been conducted in the past[93] have confirmed that:

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[90] *E.g.* EFSA targeted calls for expressions of interest for SMEs seeking pre-submission advice in the area of novel foods in 2024 and 2025 as well as fast tracking of general pre-submission advice for SMs. See also https://www.efsa.europa.eu/en/applications/about/services/sme.

[91] *E.g.* the Small Business Act for Europe (SBA) in 2008 or the Regulatory Fitness and Performance Programme (REFIT).

[92] See at: https://food.ec.europa.eu/document/download/fcfe7958-72ab-47b6-8b38-0c5473bde0da_en?filename=gfl_fitc_comm_staff_work_doc_2018_part1_en.pdf.

[93] In the context of the REFIT Evaluation of General Food Law (2018), it was found that the systematic application of the risk analysis principle – with EFSA performing the EU risk assessment – across EU food law, provided a comparative advantage for EU manufacturers. For example, foods accompanied by a health claim approved on scientific grounds (EFSA's positive assessment) provides a higher marketing value and create long term consumer trust on the food chain vis-à-vis other unsubstantiated claims on foods in other markets that do not require scientific grounds for their authorisation. See at: https://food.ec.europa.eu/document/download/fcfe7958-72ab-47b6-8b38-0c5473bde0da_en?filename=gfl_fitc_comm_staff_work_doc_2018_part1_en.pdf. This was also confirmed in the 2016 Competitiveness Study performed by DG GROW, to be found at:https://www.gpp.pt/images/Agricultura/Organizacao_da_Producao_e_Cadeia_Alimentar/CompetpositEuropfooddrinkindustFR.pdf; These findings have also been reconfirmed by Intellera et al. (2025): Study supporting the Evaluation of the European Food Safety Authority 2017-2024 (forthcoming).
Similarly, sectoral evaluations of EU legislation regarding pre-market authorisations have reached the same conclusion, see https://food.ec.europa.eu/document/download/e2029994-aa27-49f0-9ab6-18cfa81e29fe_en?filename=animal-feed_additives_eval-legis_reg-2003-429_swd_2024-46.pdf/.
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- the high safety standards set at EU level have also provided incentives to develop more innovative products that better protect public health and have equivalent or better efficacy[94];
- the 'EU seal of approval' (EU pre-market authorisations granted) renders business operators competitive in the international field, as the relevant products are perceived of 'high quality' allowing them to penetrate the market of third countries, where third-country authorities increasingly use the EU dossier as a reference point[95].

It can therefore be assumed that in the upcoming future, **the EU food law will continue to support the European market position of the food chain industry**, and especially the food industry which is the largest manufacturing and employment sector in the EU.

Nevertheless, this **competitive advantage is curtailed by the length of the risk analysis process in certain sectors relating to innovative products** due to delays that are often observed during the risk assessment. These delays are caused by long stop-the-clock procedures, which are mainly attributed to low quality dossiers (see dimension above: administrative costs), and can increase administrative costs, resulting in lost revenues or uncertainty of potential investors[96].

Functioning of the internal market and competition

Under the baseline, it is assumed that the current EU food law legislation will continue to contribute to the functioning of the internal market and competition. Compared with EU legislation before 2002, when the EU food law was a patchwork of vertical legislation[97], the introduction of General Food Law and subsequent EU sectoral legislation provides **a common framework** for the intended integrated approach and ensures that across all Member States uniform food law definitions and principles are applied. This has been confirmed by the 2018 Fitness Check on General Food Law Regulation.[98] One main finding was that the current legislative framework not only achieved its goals for a high level of protection of public health and consumers' interests in relation to food, but also enhanced the functioning of the internal market in the EU by providing a level playing field throughout the EU single market. Furthermore, the current regulation had led to

[94] For example, the removal of plant protection products from the EU market which do not meet the safety criteria set out in the EU legislation have provided incentives for the development of more innovative products that better protect public health and have equivalent or better efficacy. See REFIT Evaluation of General Food Law (2018) at: https://food.ec.europa.eu/document/download/fcfe7958-72ab-47b6-8b38-0c5473bde0da_en?filename=gfl_fitc_comm_staff_work_doc_2018_part1_en.pdf.

[95] Intellera et al. (2025): Study supporting the Evaluation of the European Food Safety Authority 2017-2024 (forthcoming)

[96] REFIT Evaluation of GFL (2018). This finding was recently reconfirmed by Intellera et al. (2025): Study supporting the Evaluation of the European Food Safety Authority 2017-2024 (forthcoming)

[97] For the situation prior to 2002, see REFIT Evaluation of GFL (2018):https://food.ec.europa.eu/horizontal-topics/general-food-law/fitness-check-general-food-law_en.

[98] For more information see: REFIT Evaluation of GFL (2018): https://food.ec.europa.eu/horizontal-topics/general-food-law/fitness-check-general-food-law_en. More specifically see at: https://food.ec.europa.eu/document/download/fcfe7958-72ab-47b6-8b38-0c5473bde0da_en?filename=gfl_fitc_comm_staff_work_doc_2018_part1_en.pdf.

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greater harmonization across the EU compared to EU legislation before that was characterized by complexity, duplication, overlaps and inconsistencies[99].

For instance, the coherence of food law is particularly demonstrated by the systematic application of the risk analysis principle – set out in the General Food Law – in all EU food secondary food legislation (and not limited to food safety), where relevant. Moreover, EFSA's input is not only required for legislation governing feed and food per se, but a more holistic approach has been put in place covering all scientific issues pertinent for the food chain, e.g. plant protection products and food contact materials, promoting coherence of food law in general. At the same time, setting an acceptable level of risk at EU level through a centralised science-based approach (EFSA) results in a higher level of scientific expertise, while preventing the duplication of efforts in Member States in terms of risk assessments and risk management decisions. Moreover, centralised authorisation procedures have resulted **in significant cost savings for Member States**, especially for the smaller Member States that cannot afford to invest in the required scientific capacity. They have also resulted in cost savings **for applicants as they only have to submit a single application dossier instead of multiple national applications.**[100]

Nevertheless, while the current framework ensures a high degree of harmonisation and a level playing field in legal terms, its effectiveness in practice may be constrained by delays in the risk analysis process in certain sectors relating to innovative products. These delays, which are mainly attributed to low quality dossiers and the resulting stop-the-clock procedures and additional requests for information, may slow down the placing of products on the EU market and the speed at which operators can effectively access the internal market. As a result, while the internal market framework is structurally well-functioning, when authorised innovative products are placed on the market, the full benefits of the internal market materialise in practice with certain delays impacting the return on investment for innovative business operators.

Innovation and research

Under the baseline, the **full potential of innovation and research in the food and feed sector, especially regarding start-ups and SMEs, is generally hindered** by the often-observed delays in risk assessment attributed to low quality of application dossiers; these delays have been found to have a negative impact on innovation, in terms of expected return on investment.[101]

This is further exacerbated by the current situation regarding regulatory sandboxes in the EU food and feed area, which is marked by fragmentation and an underuse of their potential in contributing to the development of innovative products and/or a faster

[99]https://food.ec.europa.eu/document/download/fcfe7958-72ab-47b6-8b38-0c5473bde0da_en?filename=gfl_fitc_comm_staff_work_doc_2018_part1_en.pdf

[100] REFIT Evaluation of GFL (2018), see https://food.ec.europa.eu/horizontal-topics/general-food-law/fitness-check-general-food-law_en. This finding was recently reconfirmed by Intellera et al. (2025): Study supporting the Evaluation of the European Food Safety Authority 2017-2024 (forthcoming).

[101] REFIT Evaluation of GFL (2018), see https://food.ec.europa.eu/horizontal-topics/general-food-law/fitness-check-general-food-law_en. This finding was recently reconfirmed by Intellera et al. (2025): Study supporting the Evaluation of the European Food Safety Authority 2017-2024 (forthcoming).

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adaptation of the regulatory framework to emerging needs. A few Member States have put in place sandbox-type mechanisms, but these tend to be horizontal when connected to food and feed law, and not anchored in a clear, harmonised EU framework under the General Food Law.[102] In the public consultation of the proposed European Biotech Act, it was also claimed that the absence of regulatory sandboxes[103] and limited opportunities for real-world testing prevent innovators from gathering essential data and feedback, further slowing the development and scaling of new solutions.[104] Any existing regulatory sandboxes are also not systematically linked to EFSA's scientific work or meant to contribute to an evidence-based proposal for a possible adaptation of regulatory requirements. As a result, **opportunities for structured, supervised experimentation in real conditions** that could facilitate innovation and inform future adaptations of EFSA's guidance (e.g., in relation to data requirements) and/or of regulatory requirements **remain largely missed or underused**.

Public authorities

Under the baseline, it is assumed that EFSA's general pre-submission advice continues to exclude scientific matters such as study design and testing strategies and that there is a separation between the EFSA staff that provide such advice and the EFSA staff that support the Panels during the risk assessment.

EFSA's Panels/Scientific Committees will continue to be chaired by experts while EFSA staff will only be providing support to the Panels/Scientific Committees, by organising their work, including preparatory work. Under the current regulatory framework, national competent authorities do not have the opportunity to test data requirements or alternative regulatory requirements in controlled environments under a clearly defined framework.

Under the baseline, the current structure of European Food Safety Authority's pre-submission advice regime is expected to persist, continuing to affect the quality and efficiency of dossier preparation and assessment, by limiting applicants' ability—particularly SMEs and start-ups—to refine study designs and data-generation strategies in line with EFSA's latest scientific expectations and by increasing administrative effort for EFSA staff at validation and during risk assessment through follow-up requests to address gaps in dossiers, thereby contributing to lengthy risk assessment periods. With regard to the governance of EFSA's Panels, the current model – under which scientific experts chair the Panels/Scientific Committee – has implications for steering, internal coherence across assessments and the overall efficiency of the system. While expert chairs bring strong scientific credibility and ownership of the assessments, their dual role may reduce the scope for more centralised EFSA-level steering of priorities, methods and timelines. This limited institutional steering may, at least indirectly, contribute to heterogeneity in practices and, potentially, to longer or less predictable risk assessment processes. Another

[102] *E.g.* In 2025, Spain launched a broad national innovation sandbox, the 'Agrifoodtech Sandbox', managed by CNTA (EATEX Food Innovation Hub), covering agrifood and biotech.
[103]https://www.cambridge.org/core/journals/european-journal-of-risk-regulation/article/regulatory-sandboxes-for-novel-foods/D8A2B8E29D2F32DE0334DBCE9AF27188
[104] E.g., https://gfieurope.org/wp-content/uploads/2025/11/EU-Biotech-Act-Public-Consultation.pdf

issue is that under the current regulatory framework national competent authorities have very limited scope to test data requirements or alternative regulatory approaches in controlled environments under a clearly defined and commonly agreed framework. While some Member States have started to experiment with regulatory sandboxes, these initiatives tend to be ad hoc, unevenly structured and insufficiently embedded in a broader EU-level governance architecture. As a result, their potential to generate robust evidence, inform adjustments to data requirements, and support innovative risk assessment and risk management approaches is not fully realised, and lessons learned remain fragmented rather than systematically feeding back into the evolution of the EU food safety system.

Public health and safety

Under the baseline, the EU will continue to set high standards on food, feed and other food chain inputs, especially for those subject to pre-market authorisations, and contribute to sustainable development and food safety within and outside the EU, providing incentives for the development of more innovative products that better protect public health and have equivalent or better efficacy (as has been shown, for example, for plant protection products[105]). However, these innovation opportunities cannot be fully exploited due to lengthy risk assessment processes mainly attributed to low quality application dossiers.

The current legislation also faces limitations in addressing the scientific aspects that may arise from the expected increase in the prevalence of diet related health issues in the coming years due to the limited mandate of EFSA to deliver scientific advice in relation to nutrition matters such as the nutritional properties of food products and practices derived from advanced biotechnological processes.

1.2 Expected impacts

Conduct of business

The proposed scope extension of EFSA's general pre-submission advice might help businesses towards **faster market authorisation** by reducing delays during risk assessment but also at the stage of validation of dossiers because of their low quality. The inclusion of scientific aspects, such as study design and testing strategies, in the scope of pre-submission advice may be particularly valuable for SMEs and start-ups, often first and only time applicants, who often lack the understanding what type of requirements they must provide within their dossiers[106]. This should also improve timeliness by facilitating the reduction of deficiencies and data gaps in dossiers that currently trigger delays during the validation process and/or "stop-the-clock" processes during risk assessment. The proposed enhanced general pre-submission advice provided by EFSA, upon request, would remain non-committal (as it is currently the case). It would also not undermine EFSA's independence and accountability since summaries of EFSA's pre-submission advice would

[105] REFIT Evaluation of General Food Law (2018). See https://food.ec.europa.eu/document/download/fcfe7958-72ab-47b6-8b38-0c5473bde0da_en?filename=gfl_fitc_comm_staff_work_doc_2018_part1_en.pdf
[106] https://foodhealthlegal.eu/?p=1380

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continue to be published once a valid application is submitted, ensuring the transparency of the process.

By shortening the procedural delays (penalty) for non-compliance with study notification obligations **from six to three months**, the proposed measures could further contribute to faster time-to-market as delays at pre-submission phase will be further reduced. While keeping highest safety standards through elaborated risk assessments, the proposed instruments may thus make the EU **regulatory framework more innovation-friendly** by supporting businesses in preparing and submitting higher-quality dossiers[107].

The proposed introduction of **regulatory sandboxes** may also have positive impacts for businesses, by enabling them to test new products and processes in a safe, controlled environment before market entry.

Innovation and research

The proposed measure of extending the scope of EFSA's general pre-submission advice might help businesses towards faster market authorisation by reducing delays during risk assessment but also at the stage of validation of dossiers because of their low quality (see dimension: conduct of business). This in turn could foster innovation due to an improved expected return on investment.[108]

Moreover, introducing a regulatory framework for sandboxes would likely change how companies, especially start-ups and SMEs, approach innovation. By allowing them to test technologies, products and substances under controlled conditions at pre-market and pre-authorisation stage, sandboxes would substantially reduce both research and development (R&D) and regulatory risk. Within such sandboxes, real-world testing would also enable much faster learning cycles. Firms could observe how their innovations perform in practice – on safety, quality, usability and acceptance – and adapt their products and processes accordingly. This would shorten development cycles and help viable innovations reach the market more quickly.[109] At the same time, formal sandbox participation, with visible regulatory engagement, could serve as a strong positive signal to investors and industrial partners making it easier for start-ups and SMEs to attract funding and strategic collaborations to support their research and innovation activities.

Nevertheless, the European Biotech Act proposes the exclusion of novel foods from the scope of regulatory sandboxes as such products involve complex scientific considerations, which require thorough oversight. Moreover, experience has shown that certain types of novel foods trigger ethical or cultural concerns among various consumer groups. As such, novel foods were considered less suited to the flexible, experimental nature of sandboxes.

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[107] https://medfilesgroup.com/european-biotech-act/

[108] REFIT Evaluation of GFL (2018), see https://food.ec.europa.eu/horizontal-topics/general-food-law/fitness-check-general-food-law_en. This finding was recently reconfirmed by Intellera et al. (2025): Study supporting the Evaluation of the European Food Safety Authority 2017-2024 (forthcoming)

[109] https://doi.org/10.1080/23311975.2025.2510555

Industry stakeholders consider this decision as a missed opportunity to form an open dialogue that could enhance consumer confidence.[110]

Public authorities

The proposed amendment enlarging the scope of, and streamlining the pre-submission advice mechanism could in this regard simplify administrative work at EFSA as applicants are expected to increase the uptake of such advice and accordingly prepare better quality dossiers and be better informed of the procedural requirements at pre-submission phase, avoiding additional requests for information by EFSA to applicants that may have also a resource cost of EFSA as public authority. This could result in a decrease of time between the submission of an application dossier and its validity assessment as well as the time between validated application dossiers and the delivery of EFSA's scientific output. Furthermore, such simplification could also lead to more compliance during the whole process from application to authorisation and lead to a reduction of stop-the-clock procedures. Hence, a possible impact could be the decrease in number of stop-the-clock incidents, freeing EFSA's resources that can be effectively focusing on supporting the work of the Panels/Scientific Committee and their Working Groups, including the preparation of scientific opinions and/or redeployed at pre-submission phase.

In addition, allowing experts but also EFSA staff supporting the Panels/Scientific Committee and their Working Groups in the risk assessment phase to also be involved in the provision of pre-submission advice will help to ensure alignment of that advice with evolving scientific practice and thereby contribute to higher-quality, more targeted application dossiers. The same effect is expected through the extension of the pre-submission advice to scientific matters. It is also expected that through the expanded scope of the pre-submission advice additional EFSA staff would be needed; in that respect, additional resources are foreseen for supporting EFSA in this task. Finally, adjusting the scientific panel governance has the potential to strengthen the coherence as EFSA staff would chair these panels to ensure synergies related to the use of methodologies and risk assessment approaches in a consistent and efficient manner.

Considering the introduction of **regulatory sandboxes**, it can be assumed that these experimental environments could lead to the collection of evidence that could support a faster adaptation of data requirements, especially when those are set out in EFSA guidances without jeopardising a high level of protection of public health and while ensuring the excellence of EFSA's scientific outputs. That is all the more the case since EFSA can participate in those regulatory sandboxes together with other agencies promoting also further coherence and more on-spot outcomes. In addition to positive impacts for businesses that have been described above, EFSA staff and public authorities in Member States could benefit from structured regulatory learning through sandboxes (see next impact dimension: public health and safety).

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[110] https://www.foodbev.com/news/eu-biotech-act-s-exclusion-of-novel-foods-from-regulatory-sandbox-is-a-missed-opportunity-for-food

Public health and safety

The targeted amendments to improve timeliness and coherence of EFSA risk assessment may foster the development and the placing on the EU market of innovative products that not only meet the high food safety standards set out in EU food law, but it may also provide additional positive health effects.

In the area of nutrition, biotechnology can enhance nutritional properties. The expanded mandate of EFSA on nutrition matters, enabling EFSA to provide advice concerning enhanced nutritional properties of food products and/or beneficial practices to nutrition matters derived from advanced biotechnological processes, will further equip EU regulators with the necessary scientific knowledge to address challenges relating with the increasing prevalence of diet-related health issues.

Furthermore, the introduction of a harmonised regulatory framework for sandboxes relating to the food chain in the EU could, in the long run, inform future adaptations of the applicable framework in terms of alternative regulatory requirements to address technological developments by harvesting evidence in controlled environments and under the supervision of competent authorities and the possible participation of EU decentralised agencies entrusted with risk assessment tasks, without jeopardising a high level of protection of public health. Accordingly, regulatory sandboxes are considered to be a "learning tool"[111].

By allowing controlled, pre-market testing of innovative technologies, products and substances, sandboxes could generate earlier and richer real-world data on hazards, exposure and patterns of use. Authorities could see how products behave outside the laboratory, detect risk factors, and identify vulnerable groups more accurately. If sandboxes are also used to test and compare data requirements vis-à-vis the objectives pursued, regulators can empirically determine the effectiveness and efficiency of alternative data requirements and compare them with the existing ones in order to determine the appropriate course of action in light of the objectives pursued by the sectoral legislation (for instance the effectiveness of 'new approach methodologies' as opposed to animal testing that is currently required by certain sectoral legislation in the context of pre-market authorisations). This enables them to refine guidance and potentially even legal requirements so that future applications contain the necessary data requirements. Similarly, experimenting with alternative regulatory requirements (such as alternative means of communicating food information to consumers such as digital labelling, conditions of use or monitoring schemes) creates evidence on which risk-management options actually work in practice, including how they influence consumer understanding and behavior.

For public authorities, these mechanisms could amount to **structured regulatory learning**. They could help EFSA and national bodies to adapt methodologies and frameworks to emerging technologies and to identify methodological and resource gaps early on. A better, more targeted database gained through sandboxes would thus support

[111] https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/06/regulatory-sandbox-toolkit_cc8d3e50/de36fa62-en.pdf

more accurate risk assessment and more effective, proportionate risk-management measures. In the long run, this could translate into higher public health and safety: safety issues are more likely to be detected at small scale in a controlled environment; authorisation decisions can be better calibrated to real risks; and regulatory responses to new technologies can be faster and more preventive.

However, these benefits depend on key design conditions: sandboxes must operate under strict safeguards (limited scale, clear eligibility and stop-rules), data must be systematically collected, standardized and fed into EU-level processes, and authorities must have enough capacity to analyse and use the additional information. If these conditions are met, sandbox-generated evidence is likely to strengthen the EU's high level of health and consumer protection.

2 INTERVENTION N°3: TARGETED REGULATORY REFORM OF THE ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPS) FRAMEWORK

2.1 Proposed measures

The measures are differentiated into two components: (1) ERA derogations for GMO-containing investigational ATMPs and (2) update of tissue engineered products (TEP)definition.

Regulatory simplification of environmental risk assessment (ERA) exemptions for certain ATMPs containing or consisting of GMOs

The proposal amends Regulation (EC) No 1394/2007 to exempt clinical trial sponsors from the obligation to submit an ERA for clearly delineated categories of investigational ATMPs that consist of or contain GMOs presenting no or negligible risks to human health and the environment (e.g., replication-defective viral vectors).The aim is to reduce administrative burden within the framework of Regulation (EU) No 536/2014,

Instead of an ERA, sponsors must submit, as part of the clinical trial application, a declaration explaining why the investigational ATIMP falls into one or more of the specified no or negligible-risk categories. The CHMP will verify such declaration.

The same categories are proposed to be exempted from the GMO-related manufacturing and import requirements of Regulation (EU) No 536/2014. Annex I to Regulation (EU) No 536/2014, corresponding amendments are proposed.

The rational of this measure, as provided in the recital of the Commission proposal is that certain ATIMPs (for example, viral vectors rendered replication-defective by removal of wild-type genome sequences) are described as presenting at most negligible risk to human health and the environment, supporting a risk-proportionate exemption approach.

Future-proofing ATMP definitions via Delegated acts

To future- proof the ATMP-framework, the proposal empowers the Commission to adopt delegated acts to amend the definition of a tissue engineered product (TEP) in Regulation (EC) No 1394/2007, in light of technical and scientific advancements in the field of

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ATMPs, provided such amendments do not extend the scope of those definitions. The Commission will have to carry out appropriate consultations with the Agency (EMA) and the Substances of Human Origin Coordination Board (SCB) when preparing such delegated acts.

Summary of objectives

Together, these changes aim to:

- Simplify regulatory procedures by eliminating full ERA submissions for negligible-risk ATMPs.
- Future-proof the ATMP framework through clarified and adaptable definitions that account for scientific and technical advancements.

2.2 Baseline and counterfactual scenario

2025: Base year

Three structural problems characterise the baseline:

- GMO-related dual burden: All ATMP clinical trials involving ATMPs with a GMO component require parallel GMO environmental risk assessments under national legislation, resulting in duplicated procedures, variable timelines and additional administrative burden.[112]
- TEP definition ambiguity: The definition present in the ATMP regulation of tissue engineered products (TEPs) does not cover *in viv*o tissue generation, acellular therapies, and bio-synthetic hybrids. This leads to case-by-case classification disputes, forcing some developers to launch outside EU first. Other regulators, notably FDA- approve products that fall outside EU categories, undermining EU competitiveness.[113]-Other regulators, notably FDA- approve products that fall outside EU categories, undermining EU competitiveness.[114]

Legislative Architecture: Three Relevant Instruments

The baseline must be understood against the legislative architecture governing GMO-containing investigational medicinal products. Three instruments are relevant, with different scopes and timelines.

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[112] Whomsley R, et al. Environmental risk assessment of advanced therapies containing genetically modified organisms EU. Br J Clin Pharmacol. 2021 87, p. :2458

[113] European Medicines Agency (2015) *Reflection paper on classification of advanced therapy medicinal products.* EMA/CAT/600280/2010 Rev.1. [Online] London: European Medicines Agency. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-classification-advanced-therapy-medicinal-products_en.pdf

[114] European Medicines Agency (2015) *Reflection paper on classification of advanced therapy medicinal products.* EMA/CAT/600280/2010 Rev.1. [Online] London: European Medicines Agency. Available at: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-classification-advanced-therapy-medicinal-products_en.pdf

- **Article 177 of the new Pharmaceutical Regulation (NPL), inserting Article 5a into the Clinical Trials Regulation**: applies to all GMO-containing investigational medicinal products, regardless of product type. It introduces a centralised, CHMP-led ERA assessment submitted through CTIS, replacing the current fragmented system of parallel national ERA submissions. The political agreement on the NPL has been reached in December 2025 and is expected to apply from end of-2028.
- **The delegated act under Article 5a(8) of the CTR**: anchored in the NPL, not the Biotech Act. It will specify the harmonised ERA procedure and content and must take into account existing EMA Good Practice Documents. Critically, this delegated act must be developed during the NPL implementation period and be ready and in force before the NPL applies in mid-2028 — it is a prerequisite for the Article 5a provisions to function operationally.
- **Article 57 of the Biotech Act, amending Regulation (EC) No 1394/2007 and inserting Article 4a**: applies exclusively to ATMPs. Article 4a creates a derogation from the Article 5a ERA requirement for the subset of ATMPs belonging to one of the four defined categories presenting no or negligible risk. The two instruments are complementary. Article 177 of the NPL delivers centralisation for all GMO-containing IMPs; Article 4a of the proposed European Biotech Act delivers a full ERA derogation for a defined subset of ATMPs.

2025–2028: Near-Term Projections (Pre-NPL Application)

- Until the NPL applies in mid-2028, the current fragmented system of parallel national ERA submissions persists in full. Neither Regulation 1394/2007 nor Regulation (EU) 536/2014 currently provides risk-based derogations for low-risk ATMPs. All ATMP clinical trials involving a GMO component remain subject to parallel ERA obligations under national legislation, with the procedural complexity, timeline variability, and administrative burden this entails.
- Ambiguity of TEP definitions will remain.

From mid-2028: Post-NPL Baseline Without Biotech Act

- From mid-2028, Article 177 of the NPL will replace the fragmented national ERA system with a centralised, CHMP-led ERA submitted through CTIS for all GMO-containing IMPs. This delivers a significant structural improvement regardless of the proposed European Biotech Act. The NPL amendments to Articles 61 and 91 of the CTR also remove parallel national contained-use authorisation requirements under Directive 2009/41/EC for clinical trials within the scope of the CTR, addressing one of the most practically significant comprehensiveness concerns. Read together with Article 5a(3)'s disapplication of Articles 6 to 11 of Directive 2001/18/EC, the expected combined effect is to remove both the deliberate release consent track and the contained-use track as parallel national requirements, replacing them with the single centralised CTIS-based ERA procedure. Under the baseline however, all ATMP clinical trials involving a GMO component — including those with replication-defective viral vectors presenting negligible environmental risk — would continue to undergo a full ERA under the centralised Article 5a procedure.

- The TEP definition ambiguity would also remain unresolved under the baseline, sustaining classification disputes and unpredictability for emerging ATMP modalities such as in vivo genome editing, acellular therapies, and cell-device combinations.

2.3 Expected impacts

Administrative costs on businesses, including SMEs

The proposed reform complements the ongoing revision of the EU pharmaceutical legislation and aligns with the Pharmaceutical strategy for Europe, ensuring that regulatory requirements for GMOs in medicines are fit for purpose.

The exemption from the ERA requirement for GMO-ATMPs falling within clearly defined negligible-risk categories **eliminates ERA preparation costs** for qualifying products. While no official EU estimate exists for these costs in the ATMP context, industry-estimates suggest the reform primarily removes **administrative and procedural duplication rather than scientific work,** with FTE savings concentrated in regulatory and coordination activities.

For qualifying products, the current obligation to provide detailed environmental risk data is replaced by a **simplified declaration**, in which the sponsor explains the applicable risk categorisation and demonstrates compliance with predefined criteria. This mirrors the tiered, risk-proportionate system used for contained use of GMOs.

Estimated FTE savings per CTA application:

lower bound: ~0.15 FTE-year

upper bound: ~0.3 FTE-years.

This corresponds to approximately **50–70% of the GMO-specific administrative workload**, while the underlying ERA data generation effort is retained.

Regulatory frameworks that introduce **clear, risk-tiered criteria** allow sponsors to self-assess regulatory obligations and can reduce reliance on specialised consultancy services for interpretation and compliance planning. This is widely recognised in regulatory policy literature as a means to lower compliance costs and enhance predictability.

Importantly, safety oversight is maintained: the Committee for Medicinal Products for Human Use (CHMP) will continue to verify all ERAs as part of the centralised marketing authorisation procedure, ensuring ongoing safety verification for all GMO-ATMPs.

Competitiveness, trade and investment flows

The temporary COVID-19 derogation from GMO legislation granted by the European Commission provided direct evidence of what a risk-proportionate exemption delivers in practice: Pizevska et al. (Frontiers in Medicine, 2022) confirmed that the derogation had documented timely and administrative benefits for sponsors and trial sites, demonstrating that removing the ERA obligation for low-risk investigational products reduces procedural

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delays without compromising safety oversight. ARM, EFPIA, and EuropaBio drew explicitly on this precedent in calling for a permanent exemption, noting that without it, GMO requirements would continue to threaten EU competitiveness in a sector where other jurisdictions apply less cumbersome frameworks (EFPIA joint statement, May 2021). The Article 4a derogation under the Biotech Act operationalises this evidence-based approach on a durable legislative basis, for clearly defined negligible-risk ATMP categories. From mid-2028, its interaction with the NPL's centralised Article 5a ERA procedure — which will itself replace the current fragmented national submission system for all GMO-containing IMPs — further reduces the residual procedural burden for those ATMPs not qualifying for the derogation.

On TEP definition ambiguity, the consequences of the static 2007 definition are documented in the clinical trial data. TEPs represent fewer than 5% of ATMPs in EU clinical trials and received only 5.1% of ATMP-designated trial funding in 2019. Of the 90 TEP-based EU trials undertaken since 2009, only four TEPs have ever received a marketing authorisation, with two subsequently withdrawn (Joyce et al., Cell Transplantation, 2022)[115]. As of February 2025, only three authorised ATMPs in the EU are human cell and tissue products — two TEPs and one somatic cell therapy — with no significant increase projected, in part reflecting the classification burden and regulatory uncertainty the 2007 definition creates for developers of products that do not map cleanly onto existing categories (Ongena et al., Wound Repair and Regeneration, 2025)[116]. EMA's own reflection paper on ATMP classification acknowledges that, due to the complex nature of these products and the rapid evolution of science and technology, borderline classification questions regularly arise and require case-by-case CAT assessment — generating unpredictability that is itself a competitive disadvantage (EMA Reflection Paper on Classification of ATMPs, 2015, updated). Empowering the Commission to adapt the TEP definition via delegated acts, in light of scientific advances and following consultation with EMA and the SCB, directly addresses this structural gap and reduces the risk that emerging modalities — in vivo tissue generation, acellular therapies, bio-synthetic hybrids — fall into regulatory grey zones requiring bespoke classification procedures.

Table 1. Indicators Competitiveness

Effect / impact	Indicators	Expected change	Data source for baseline
Higher investment into EU- based research and innovation	EU Horizon investments into regenerative medicine	increase	EU Horizon Europe programme: 20 ATMP projects with median funding ~ EUR 7.5 million[117]

[115] Joyce K, Buljovcic Z, Rosic G, Kaszkin-Bettag M, Pandit A. Issues with Tissues: Trends in Tissue-Engineered Products in Clinical Trials in the European Union. Tissue Eng Part B Rev. 2023 Feb;29(1):78-88. doi: 10.1089/ten.TEB.2022.0094. Epub 2022 Oct 21. PMID: 36062927; PMCID: PMC9940800.

[116] Ancira J, Gabrilska R, Tipton C, Miller C, Stickley Z, Omeir K, Wakeman C, Little T, Wolcott J, Philips CD. A structural equation model predicts chronic wound healing time using patient characteristics and wound microbiome composition. Wound Repair Regen. 2025 Jan-Feb;33(1):e70004. doi: 10.1111/wrr.70004. PMID: 39959986; PMCID: PMC11831583.

[117] According to cordis: 20 projects funded on ATMPs in the Horizon Europe framework programme with a Median of ~ 7.500.000€ (ending between 2025 to 2031)

More favourable EU innovation investment location decision	Number of EU-headquartered gene therapy developers	increase	Alliance for Regenerative Medicine (2026), ARM Q4 2025 CGT Sector Data" (396, incl. 145 private)[118]
Higher EU share of global regenerative medicine funding	EU share of global funding	increase	Europe Regenerative Medicine Market Size & Outlook, 2025-2033[119]

Innovation and research

Removing or reducing regulatory requirements- such as exempting qualified GMO-containing ATMPs and broadening the TEP definition to a flexible, risk-based umbrella would lower operational costs and speed up the transition from research to clinical development. This particularly benefits smaller organizations and SMEs, which represent over 60% of ATMP developers in Europe.

In some Member States, ATMP SMEs have reported workforce growth of over 180%- in five years, indicating strong employment and innovation potential when regulatory barriers are reduced.[120] Simplifying requirements is expected to improve capital efficiency and survival rates of SMEs in early clinical phases.[121]

Harmonizing and simplifying the Regulation (EU) No 536/2014 in combination with harmonized ERA requirements and clearer ATMP classification is expected to improve the feasibility of multinational trials, —particularly critical in rare disease indications where patient populations are small and cross-border recruitment is essential.[122] By simplifying the regulatory environment, the EU would become more attractive for ATMP research and investment, supporting the growth of over 580 ATMP companies across more than 20 Member States[123].

Faster Patient Access and Data Generation: Simplified pathways would accelerate patient recruitment and data generation, reducing uncertainty for investors and developers. For example, protocol amendments in Europe can currently take up to 90 days, compared

[118] Alliance for Regenerative Medicine (2026) ARM Q4 2025 CGT Sector Data. [Online] Washington, DC: Alliance for Regenerative Medicine. Available at: https://alliancerm.org/wp-content/uploads/2026/01/ARM-Q4-2025-CGT-Sector-Data.pdf

[119] Reed Intelligence (2025) Europe Regenerative Medicine Market Size & Share Report By 2033. [Online] Reed Intelligence. Available at: https://reedintelligence.com/insights/regenerative-medicine-market/europe

[120] ARM: Seizing Europe's Opportunity for Transformative Medicine FINAL_ARM_Policy-Blueprint_Biotech-Act_CEO-Letter.pdf 2025

[121] Joyce, K., Buljovcic, S., Jerez, L., McCarthy, C. and Barry, F. 2023, 'Issues with Tissues: Trends in Tissue-Engineered Products in Clinical Trials in the European Union', *Tissue Engineering Part B: Reviews*, 29(1), pp. 78–88. doi: 10.1089/ten.teb.2022.0094.

[122] ATMP industry coalition, response to the Call for Evidence on the European Biotech Act, June 2025

[123] AR Alliance for Regenerative Medicine (2026) ARM Q4 2025 CGT Sector Data. [Online] Washington, DC: Alliance for Regenerative Medicine. Available at: https://alliancerm.org/wp-content/uploads/2026/01/ARM-Q4-2025-CGT-Sector-Data.pdf

to around 30 days in other regions.[124] Reducing these timelines would directly support both faster innovation cycles and access to potentially curing treatments for patients.

Table 2. Indicators Innovation and research

Effect / impact	Indicators	Expected change	Data source for baseline
Higher research (and patenting) activities	• Rate of In Vivo Approvals • Rate of Acellular Therapy Approvals • Number of Gene Therapy Clinical Trials initiated in EU • Share of publications and patents worldwide	Increase Increase Increase increase	~15% cell-based therapies[125] ~70% acellular gene therapies[126] Alliance for Regenerative Medicine (2026), ARM Q4 2025 CGT Sector Data" [127] Fraunhofer ISI / VFA (2023), Technologische Souveränität Pharma/Biotech
More investment in Gene Therapy Research in EU	Share of global market of EU gene therapy	increase	EU Horizon Europe programme: 20 ATMP projects with median funding ~EUR 7.5 million EUR million[128]

Public health and safety

Reducing avoidable regulatory steps at the clinical development stage could contribute to earlier initiation of trials and earlier availability of innovative ATMPs for patients with high unmet medical need. However, this effect would only apply to GMO -ATMPs falling within the exempted categories. The ERA exemption is not a waiver of safety oversight; rather, it replaces a full ERA dossier with a declaration verified by CHMP using existing scientific knowledge., preserving the same level of safety assurance while eliminating redundant procedural steps.

Clarifying the definition TEPs and modernising regulatory provisions to reflect modular gene and cell technologies could reduce classification uncertainty and procedural delays. Given that ATMP development often involves small patient populations, complex manufacturing chains and iterative product modifications, greater procedural coordination

[124] Alliance for Regenerative Medicine (2026) ARM Q4 2025 CGT Sector Data. [Online] Washington, DC: Alliance for Regenerative Medicine. Available at: https://alliancerm.org/wp-content/uploads/2026/01/ARM-Q4-2025-CGT-Sector-Data.pdf

[125] ARM Q4 2025 data shows that of the global ATMP pipeline, approximately 15% are cell-based therapies and 70% are gene therapies, with the remainder being tissue-engineered products.

[126] Rapid Assessment Scenario Study (forthcoming), stakeholder consultation

[127] Alliance for Regenerative Medicine (2026) ARM Q4 2025 CGT Sector Data. [Online] Washington, DC: Alliance for Regenerative Medicine. Available at: https://alliancerm.org/wp-content/uploads/2026/01/ARM-Q4-2025-CGT-Sector-Data.pdf

[128] https://cordis.europa.eu/search?q=contenttype%3D%27project%27 AND frameworkProgramme%3D%27HORIZON%27 AND language%3D%27en%27%2C%27de%27%2C%27es%27%2C%27fr%27%2C%27it%27%2C%27pl%27 AND (%27ATMP%27)&p=1&num=10&srt=Relevance:decreasing

between national competent authorities, ethics committees, and EMA structures could reduce inconsistencies and improve predictability. .

Safety is specifically preserved through:

- CHMP verification of sponsor declarations regarding negligible-risk status.
- Comprehensive risk-benefit assessment as part of the clinical trial and marketing authorisation processes.
- Existing pharmacovigilance mechanisms, including risk management plans and long-term follow-up obligations.

Table 3. Public Health and Safety Indicators

Effect / impact	Indicators	Expected change	Data source for baseline
Maintaining high safety standards	ATMP withdrawals for safety reasons	no change	EMA annual reports no withdrawals for safety reasons reported[129]

2.4 Summary of impacts:

Economic Impacts on Businesses

Exempting clearly delineated negligible-risk categories of investigational GMO-containing ATMPs from the full Environmental Risk Assessment (ERA) eliminates preparation costs and certain GMO-related manufacturing and import requirements. While this is expected to substantially reduce administrative costs for sponsors—particularly small and medium-sized enterprises (SMEs)—explicit quantifications could not be fully estimated at this stage[130].

A streamlined procedure requiring sponsors to submit a declaration justifying that the product falls within predefined no-risk or negligible-risk categories, verified by the CHMP, is expected to save considerable time and resources while increasing the predictability of regulatory requirements.

Adapting the definition of tissue engineering products (TEPs) via delegated acts is expected to future-proof the regulatory framework by allowing products to be classified according to their intended purpose and risk profile. Stakeholder interviews confirm the need for this flexibility, emphasising that it enables greater regulatory adaptability to scientific and technological advances.

[129] https://www.ema.europa.eu/en/documents/report/annual-activity-report-2024_en.pdf

[130] EFPIA, EUCOPE, EuropaBio. *Industry survey on GMO-IMPs under the EU CTR*. (Data referenced in the original text and in Beattie et al., *Cell & Gene Therapy Insights*, 2024); ATMP2030 Annual Report 2024 (ATMP Sweden, September 2024).

The combination of more predictable, internationally coherent definitions and robust EU public health and safety standards is viewed by relevant stakeholders as a competitive asset relative to jurisdictions such as the United States[131].

Impact on Innovation, Competitiveness, and Patient Access

Exempting qualified GMO-containing ATMPs from full ERA requirements, alongside broadening the TEP definition into a flexible, risk-based ATMP umbrella, is expected to lower operational costs and accelerate the transition from research to clinical development. This will particularly benefit smaller organisations and SMEs, which represent over 60% of ATMP developers in Europe[132].

Public Health and Safety

The reform targets procedural simplification rather than a substantive relaxation of safety standards. ERA exemptions apply only to investigational ATMPs that fall into clearly defined negligible-risk categories. By reducing unnecessary procedural delays, the measures are expected to enable earlier initiation of trials and potentially earlier access to safe, effective, and transformative ATMPs for EU patients — particularly in areas of high unmet medical need.

The ability to adapt TEP definitions to scientific progress reduces the risk of regulatory blind spots for emerging technologies, helping ensure that innovative ATMPs are brought under appropriate oversight rather than remaining in a regulatory grey zone.

3 INTERVENTION N°4: TARGETED REGULATORY REFORM OF CLINICAL TRIALS

The following policy measures have been discarded[133]:

1. Consideration was given to establishing a centralised assessment body to oversee the authorisation of the initial applications of multinational clinical trials as well as applications for substantial modifications to such trials at the EU level. This body was intended to manage the scientific, regulatory, and ethical reviews of such trials. However, the proposal was discarded for the following reasons. Firstly, approximately 60% of clinical trial applications are mononational and do not require cross-border collaboration. Secondly, national-specific aspects of the applications, detailed in Part II of the dossier, would still need to be evaluated by the Member State concerned. Hence,

[131] Bech-Bruun. *Analysis of the Biotech Act*. March 2026. The EU Biotech Act: A targeted solution to Europe's biotech challenges.

[132] EFPIA, EUCOPE, EuropaBio. *Industry survey on GMO-IMPs under the EU CTR*. (Data referenced in the original text and in Beattie et al., *Cell & Gene Therapy Insights*, 2024); ATMP2030 Annual Report 2024 (ATMP Sweden, September 2024).

[133] The *Study Regulatory Framework Study (forthcoming)* assesses the impact of four different sets of policy measures: (i) Shortening timelines for the assessment procedures and improved coordination via a strengthened role of the reporting Member States; (ii) the establishment of centralised assessment body for scientific and ethic review, (iii) the establishment of a centralised assessment body limited to public health emergencies, and (iv) a shortening of the timelines without procedural changes. For further details, please see the report.

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creating this body would potentially result in two separate procedures, one for mononational and one for multinational trials, ultimately leading to increased fragmentation and retaining procedural complexity related to site and investigator suitability, compensation, or insurance. Survey results[134] indicate that Member States consider the establishment of a centralised body, particularly for the assessment of the ethical review, as a risk of further fragmentations, while large enterprises rather favour a centralisation.

2. Reducing the timelines for clinical trial authorisation without altering the authorisation procedure for clinical trials was also considered. However, this would not address significant demands for reducing complexity through simplification, such as *e.g.* the introduction of a single core dossier for trials using the same IMPs, a single legal basis under the requirements of the GDPR for processing of personal data and a single authorisation procedure for combined studies. Moreover, shortening timelines without streamlining the authorisation procedure would have placed additional pressure on already strained national capacities and could have compromised both the quality and safety of the authorisation process.
3. It was considered to apply the amendments to the Clinical Trial Regulation under the proposed European Biotech Act specifically to biological and not to chemical products**.** However, implementing distinct authorisation procedures or timelines might lead to fragmentation and increased complexity. Also, not all the Member States would have the resources to accommodate two distinct authorisation procedures which would have to create a potential discrimination of access to clinical trials for EU patients depending on their country of residence.

4 INTERVENTION N°5: TARGETED REGULATORY REFORM OF VMPS

4.1 Detailed description of the proposed measures

Measure 1: Exemption from GMO framework and single assessment under pharma framework

The Act proposes to establish a 'One-Stop-Shop' principle, removing the dual-track regulation and establishing Regulation 2019/6 as the specific and sole legal framework for these products:

- **For clinical trials**: veterinary competent authorities assess environmental risks within the clinical trial evaluation, with the possibility to consult with national GMO bodies, particularly for novel questions or first-in-class products.

[134] See *Regulatory Framework Study (forthcoming)*

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- **For marketing authorisation**: the requirement to submit documentation as required under the GMO Directive is removed. EMA may consult national GMO authorities, in particular for first-in-class products or novel questions.

Furthermore, the proposed Act introduces a **legal clarification regarding the downstream status of animals treated with VMPs**: the administration of VMPs does not bring the treated animal or their derived products under the scope of Union GMO legislation.

Measure 2: Targeted SPC extension for zoonotic biotech products

The proposed Act creates a **12-month extension of the SPC** duration beyond the standard maximum of 5 years, thus creating targeted an incentive for biotechnology-derived veterinary products addressing zoonotic diseases. Eligibility requires satisfaction of five cumulative conditions: (1) the product must be developed by means of a biotechnology process as defined in Article 42(2)(a) of Regulation 2019/6; (2) it must be intended to diagnose, treat, or prevent zoonotic diseases; (3) it must contain a new active substance distinctly different from any authorised medicinal product in the Union; (4) it must have a mechanism of action distinctly different from existing products for the same zoonotic disease, with at least equivalent safety and efficacy; and (5) at least one manufacturing step (excluding packaging, quality testing, and certification) must be performed in the Union.

EMA assesses **compliance** with these conditions as part of the marketing authorisation procedure and issues a statement confirming eligibility, which is then included in the SPC extension application to national patent offices.

Measure 3: Regulatory sandbox for animal health innovation

The proposed Act establishes a framework for regulatory sandboxes, specific to innovations in animal health not regulated under other Union legislation. The Commission may establish a sandbox where two conditions are satisfied: (a) the technology can be expected to have a positive impact on animal health without unacceptable negative impacts on human health or the environment; and (b) the development, placing on the market, or use is hindered by the lack of a harmonised legal framework.

The process begins with an application to EMA from developers of eligible innovations. EMA assesses applications and may submit a recommendation to the Commission including justification, identification of regulatory challenges, estimation of benefits and risks, mapping of available expertise, and a proposed duration. The Commission decides by implementing act whether to establish the sandbox and specifies its duration.

Once established, EMA develops technical and scientific requirements, provides scientific advice, and assesses benefits and risks of specific products, technologies or methods. Products, technologies or methods developed under the sandbox cannot be placed on the market or used in the Union until authorised by the Commission by an implementing act. National competent authorities retain supervisory competences and are empowered to take interim measures, including the suspension or recall, where serious risks are identified. In such cases, an assessment by EMA takes place and eventually the Commission takes a final decision by means of an implementing act. Two years before the end of an established

sandbox period, EMA must submit an assessment report to the Commission including recommendations for a regulatory framework after termination. The Commission may take appropriate actions regarding permanent regulatory requirements, or extend the sandbox duration where justified.

Measure 4: Reduction of burden for the handling of VNRAs

The proposed amendments introduce two significant modifications:

- First, the right to implement VNRAs is explicitly codified, strengthening legal certainty for companies by removing the confirmation step by competent authorities. Moreover, an anti-circumvention clause is added, balancing the increased flexibility with enhanced enforcement capability during inspections.
- Second, for VNRA with no impact on product information, submissions can be consolidated on a yearly basis. The 30-day deadline is only maintained for variations affecting the summary of product characteristics, labelling, or package leaflet; changes that veterinarians and users need to access immediately.

4.2 Baseline description (2025-2040)

Conduct of business

The dual-track regulatory system governing GMO-containing VMPs will persist through 2040, with no autonomous convergence expected between the veterinary and GMO legislative frameworks. The **clinical trial** approval differential (currently estimated at 2–3 times longer for the GMO process compared to the standard CTA process), will remain. As the number of GMO-based VMPs entering development grows steadily, the annual volume of clinical trial applications subject to this duplicative burden will increase in parallel. **At an estimated rate of approximately 10 new GMO-containing VMPs entering development per year with an 8–10 year development cycle**, the throughput of products requiring dual CTA submissions across fragmented national GMO authorities will scale over the projection period.

At the **marketing authorisation (MA)** stage, the GMO consultation with national competent authorities will continue to run in parallel to EMA's scientific assessment, leading to a growing absolute number of GMO-containing products going through the consultation process, with **increasing resources being devoted to this process in the rapporteur's teams**. Under accelerated or conditional assessment pathways (relevant for emergency disease responses), the GMO consultation requirement will continue to constitute a constraint on time-to-market.

Regarding **commercial uptake of novel biotech VMPs** in food-producing species, the legal ambiguity concerning the GMO status of treated animals and their products will persist. The risk that this impacts commercial uptake is projected to increase over the baseline period as the number of GMO-based vaccines and therapies targeting food-producing species increases.

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Administrative costs on businesses, including SMEs

For the GMO-related component, the burden of **MA dual-dossier requirement** is higher than for non-GMO products. With an estimated pipeline of approximately 100 GMO-containing VMPs up to 2040; the aggregate administrative cost of dual compliance will scale. This burden is expected to intensify in relative terms as third-country jurisdictions streamline their processes: the absolute per-product cost may remain broadly stable, but the EU's comparative regulatory overhead grows, placing increasing competitive pressure on companies operating in the single market.

For **VNRAs**, the Union Product Database (UPD) recorded 23,777 submissions encompassing 185,662 individual VNRAs between 31 January 2022 and 12 December 2025. A survey by a trade association covering responses from holders of approximately 4000 marketing authorisations shows that the submissions of VNRAs has more than doubled as compared with the number of submissions for Type IA variations under the previous framework (from approximately 2,150 submissions of Type IA variation in 2021 to over 4,500 submissions of VNRAs in 2023). This confirms the growing increase of administrative burden. As new MAs are awarded (according to UPD data, it is estimated that there are currently 40,000-45,000 active MAs[135], and this number is expected to grow) the aggregate base of products requiring VNRA management expands. Assuming that active portfolios generating 2-3 VNRAs per MA annually, and with each submission requiring 2-5 or more hours of staff time, **the aggregate annual FTE burden will grow broadly in proportion to the expanding MA base.** The uniform 30-day reporting deadline will continue to force a reactive compliance pattern amplifying the per-unit cost of each submission. As the 30-day uniform deadline persists, the aggregate **VNRA volume** grows in rough proportion to the expanding MA base (a conservative compounding growth rate of approximately 2-3% per year in active MAs). This brings the MA base to roughly 55,000-60,000 by 2040. In the absence of legal changes, **the aggregate FTE burden, fees, and compliance cost will scale proportionally.** The aggregate **VNRA fee burden**, currently estimated at approximately EUR 5 million per year sector-wide, is projected to grow in proportion to the expanding MA base and maintained fee structures. Cross-country variation in fees will persist, continuing to penalise companies with broad European portfolios.

Competitiveness, trade and investment flows

The absence of **SPC extensions** for biotechnology-derived zoonotic VMPs will remain unchanged. The rate of eligible products emerging will continue at the current pace of approximately 1 potentially SPC-eligible biotech VMP for zoonotic diseases every 2 years. In terms of competitiveness, although no veterinary biosimilars have been authorised in the EU at T0, this is not likely to remain static through 2040. Technology maturation and declining biologics manufacturing costs will progressively lower the entry threshold. Over a 15-year horizon, it can be expected that originator companies developing biotechnology-derived VMPs for zoonotic diseases will increasingly confront a competitive environment

[135] The absolute number of products registered in UPD is close to 50.000 but it includes also authorisations which are not relevant to the analysis, such as authorisations under Article 5(6) or authorisations for parallel trade.

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in which biosimilar entry, while structurally less aggressive than in human pharmaceuticals, becomes a commercially relevant consideration.

Innovation and research

The **GMO-containing VMP development pipeline** is projected to grow steadily throughout the baseline period. At T0, among the 8 vaccines authorised under exceptional circumstances in 2024–2025, 5 employed biological recombinant approaches and 3 were GMOs. All four vaccine platform technologies certified to date under Regulation 2019/6 are GMO-based. At an estimated entry rate of approximately 10 new GMO-containing VMPs into development per year, with 8-10 years development timelines, the pipeline is expected to encompass roughly 100 products in various stages of development by 2040.

While the persistence of the dual regulatory pathway is unlikely to prevent any GMO-containing VMPs from ultimately reaching the market, the current system would lead to higher-than-necessary costs and delays to market. The net effect on innovation is negative: a systematic increment to development timelines, costs, and operational complexity that reduces the efficiency of translating scientific opportunity into marketed products, without a commensurate safety or environmental benefit.

Moreover, the current regulatory framework is a disadvantage for operators wanting to conduct their innovation in the Union. Therefore, it can be expected that more operators will move their activities to jurisdictions offering faster and more predictable pathways and that emerging animal health innovation will progressively divert to third countries. Thus, clinical trials, and over time the upstream R&D infrastructure that clusters around trial activity, are likely to take place outside of the EU. Consequently, the EU is likely to increasingly import the products of innovation conducted in third countries, deepening a technological dependency that is difficult to reverse once the relevant expertise ecosystems have relocated.

Under the baseline, there is no **EU-level sandbox**. Technological innovation is expected to continue to outpace regulatory framework evolution, progressively widening the gap between commercially deployable technologies and those with clear EU regulatory pathways. Products that do not fall within the existing definition of a veterinary medicinal product will continue to encounter regulatory limbo irrespective of their safety or efficacy profile. Regulatory uncertainty is expected to extend throughout the baseline.

Public health and safety

Public health and safety are shaped by the downstream consequences of the regulatory barriers that persist under the baseline. First, the **legal ambiguity surrounding the GMO status** of animals treated with biotech-derived VMPs sustains a commercial risk under which farmers and supply chain actors may prefer conventional treatments, including antimicrobials, over novel biotech vaccines with potentially superior efficacy profiles in food-producing species. While there is no evidence that this risk has materialised yet, the conditions for such discrimination will become more pronounced over the projection period as GMO-based vaccines increasingly target food-producing species. Second, the absence of a **regulatory sandbox mechanism** and the expected impact on EU market access to innovative technologies with potential public health benefits will remain. The

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gap between technological capability and regulatory accommodation is projected to widen steadily, deferring potential public health gains from emerging approaches. In aggregate, the baseline is characterised by **a slower-than-achievable realisation of the public health benefits** that veterinary biotechnology innovation is technically capable of delivering.

4.3 Expected impacts

Conduct of business

On the average time for CTA, the reform eliminates the procedural duplication.

Under the current framework, the slower of the two authorisations required to conduct a clinical trial determines the pace.

Further, at present, applicants must manage interactions with distinct authorities in every Member State where they conduct a clinical trial. An EU level trade association estimated that the one-stop shop approach would save approximately 3-6 months per CTA. This estimate encompassing both the direct timeline reduction and the indirect reduction in coordination-related delays and uncertainties.

Given the heterogeneity across Member States, a weighted approach is appropriate. Taking data from an NCA on the well-synchronised end (0 to 30 days additional time) and feedback from an EU-level trade association (90-180 day) time estimate as representative of the poorly synchronised end, a **conservative estimate for the average per-CTA process timeline saving across the EU is 1-3 months**, i.e. 30-90 days.

At an estimated throughput of 8-15 CTA applications per year subject to the dual-track burden at baseline, rising to 12-20 per year by 2040 (reflecting pipeline growth), and applying the central per-CTA saving of 30-90 days, **the reform eliminates approximately 8-45 product-months of aggregate delay per year at current pipeline volumes, rising to 12-60 product-months per year by 2040.**

As regards marketing authorisation procedures, under standard evaluation timelines, **the reform will have no measurable impact on the average number of days.** First, the GMO consultation currently occupies a window within the first 90-100 days of the assessment phase and runs concurrently with the CVMP's scientific evaluation. As the CVMP's evaluation takes the full 198 days on average, the assessment phase remains unchanged. Second, the reform converts the mandatory consultation into an optional one.

However, a positive impact of this measure on marketing authorisation timelines can be identified in two specific scenarios:

- **Accelerated assessment pathways,** which are relevant for disease outbreaks, the removal of the mandatory requirement provides regulatory authorities with the procedural flexibility to consult with the GMO authorities solely when additional expertise can add value. The frequency and circumstances of accelerated assessments are inherently unpredictable, which is thus difficult to quantify. However, between 2024-2025, 8 vaccines were authorised under exceptional circumstances, of which 3 were GMOs. For these products, the elimination of a mandatory parallel consultation could plausibly **save 30-60**

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days in the accelerated pathway. This saving applies to a small number of products per year (estimated at **1-3 under emergency circumstances).**

- **With regards to the dossier preparation phase** (upstream of the submission of the marketing authorisation application), the elimination of the requirement to compile Annex III documentation under Directive 2001/18/EC (in addition to information requirements under the pharma framework that overlap) will bring some administrative savings. Further savings can arise during the assessment, insofar as companies require less time to prepare responses to questions from national GMO bodies channelled through EMA. This effect is captured under the indicators on **administrative burden for marketing authorisation dossier preparation**, with an associated cost saving estimated at approximately **EUR 7,000 per marketing authorisation dossier**.

Administrative costs on businesses, including SMEs

The proposed changes in the handling of VNRAs will lead to savings per-unit administrative cost of the submissions related to **variations that must be reported**. The impact manifests as a structural **redistribution of the volume of notifications across time**, with cascading effects on staff effort, fees, and compliance cost.

It is estimated that 70-80% of VNRAs do not affect the SPC, labelling, or package leaflet. Absent broader survey data, adopting a sector-wide estimate of 75% as a central assumption is reasonable, with sensitivity bounds of 65-85% reflecting portfolio heterogeneity. This means that, with a conservative baseline of 42,500 annual VNRAs per year, , approximatively **10,625 VNRAs** (25%) remain subject to the 30-day deadline (SPC/labelling changes) and **31,875 VNRAs** (75%) become eligible for annual reporting. **Thus, 75% of the volume migrates from continuous monthly submissions to consolidated periodic filings**.

The UPD data shows 23,777 submissions for 185,662 VNRAs, yielding an average of approximately 7.8 VNRAs per submission. The batching enabled by the annual deadline will increase this ratio substantially **for the 75% of VNRAs that qualify**. If companies consolidate VNRAs with no impact on product information into 2 annual submission windows rather than continuous 30-day filings (with required 10-12 filing cycles per year), **the number of discrete submission events for those VNRAs could fall by roughly 60-70%**.[136] **However, the 25% of VNRAs still under the 30-day deadline continue to generate continuous submission events.**

Indicatively, at sector level, the total **number of submission events** (currently approximately 6,100 per year, derived from the 23,777 over 3.9 years) **would**

[136] Moving from 10-12 cycles to 2 would yield an 80-83% reduction. The 60-70% figure is a downward adjustment reflecting that not all companies currently file at full monthly frequency and some individual submission events contain a mix of SPC-affecting and non-SPC VNRAs, meaning they cannot be cleanly separated into the two cohorts, and the transition will not be perfectly clean, with some ad hoc submissions persisting outside the two main windows.

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approximately be 1,525 events for the 30-day cohort and 4,575 for the annual cohort[137].

Thus, the total number of submission events could decline by an estimated **45-55%**, to approximately **2,900-3,400 per year**. This reduction represents a meaningful decrease in the frequency of UPD interactions.

Based on a survey from an EU level trade association, each VNRA is estimated to cost for marketing authorisation holder between 2 and 5+ hours of staff time. The aggregate per-MAH burden is estimated at 0.2 FTE per year (approximately 344 hours, assuming 1,722 hours per FTE[138]). **Another EU level trade association estimated up to 20% reduction in total man-hours through operational efficiencies gained from the possibility to consolidate submissions of VNRAs over a period of time**. While the preparation work per VNRA persists, the consolidation would eliminate most of the repetitive overhead of individual UPD submission events. **Thus, a 10-20% range is estimated for efficiency gain from consolidated workflows, even if the substantive documentation effort is largely invariant. Based on a 15% reduction, EUR 1.46 million per year in staff cost savings are estimated.**

Taking into account compounding growth drivers for 2025–2040 growth, the **present-value cumulative saving in real terms**: **EUR 15-30 million over 2025–2040**, with a central estimate of **EUR 22.5 million**.

Although the confirmatory assessment by competent authorities is the principal basis on which several Member States charge per-VNRA fees, Member States can charge administrative processing fees.[139] It is thus assumed that Member States currently charging explicit per-VNRA assessment-related fees will reduce or eliminate them, while those already embedding VNRAs in annual maintenance fees will not make changes. Around **50% of the EUR 5 million** in fees is estimated to be attributable to the confirmatory step, thus the potential fee reduction is approximately **EUR 2.5 million per year**.

As the **EMA** will need to adapt the UPD system to accommodate the bifurcated deadline and remove the approve/reject functionality for NCAs**, the cost of the EMA is estimated at EUR 150-300 thousand (3-6 months, 1 IT team), representing a one-off implementation cost.** No recurring operational cost increase was identified.

On the FTEs dedicated to the CTA process for GMO-VMPs, a standard CTA preparation and management cycle (6-12 months, midpoint ~9 months) engages a small regulatory affairs team. The GMO-specific FTE overhead is conservatively estimated at approximately **0.3-0.5 FTE-years per CTA application**, **representing roughly 15–25% of total CTA effort**. This range accounts for the fact that the ERA data generation itself

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[137] Annual cohort at 60% reduction is 1,830 (total for both cohorts 3,355) and annual cohort at 70% reduction is 1,373 (total for both cohorts 2,898).

[138] Eurofound. (2025). *Balancing the clock: How Europe works and rests.* https://www.eurofound.europa.eu/en/publications/all/balancing-the-clock-how-europe-works-and-rests

[139] An EU level trade association expressed that there is a risk that members expressed concerns that some Member States may continue charging fees by invoking administrative handling in UPD or national systems/legislation, or, alternatively, stop fees for VNRAs and instead shift costs by increasing annual licensing/maintenance fees.

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(the most labour-intensive component) is retained, while the administrative duplication is eliminated. By 2040, with an expanding pipeline and an estimated throughput of **12-20 GMO-related CTA applications per year** (reflecting pipeline growth), the aggregate annual GMO-specific FTE burden would rise to approximately **3.6-10 FTE/year**, or **EUR 403,000-1,119,000** per year. Thus, cumulative over the 15-year projection period, assuming linear growth from current levels: approximately 45-130 FTE-years, or approximately **EUR 5-14.5 million in total GMO-specific CTA administrative costs savings.**

The **GMO-specific increment at the MA stage** is much smaller than at the CTA stage. Based on the estimate that 1 full-time regulatory affairs specialist working for 3 weeks per MA dossier, amounts to ~108 hours or ~0.06 FTE-year, leading to a **cost saving of approximately EUR 7,000 per MA dossier/application.**

With an estimated 3-5 MA applications per year and assuming moderate growth yielding approximately **5-8 GMO-containing MA applications per year by 2040**, the cumulative total of approximately **80 GMO-containing MA applications**, corresponding to a cumulative sector-wide saving of approximately **EUR 560 thousand** in eliminated duplicative dossier preparation costs.

Competitiveness, trade and investment flows

On the biotechnology-derived VMPs awarded SPC extensions, a forward-looking estimate is **an average of 3 eligible products per year over 2026-2040**. It is based on the retrospective eligibility analysis (8 out of 28 over 16 years ≈ 2/year) and adjusted upward modestly to reflect the growing share of biotech vaccines in the pipeline. The commercial benefit of an additional 12 months of SPC duration depends on whether biosimilar competition would otherwise materialise immediately upon expiry. At T0, no veterinary biosimilars have been authorized. Therefore**, the marginal revenue preserved by the extension is, for all practical purposes, close to zero in the short to medium term.** Under the forward-looking scenario in which veterinary biosimilar competition begins to materialise by the mid-2030s, the narrow pool of eligible products and the fact that data protection typically outlasts patent/SPC terms **mean the number of cases where the 12-month extension is the binding margin of protection would be very small**.

In terms of costs, the measure creates **a modest new tasks for EMA** (eligibility statements assessment as part of the MA procedure) **and for national patent offices** (processing the extended SPC applications). Given the very low volume, these costs are negligible in aggregate.

Therefore, the impact of this measure is not appropriately captured through quantification of direct commercial or cost effects, because the primary function of the SPC extension is not to deliver measurable near-term revenue protection but to serve three signalling and future-proofing purposes. First, the measure serves as a **signal on the EU institutional commitment to veterinary biotechnology innovation addressing zoonotic diseases**, potentially influencing long-term R&D allocation decisions at the margin. Second, **the measure is expected to make the legislation future-proof**. Should veterinary biosimilar competition eventually materialise, the mechanism would already be in place. Third, the requirement that at least one manufacturing step be performed in the Union introduces **an**

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explicit industrial policy lever. However, stakeholders indicated that manufacturing location decisions are dominated by existing capacity, and the marginal influence of an additional 12 months of SPC on site selection is very limited.

As a conclusion, Measure 2 is a very low-cost, low to medium impact instrument whose principal value lies in its signalling and institutional-readiness functions (medium- to long-term) rather than in any quantifiable near-term economic effect.

Innovation and research

Although **measure 1 is not expected to increase the number of GMO-containing VMPs marketed in the EU, it is expected to lead to benefits in terms of research activities conducted in the Union.**

Stakeholder consultations indicate that no additional GMO-containing VMPs are likely to reach the market over the next 15 years as a direct result of this change, because the current authorisation pathway does not prevent authorisation outcomes. The dual-track system has never generated a negative opinion on the GMO component of any VMP. Furthermore, the pipeline growth rate is primarily driven by scientific and technological imperatives and by market demand, which are exogenous drivers to the reform. Some indirect benefits are nevertheless expected. First, for smaller developers with constrained budgets, **the cumulative effect of reduced procedural costs and improved timeline predictability could tip individual investment decisions**. This effect cannot be quantified as it concerns projects that do not yet exist and whose existence would depend on firm-specific financial conditions. Second, the reform may lead products already in the pipeline to progress faster (captured under Indicators 1 and 4).

Moreover, the key expected benefit is to incentivise research activities in the Union, avoiding that the conduct of clinical trials with GMO VMPs is moved to outside the Union to avoid the heavy regulatory framework. This is not a hypothetical risk but an observed pattern: **regulatory complexity does not suppress innovation globally; it displaces it geographically**. This risk would lead the Union to become a recipient rather than an originator of next-generation veterinary biotechnology. **Products developed under non-EU regulatory frameworks are typically launched first in the jurisdictions where they were developed and trialled**, meaning that EU farmers and veterinarians gain access to critically needed innovations, particularly during zoonotic disease outbreaks, later than their counterparts in competing markets, with direct implications for outbreak response capacity and One Health preparedness.

On the impact of the sandbox mechanism, stakeholder consultations indicate an average of **one sandbox per five years**, since the mechanism operates per technology area rather than per product. Each sandbox requires a Commission implementing act, which also involves institutional effort.

On this basis, for the 2026–2040 period, 3-4 sandbox applications are estimated, of which potentially 2-3 result in established sandboxes. This is estimated based on the 15-year projection window divided by the estimated 5-year cycle per sandbox; the time for EMA to develop application procedures and assessment criteria (i.e. application is unlikely before 2028); and the narrow eligibility scope of the sandboxes.

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With regards to the effects of the sandboxes on innovation, it is likely that each established sandbox provides a time-limited pathway for specific innovations to be developed, tested, and potentially authorised under regulatory supervision **which could lead to several products or technologies that would otherwise have no EU market pathway**. In addition**, the two-year reporting requirement before sandbox expiry means each sandbox generates structured evidence to inform permanent regulatory framework development.** Thus, each sandbox effectively conducts a regulatory pilot that would otherwise require years of legislative deliberation. Furthermore, stakeholders consulted noted that **the sandbox is likely to have a broader signalling function**, demonstrating that a regulatory pathway exists, potentially unlocking investment currently stalled by regulatory uncertainty.

In terms of quantitative impacts[140], **costs are likely modest and fall primarily on public authorities.** Each sandbox requires EMA resources for application assessment, technical requirement development, scientific advice, risk-benefit assessment, and the two-year assessment report plus Commission resources for the implementing act.

Public health and safety

With regards to the uptake of GMO-containing VMPs in food-producing species, the impact of the **legal clarification** should be understood as the **averted cost of a counterfactual scenario** in which, absent the firewall, the legal ambiguity eventually crystallises into a concrete market disruption. The measure eliminates a tail risk whose expected cost, while difficult to quantify precisely, is potentially very large given the economic and health stakes involved.

It is estimated[141] that even a modest suppression of farmer uptake of next-generation biotech vaccines (e.g., a 5–10% avoidance rate in food-producing species), would translate into foregone disease prevention benefits worth potentially hundreds of millions of euros annually across the Union, when accounting for both on-farm productivity losses and downstream public health costs.

The legal clarification does not impose compliance costs on any actor. There is no implementation cost for Member States, EMA, or industry.

As a conclusion, Measure 1 delivers a **high-value, zero-cost legal clarification** which is characterised as insurance against a growing and potentially costly downside risk.

5 INTERVENTION N°7: TARGETED REGULATORY REFORM OF THE DIRECTIVE ON THE DELIBERATE RELEASE INTO THE ENVIRONMENT OF GMOS

This Annex summarises the key statements of the scientific and technical reports of the European Food Safety Authority (EFSA) (**section 5.1.1**) and the European Network of GMO Laboratories (ENGL) (**section 5.1.3**) that provide scientific justification to various

[140] Based on the 3-4 applications (yielding 2-3 established sandboxes), the first established sandbox plausibly operational by 2029 and 1-3 possible products/technologies per sandbox (yielding a cumulative total of around 2-9 innovations with EU market access)
[141] See the Rapid assessment scenario study for more details

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elements of the legislative proposal to amend Directive 2001/18/EC as regards genetically modified micro-organisms (GMMs). In addition, it explains the development and application of the Qualified Presumption of Safety (QPS) approach in the context of EFSA risk assessments (**section 5.1.3**), a concept relied on for certain provisions of the proposal. **Section 5.2** provides an overview of the applications of GMMs in the areas in the scope of the proposal.

5.1 Scientific Context

5.1.1 EFSA scientific opinions and guidance on GMMs

At the request of the Council, the Commission published in 2021 a study on new genomic techniques (NGTs) applied to plants, animals and micro-organisms[142], which identified significant developments in all three areas. NGTs are techniques that are capable of altering the genetic material of an organism and that have emerged or have been developed since 2001, when the current legislation on genetically modified organisms (GMOs) – namely Directive 2001/18/EC - was adopted. Following up on this report, the Commission adopted a legislative proposal for a Regulation on plants developed with certain NGTs[143]. In the area of micro-organisms, the study, however, concluded that data, especially as regards safety aspects, were still limited and did not provide an adequate basis for taking any policy action in this area. The Commission indicated it intended to continue building up the required scientific knowledge, in view of possible further policy actions.

As a follow-up, the Commission mandated EFSA to prepare a **scientific opinion on new developments in biotechnology applied to micro-organisms**[144] that covered products containing or consisting of GMMs for environmental release as well as food and feed products containing, consisting of or produced from such GMMs. EFSA adopted the opinion in 2024. While the focus of this opinion is on new developments in biotechnology, notably NGTs, EFSA also draws conclusions that are relevant for GMMs or micro-organisms in general. EFSA considers that any new possible hazard relates to genotypic and phenotypic changes introduced in the micro-organism and not to the method used for the modification. In other words, this means that any new potential hazards of a GMM compared to the parental organism are related to new properties conferred to the micro-organism regardless of the method used to give rise to these changed properties. For this reason, EFSA recommends that "*the risk assessment approach of micro-organisms should be based on the strain/product itself, independently of the method used to alter the genotypic or phenotypic characteristics*", i.e. NGT, established genomic technique (i.e. genetic modification techniques developed before 2001) or conventional (random) mutagenesis (i.e. the application of chemical or physical mutagens).

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[142] Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) 92 final. https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf

[143] COM(2023) 411 final – COD 0226/2023. A provisional political agreement was reached on 3 December 2025.

[144] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Jimenez Saiz, R., Ruiz Garcia, L., Aguilera Entrena, J., Gennaro, A., Schoonjans, R., Kagkli, D. M., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895. https://doi.org/10.2903/j.efsa.2024.8895

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Furthermore, the scientific opinion formulates some concrete recommendations for the risk assessment of GMMs and related products. In particular, EFSA asserts that, on a case-by-case basis, some data requirements may not be needed to assess the safety of the micro-organism or its products for humans, animals and the environment and gives concrete examples of some areas. Toxicology studies may not be necessary for certain GMMs, for example if the GMM qualifies for the Qualified Presumption of Safety (QPS) status (for a detailed explanation of QPS see below). The assessment of the possibility of horizontal gene transfer may be waived, on a case-by-case basis, depending on the nature of the modification and the resulting new trait of the GMM, for example in cases where the GMM was only modified by introducing genes of the same or closely related species (so-called self-cloning) or site-specific changes (or edits) in the DNA sequence, or by introducing deletions of sequences to remove or inactivate genes. Likewise, post-market environmental monitoring may not be needed for certain GMMs, especially those modified by self-cloning, by introducing deletions or by introducing edits.

In addition, EFSA published in 2025 a new **guidance on the characterisation of micro-organisms**[145] in support of the risk assessment of micro-organisms in products under the remit of EFSA. It addresses both genetically modified as well as not genetically modified micro-organisms, reflecting the key recommendation of the above scientific opinion that the approach to risk assessment for micro-organisms should be governed by the properties of the micro-organism or product irrespective of the technique used for its modification. In this respect, wherever product-specific legal obligations allow, the guidance provides a uniform approach to risk assessment of micro-organisms regardless of any potential use of genetic modification techniques.

The micro-organisms covered are bacteria, yeasts, filamentous fungi, microalgae and other protists, and viruses, including bacteriophages. The guidance addresses aspects regarding the taxonomic identification of a micro-organism, particularly in view of fulfilling the requirements originating from the assignments of a potential QPS status, the presence of genes of concern in the micro-organism's genome, the presence of viable cells, genetic material or substances of concern in the final product, and the possible impacts of products containing living micro-organisms on the environment.

As the above-mentioned opinion, this guidance asserts that, in principle, for micro-organisms belonging to taxonomic units listed in the QPS list, information regarding toxigenicity, pathogenicity, infectivity and history of use does not need to be provided by the applicant for the purpose of risk assessment. Similarly, for micro-organisms having obtained the QPS status no further assessment of environmental safety is required unless genetic modifications have been introduced, which may lead to potential adverse environmental effects.

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[145] EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., … Brétagne, S., Christensen, H., Cocconcelli, P.S., Herman, L., Prieto-Maradona, M., Mayo, B., Peláez, C., Saarela, M., Sánchez Serrano, J., Vernis, L., Yurkov, A., Aguilera, J., Anguita, M., Bozzi Cionci, N., Brozzi, R., Correia, S., García-Cazorla, Y., Istace F., Pettenati, E., Revez, E., Schoonjans, R., Valeri, P., Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. EFSA Journal, 23(11), e9705. https://doi.org/10.2903/j.efsa.2025.9705

Concretely, for the areas of risk that must be addressed in an environmental risk assessment of a GMM in accordance with Annex II to Directive 2001/18/EC, EFSA indicates some possible simplifications and flexibility in data requirements. Persistence, invasiveness and selective advantage may not need to be assessed if the GMM qualifies for QPS or belongs to a species commonly found in the microbiome of the receiving environment and its genetic modification leads to a trait known to be present in the microbiome of the receiving environment. Horizontal gene transfer may not need to be assessed if the genetic modification only results in deletions or insertions of sequences conferring traits that are already present in the microbiome of the receiving environment. Effects on non-target organisms, including on humans or animals may not need to be assessed if the GMM cannot produce new compounds or metabolites or higher quantities of endogenous compounds or metabolites compared to the unmodified parental strain or if the non-target organisms, including humans or animals would already naturally be exposed to those compounds or metabolites. Similarly, the effect on geochemical processes should only be assessed if the genetic modification –may cause higher expression of endogenous compounds or metabolites of concern, may lead to the expression of new compounds or metabolites not known to be naturally present in the microbiome of the receiving environment, or introduces metabolic pathways that would be new to the microbiome of the receiving environment.

The above findings and conclusions of EFSA's 2024 scientific opinion on new developments in biotechnology applied to micro-organisms and its 2025 new guidance on the characterisation of micro-organisms have been relied on to propose the adaptation of the data requirements for the environmental risk assessment of GMMs (new Article 24b in Directive 2001/18/EC), to propose the use of the QPS status as one criterion to determine GMMs which could profit from a streamlined consent procedure (new Article 24e in Directive 2001/18/EC) and, finally, to propose greater flexibility in the requirement of post-market environmental monitoring for certain GMMs (new Article 24f in Directive 2001/18/EC). In addition, EFSA's conclusion that risks of a GMM relate to the properties introduced rather than the method used for the genetic modification inform the choice to adapt current rules to the specificity of GMMs regardless of the (new or established) technique used for their modification.

5.1.2 The QPS approach

To provide background to and further rationale for the use of the QPS approach in the proposal (new Article 24e in Directive 2001/18/EC), this section summarises how the approach was developed, its evolution and implications as well as the use in the context of risk assessments.

In 2002, a working group consisting of members of the Scientific Committee on Animal Nutrition, the Scientific Committee on Food and the Scientific Committee on Plants of the European Commission (predecessors of EFSA) started developing a working paper on a generic approach for the safety assessment of micro-organisms used in food and feed or in their production. In this Commission working paper[146], a process was initially envisaged

[146] European Commission working paper, On a generic approach to the safety assessment of micro-organisms used in feed/food and feed/food production; 2003. https://food.ec.europa.eu/system/files/2020-12/sci-com_scf_out178_en.pdf

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that should, similarly to the concept and purpose of the Generally Recognised As Safe (GRAS) approach of the USA[147], allow for a generic pre-assessment of the safety of micro-organisms used in food and feed and the wider food and feed chain, including plant protection products. The core of this system was the assignment of the status of so-called Qualified Presumption of Safety (QPS) to defined groups (taxonomic units, usually a species) of micro-organisms on the basis of available evidence on the safety (body of knowledge) of and familiarity (history of use) with the micro-organism. The goal was to make the safety assessment of micro-organisms across the food and feed chain more consistent and make better use of resources without compromising safety. For taxonomic units of micro-organisms with QPS status, a complementary case-by-case risk assessment was then to focus on specific aspects relevant to the particular micro-organism or product type.

This initial work was, after a public consultation on the concept, advanced by EFSA, who in 2007 published the first list of micro-organisms with QPS status and formally integrated it into its risk assessment procedures, initially only for products directly consumed as or in food or feed[148]. In 2009, the approach was extended to micro-organisms used as active substances in plant protection products. As in the initial Commission working paper[149] referred to above, EFSA sees the QPS approach as a practical tool for building on available knowledge and experience, avoiding the reassessment of aspects known not to cause concern in relation to the specific micro-organism (at taxonomic unit level, usually the species) and to concentrate the assessment where there is still uncertainty about potential risks[150].

Today, QPS assessments are conducted by the EFSA Biological Hazards (BIOHAZ) Panel with support of the QPS working group and EFSA staff when EFSA receives an application for authorisation of a regulated product or active substance under their remit that entails a micro-organism not yet granted QPS status. Micro-organisms previously excluded from the QPS process or that have recently been assessed are not subject to a renewed QPS assessment[151]. The QPS assessment is made independently of the legal framework under which the application for authorisation was made and the data contained in that application and without prejudice to further assessment that might be needed under that framework.

The QPS approach is based on four pillars:

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[147] https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras

[148] Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. The EFSA Journal (2007) 587, 1-16; https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2007.587

[149] European Commission working paper, On a generic approach to the safety assessment of micro-organisms used in feed/food and feed/food production; 2023. https://food.ec.europa.eu/system/files/2020-12/sci-com_scf_out178_en.pdf

[150] Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. The EFSA Journal (2007) 587, 1-16; https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2007.587

[151] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Allende, A., Alvarez-Ordóñez, A., Bortolaia, V., Bover-Cid, S., De Cesare, A., Dohmen, W., Guillier, L., Jacxsens, L., Nauta, M., Mughini-Gras, L., Ottoson, J., Peixe, L., Perez-Rodriguez, F., Skandamis, P., Suffredini, E., Chemaly, M., Cocconcelli, P. S., Fernández Escámez, P. S., Herman, L. (2026). Update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA. EFSA Journal, 24(1), e9823. https://doi.org/10.2903/j.efsa.2026.9823

1. establishing the taxonomic identity of the micro-organism under assessment;
2. identifying the existing body of knowledge about the micro-organism, including any history of use;
3. identifying any known safety concerns for humans, animals and the environment, primarily linked to pathogenicity and similar aspects;
4. establishing the intended form of use of the micro-organism in products or in their manufacturing, i.e. as living micro-organism, as biomass or as production strain[152].

The maintenance of the QPS list is based on extensive literature searches (ELS). To accommodate any advancement in knowledge, in particular any arising safety concerns, this literature review is updated every 6 months. Any new additions to the QPS list[153] and micro-organisms notified for QPS assessment[154] are published every 6 months by EFSA, together with the detailed protocol for the literature review[155] and used search terms[156]. In addition, every 3 years EFSA publishes a scientific opinion summarising the evolution of the list over the last 3-year period and announcing any updates to the approach considering developments regarding established methodologies in microbiology, new scientific insights and new applications of micro-organisms in the food and feed chain[157]. Micro-organisms having obtained QPS status are listed in a public database[158].

When assigning QPS status to a certain taxonomic unit, EFSA is satisfied that the available knowledge documented in the literature, expert knowledge and the experience from previous use are sufficient to exclude certain potential adverse effects on human and animal health and the environment and that the same degree of confidence is achieved as would be the case with a case-by-case assessment. In this evaluation, the available scientific evidence indicating an exposure of humans and animals through food and feed, the distribution of the micro-organism in natural environments and their routes of dispersal, as well as the history of use in agricultural and food manufacturing systems and for biotechnological and medical purposes are considered. In addition, with increasing availability of whole genome sequencing data the screening for the presence of any virulence factors and other genes of concern has been incorporated[159].

If a specific safety concern is identified that is applicable to a defined sub-group of the species or specific uses, a condition to applying the QPS status, a so-called ”qualification“, is formulated to exclude the identified safety concern. In that case, the QPS status is only

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[152] See footnote 170

[153] https://doi.org/10.2903/j.efsa.2026.9824https://zenodo.org/records/15827398

[154] https://zenodo.org/records/18335928

[155] https://zenodo.org/records/18336181

[156] https://zenodo.org/records/18336241

[157] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Allende, A., Alvarez-Ordóñez, A., Bortolaia, V., Bover-Cid, S., De Cesare, A., Dohmen, W., Guillier, L., Jacxsens, L., Nauta, M., Mughini-Gras, L., Ottoson, J., Peixe, L., Perez-Rodriguez, F., Skandamis, P., Suffredini, E., Chemaly, M., Cocconcelli, P. S., Fernández Escámez, P. S., Herman, L. (2026). Update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA. EFSA Journal, 24(1), e9823. https://doi.org/10.2903/j.efsa.2026.9823

[158] https://zenodo.org/records/18329226

[159] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Allende, A., Alvarez-Ordóñez, A., Bortolaia, V., Bover-Cid, S., De Cesare, A., Dohmen, W., Guillier, L., Jacxsens, L., Nauta, M., Mughini-Gras, L., Ottoson, J., Peixe, L., Perez-Rodriguez, F., Skandamis, P., Suffredini, E., Chemaly, M., Cocconcelli, P. S., Fernández Escámez, P. S., Herman, L. (2026). Update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA. EFSA Journal, 24(1), e9823. https://doi.org/10.2903/j.efsa.2026.9823.

valid if the specific microbial strain used in a product or in its manufacturing fulfils the qualification. Currently established qualifications are, e.g. the "absence of acquired resistance genes to therapeutic antimicrobials", the "absence of toxigenic activity"and "for production purposes only". Any micro-organism requiring assessment by EFSA that can be unambiguously assigned to a taxonomic unit with QPS status and that fulfils any potential qualifications linked with this status does not require assessment of certain aspects of safety already addressed in the QPS assessment[160].

As indicated above, the main focus of the QPS assessment is to identify possible safety concerns linked to pathogenicity, virulence and toxigenicity for humans and animals, which will need to be excluded for all regulated products assessed by EFSA, including for GMMs. To some degree these aspects are also addressed in respect to plant health[161]. A taxonomic unit is included in the QPS list when certain risks for human and animal health have been excluded allowing for a simplified assessment -of a product containing a specific strain of this taxonomic unit. Therefore, for strains belonging to that taxonomic unit and complying with the existing qualifications, specific data, e.g. on antimicrobial production, toxigenicity and pathogenicity, are generally not required[162].

At the same time, the QPS approach does not cover the entire spectrum of potential safety concerns that may arise in relation to microbial products. For this reason, the QPS approach was from its conception envisaged as a tool to simplify the assessment of certain recurring safety concerns, while being complemented by a product-specific risk assessment to address remaining specific safety concerns. As a consequence, safety concerns that are relevant only for specific regulated products under EFSA remit, for example those regarding the wider environment in case of plant protection products or GMMs, will not be fully addressed by the generic QPS assessment but require a product-specific risk assessment on a case-by-case basis.

The concept of QPS is now relied upon in several areas of EU legislation. In the areas of plant protection products[163] and food enzymes[164], applicants can refer to the QPS status of the micro-organism in the product to justify not providing certain data during the respective

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[160] Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. The EFSA Journal (2007) 587, 1-16; https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2007.587.

[161] EFSA BIOHAZ Panel, Allende, A., Alvarez-Ordóñez, A., Bortolaia, V., Bover-Cid, S., De Cesare, A., Dohmen, W., Guillier, L., jacxsens, . liesbeth ., Nauta, M., Mughini-Gras, L., Ottoson, J., Peixe, L., Perez-Rodriguez, F., Skandamis, P., Suffredini, E., Cocconcelli, P. S., Fernández Escámez, P. S., Maradona, M. P., … Correia, S. (2026). Protocol for Extensive literature search (ELS) for the maintenance and update of list of QPS-recommended biological agents. Zenodo. https://doi.org/10.5281/zenodo.18336181.

[162] EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Allende, A., Alvarez-Ordóñez, A., Bortolaia, V., Bover-Cid, S., De Cesare, A., Dohmen, W., Guillier, L., Jacxsens, L., Nauta, M., Mughini-Gras, L., Ottoson, J., Peixe, L., Perez-Rodriguez, F., Skandamis, P., Suffredini, E., Chemaly, M., Cocconcelli, P. S., Fernández Escámez, P. S., Herman, L. (2026). Update of the list of QPS-recommended biological agents intentionally added to food or feeds as notified to EFSA. EFSA Journal, 24(1), e9823. https://doi.org/10.2903/j.efsa.2026.9823.

[163] Commission Regulation (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms; see Annex II, Part B, Section 2, points 2.1.3. and 5.2.

[164] Commission Implementing Regulation (EU) No 562/2012 of 27 June 2012 amending Commission Regulation (EU) No 234/2011 with regard to specific data required for risk assessment of food enzymes Text with EEA relevance; see Article 1a and Article 8(3) and (5) of Commission Regulation (EU) No 234/2011; see also recital (6) of Commission Implementing Regulation (EU) No 562/2012.

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authorisation procedures. In the area of fertilising products[165], having QPS status is used as one criterion on the basis of which a microbial species may be allowed as a component of fertilising products. QPS is also a determining criterion for assigning the Ecolabel[166] to detergents containing a micro-organism.

5.1.3 ENGL report on detection of micro-organisms obtained with NGTs

The provision in the proposal that the modalities to comply with analytical method requirements may be adapted if compliance may otherwise not be feasible (new Article 24d in Directive 2001/18/EC) takes into account the work of the ENGL on detection methods for GMMs.

To implement and enforce traceability and labelling requirements in accordance with Directive 2001/18/EC, notifiers under Part C of that Directive need, as part of the information required for notifications defined in its Annex III, to present a detection method that is suitable to detect (i.e. prove the presence of a known genetic modification), identify (i.e. prove that the detected genetic modification is attributable to the presence of a particular regulated GMO or its product) and quantify (i.e. measure the relative quantity of the identified GMO or its product in a given sample). Providing such a detection method is a mandatory prerequisite for the granting of consent for placing on the market of a GMO, including GMMs, as or in products in the EU.

The Commission requested from the European Network of GMO laboratories (ENGL) a technical **report on the detection of micro-organisms obtained by NGTs in food and feed products**[167] to address knowledge gaps regarding GMMs identified in the 2021 Commission study on NGTs applied to plants, animals and micro-organisms[168]. A similar report was previously published on plant-based food and feed in 2019[169] and updated in 2023[170].

The ENGL's report on GMMs published in 2025 investigates the analytical possibilities and challenges linked to the detection of micro-organisms obtained with NGTs that do not entail the insertion of foreign genetic material. It concludes that detecting certain GMMs obtained with NGTs poses considerable analytical challenges as certain genetic modifications obtained with NGTs may be indistinguishable from those that can arise in

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[165] Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003; see Article 42(4).

[166] Commission Decision (EU) 2017/1217 of 23 June 2017 establishing the EU Ecolabel criteria for hard surface cleaning products (notified under document C (2017) 4241). https://eur-lex.europa.eu/eli/dec/2017/1217/oj; see in Annex, criterion 4, lett. (h), point (ii)..

[167] Sowa, S., Broothaerts, W., Burns, M., De Loose, M., Debode, F. et al., Detection of microorganisms, obtained by new genomic techniques, in food and feed products, Publications Office of the European Union, Luxembourg, 2025, JRC143597. https://publications.jrc.ec.europa.eu/repository/handle/JRC143597

[168] Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD (2021) 92 final. https://food.ec.europa.eu/system/files/2021-04/gmo_mod-bio_ngt_eu-study.pdf

[169] European Network of GMO Laboratories (ENGL), Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019 (JRC116289). https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

[170] European Network of GMO Laboratories, Detection of food and feed plant products obtained by targeted mutagenesis and cisgenesis, Publications Office of the European Union, Luxembourg, 2023, doi:10.2760/007925, JRC133689. https://publications.jrc.ec.europa.eu/repository/handle/JRC133689

nature or by using conventional mutagenesis techniques. This problem may be exacerbated, compared to plants, by the high genetic diversity of micro-organisms. Tracing back such modifications to the use of NGTs for genetic modification of a GMM or its product will not be possible through analytical means, i.e. identification and quantification may not be possible in those cases. According to the ENGL, technical advancement, such as high-throughput sequencing technologies, may further support enforcement in the future but will be unlikely to resolve the particular problem of identification.

5.2 Applications of GMMs As or In Products

5.2.1 Overview of Applications

The Commission's Joint Research Centre (JRC) has conducted in 2026 an up-to-date analysis of GMM products for environmental release in development around the world to supplement this staff working document[171]. It complements previous work by the JRC on current and future market applications of NGTs, including when applied to micro-organisms, which supported the Commission's 2021 NGT study[172]. An external study on the assessment of policy scenarios in the area of biotechnology conducted to support this staff working document provided in addition estimates on the global market sizes for some areas of microbial products[173].

The **JRC report on current and future applications of GMMs for environmental releases**[174] referenced above found that there is a growing interest to leverage GMMs for applications involving environmental releases. These applications span a wide variety of product types and sectors. The following product types and applications (for uses other than food and feed which are outside the scope of this proposal) have been identified in the JRC report. Where available, the sections below also include data on market sizes from the mentioned external study.

Agriculture

The use of microbial solutions is not new in the agricultural sector to maintain or increase productivity, while reducing environmental impact. However, conventional microbial strains do not always provide equally efficient alternatives to the wide range of applications for chemical agricultural inputs. GMMs as biofertilisers, biopesticides and biostimulants can provide improved functionality and reliability compared to conventional microbial and chemical products. The first GM biofertilisers and GM biopesticides are already on the market in the U.S.

The external study referred to above reported one estimate of the global biofertilisers sector at EUR 1.18 billion in 2024 with a projection to reach EUR 2.42 billion by 2030, growing

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[171] Lowe, C.R., Ponferrada, V., Ruiz Aquino, C., Compaño, R., Nanda, A.K. (2026). Current and future market applications of genetically modified microorganisms (GMMs) to be placed on the market or for environmental release. JRC Technical Report, Publications Office of the European Union, Luxembourg (publication forthcoming).
[172] Parisi, C. and Rodriguez Cerezo, E. (2021) Current and future market applications of new genomic techniques, Publications Office of the European Union, Luxembourg, https://data.europa.eu/doi/10.2760/02472, JRC123830.
[173] Rapid assessment scenario study - forthcoming.
[174] Lowe, C.R., Ponferrada, V., Ruiz Aquino, C., Compaño, R., Nanda, A.K. (2026). Current and future market applications of genetically modified microorganisms (GMMs) to be placed on the market or for environmental release. JRC Technical Report, Publications Office of the European Union, Luxembourg (publication forthcoming)

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at a Compound Annual Growth Rate (CAGR) of 12.8% from 2025 to 2030[175]. Another estimate from this study reported the global market size even at EUR 2.65 billion in 2023, projected to reach EUR 4.45 billion by 2028 with a CAGR of 10.9%[176]. However, both these estimates relate to microbial fertilisers in general and only a part will be attributable to GMMs. So far, commercial biofertiliser products are mostly not genetically modified, yet various GMMs are in a research and development phase. For commercially available GMM biofertiliser products, see the case study below in section 3.

With regard to the microbial biocontrol sector, including microbial biopesticides, the above-mentioned study reports an estimated market size of EUR 5.56 billion in the year 2025, which is expected to increase to EUR 14.2 billion by 2032, growing at a CAGR of 14.3%[177]. In 2024, microbial solutions (bacteria, fungi, viruses) comprised over 58% of all biocontrol agent units globally[178]. However, the study reports that there are no estimates available specifically for GMMs and of the part of the market that will be attributable to GMM-based products.

Bioremediation

Bioremediation is the use of living organisms, such as bacteria, fungi, or plants, to remove, neutralise, or degrade pollutants (e.g., heavy metals, oil, pesticides) from contaminated soil, water, or air.

GMMs can improve bioremediation by providing enhanced functionalities compared to non-genetically modified microbes. They can be used to degrade pollutants such as oil, plastics, heavy metals and persistent chemicals (e.g. per- and polyfluoroalkyl compounds (PFAS)). So far, many genetically modified strains have been developed for bioremediation purposes, and further progress promises to enable wider deployment beyond field trials[179].

One U.S. start-up, for example, offers tailored genetically modified micro-organisms to address chemical pollution of industrial sites. The GMMs are engineered to improve and combine natural abilities of certain micro-organisms to degrade chemicals, for example PFAS, into less or non-toxic compounds[180].

The above-mentioned external study reports that the global bioremediation market size was valued at EUR 14.1 billion in 2024 and is projected to grow from EUR 15.5 billion in 2025 to EUR 32.9 billion by 2033, growing at a CAGR of 9.93% during the forecast period

[175] Grand View Research. Biofertilizers Market (2025 - 2030). https://www.grandviewresearch.com/industry-analysis/biofertilizers-industry.
[176] Markets and Markets. Global Biofertilizers Market Size, Trends, Growth Forecast (2023–2028). 13 November 2025. https://www.marketsandmarkets.com/blog/FB/biofertilizers-market.
[177] ReAnIn. Biocontrol Agents Market Size & Share Analysis - Growth Trends and Forecast (2025 - 2032). March 2026. https://www.reanin.com/reports/biocontrol-agents-market
[178] Industry Research Biz. Biocontrol Market Size, Share, Growth, and Industry Analysis, By Type (Microbials, Macrobials, Biochemicals), By Application (Grains and Cereals, Oilseeds and Pulses, Fruits and Vegetables, Other Crop Applications), Regional Insights and Forecast to 2035. January 2026. https://www.industryresearch.biz/market-reports/biocontrol-market-113645
[179] Singh JS, Abhilish PC, Singh HB, Singh RP & Singh DP (2011) Genetically engineered bacteria: An emerging tool for environmental remediation and future research perspectives. Gene 480, 1-9.
[180] Paliwoda Group. Lysosome Resources. January 2026. https://www.paliwoda.com/lysosomeresources.php

(2026 – 2033)[181]. Other estimates even expect a CAGR of 13.0% from 2025 to 2034[182]. Although there are no specific data for a GMM bioremediation market available, the use of GMMs is marked as a "key market trend"[183].

Wastewater treatment & pollution control

Water pollution through industrial releases such as agricultural, mining and industrial wastes and domestic effluents and its subsequent treatments have become major global concerns. GMMs can offer tailored solutions for wastewater treatment by enhancing the removal of a multitude of pollutants and making treatment more efficient, cost-effective and eco-friendly. Large scale release of these solutions is so far limited although they are frequently used in contained settings[184].

Biomining, bioleaching and bioaccumulation

Biomining uses micro-organisms to extract metals from ores, while bioleaching specifically employs bacteria to dissolve metals via acidic solutions, and bioaccumulation describes how micro-organisms absorb and concentrate substances (e.g. metals) from their environment.

At present, there are no GMMs used in global commercial scale biomining operations, but this is an active area of research to enhance the efficiency, speed and environmental sustainability of metal recovery via bioleaching, bio-oxidation and bioaccumulation[185,186]. Bioleaching is employed in two separate scenarios which differ in scale: urban waste streams containing critical metals, which is mostly done in contained environments but may also be used in environmental release scenarios; and natural ore processing at scale using environmental releases directly within the geographical locations. Conventional microbes have been used in ore bioleaching. However, GMMs are now being developed to overcome limitations of conventional microbes, such as slow process times and sensitivity to fluctuating site conditions like temperature, pH and metal concentrations. GMMs provide, for example, unique opportunities for biomining rare earth elements,

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[181] SkyQuest Technology Consulting Pvt. Ltd. Bioremediation Market Size, Share, and Growth Analysis. Bioremediation Market By Type (Situ Bioremediation, And Ex Situ Bioremediation), By Technology (Biostimulation, Phytoremediation), By Service (Soil Remediation, Oilfield Remediation), By Region - Industry Forecast 2026-2033. November 2024. https://www.skyquestt.com/report/bioremediation-market

[182] Dimension Market Research. Bioremediation Market. Bioremediation Market By Type (In Situ Bioremediation, Ex Situ Bioremediation), By Technology, By Service - Global Industry Outlook, Key Trends and Forecast 2025-2034. November 2024. https://dimensionmarketresearch.com/report/bioremediation-market/

[183] SkyQuest Technology Consulting Pvt. Ltd. Bioremediation Market Size, Share, and Growth Analysis. Bioremediation Market By Type (Situ Bioremediation, And Ex Situ Bioremediation), By Technology (Biostimulation, Phytoremediation), By Service (Soil Remediation, Oilfield Remediation), By Region - Industry Forecast 2026-2033. November 2024. https://www.skyquestt.com/report/bioremediation-market

[184] Gaurav Pant, Deviram Garlapati, Urvashi Agrawal, R. Gyana Prasuna, Thangavel Mathimani, Arivalagan Pugazhendhi, Biological approaches practised using genetically engineered microbes for a sustainable environment: A review, Journal of Hazardous Materials, Volume 405, 2021, 124631, ISSN 0304-3894, https://doi.org/10.1016/j.jhazmat.2020.124631.

[185] Chen J, Liu Y, Diep P & Mahadevan R (2022) Harnessing synthetic biology for sustainable biomining with Fe/S-oxidising microbes. Front Bioeng Biotech 10, 920639

[186] Gumulya Y, Boxall, NJ, Khaleque HN, Santala V, Carlsson RP & Kallsonen AH (2018) In a quest for engineering acidophiles for biomining applications: Challenges and opportunities. Genes 9, 116. https://doi.org/10.3390/genes9020116

which are critical elements for renewable energy, military equipment, electric vehicles and other products of advanced engineering.

One concrete example comes from a U.S. start-up developing a genetically modified yeast that binds cobalt in wastewater streams from mining operations. This approach aims, on the one hand, to prevent ecological damages stemming from heavy metal contamination of water sources and, on the other hand, to retain the valuable metal, while being more cost effective than the conventional method of membrane filtration and avoiding the use of chemicals for precipitation. The company claims that their use of the GMM enables the recovery of 97% of the cobalt contained, also cleaning the wastewater to fulfil the U.S. Environmental Protection Agency's wastewater standards, and that it can save 50% of energy compared to conventional methods[187].

The above-named external study reports the market size estimate at EUR 8.70 billion in 2024, with a projection to reach EUR 18.3 billion by 2033, growing at a CAGR of 8.9% from 2025 to 2033[188]. Another reported estimate values the market size at EUR 9.58 billion in 2025 and projects it to grow from EUR 10.4 billion in 2026 to EUR 20.9 billion by 2034, exhibiting a CAGR of 9.06% during the forecast period[189]. Specific GMM-related data are not available, but GMMs are mentioned as future opportunity and potential field of innovation[190].

Construction materials

Biomaterials have been proposed as a sustainable alternative to e.g., plastics and concrete in the construction and infrastructure sectors. Engineered Living Materials (ELMs)[191] applied to the construction industry provide a new class of sustainable biomaterials that can be grown from living organisms or incorporate living cells to furnish entirely unique capabilities such as self-healing and carbon sequestration. Their deployment requires environmental release of the GMM. The leading-edge of construction biotechnology could leverage GMMs as biosensors i.e., to detect environmental cues, such as moisture, pH shifts or mechanical stress. The GMMs can then initiate selective responses, including carbonate precipitation, polymer secretion or the release of "healing compounds". Such ELMs could lead to the development of adaptive, intelligent self-regulating infrastructure capable of sensing environmental changes via real-time monitoring and stress-responsive functions.

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[187] MIT Solve. 2025 Global Climate Challenge. Aquasaic: Bioengineered yeast for eco cobalt recovery. August 2025. https://solve.mit.edu/solutions/102928

[188] Grand View Research. Bioleaching Market (2025 - 2033) Size, Share & Trends Analysis Report By Metal (Copper, Gold, Zinc & Nickel), By Source (Primary Ores, Mine Tailings), By Region (North America, Europe, Asia Pacific), And Segment Forecasts. https://www.grandviewresearch.com/industry-analysis/bioleaching-market-report

[189] Fortune Business Insights. Bioleaching Market Size, Share, and Industry Analysis By Metal Type (Gold, Copper, Nickel, Cobalt, and Others), By Microorganism Type (Bacteria, Fungi, and Others), By Application (Mining, E-Waste Recycling, Industrial Waste Treatment, Agriculture, and Others), and Regional Forecast, 2026-2034. March 2026. https://www.fortunebusinessinsights.com/bioleaching-market-110894

[190] Grand View Research. Bioleaching Market (2025 - 2033) Size, Share & Trends Analysis Report By Metal (Copper, Gold, Zinc & Nickel), By Source (Primary Ores, Mine Tailings), By Region (North America, Europe, Asia Pacific), And Segment Forecasts. https://www.grandviewresearch.com/industry-analysis/bioleaching-market-report

[191] Gilbert C and Ellis T (2019) Biological Engineered Living Materials: Growing Functional Materials with Genetically Programmable Properties. ACS Synthetic Biology 2019 8 (1), 1-15 https://doi.org/10.1021/acssynbio.8b00423

Cutting edge research and development on ELMs is funded by the European Innovation Council[192]. One of the funded projects, the REMEDY Consortium entailing partners from Austria, the Netherlands, Slovakia and Slovenia, aims to develop substances containing mixtures of micro-organisms that can be printed onto surfaces of buildings. This "microbial ink" is intended to improve local air quality in built-up areas by producing oxygen, sequestering carbon dioxide and degrading pollutants[193].

Defence

Recent developments in genetic engineering are creating new paradigms for biodefense, national security, medical countermeasures and advanced materials. Examples of key defence applications of GMMs in research and development include submarine detection with marine bacteria that react to emissions from submarines, GMMs able to detect explosives in e.g., landmines, advanced protective and responsive garments and self-healing ELMs for camouflage, construction, ships and aircraft (also see "construction materials" above)[194]. Most of these applications would entail the environmental release of the GMM.

Carbon capture

Advances in biotech now enable the optimisation of carbon capture with more precision by tailoring GMMs to boost their photosynthetic capacity and absorb greater amounts of CO_2 from the atmosphere. In addition, GMMs are being used to sequester carbon in a stable form that prevents its release into the atmosphere, whilst the stable carbon-rich compounds can either be stored long-term[195] or used to generate renewable energy[196] or act as substrates for biomanufacturing of higher value products in contained systems[197]. While most of the applications are currently limited to contained use, the scale of what is needed to effectively capture and store enough carbon to mitigate climate change would require strategies including environmental releases in order to be viable[198].

Cosmetic products and personal care

Currently, the use of GMMs in the cosmetics and personal care industry is mostly limited to contained use, through the production of key compounds and ingredients through industrial fermentation. However, they are also increasingly being developed for direct use

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[192] European Commission: European Innovation Council and SMEs Executive Agency, EIC pathfinder portfolio – Engineered living materials – Strategic plan – Brussels, November 2023, Publications Office of the European Union, 2023, https://data.europa.eu/doi/10.2826/260175

[193] Remedy Consortium. https://eic-remedy.eu/consortium/?lang=en

[194] Lowe, C.R., Ponferrada, V., Ruiz Aquino C., Compaño, R., Nanda, A.K. (2026). Current and future market applications of genetically modified microorganisms (GMMs) to be placed on the market or for environmental release. JRC Technical Report, Publications Office of the European Union, Luxembourg (publication forthcoming).

[195] Onyeaka H & Ekwebelem OC (2023) A review of recent advances in engineering bacteria for enhanced CO_2 capture and utilisation. Intl J Environ Sci & Tech 20, 4635-4648. https://doi.org/10.1007/s13762-022-04303-8

[196] Priyadharshini K & Niju S (2025) Current advances in microbial carbon capture cells – a unique bioelectrochemical system for sustainable future. Sust Chem Environ 10, 100244. https://doi.org/10.1016/j.scenv.2025.100244

[197] Hoque M, Iannelli V, Padula F, Radice RP, Saha BK, Martelli G, Scopa A & Drosos M (2025) Microalgae: green engines for achieving carbon sequestration, circular economy and environmental sustainability – a review based on last ten years of research. Bioengineering 12, 909. https://doi.org/10.3390/bioengineering12090909

[198] https://luminaprobiotic.com/

in cosmetic products and personal care products[199,200]. Currently, one GMM probiotic, developed to improve dental health by reducing the build-up of lactic acid, is commercially available in the USA since 2023[201].

Table 4. Examples of GMM products[202] for environmental release in various stages of development

Micro-organism	Application	Trait	Issue addressed	Development stage	Country	Reference
Bacteria *(Klebsiella variicola* and *Kosakonia sacchari)*	Agriculture - biofertiliser	Nitrogen fixation in soil/rhizosphere	Dependency on synthetic fertiliser; Negative environmental impacts of excessive fertiliser use	Commercial; Pre-commercial	USA; Brazil	203, 204, 205, 206
Bacteria (Paenibacillus polymyxa, P. odorifer)	Agriculture - biofertiliser	Nitrogen fixation in soil/rhizosphere	Dependency on synthetic fertiliser Negative environmental impacts of excessive fertiliser use	Pre-commercial	Brazil USA	207, 208, 209, 210, 211, 212, 213
Bacteria (*Pseudomonas* species)	Agriculture - food safety	Removal of arsenic from the environment	Arsenic accumulation in agricultural produce for human consumption	R&D stage	India	214, 215

[199] Atallah, C.; El Abiad, A.; El Abiad, M.; Nakad, M.; Assaf, J.C. Bioengineered Skin Microbiome: The Next Frontier in Personalized Cosmetics. Cosmetics 2025, 12, 205. https://doi.org/10.3390/cosmetics12050205
[200] Chinjoo N & Golzary A (2025) Microalgae: revolutionising skin repair and enhancement. Biotechnol Rep 47, e00911. https://doi.org/10.1016/j.btre.2025.e00911
[201] https://luminaprobiotic.com/
[202] Based on the description of the micro-organism and in accordance with the EU GMO definition. Products may be classified as non-genetically modified in the respective 3rd country.
[203] https://www.pivotbio.com/press-releases/peer-reviewed-study-validates-pivot-bios-gene-edited-microbes-as-a-third-source-of-nitrogen-delivery
[204] https://www.pivotbio.com/product-proven40-corn
[205] https://worldwide.espacenet.com/patent/search/family/070918989/publication/WO2021221690A1
[206] https://www.prnewswire.com/news-releases/pivot-bio-readies-brazilian-operation-with-expanded-team-302265792.html
[207] https://one.oecd.org/document/ENV/CBC/MONO(2024)22/en/pdf
[208] https://www.aphis.usda.gov/sites/default/files/25-007-02air-response.pdf
[209] https://www.aphis.usda.gov/sites/default/files/25-007-02air-cbidel-a1.pdf
[210] https://www.aphis.usda.gov/sites/default/files/25-007-01air-cbidel-a1.pdf
[211] https://www.aphis.usda.gov/sites/default/files/25-007-01air-response.pdf
[212] https://www.aphis.usda.gov/sites/default/files/25-182-02air-response.pdf
[213] https://www.aphis.usda.gov/sites/default/files/25-182-02air-cbidel-a2.pdf
[214] https://microbiologyjournal.org/role-of-pseudomonas-putida-ckvf1-in-alleviating-arsenic-induced-stress-in-vicia-faba-l/
[215] https://pubmed.ncbi.nlm.nih.gov/39999859/

Bacteria (*Acetobacter, Sarcina ventriculi* and *Agrobacterium*)	Agriculture - drought resilience	Excretion of water-retaining compounds	Drought resilience	R&D stage	UK	216, 217
Bacterium (*Bacillus thuringiensis*) (multiple strains)	Agriculture - biopesticide	Expression of toxins active against lepidopterous larvae	Economic losses due to various plant pests	Commercial; Pre-commercial	China USA; Brazil	218, 219, 220
Bacterium (*Agrobacterium radiobacter/ Rhizobium rhizogenes*)	Agriculture - biopesticide	Production of antibiotic compound	Economic losses due to crown gall disease	Commercial	Australia Türkiye USA	221, 222, 223
Bacteria, Fungi	Bio-remediation	Degradation of harmful chemicals	Chemical pollution of industrial sites	R&D stage	USA	224
Bacterium (*Shewanella oneidensis*)	Bio-remediation	Degradation of DNA conferring antibiotic resistance	Antibiotic resistance gene reservoirs in wastewater	R&D stage	China USA	225
Yeast (*Saccharomyces cerevisiae*)	Biomining - wastewater treatment	Binding of cobalt	Cobalt contamination in wastewater from mining operations	R&D stage	USA	226
Microbial consortia	Construction materials – ink	Sequestration of carbon, production of oxygen or degradation of pollutants	Poor air quality in built areas	R&D stage	EU	227, 228
Bacteria (*Streptococcus mutans)*	Cosmetics – dental care	Conversion of sugar into alcohol instead of lactic acid	Tooth decay	Commercial	USA	229, 230, 231

[216] https://www.crobio.com/technology
[217] https://patents.justia.com/patent/20230034438
[218] https://www.certisbio.com/products/bt-biolarvicides/crymax
[219] https://pmc.ncbi.nlm.nih.gov/articles/PMC12665435/
[220] https://one.oecd.org/document/ENV/CBC/MONO(2024)22/en/pdf
[221] https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/related_PC-006474_1-Sep-99.pdf
[222] https://bio-caretechnology.com/
[223] https://www.mdpi.com/2073-4395/10/8/1126
[224] https://www.paliwoda.com/lysosomeresources
[225] https://www.nature.com/articles/s44221-024-00289-4
[226] https://solve.mit.edu/solutions/102928
[227] https://www.innovationnewsnetwork.com/remedy-redefining-architecture-through-engineered-living-materials/62541/
[228] https://eic-remedy.eu/research-results
[229] https://luminaprobiotic.com/
[230] https://www.scientificamerican.com/article/this-start-up-wants-you-to-put-custom-bacteria-on-your-teeth/
[231] https://sfstandard.com/2025/02/22/lumina-probiotic-cavity-bioengineered-toothpaste/

In addition, the Commission asked EFSA, in the context of its scientific opinion on new developments in biotechnology applied to micro-organisms[232], to produce a horizon scan on micro-organisms and their products obtained by new developments in biotechnology[233]. The **EFSA horizon scan** found that there is significant activity in the development of innovative GMMs by both private and public/academic entities but noted that the majority of the identified GMMs originated from the USA or China, while only a limited number were developed within the EU. EFSA identified 35 products making use of GMMs obtained by NGTs, which was the focus of the horizon scan, and primarily in the food and feed area, that are currently on the market in third countries or expected to come to the market within the next 10 years. About half of these products would contain the living micro-organism (and would therefore fall in the scope of Directive 2001/18/EC), while the other half would be derived from the GMM without containing living cells. The used micro-organisms included yeasts, bacteria, fungi and microalgae. About a quarter of the identified products were developed using a combination of NGTs and established genomic techniques.

To complement this horizon scan, EFSA conducted an online call for data in March/April 2023. The results of this call are presented in the above-named scientific opinion. This call largely confirmed the trends identified in the horizon scan, while a higher proportion (75%) of the reported products in development made use of a combination of NGTs and established genomic techniques.

5.2.2 Case Study: GMMs for Biological Nitrogen Fixation

The most advanced application of GMMs for environmental release are biofertilisers. A practical approach to reducing dependency on synthetic fertilisers is through biological nitrogen fixation (BNF) by genetically modifying nitrogen-fixing bacteria to enhance their ability to supply crops with sufficient nitrogen. This specific use is investigated by the JRC with a case study explained below[234].

While synthetic fertilisers have driven unprecedented increases in crop yields, the dependence on them raises farmers' production costs, increases energy demand, and harms the environment, contributing to greenhouse gas emissions and water contamination. A key solution to mitigate these economic and ecological impacts is replacing synthetic nitrogen inputs with nitrogen from BNF, a natural process in which soil micro-organisms convert atmospheric nitrogen into plant-available ammonia. One approach to reducing fertiliser dependency through BNF is by genetically modifying nitrogen-fixing bacteria to

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[232] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Jimenez Saiz, R., Ruiz Garcia, L., Aguilera Entrena, J., Gennaro, A., Schoonjans, R., Kagkli, D. M., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895. https://doi.org/10.2903/j.efsa.2024.8895

[233] Ballester, A.R., Roqué, M., Ricci-Cabello, I., Rotger, A., Malih, N. 2023. Horizon scanning on microorganisms and their products obtained by new developments in biotechnology. EFSA supporting publication 2023:EN-8503, 65 pp. doi:10.2903/sp.efsa.2023.EN-8503

[234] Burren, S., Palacios, J., Areal, F.J., Rodriguez-Cerezo, E., Barreiro-Hurle, J. (2026). The potential of genetically modified microorganisms to reduce nitrogen loads in the EU agricultural sector. JRC Technical Report, Publications Office of the European Union, Luxembourg

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enhance their ability to supply crops with sufficient nitrogen while ensuring the GMMs remain competitive and thrive in soil conditions.

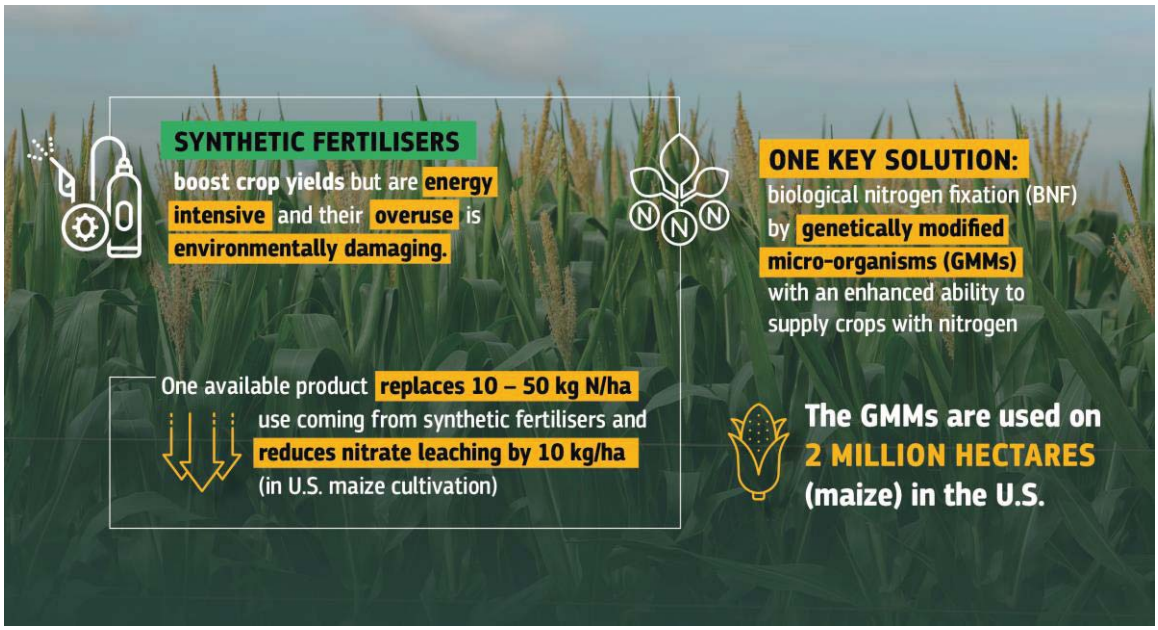
At present, at least four companies are developing GMM products to address BNF in crops. The most advanced of these companies in terms of market readiness recently launched their third generation of a GMM-based nitrogen-fixation solution in the USA, building on their first- and second-generation products introduced to the U.S. market in 2019 and 2021, respectively. In addition, this company is preparing the market entry in Brazil awaiting the approval of their commercial registration of their products. The products are designed to enhance BNF in nitrogen-rich agricultural soils – a situation typical for European agriculture. The GMMs are modified through targeted mutagenesis to convert nitrogen to ammonia, which in turn can readily be taken up and used by plants. Beyond the most used products to support the cultivation of maize, related formulations are marketed for cotton, sorghum and millet, and for small grains and oilseeds including wheat, oats, barley, rye, and sunflower. After commercial launch of the first-generation GMM in 2019, the products have been used on at least 2 million hectares of maize across the U.S.

The GMM products have been tested in multiple academic trials, third-party substitution trials, and more than 3,000 commercial farm fields, primarily in maize under U.S. agronomic conditions. Across different sources (peer-reviewed studies, commercial on-farm trials, university field trials, company reports and independent research organisations) the reported nitrogen (N) replacement values ranged from roughly 10 kg N/ha up to 50 kg N/ha. Corresponding yield increases over the use of traditional fertilisers varied between 0.10 and 0.80 t/ha resulting in income gains for farmers of typically between €20 and €60/ha per harvest. Disregarding any potential yield gains and considering the price of the product calculated by the company, traditional nitrogen sources can be replaced by the biofertiliser at no greater costs for farmers if nitrogen costs range between €0.94 per kg N (assuming 50 kg N/ha replacement) and €4.70 per kg N (assuming 10 kg N/ha replacement). Lower product costs, higher nitrogen prices or greater nitrogen placement would render the biofertiliser more cost effective than traditional solutions. Based on the recorded prices of nitrogen, having fluctuated between €0.53 and €1.73 per kg N over the past five years and given that the latest geopolitical disruptions signal towards higher fertilizer prices in the short to midterm, using the biofertiliser appears to be economically viable in the majority of use scenarios and in some situations would be economically beneficial for farmers in comparison to the use of traditional nitrogen sources. The latter is further supported when taking into account the modest yield increases the GMM product can deliver over the use of traditional fertilisers.

In addition, this economic evaluation is not considering environmental benefits that may be considerable when broader adoption of biofertilisers occurs. For example, according to company estimates, widespread adoption across the U.S. maize cultivation area could reduce synthetic nitrogen fertilizer use by approximately 12%, with associated reductions in greenhouse gas emissions and nitrate losses. One study demonstrated that use of the GMM product reduced the average amount of nitrate washed out from soil into ground and surface water (so-called nitrate leaching) by approximately 10 kg/ha relative to untreated controls and so addresses one major concern arising from the use of synthetic nitrogen

fertilisers. Taken together, the evidence suggests that BNF technologies can provide these environmental benefits at no additional costs for farmers compared to synthetic fertilisers and, if larger nitrogen-replacement rates are achieved, the price for nitrogen increases or any yield increases are realised, would lead to economic advantages to farmers over traditional nitrogen sources.

Figure 1: case study: GMMs for biological nitrogen fixation



6 Intervention n°8: Targeted legislative reform of the Directive on human organs intended for transplantation

6.1 Detailed description of the proposed measures

Measure 1: Scope expansion

The first measure amends Article 2(1) of the Directive to insert "processing" (replacing "preservation") into the list of activities to which the Directive applies, alongside donation, testing, characterisation, procurement, transport, and transplantation. Thus, preservation becomes legally subsumed as a specific type of processing, as established in the new definition of "processing" under Article 3(ka). This change establishes the prerequisite for the entire revision by bringing organ processing activities within the material scope of the Directive's quality and safety framework.

The measure also introduces a new definition of "processing", defined as any operation involving the handling of organs, including but not limited to preservation, application of chemotherapy, and surgery, performed to maintain or improve the functional status of an organ prior to transplantation. Although the definition is deliberately broad, it draws three exclusions. First, it excludes the preparatory handling of the organ during the surgical

transplantation intervention itself, as routine surgical preparation in the operating room falls within Member State competence. Second, it excludes the repurposing of organs into tissues or cells, which falls under the SoHO Regulation (EU) 2024/1938. Third, it excludes the use of pharmacologically active substances where the primary aim is to treat or prevent a disease in the recipient rather than to process the organ, drawing a functional boundary between treating the organ (regulated under the new processing regime) and treating the patient (regulated under the standard medicinal products framework).

The definition of "transplantation" in Article 3(q) is also adjusted by removing "from a donor", so that transplantation is now defined as a process intended to restore certain functions of the human body by transferring an organ to a recipient covering the case where the recipient and the donor are the same person.

Measure 2: Organ processing authorisation regime

The proposed new Article 6a aims to establish a comprehensive regulatory regime for organ processing. The foundational rule (Article 6a (1)) prohibits transplantation centres from applying a processed organ to a recipient without prior authorisation of this specific processing technology/technique from the competent authority. The authorisation requirement applies per processing technology and per transplantation centre. This prior authorisation requirement shifts organ processing from an unregulated clinical activity to one that requires formal approval of the applied processing technology from the oversight authority before clinical application.

The transplantation centre must conduct an upfront benefit–risk assessment of the processing technique, taking into account the intended clinical indication (Article 6a (2)). Based on this assessment, the competent authority grants an authorisation (implementing rules referred to in Article 6a (12)), considering the adequacy of the evidence base and whether the benefit–risk profile is favourable. Where the available evidence is insufficient to support a benefit–risk assessment or where that assessment identifies a significant risk (Article 6a(3)), the transplantation centre must submit a proposal for a clinical-outcome monitoring plan for approval by the competent authority. The extent of the clinical outcome monitoring plan will be defined by the identified risk and the availability of data. This functions as a tailored approval pathway: initial clinical use of novel or higher-risk processing techniques will be permitted in a controlled setting.

Article 6a (9) introduces change control, prohibiting transplantation centres from making significant changes to authorised processing steps without prior written agreement from the competent authority. Competent authorities can suspend authorisations where there is reasonable ground to suspect non-compliance (Article 6a (10)). The Commission will publish a list of authorised organ processing operations/techniques, including any associated medicinal products, medical devices, or SoHO preparations (Article 6a (11)). This mechanism serves a dual function: it provides a reference point for transplantation centres across the EU regarding the state of the art, and it creates the informational basis for a *de facto* convergence of practice that could facilitate cross-border organ exchange. The Commission can also adopt implementing acts laying down detailed rules for the authorisation of organ processing techniques (Article 6a (12)).

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The complementary data set in Part B of the Annex is amended to add "Processing" as an information field covering processing steps applied to the organ with the aim of improving its functional status, with a potential impact on its quality and safety. This creates the data collection mechanism that will enable competent authorities, transplant registries, and the Commission to track which organs have been processed, by what method, and, when linked to outcome data, with what clinical result. The placement in Part B (complementary data) means that reporting is not strictly mandatory in all circumstances.

Measure 3: Cross-border and cross-framework coherence

A defining feature of the regime is its cross-framework coordination mechanism (Articles 6a (4)– (8)), requiring competent authorities to verify that any such product or substance used in processing is duly authorised or certified under its respective EU legislative framework.[235] Competent authorities under the organ Directive and those under the pharmaceutical, medical device, and SoHO frameworks collaborate in order to exchange clinical outcome data. To facilitate implementation, Article 6a (5) lays down provisions on guidelines regarding the benefit risk-assessment and the management of the organ after the administration of a medicinal product.

6.2 Baseline description

Conduct of business

The total volume of organ transplants in the EU-27 is projected to continue growing at the structural CAGR of 1.54% per million population (pmp), the rate observed over the full post-transposition period of 2012–2024 following the implementation of Directive 2010/53/EU[236]. Applying this rate forward from the 2024 observed anchor of 72.0 pmp[237], the **baseline projects approximately 78.9 pmp (~35,350 transplants) by 2030, 85.2 pmp (~38,200 transplants) by 2035, and 92.0 pmp (~41,200 transplants) by 2040.**

Transplantation centres will continue to adopt machine perfusion and associated processing technologies through organic, centre-driven clinical channels, but at a limited pace. At T0, approximately 27% of the EU's 717 organ transplantation programmes (~195 programmes across an estimated 120–160 unique centres) have active organ processing capability, with adoption concentrated in 7 Member States. Finding from a national survey shows that 85% of machine perfusion programmes were established between 2020 and 2024. **Without regulatory clarity and a harmonised authorisation pathway, diffusion to the remaining 73% of programmes, smaller multi-organ programmes, and centres in Member States with less developed regulatory infrastructure, is expected to proceed slowly and unevenly.**

The share of EU transplantation programmes with active processing capability will rise to approximately 35–38% by 2030 and 42-48% by 2035, before plateauing at approximately 48–55% by 2040. This plateau effect reflects the structural barrier that legal uncertainty

[235]Article 6a(4)–(5): medicinal products under Directive 2001/83/EC or Regulation (EC) No 726/2004; Article 6a(6): medical devices under Regulation (EU) 2017/745; Article 6a(7): SoHO preparations under Regulation (EU) 2024/1938.
[236] The use of this full twelve-year period, which spans pre-pandemic expansion, pandemic disruption, and recovery, provides a more statistically robust and conservative estimate of the structural growth rate than any shorter sub-period
[237] 32,222 transplants across a population of approximately 448 million.

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discourages investment in new programmes, particularly in jurisdictions that have not developed national oversight arrangements. **Transplantation centres in the EU will increasingly bifurcate into two tiers: a first tier of large, well-resourced centres performing routine advanced processing across multiple organ types** (concentrated in approximately 6–8 Member States), **and a second tier relying predominantly on SCS or basic hypothermic preservation.** This bifurcation will be the defining feature of the conduct-of-business landscape under the baseline.

Administrative costs on businesses, including SMEs

No EU-level organ processing authorisation regime exists, and no formal, processing-specific administrative obligations stem from Union law. The average cost per organ processing authorisation application stemming from **EU level** legislation remains at zero throughout the assessment period.

However, those Member States that have developed or are developing national oversight arrangements will impose jurisdiction-specific documentation, reporting, and approval requirements on transplantation centres. Centres operating in these jurisdictions will bear the costs of preparing internal benefit-risk documentation, maintaining processing-specific quality records, and engaging with their national competent authority on an ad hoc basis. **This fragmentation generates duplicative effort and prevents the economies of standardisation that a harmonised framework would deliver.**

Conversely, transplantation centres in Member States that have not established any national processing oversight regime will face no formal administrative cost related to processing but will instead bear the **hidden costs of legal uncertainty (e.g., ad hoc costs of seeking legal advice on the permissibility of specific processing operations).** Over the assessment period, the administrative cost landscape under the baseline is therefore expected to become progressively **more heterogeneous,** with total national-level compliance costs rising in aggregate as more Member States develop national arrangements but remaining inefficient.

Functioning of the internal market and competition

Based on Eurotransplant data, over the last three years, the cross-border exchange rate fluctuated between 22.2% in 2023, 22.5% in 2024, and 20.5% in 2025.

Cross-border exchange rates within the major European organ exchange organisations are expected to remain stable throughout the assessment period, continuing to fluctuate within the range of approximately 20–23%. In addition, **bilateral exchanges and surplus-organ platforms** will likewise remain at volumes comparable to current levels. The competitive landscape for **manufacturers of perfusion devices, perfusates, and therapeutic agents will remain fragmented**, as companies continue to face a patchwork of national regulatory environments with no harmonised EU authorisation pathway for organ processing technologies, impacting market predictability and scale.

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Innovation and research

Established technologies, particularly hypothermic machine perfusion for livers and kidneys, and Ex Vivo Lung Perfusion (EVLP), will likely continue to diffuse to additional centres, driven by the growing clinical evidence base, declining equipment costs as the market matures, and peer-to-peer knowledge transfer within professional networks. **The aggregate share of programmes with active processing capability is expected to rise from approximately 27%** at T0 **to approximately 42–48% by 2035, with the most pronounced gains in liver perfusion (potentially reaching 70–75% of programmes) and EVLP (60–65%).** Kidney perfusion uptake will remain structurally limited by the fact that kidney-only centres, which account for a significant proportion of the 260 kidney programmes, typically lack the institutional infrastructure, volume, and capital to sustain a perfusion programme: **0 of 7 kidney-only centres had adopted machine perfusion is likely to persist as a structural feature.**

The unfavourable environment for next-generation and experimental processing technologies will remain. Without an EU-level authorisation framework that provides both legal certainty and a structured route from conditional (monitored) use to full clinical deployment, **developers of technologies will face an uncertain and fragmented market. The clinical evidence base for organ processing will also remain nationally siloed and methodologically inconsistent**.

Public authorities

Since no EU-level organ processing authorisation regime exists, the number of organ processing authorisations granted remains at zero throughout the assessment period under the baseline.

A subset of Member States with well-resourced transplant authorities will expectedly develop national oversight arrangements, ranging from informal guidance issued by the competent authority to more structured approval procedures embedded within existing national transplant legislation. This process will be incremental and uncoordinated, producing a growing patchwork of national approaches with no common benchmark for the stringency, scope, or procedural requirements of processing oversight. The remaining Member States, particularly those with smaller transplant systems (fewer than 3–5 transplantation centres), are unlikely to develop dedicated processing oversight.

Competent authorities will continue to lack any structured mechanism for cross-framework coordination with pharmaceutical, medical device, and SoHO authorities regarding the use of regulated products in the context of organ processing. The clinical outcome data generated when a medicinal product is administered to an organ during perfusion, or when a medical device is used in a novel ex-vivo application, will remain trapped within the organ transplant reporting system (to the extent it is captured at all) and will not be systematically shared with the relevant product-sector authorities. This regulatory silo effect represents a persistent information loss that impedes both patient safety oversight and evidence-based product regulation.

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Public health and safety

The public health and safety baseline encompasses the largest cluster of indicators and represents the domain in which the consequences of inaction are most directly measurable in-patient terms.

Organ supply: discard rate, donor utilisation, and organ yield: The EU-27 proxy organ discard rate at T0 stands at approximately 12–13% across all organ types combined, with substantial organ-specific variation (kidney ~10%, liver ~18%, pancreas ~49%, heart ~2%, lung ~6%). Thus, **the continued organic adoption of machine perfusion in leading centres is expected to produce a modest, uneven decline in the discard rate**. A reduction to approximately 11–12% by 2030, 10–11% by 2035, and 9–10.5% by 2040 is projected. The gains will be concentrated in liver and lung, where machine perfusion is most clinically mature, and will be minimal for pancreas and heart. The deceased donor utilisation rate (94.8% at T0) is expected to improve marginally to approximately 95.5–96% by 2035 and 96–96.5% by 2040, with the most significant improvements among DCD donors (whose utilisation rate of 85.2% globally at T0 has the greatest room for improvement). The organ yield per utilised deceased donor (2.77 at T0) is projected to rise modestly to approximately 2.85–2.90 by 2035 and 2.90–2.95 by 2040, driven primarily by the rehabilitation of individual organs within multi-organ donors. These projections are below the gains achievable with wider processing adoption: a national survey's finding of a ~10% increase in organ utilisation attributable to machine perfusion, applied across all EU programmes, would imply substantially larger improvements.

Patient safety: SAE/SAR rate: The proxy EU-27 SAE/SAR rate at T0 is approximately 4 per 1,000 organ recipients per year (plausible range: 3-6), corresponding to an estimated 130 SAE/SAR cases annually, with approximately 17 proven or probable disease transmission events and 3-4 associated deaths. Under the baseline, this rate is expected to remain broadly stable or may trend modestly upward over the assessment period. The critical dynamic is that the expansion of processing, which involves the introduction of new pharmacological, surgical, and biological interventions on the organ, creates new risk categories that the existing SAE/SAR reporting system was not designed to capture. Without a mandatory benefit-risk assessment requirement, a structured clinical-outcome monitoring obligation, or an EU-level mechanism for disaggregating adverse events attributable to processing from those attributable to other causes, the safety profile of organ processing techniques will depend entirely on the internal governance standards of individual transplantation centres and, where they exist, national oversight frameworks. As processing volumes grow, the absolute number of processing-related adverse events is likely to increase, but many of these events may go undetected or unreported because the existing reporting taxonomy does not include processing as a distinct cause category.

Waiting time and waiting-list mortality: The aggregate EU-27 waiting-list turnover ratio at T0 is approximately 19.5 months, overwhelmingly driven by the kidney waiting list (42,855 patients, turnover ratio of ~26.8 months). Under the baseline transplant growth trajectory of 1.54% CAGR, annual transplant volumes will rise from 32,222 (2024) to approximately 38,200 by 2035 and 41,200 by 2040. However, on the demand side, waiting lists are expected to grow in parallel, driven by demographic ageing (which increases the incidence of end-stage organ failure, particularly for kidneys), the progressive expansion of transplant listing criteria, and improvements in dialysis and bridge therapies that keep

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patients alive and on the list for longer. It is assumed that the EU-27 waiting list grows at approximately 0.5% per year (plausible range of 0.35-0.65%), reflecting the net balance between rising incidence of end-stage organ failure on the demand side and the absorptive effect of growing transplant volumes on the supply side. This rate is broadly consistent with the Eurotransplant experience, where the active waiting list has remained approximately stable in recent years despite concurrent growth in transplant activity, and is conservative relative to the demand-side pressures described above.[238] Applied to the T0 waiting list of 52,488, this projects approximately **55,000-56,500 active patients by 2035 and 57,000-58,000 by 2040.** The net effect is that waiting times are projected to decline only modestly: the aggregate turnover ratio may fall from ~19.5 months to approximately **17-18 months by 2035 and 16-17 months by 2040, with kidney remaining above 22-24 months throughout.** Waiting-list mortality, currently estimated at approximately 3,366 deaths per year (an average of 9 patients per day in the EU-27), is projected to decline marginally to approximately **3,100-3,200 per year by 2035 and approximately 2,900-3,100 by 2040**, representing a persistently high and only slowly diminishing toll.

Burden of kidney disease and dialysis dependence: The EU's dialysis-dependent population (approximately 310,000 at T0, out of an estimated 511,549 on kidney replacement therapy) is expected to grow over the assessment period, driven by the rising incidence of chronic kidney disease associated with population ageing, the increasing prevalence of diabetes and hypertension, and the widening of dialysis initiation criteria. Under the baseline, the dialysis-dependent population is projected to rise to approximately 330,000-340,000 by 2035 and 350,000-365,000 by 2040. While the transplant rate will also grow (kidney transplants are projected to rise from 19,170 in 2024 to approximately 22,700 by 2035 under the 1.54% CAGR), the demand-side growth will outpace the supply-side gains, meaning the proportion of kidney replacement therapy patients living with a functioning transplant rather than on dialysis will, at best, remain stable and may marginally decline. This represents a structural constraint: absent a step-change in the transplantable kidney supply, the kind of step-change that wider adoption of kidney processing technologies could deliver, the baseline trajectory is one of growing, not shrinking, unmet transplantation needs.

6.3 Expected impacts

The estimated impact on the **adoption of organ processing technologies** is based the triangulation of three elements. First, **the growth regimes in EU transplant activity** (**0.59% pmp** (2005–2012) and **1.54% pmp** (2012–2024), yields an incremental **acceleration effect of +0.95 percentage points per annum since the transposition of the Directive in 2012**. Second, the **expected programme-level adoption** rises from 27% of EU programmes at T0 to 42-48% by 2035, plateauing at 48-55% by 2040. The clinical ceiling is estimated at 65-80% of programmes across all organ types. The gap between the baseline plateau and the clinical ceiling (approximately 15-25 pp) represents the adoption headroom that the regulatory intervention can unlock. Three scenarios assume that the

[238] The 0.5% annual growth rate implies that the EU-27 waiting list grows from 52,488 (end-2024) to approximately 55,400 by 2035 and 56,800 by 2040. Combined with the baseline transplant projection (1.54% CAGR), this yields aggregate turnover ratios of approximately 17.5 months (2035) and 16.6 months (2040). The plausible range of 0.35–0.65% is determined by the joint constraint that the turnover ratio falls within 17-18 months by 2035 and 16-17 months by 2040; a waiting-list growth rate below 0.28% or above 0.66% would violate one or both of these constraints.

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framework closes 25%, 50%, and 100% of this headroom, respectively. Third, **on organ-level processing intensity**, the proposed framework is expected to shift from "selective use" toward "systematic use" by standardising benefit–risk assessment and generating structured outcome data that strengthen the evidence case for routine application.

Table 5. Pillar 1: Programme-level adoption of organ processing

Indicator / horizon	T0 (2024)	2030	2035	2040	Δ vs baseline (2035)
Baseline (no policy change)	27%	35–38%	42–48%	48–55%	—
Conservative (25%)	27%	38–42%	50–55%	55–62%	+5-8 pp
Moderate (50%)	27%	42–48%	55–63%	62–70%	+10-15 pp
Optimistic (100%)	27%	48–55%	63–72%	70–78%	+15-22 pp
Clinical ceiling (benchmark)	—	—	65–80%	65–80%	—

Source: Estimates based on EDQM data, German national survey (Ibrahim *et al*., 2025), Italian national survey (Trapani *et al*., 2022), and ONT (2025). The clinical ceiling is derived from Spanish (49% of transplanted organs processed) and Italian data (62-70% of centres with MP experience by 2021), adjusted for EU-27 heterogeneity. Scaling factors represent the assumed proportion of the 15-25 pp adoption headroom closed by the framework.

Under the moderate scenario, approximately **70-110 additional programmes adopt active processing capability by 2035** that would not have done so under the baseline. The incremental effect is concentrated in two categories: a) "second-tier" centres in advanced Member States that have clinical capacity but currently lack institutional confidence without regulatory validation; and b) centres in Member States with less developed oversight infrastructure where an EU-level pathway substitutes for absent national arrangements.

Table 6. Pillar 2: Organ-level processing intensity

Scenario	T0 (2024)	2030	2035	2040	Δ vs baseline (2035)
Baseline	10–15%	14–18%	18–22%	20–25%	—
Conservative (25%)	10–15%	16–20%	22–26%	25–30%	+3-5 pp
Moderate (50%)	10–15%	18–23%	25–30%	30–36%	+6-10 pp
Optimistic (100%)	10–15%	22–28%	30–38%	36–45%	+10-16 pp

Source: T0 value derived from the German organ-level data (~20% of DBD livers, ~0.6% of DBD kidneys perfused), weighted by EU-27 transplant volumes and adjusted upward to account for Spanish and Italian processing rates. The moderate scenario assumes the framework shifts the centre-level equilibrium from selective to more systematic application of processing, consistent with the transition from the German model (~20% of livers perfused selectively) toward the Spanish model (~49% processed systematically).

Table 7. Pillar 3: Downstream transplant volume effect

Scenario	Additional CAGR increment	Additional transplants/year by 2035	Cumulative additional (2028–2035)	Transplant rate 2035 (pmp)
Baseline	—	—	—	85.2
Conservative (25%)	+0.24 pp/year	~730	~3,150	86.8
Moderate (50%)	+0.47 pp/year	~1,435	~6,205	88.4
Optimistic (100%)	+0.95 pp/year	~2,950	~12,685	91.8

Source: The baseline CAGR of 1.54% pmp is applied forward from the 2024 anchor of 72.0 pmp; scenario CAGRs add the scaled Directive effect (+0.95 pp × 25%/50%/100%) to the baseline rate from 2027 onwards. Cumulative figures cover 2028–2035 (eight full years), as the 2027 start year marks entry into force of the authorisation regime, with the first full-year effect materialising in 2028. Additional transplants/year by 2035 and pmp values are computed from year-by-year compound growth. Assumes a stable EU-27 population of ~448 million and no major external shocks.

Table 8. Consolidated estimate and central scenario

Impact dimension	Conservative	Moderate (central)	Optimistic
Programme adoption (Δ by 2035)	**+35–55 programmes (+5–8 pp)**	**+70–110 programmes (+10–15 pp)**	**+110–160 programmes (+15–22 pp)**
Organ-level processing (Δ by 2035)	**+3–5 pp**	**+6–10 pp**	**+10–16 pp**
Additional transplants/year by 2035	**~730**	**~1,435**	**~2,950**
Cumulative add. transplants (2028–35)	**~3,150**	**~6,205**	**~12,685**
Discard rate reduction (Δ by 2035)	**Additional −1–1.5 pp vs baseline**	**Additional −1.5–2.5 pp vs baseline**	**Additional −2.5–4 pp vs baseline**

The three pillars converge on the **moderate scenario as the most defensible central estimate**. Four factors support a scaling factor closer to 50% than to 25%. First, the technology is at an inflection point on its adoption S-curve (85% of German MP programmes established 2020–2024), the moment at which a regulatory framework has its greatest catalytic effect on fast followers. Second, the proposed model is an adaptation of the tested SoHO Preparation Authorisation framework under Regulation (EU) 2024/1938, reducing implementation risk. Third, 73% of EU programmes currently lack processing capability, representing a large untapped adoption pool concentrated precisely in settings where an EU harmonisation instrument has the greatest marginal impact. Fourth, the framework's primary function is to remove institutional and legal friction that slows translation of existing evidence into practice.

Two countervailing factors constrain the estimate below. First, many national transplant authorities will need to build multi-disciplinary assessment capabilities. Second, costs of processing equipment (EUR 150,000–300,000 per perfusion device, plus recurrent perfusate costs) will remain a barrier for less-resourced centres.

The estimated impact **of MP on organ discard rate** allows to estimate additional transplants attributable to wider processing adoption. The EU-27 proxy baseline discard rate is approximately **12-13% across all organs combined**, implying approximately **4,110 organs discarded annually** out of estimated 32,766 procured (deceased donors).

Liver

Table 9. Liver

Source	Design	Key Finding
Nasralla *et al*., 2018[239]	**RCT (n = 220)**	**~50% lower liver discard rate with NMP vs. SCS (P = 0.008)**
Mergental *et al*. (VITTAL), 2020[240]	**Prospective single-arm trial**	**71% of discarded livers passed NMP viability criteria; 22 transplanted, all functioning at 90 days**
Hospital HTA review, BMC, 2022[241]	**HTA meta-review**	**Up to 50% lower graft discard; comparable/improved 1-year survival**

A conservative range (discounted for real-world selection effects) of **30–50% reduction in liver discard rate** where NMP is applied.

Lung

Table 10. Lung

Source	Design	Key Finding
Keshavjee *et al*. (2025)[242]	**Single-centre retrospective (n = 1,000)**	**65% of EVLP-assessed marginal lungs accepted for transplant, representing 29% of all transplants performed during the study period.**
Tian *et al.* (2019)[243]	**EVLP systematic review and meta-analysis (8 studies, n = 1,191)**	**Successful transplantation of lungs with significantly worse donor baselines (lower PaO2/FiO2, more abnormal CXR, higher smoking rates) compared to non-EVLP standard grafts, resulting in similar post-transplant outcome.**
Chakos *et al*. (2020)[244]	**Meta-analysis / 13 studies, 407 EVLP lung transplants and 1,765 as per standard protocol.**	**EVLP and standard protocol lungs show no significant survival difference, despite EVLP lungs having significantly worse PaO2/FiO2 ratios and a higher rate of abnormal chest X-rays. EVLP expands the transplantable donor pool.**

EVLP enables a **20-29% increase in programme transplant volume** by rescuing marginal donor lungs.

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[239] Nasralla, D., Coussios, C. C., Mergental, H., *et al*. (2018). A randomized trial of normothermic preservation in liver transplantation. Nature, 557(7703), 50–56. https://doi.org/10.1038/s41586-018-0047-9

[240] Mergental, H., Laing, R. W., Kirkham, A. J., Perera, M. T. P. R., Boteon, Y. L., Attard, J., Barton, D., Curbishley, S., Wilkhu, M., Neil, D. A. H., Hübscher, S. G., Muiesan, P., Isaac, J. R., Roberts, K. J., Abradelo, M., Schlegel, A., Ferguson, J., Cilliers, H., Bion, J., Adams, D. H., … Mirza, D. F. (2020). Transplantation of discarded livers following viability testing with normothermic machine perfusion. *Nature communications*, *11*(1), 2939. https://doi.org/10.1038/s41467-020-16251-3

[241] De Simone, P., & Ghinolfi, D. (2022). Hospital-Based Health Technology Assessment of Machine Perfusion Systems for Human Liver Transplantation. *Transplant international : official journal of the European Society for Organ Transplantation*, *35*, 10405. https://doi.org/10.3389/ti.2022.10405

[242] Keshavjee, S., Sage, A. T., Borrillo, T., Yeung, J. C., Piyasena, D., Wakeam, E., Donahoe, L., Waddell, T. K., De Perrot, M., Pierre, A., Balachandran, S., Ghany, R., Ali, A., Yasufuku, K., & Cypel, M. (2025). One thousand cases of ex vivo lung perfusion for lung transplantation: A single-center experience. *Journal of Thoracic and Cardiovascular Surgery*, *171*(2), 540-550.e2. https://doi.org/10.1016/j.jtcvs.2025.08.036

[243] Tian, D., Wang, Y., Shiiya, H., Sun, C., Uemura, Y., Sato, M., & Nakajima, J. (2019). Outcomes of marginal donors for lung transplantation after ex vivo lung perfusion: A systematic review and meta-analysis. *Journal of Thoracic and Cardiovascular Surgery*, 159(2), 720-730.e6. https://doi.org/10.1016/j.jtcvs.2019.07.087

[244] Chakos, A., Ferret, P., Muston, B., Yan, T. D., & Tian, D. H. (2020). Ex-vivo lung perfusion versus standard protocol lung transplantation-mid-term survival and meta-analysis. *Annals of cardiothoracic surgery*, *9*(1), 1–9. https://doi.org/10.21037/acs.2020.01.02

Kidney

HPM primarily mitigates discard driven by extended cold ischaemia time (CIT). A large OPTN population cohort study (n = 137,835) demonstrates that end-ischaemic HMP is frequently deployed to rescue kidneys with significantly longer CITs (median 23.0 hours versus 17.3 hours for the general pool), thereby preventing discard of organs delayed by logistical or geographic barriers.[245] The Cochrane kidney review further confirms that HMP improves one-year graft survival to 94% compared to 90% for SCS.[246] In the UK, 'poor perfusion' accounts for nearly 20% of the roughly 350 annual kidney organ discards after retrieval.[247]

HMP/NMP could **reduce kidney discards by 10-20%** (reflecting indirect mechanism via DGF prevention rather than direct viability assessment).

Conduct of business

Number and proportion of transplanted organs

The reform introduces a prior authorisation obligation that fundamentally restructures this conduct of business. The new obligations impose operational requirements that centres must integrate into their workflows, including documentation, data collection, and engagement with the competent authority. The establishment of a clear regulatory pathway resolves the legal ambiguity that, under the baseline, operates as a structural drag on institutional decision-making.

The conduct-of-business impact is assessed along two dimensions: the change in the operational model of transplantation centres (qualitative) and the change in transplant output attributable to the policy-induced shift in processing adoption (quantitative).

Under the moderate policy scenario, the authorisation framework is projected to close approximately 50% of the adoption headroom between the baseline plateau and the clinical ceiling (estimated at 65-80% of programmes). This implies that programme-level adoption reaches 55-63% by 2035, representing **approximately 70-110 additional programmes with active processing capability** beyond the baseline. This means 70-110 programmes (residing in an estimated 50-80 additional unique centres) transition from the second tier to the first, adopting structured processing workflows under the Article 6a regime. These centres will need to invest in processing equipment (MP device, recurrent perfusate and disposable costs, etc.), train clinical and technical staff, and integrate the authorisation process into their institutional governance.

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[245] Amarnath, D. R., Kourounis, G., Massie, A., Segev, D., Jochmans, I., Wilson, C. H., & Tingle, S. J. (2026). Machine perfusion modulates cold preservation injury in kidney transplantation: IDEAL Stage 4 OPTN Population Cohort study. *American Journal of Transplantation*. https://doi.org/10.1016/j.ajt.2026.02.025

[246] Tingle, S. J., Figueiredo, R. S., Moir, J. A., Goodfellow, M., Talbot, D., & Wilson, C. H. (2019). Machine perfusion preservation versus static cold storage for deceased donor kidney transplantation. *The Cochrane database of systematic reviews*, *3*(3), CD011671. https://doi.org/10.1002/14651858.CD011671.pub2

[247] Fallon, J., Sagar, A., Elzawahry, M., Sadik, H., Gyoten, K., Abbas, S. H., Dumbill, R., & Friend, P. (2025). The Hitchhiker's guide to isolated organ perfusion: a journey to 2040. *Frontiers in transplantation*, *4*, 1642724. https://doi.org/10.3389/frtra.2025.1642724

The operational model of existing first-tier centres also changes under the policy: centres that currently process organs on an ad-hoc, selective basis are expected to shift toward more systematic application. **Organ-level processing intensity rises from a baseline of 18-22% by 2035 to 25-30% under the moderate scenario, a gain of 7-8 percentage points**. This shift is partially driven by the evidence-validation mechanism embedded in the authorisation regime: the structured clinical-outcome data generated under Article 6a (3) monitoring plans progressively strengthens the evidence base for routine (as opposed to selective) processing.

The downstream transplant volume effect of this conduct-of-business transformation is estimated at approximately 1,435 additional transplants per year by 2035 under the moderate scenario, cumulating **to approximately 6,205 additional transplants over the 2028-2035 period.** This increment is composed of two channels: additional transplants in centres that newly adopt processing capability and additional transplants in existing processing centres that deepen their organ-level application rate.

As ~70-110 newly processing programmes represent roughly 10-15% of all EU programmes, and assuming that these operate at the processing intensity of a centre in its first 3-5 years of adoption (~10-15% of organs processed, below the EU-wide average intensity of 25-30%), and that each programme performs, on average, approximately 55 transplants per year (derived from the EU aggregate of ~38,200 transplants across ~717 programmes under the 2035 baseline), **the newly processing programmes contribute approximately 385-905 additional organs processed annually**. Applying an estimated **additional-transplant yield of approximately 15-20% of processed organs** (reflecting the combined effect of discard reduction, expanded acceptance of marginal donors, and improved preservation enabling transplantation of organs that would otherwise have been declined), **this implies approximately 60-180 additional transplants per year from the extensive margin.** The remainder of the ~1,435 total (approximately 1,255-1,375 per year) is attributable to deeper processing within existing first-tier centres and the compound growth effect captured by the CAGR-proxy model.

The primary operational cost borne by transplantation centres under the policy, is the **administrative cost of the authorisation process itself**. The equipment costs are not attributable to the regulatory changes, since centres would face these costs under the baseline if they chose to adopt processing on their own initiative. **The framework's marginal contribution to equipment expenditure is indirect** (i.e., accelerating adoption in 70-110 additional programmes, residing in an estimated 50-80 additional unique centres, that would not have adopted under the baseline).

The authorisation regime imposes proportionate operational requirements on transplantation centres while simultaneously removing the legal uncertainty that has functioned as an institutional barrier to processing adoption.

Public health and safety

Organ discard rate

The authorisation regime accelerates the adoption and deepens the application of machine perfusion and associated reconditioning technologies.

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Drawing on the assumptions applied at the moderate-scenario organ-level processing intensity of 25-30% by 2035, the organ-specific additional transplants attributable to discard reduction are estimated as follows:[248]

- **Liver** Applying the 30-50% rescue rate yields approximately **120-265 additional livers transplanted per year** by 2035 beyond the baseline. The liver accounts for the single largest absolute discard reduction.
- **Lung** Applying a conservative EVLP rescue rate of 50-65% to the approximately 70-125 would-be discarded within the processed pool, this implies approximately **35-80 additional lungs transplanted per year** by 2035.
- **Kidney** Applying the 10-20% rescue rate yields approximately **45-110 additional kidneys transplanted per year** by 2035. The kidney estimate is the most conservative of the three quantified organs, reflecting the indirect mechanism of action (HMP primarily prevents delayed graft function and thereby avoids secondary discard, rather than directly rehabilitating already-compromised organs as with NMP for livers).
- **Heart and pancreas**: As DCD heart transplantation using normothermic regional perfusion is at an early stage in the EU, and pancreas discard is driven primarily by anatomical fragility during procurement rather than by preservation-related deterioration, a negligible marginal discard reduction for these organs in the assessment period is therefore assumed.

The organ-specific estimates sum to approximately **200-455 additional transplants per year** by 2035 attributable to the discard-reduction channel alone. This is substantially below the central estimate of ~1,435 additional transplants per year, which is derived from the top-down CAGR-proxy model.

Each additional organ transplanted represents a high-value therapeutic intervention. While the economic value of a transplant varies by organ type and Member State, an indicative estimate can be constructed for kidneys, which dominate the additional transplant pool. Evidence suggests a median annual cost of in-centre haemodialysis at approximately EUR 18,000-43,000 per patient (with wide cross-country variation)[249], while the annual maintenance/care cost of a kidney transplant **recipient is approximately EUR 10,000-30,000 per year on average during the first three years post-transplantation**.[250] Adopting a mid-range estimate of EUR 20,000 in net annual savings per kidney transplant (dialysis costs avoided minus transplant maintenance), the ~847 additional kidney transplants per year by 2035 imply recurrent annual savings of approx. **EUR 17 million per year from each annual cohort of additional transplants** (of which approximately 45-110 stem from the reduction in organ discard rate, accounting for EUR

[248] For each organ, the number of procured organs at 2035 is derived by dividing the projected baseline deceased-donor transplant volume (T0 deceased-donor transplants × the 1.1855 baseline growth factor) by (1 − baseline 2035 discard rate). The additional transplants are then computed as: procured organs × processing intensity × baseline discard rate × evidence-based discard reduction rate.

[249] ERA. (2025). *Chronic Kidney Disease in Europe: The Missing Link in Cardiovascular Risk Assessment.* https://www.era-online.org/publications/chronic-kidney-disease-in-europe-the-missing-link-in-cardiovascular-risk-assessment/

[250] Chamberlain, George & Baboolal, Keshwar & Pockett, Rhys & Mcewan, Phil & Sabater, Javier & Sennfält, Karin. (2014). The Economic Burden of Posttransplant Events in Renal Transplant Recipients in Europe. *Transplantation.* 97. 854-61. 10.1097/01.TP.0000438205.04348.69

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0.9-2.2 million/year). This estimate excludes the substantial additional savings from avoided dialysis among patients who receive additional liver, lung, and other organ transplants (who would otherwise face end-stage organ failure with its associated intensive care and palliative costs), and it does not account for the productivity gains from returning transplant recipients to an active life.

Deceased donor utilisation rate

The **deceased donor utilisation rate** measures whether a donor from whom organs are procured ultimately yields at least one transplant.

Under the moderate scenario, the accelerated adoption of processing technologies is expected to yield an additional 0.5-1.0 percentage point improvement, reaching approximately 96-97% by 2035. Applied to the projected number of actual deceased donors (~12,000-12,500 by 2035, assuming modest growth in the donor pool), this implies that an **additional 60-125 donors would proceed to at least one transplant annually** compared with the baseline. The gains are expected to be concentrated among DCD donors, where the policy-induced improvement may be as large as 2-3 percentage points (from a baseline-projected ~88% to ~90-91%), reflecting the particular clinical value of machine perfusion in managing the ischaemic injury inherent in circulatory-death donation.

This indicator measures donor-level salvage rather than organ-level salvage. A donor who, under the baseline, would have been abandoned entirely because all procured organs were deemed unviable may, with processing, yield one or more transplantable organs. **The combined effect of the above indicators is therefore larger than either alone.**

Organ yield per utilised deceased donor

Processing technologies rehabilitate individual organs within multi-organ donors that would otherwise be discarded, thereby increasing the per-donor transplant count.

Under the moderate scenario, the broader adoption of processing is expected to increase organ yield by an additional 0.05-0.15 per utilised donor beyond the baseline, reaching approximately 2.90-3.05 by 2035. Applied to approximately 11,663-11,868 utilised donors projected by 2035[251], this translates to approximately **583-1,780 additional organs per year,** a range that brackets central estimate of ~1,435 additional transplants per year, providing internal consistency.

While the discard rate captures whether a specific procured organ is transplanted, **the organ yield captures the aggregate recovery per donor**. A centre that begins processing livers may simultaneously discover that viability assessment enables it to accept additional kidneys from the same donor, a synergistic "technology spillover" effect that is well-documented in the clinical literature.

[251] The baseline projects total transplants at ~38,200 by 2035. Living-donor transplants at T0 are ~3,691 (11.5% of 32,222). Deceased-donor transplants by 2035: 38,200 × (1 – 0.115) = ~33,824. Dividing by the baseline organ yield of 2.85-2.90 gives: 33,824 / 2.90 = 11,663 to 33,824 / 2.85 = 11,868 utilised donors.

Rate of serious adverse events and reactions (SAE/SAR)

The proposed authorisation regime introduces three safety-relevant mechanisms that are absent under the baseline: a) mandatory benefit–risk assessment prior to the clinical application of any processing technique; b) mandatory clinical-outcome monitoring plans for novel or higher-risk processing techniques, which generate structured evidence on processing-related adverse events; and c) the addition of "Processing" as a data field in the complementary data set, which creates the taxonomic infrastructure to disaggregate processing-attributable events from those attributable to other causes.

The impact of the authorisation regime on SAE/SAR rates could not be quantified. First, the available evidence does not disaggregate processing-attributable adverse events, thus there is no baseline against which to measure a processing-specific safety improvement. Second, the initial effect of improved reporting infrastructure is likely to increase recorded SAE/SARs, an artefact of better detection rather than worse safety. Third, the adverse events prevented by the ex-ante safety filter (i.e., processing techniques that are not authorised because they fail the benefit–risk assessment) are counterfactual events.

A first qualitative conclusion is that the authorisation regime will **create a systematic capacity to detect and attribute processing-related adverse events at the EU level**. This is a significant safety improvement over the baseline, where processing-related harms may be occurring but going unrecorded because the existing vigilance taxonomy does not include processing as a cause category. A second qualitative conclusion is that **each organ lost to an unregulated, ineffective processing attempt represents both a direct patient-safety failure** (potential harm to the intended recipient) **and an indirect harm** (denial of a viable organ to another patient on the waiting list).

Over the medium term (post-2035), the accumulation of structured clinical-outcome data from monitoring plans under Article 6a (3) will enable evidence-based refinement of processing protocols, progressively improving the safety profile of the field.

Average waiting time to transplantation

Additional transplants generated by the policy reduce the backlog of patients on the waiting list, shortening the average time to transplantation. The effect is organ-specific and is most consequential for kidneys (42,855 of 52,488 active patients at end-2024, i.e. 82%).

Under the moderate scenario, the ~1,435 additional transplants per year by 2035 would further reduce the turnover ratio. Under the baseline, 2035 transplant volumes are projected at ~38,200 against a waiting list of approximately 55,000-56,500 (derived from the T0 waiting list of 52,488 growing at the assumed 0.5% per year). This yields a baseline turnover ratio of approximately 17.2-17.8 months. With the additional ~1,435 transplants, the denominator rises to ~39,635, producing a turnover ratio of approximately 16.5-17.1 months; a reduction of approximately 0.6 months (roughly 2.5 weeks) relative to the baseline. For kidney specifically, where ~847 additional transplants (59% of 1,435) are projected, and applying the same demand-side growth rate to the kidney waiting list (from 42,855 at T0 to approximately 44,500-46,000 by 2035), **the kidney turnover ratio declines from a baseline of approximately 23.5-24.5 months to approximately 22.5-23.5 months, a reduction of approximately 1 month.** This aggregate effect is modest, as

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the demand side (driven by demographic ageing and the rising prevalence of chronic kidney disease) is growing in parallel with the supply side, and the ~1,435 additional transplants per year represent a ~3.8% increment over the baseline transplant volume of ~38,200. **A step-change in waiting times would require a substantially larger supply expansion than the processing amendments alone can deliver.** Stakeholders representing European societies of relevant healthcare professionals identified domestic donation infrastructure (consent laws, transplant coordinators, elimination of conflicts of interest) rather than processing technology as the primary variable affecting system performance. However, the modest aggregate conceals a more meaningful effect for specific patient populations. **Additional liver transplants (estimated 120-265/year) against a liver waiting list of ~4,500 by 2035 would reduce the liver turnover ratio by approximately 0.1-0.2 months.**[252] **For lung, additional transplants (35-80/year) against a smaller waiting list (1,600) would reduce the turnover ratio by approximately 0.1-0.2 months**.[253] **While organ-specific discard-reduction channel alone produces small waiting-time effects, but that the total policy effect (captured by the aggregate ~1,435 figure) delivers the approximately 0.5-0.7-month aggregate reduction**.

Burden of kidney disease and dialysis dependence

Each additional kidney transplant removes one patient from chronic dialysis. Under the moderate scenario, approximately 847 additional kidney transplants per year by 2035 (59% of the total ~1,435 additional transplants) would be performed. Cumulated over the 2028-2035 period, this yields approximately 3,660 additional kidney transplants beyond the baseline. Assuming an average five-year kidney graft survival rate of approximately 90% (consistent with European registry data), approximately 3,295 additional patients would be living with a functioning transplant rather than on dialysis by 2035. Against a projected dialysis-dependent population of ~335,000 under the baseline, this represents a reduction of approximately 1.0%. **The proportion of KRT patients on dialysis would decline from approximately 60.6% (baseline) to approximately 60.0% (policy scenario),** a measurable but structurally modest shift. The policy only slows the growth of the dialysis-dependent population: the additional ~847 kidney transplants per year represent a ~3.7% increment over baseline kidney transplant volumes, while the dialysis-dependent population is growing by approximately 1–1.5% per year (roughly 3,000-5,000 additional dialysis patients annually).

Using the conservative estimate of EUR 20,000 in net annual savings per kidney transplant patient (dialysis avoided minus transplant maintenance), the approximately 3,295 additional patients living with a functioning transplant by 2035 (representing the decrease

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[252] Baseline liver transplants 2035 (total, including living donor at 3% share): 8,015 × 1.1855 growth factor = ~9,502. Baseline liver turnover: (4,500 / 9,502) × 12 = 5.68 months.

- With +120 additional: (4,500 / 9,662) × 12 = 5.61 months → reduction = **0.07 months (approx. 0.1)**
- With +265 additional: (4,500 / 9,752) × 12 = 5.53 months → reduction = **0.15 months (approx. 0.2)**

The aggregate growth factor of 1.1855 is the ratio of projected baseline total transplants in 2035 to total transplants at T0 (38,200 / 32,222).

[253] Baseline lung transplants 2035: 2,221 × 1.1855 = ~2,633. Baseline lung turnover: (1,600 / 2,633) × 12 = 7.29 months.

- With +35: (1,600 / 2,668) × 12 = 7.20 months → reduction = **0.10 months (approx. 0.1)**
- With +80: (1,600 / 2,713) × 12 = 7.08 months → reduction = **0.22 months (approx. 0.2)**

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in dialysis-dependent population by 2035) **would generate recurrent annual healthcare savings of approximately EUR 66 million per year from 2035 onwards. The cumulative dialysis cost avoidance over the 2028–2035 period is estimated at approximately EUR 158 million**.[254] This estimate applies the lower bound of the net savings range derivable from European health-economic literature, and excludes the broader economic benefits of reduced hospitalisation, improved quality of life, and restored workforce participation among transplant recipients.

Waiting-list mortality

Each additional transplant removes a patient from the waiting list and eliminates their exposure to waiting-list mortality risk.

To estimate the policy impact, the **annual waiting-list mortality rate to the patient-years of waiting-list exposure averted by additional transplants** is applied. The annual waiting-list mortality rate at T0 is approximately 6.4% (3,366 deaths / 52,488 patients). By 2035, this rate may decline modestly to approximately 5.5-6.0% as transplant volumes grow. The ~1,435 additional transplants per year by 2035 each remove one patient from the waiting-list mortality risk pool. Not all additional transplants avert a death: many patients on the waiting list, particularly those with less urgent need, would survive to receive a transplant under the baseline regardless. The marginal mortality-prevention effect of an additional transplant depends on the urgency profile of the patients reached.

If the annual waiting-list mortality rate among the marginal patient population (those who receive an additional transplant earlier than they would have under the baseline) is approximately 4-5% (lower than the average, reflecting that the most urgent patients are already prioritised under existing allocation systems), **~1,435 additional transplants per year would prevent approximately 57-72 waiting-list deaths per year by 2035**. Over the cumulative period 2028–2035, with a progressive ramp-up of additional transplant volumes, the **total number of waiting-list deaths averted is estimated at 248-311.**

This estimate can be cross-validated against organ-specific waiting-list mortality data. The ~1,435 additional transplants per year by 2035 are allocated across organ types using the T0 EU-27 transplant distribution, yielding approximately 847 additional kidney transplants (~59%), 357 liver transplants (24.9%), and 99 lung transplants (6.9%). Applying the organ-specific annual waiting-list mortality rates: kidney: 4.2% (1,797 deaths / 42,855 active

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[254] Assumption: Net savings begin the year after transplant (year 1 is absorbed by surgery costs), with 2% annual graft attrition.
Each cohort generates savings only in subsequent years within the period, discounted by graft loss:

- 2028 cohort (94 patients): savings in 2029–2035 = 94 × (0.98 + 0.98^2 + … + 0.98^7) = 94 × 6.48 = **609** patient-years
- 2029 cohort (191): savings in 2030–2035 = 191 × 5.60 = **1,070**
- 2030 cohort (291): savings in 2031–2035 = 291 × 4.71 = **1,371**
- 2031 cohort (395): savings in 2032–2035 = 395 × 3.81 = **1,504**
- 2032 cohort (502): savings in 2033–2035 = 502 × 2.88 = **1,446**
- 2033 cohort (614): savings in 2034–2035 = 614 × 1.94 = **1,191**
- 2034 cohort (729): savings in 2035 only = 729 × 0.98 = **714**
- 2035 cohort (847): no savings within period (surgery year) = **0**

Total: **7,905 patient-years** × EUR 20,000 = **~ EUR 158 million**

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patients); liver: 21.9% (934 / 4,270); lung: 14.7% (221 / 1,500), **the following averted deaths per year by 2035 are estimated: kidney ~36; liver ~78; lung ~15; summing to approximately 129 averted deaths per year.**

This estimate substantially exceeds the aggregate estimate of 57–72 derived above. The divergence is a direct consequence of the methodological difference between the two approaches. The aggregate estimate applies a flat marginal mortality rate of 4–5%, deliberately calibrated below the overall waiting-list average of 6.4% to reflect the assumption that marginal transplants disproportionately benefit less-urgent patients. The organ-specific approach applies actual waiting-list mortality rates and reveals that the additional transplant pool includes approximately 25% liver, an organ type whose waiting-list mortality (21.9%) is more than five times the flat rate assumed. The organ-weighted average mortality rate across the additional transplant pool is approximately 9.8%, roughly double the flat-rate assumption.

The conservative aggregate estimate of 57–72 averted deaths per year is adopted. Each averted waiting-list death represents a life prolonged by transplantation. While assigning a monetary value to prevented premature death is methodologically and ethically contested, the European Commission reference value of a statistical life year (VOLY) (~ EUR 115,000)[255] provides a reference frame. If the average additional life expectancy conferred by transplantation is approximately 10-15 years, the **cumulative value of 248-311 averted deaths over the 2028–2035 period[256] is in the range of EUR 285–537 million.**

Administrative costs on businesses, including SMEs

Cost of organ processing authorisation application

Transplantation centres that perform processing must submit either a benefit–risk assessment (Article 6a(2)) or a clinical-outcome monitoring plan (Track 2, Article 6a(3)) to the competent authority, verify the regulatory status of any products used in processing across the pharmaceutical, medical device, and SoHO frameworks (Articles 6a(4)–(7)), manage the ongoing authorisation relationship (Article 6a(9)), and collect and report processing-specific data under the amended Annex (Part B).

The administrative cost falls on transplantation centres as the applicants, while the competent authorities bear a corresponding assessment cost. The proposal does not introduce a fee mechanism.

One national transplant authority estimates that the assessment of a single processing authorisation application requires approximately 15 working days for one person on the competent authority side, excluding external expert consultations. On the applicant (transplantation centre) side, the preparation effort is expected to be of a higher magnitude, as the centre must compile the clinical evidence, perform or commission the benefit–risk

[255] European Commission. (2024). *Commission staff working document: impact assessment report. SWD(2024) 63 final.*
[256] At 4%: Σ(year-by-year additional transplants × 0.04) = 248; At 5%: Σ(year-by-year additional transplants × 0.05) = 311.

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assessment, document the processing protocol, and assemble the cross-framework verification dossier. This effort can be differentiated as follows:

- **Track 1 (full authorisation, Article 6a (2)):** applicable to well-established processing techniques with a robust evidence base. Estimated effort is 15 working days of senior clinical/scientific staff, 10 working days of regulatory/quality staff, and 5 working days of administrative support. This leads to approximately **EUR 11,500.**
- **Track 2 (conditional authorisation with clinical-outcome monitoring, Article 6a (3)):** applicable to novel or higher-risk techniques where the evidence base is insufficient for a full benefit–risk assessment. Estimated effort is 20 working days of senior clinical/scientific staff, 15 working days of regulatory/quality staff, and 10 working days of administrative support. This leads to approximately **EUR 16,750.**

These estimates are based on EU-level loaded labour costs for healthcare professionals (Eurostat, NACE Rev.2 Section Q), which incorporate gross wages, employer social contributions, and institutional overhead: senior clinical/scientific staff at EUR 350-450 per working day; regulatory/quality officers at EUR 250-350 per working day; and administrative support at EUR 150-250 per working day.

Furthermore, **centres authorised under Track 2** bear **recurrent data collection, analysis, and reporting obligations for the duration of the monitoring period**. These are estimated at approximately 5 working days per quarter (20 days per year) of clinical/quality staff time, amounting to **EUR 9,000 per year per active monitoring plan.**

The weighted average per-application cost depends on the expected distribution between Track 1 and Track 2 applications. In the initial transition phase (years 1-3 post-transposition), the majority of applications will concern established techniques for which substantial clinical evidence already exists: we estimate approximately 70-80% Track 1 and 20-30% Track 2. Over time, as the field shifts toward more novel processing modalities, the Track 2 share will rise progressively. For the initial transition phase, the weighted average cost per application is approximately **EUR 12,800.**

The total EU-27 administrative burden depends on the volume of authorisation applications. This is estimated as follows, anchored in stakeholder consultations:

1. **Initial transition phase (years 1-3 post-transposition, approximately 2029-2031):** The entry into force of the regime will generate a transitional surge of applications as centres seek to regularise processing techniques already in clinical use. At T0, approximately 195 programmes across an estimated 120-160 centres have active processing capability. Each centre will need to secure authorisation for each distinct processing technique it employs. The number of distinct techniques requiring separate authorisation per centre is estimated at 1-3. However, a competent authority's assessment of a given technique may apply to multiple centres within the same jurisdiction. Therefore, the total initial application volume at the Member State level is estimated at: approximately 15-18 Member States with active processing centres, each processing 4-8 distinct technique-level applications during the transition, yielding approximately **60-**

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145 applications across the EU-27 during the transition period (central estimate: ~100). At a weighted average cost of ~EUR 12,800 per application, **the total transition-phase administrative cost for transplantation centres is approximately EUR 768,000-1,856,000, spread over three years.**

For Track 2 authorisations, the ongoing monitoring obligation generates a persistent annual cost. If approximately 25% of all authorisations issued are Track 2, and at and additional EUR 9,000 per monitoring plan per year (EUR 27,000 over three years), the aggregate recurrent monitoring cost over the three years is **approximately EUR 405,000-980,000. This brings the total to EUR 1,173,000-2,836,000 (central estimate per year: ~EUR 670,000).**

2. **Steady-state phase (from approximately 2032 onwards):** One national transplant authority consulted estimate of 2-3 applications per year for its Member State provides the anchor. Assuming 2 applications per Member State and extrapolating to the EU-27 by scaling for the number of active processing centres relative to this same Member State, the steady-state flow is estimated at approximately **7-10 applications per year across the EU-27**. The annual steady-state administrative cost on transplantation centres is therefore approximately EUR 90,000-128,000 per year. An additional EUR 16,000-22,500 in recurrent monitoring costs can be expected, bringing the **total to approximately EUR 106,000-150,500 (central estimate: ~EUR 130,000).**

Over the 2029-2035 assessment period, the cumulative administrative cost on transplantation centres is estimated at approximately **EUR 2.5 million.**

This estimated gross administrative cost must be assessed against the counterfactual baseline costs. Under the baseline, transplantation centres in Member States that develop national oversight arrangements bear jurisdiction-specific documentation, reporting, and approval costs that are fragmented, duplicative, and non-standardised. The harmonised EU framework replaces this patchwork with a standardised administrative process that delivers two efficiency gains: a) centres can use common templates and evidentiary standards, reducing duplicative preparation effort; and b) the published list of authorised processing operations (Article 6a(11)) means that a technique authorised in one Member State generates transferable evidence for formal authorisation at the national level. The net incremental administrative cost of the policy, relative to the baseline, is therefore lower than the gross estimates above.

Functioning of the internal market and competition

Cross-border organ exchange

By establishing common EU-level quality and safety standards for organ processing, the framework enables competent authorities in receiving Member States to accept processed organs originating elsewhere on the basis of a recognised authorisation rather than ad hoc bilateral assessment. MP also extends the viable preservation time of organs, thereby widening the geographic catchment area within which an organ can be allocated.

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The policy is expected to generate a **modest but real upward shift in cross-border exchange**, operating primarily through the trust channel rather than through an increase in the absolute number of organs available for export. Based on stakeholder consultations, the magnitude of this effect is expected to be limited by the fact that domestic demand absorbs the large majority of processing-enabled additional organs; by the cumbersome logistical burden of cross-border transport of organs on perfusion devices; and by the fact that cross-border kidney exchange programmes primarily serve hyperimmunised patients (approximately 5% of kidney waiting lists).

The **harmonisation effect is important for two reasons.** First, within existing exchange organisations, the proportion of exchanged organs that have undergone processing is expected to rise materially over the assessment period. If the share of transplanted organs that undergo processing rises to 25-30 % by 2035 under the moderate scenario, then approximately **one in four cross-border organs would be a processed organ, a proportion at which the absence of harmonised standards would constitute a material barrier**. Second, the extension of viable preservation time enabled by wider perfusion adoption **enlarges the effective catchment area for organ allocation within existing exchange systems.**

Under the moderate policy scenario, total EU-27 transplant volumes are projected at approximately 39,635 by 2035 (38,200 baseline + ~1,435 additional). Within Eurotransplant, which performs over 22% of EU transplants (7,160/32,222), this implies approximately 9,100 allocated organs by 2035. If the harmonised framework enables an increase in the cross-border exchange rate of 1-2 percentage points (from the baseline ~20-23% to ~22-25%), this would correspond to approximately 90-180 additional cross-border organ exchanges per year within the Eurotransplant system alone. Extrapolating proportionally to the full EU-27, the total increment is estimated at approximately **120-250 additional cross-border organ exchanges per year by 2035**. The effect is concentrated in hearts and lungs, where cross-border exchange rates are already highest (31.8% and 28.9% respectively within Eurotransplant at T0) and where MP most directly extends the allocation radius. This estimate reflects both the stakeholder views on the structural constraints described above and the observation that Eurotransplant's cross-border exchange rate has remained stable at **20-23% over recent years despite concurrent processing adoption.**

Innovation and research

Transplantation centres actively performing advanced organ processing

First, the establishment of a defined EU-level pathway for organ processing removes the legal uncertainty that, under the baseline, functions as a structural deterrent to institutional investment in processing capability. Second, the mandatory clinical-outcome monitoring plans generate structured, standardised outcome data that do not currently exist at the EU level. This data infrastructure enables cross-centre and cross-country comparison of processing outcomes, supports the progressive strengthening of the evidence base for specific techniques, and provides the empirical foundation for future evidence-based regulatory refinement. Third, the dual-track authorisation model seeks to accommodate next-generation processing technologies that are at earlier stages of clinical development.

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The quantitative impact of the policy on the **rate of processing technology adoption** can be summarised as follows. Under the baseline, the share of EU-27 programmes with active processing capability is projected to rise from approximately 27% at T0 to 42-48% by 2035, plateauing at 48-55% by 2040. The clinical ceiling, derived from benchmarking against Spain, Germany, and Italy, is estimated at 65-80% of programmes. **Under the moderate policy scenario, adoption reaches 55-63% by 2035, representing approximately 70-110 additional programmes** (residing in an estimated 50-80 additional unique centres) transitioning to active processing capability beyond the baseline.

With regards to the **clinical evidence base** for organ processing, the policy transforms the nationally siloed environment **as the clinical-outcome monitoring plans generate structured, prospective outcome data for novel or higher-risk processing techniques.** Assuming that approximately 25% of authorisations issued during the transition phase are Track 2, this implies approximately **15-36 active monitoring plans across the EU-27 during the transition period**, each generating structured data on processing-specific outcomes. Moreover, **the addition of "Processing" as a data field in the complementary data set (Part B of the Annex)** creates the taxonomic infrastructure to disaggregate processing-attributable outcomes from those attributable to other causes.

The most consequential long-term innovation effect may be the framework's impact on **next-generation processing technologies**. Under the baseline, these technologies face an uncertain and fragmented regulatory environment that could deter the private investment necessary for clinical translation. The conditional-authorisation pathway under Article 6a (3) is specifically designed to address this. The absence of such a pathway risks either driving innovation outside the EU or allowing unregulated experimentation that could compromise patient safety and undermine public trust in the technology.

Public authorities

Organ processing authorisations granted

The proposed Article 6a regime introduces a new supervisory mandate for national competent authorities, requiring them to receive, assess, and determine applications for organ processing authorization.

During the **transition phase (approximately 2029–2031),** the authorisation regime's entry into force generates a transitional surge of applications as centres regularise processing techniques already in clinical use. The total initial application volume is estimated at approximately 60-145 applications across the EU-27 over this three-year period (central estimate: ~100). Each application requires competent-authority assessment. The national transplant authority consulted estimated the processing time per assessment at approximately 15 working days for one person, excluding external expert consultations. Applying this estimate, and incorporating the cost of external expert consultations (estimated at 3-5 days per assessment at approximately EUR 400-500 per day for clinical and pharmacological specialists), the per-assessment cost on the competent authority side is estimated as follows:

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- Internal assessment staff: 15 working days × EUR 350-450 per day (loaded labour cost for senior health-authority officials, Eurostat NACE Q) = EUR 5,250-6,750
- External expert consultation: 3-5 days × EUR 400-500 per day = EUR 1,200-2,500
- Administrative overhead (documentation, correspondence, cross-framework verification under Articles 6a (4)– (7)): estimated at approximately EUR 500-750 per assessment
- **Total per-assessment cost on the competent authority side: approximately EUR 7,000-10,000** (central estimate: ~EUR 8,500)

For the transition phase, the aggregate competent-authority cost is therefore approximately **EUR 420,000-1,450,000 over three years** (central estimate: ~EUR 850,000, or ~EUR 280,000 per year). Distributed across 15-18 Member States with active processing centres, this equates to approximately **EUR 28,000-96,000 per Member State over the full transition period**.

During the **steady-state phase (from approximately 2032 onwards**), the steady-state application flow is estimated at approximately 7-10 applications per year across the EU-27. At the per-assessment cost of ~EUR 8,500, the annual steady-state competent-authority assessment cost is approximately **EUR 60,000-85,000 per year** across the EU-27. This is a modest recurrent cost in absolute terms, but it is unevenly distributed: larger Member States with multiple active processing centres (Germany, France, Italy, Spain) will handle the majority of applications, while smaller Member States may process one application every several years or none at all.

In addition, for processing techniques authorised under Track 2 (conditional authorisation with clinical-outcome monitoring), competent authorities must review periodic monitoring reports, assessed whether the evidence supports transition to full authorisation or warrants withdrawal, and coordinate data interpretation with the centres. **This recurrent monitoring oversight** is estimated at approximately 3-5 working days per active monitoring plan per reporting cycle (assumed quarterly), equating to approximately 12-20 days per year per active Track 2 authorisation. If approximately 15–36 monitoring plans are active during the transition phase (25% of ~60–145 authorisations), the **aggregate monitoring oversight cost is approximately EUR 63,000-216,000 per year during the transition phase** (declining in the steady state as monitoring plans convert to full authorisations or are withdrawn).

Furthermore, the upfront institutional investment required to establish the assessment capability (capacity-building cost) encompasses recruitment or training of staff with multidisciplinary assessment expertise; establishment of formal cooperation channels with pharmaceutical, medical device, and SoHO authorities (as mandated by Articles 6a (4)–(8)); and development of internal procedures and assessment templates. **Quantification of these one-time institutional costs is not possible with precision from the available evidence**.

Moreover, the proposal formalises and mandates coordination with pharmaceutical, medical device, and SoHO authorities regarding the regulatory status and clinical outcome data of products used in organ processing. The recurrent cost of this coordination is

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difficult to isolate from the per-assessment cost estimated above (which already includes cross-framework verification time), **but it represents a qualitative expansion of the competent authority's relational network that, over time, will require established inter-authority communication protocols and possibly joint assessment procedures**. It is worth noting that cooperation with the medicines agency in the SoHO context is already smooth and operational in some Member States; the marginal effort to extend this model to the organ processing context is expected to be limited in Member States with existing cooperation infrastructure but more substantial in those without.

The proposal also generates **administrative costs at the EU level**. The Commission is tasked with: adopting implementing acts to establish the detailed authorisation procedure (Article 6a(12)); maintaining and updating the publicly accessible list of authorised processing operations (Article 6a(11)); and facilitating the exchange of clinical outcome data between competent authorities (Article 8, as amended). The magnitude of the Commission-level investment is not quantifiable from the available evidence, but the SoHO Regulation (2024/1938), which establishes a comparable framework for SoHO preparation authorisation, provides an indicative precedent.

Overall, **the marginal cost per assessment should decline over time as the body of authorised techniques grows.** The net incremental cost of the policy on public authorities, relative to the baseline, is therefore **lower than the gross estimates above, and the qualitative benefits** (systematic oversight capability, cross-framework coordination, EU-level evidence infrastructure) **represent a structural improvement in the public-authority governance of organ transplantation that cannot be replicated by fragmented national action.**

7 INTERVENTION N°9: RECOGNITION AND SUPPORT OF STRATEGIC HEALTH BIOTECHNOLOGY PROJECTS

7.1 Detailed description of the proposed measures

The measure establishes a framework for the recognition and support of health biotechnology strategic projects within the Union, with the objective to address bottlenecks in project execution and scale-up by reducing regulatory fragmentation, shortening permitting timelines, improving administrative coordination, and facilitating access to funding and investment.

Under this framework, Member States designate, by reasoned decision, projects located in the Union that make a substantial contribution to the objectives of strengthening industrial capacity, securing value chains, and accelerating the development and deployment of biotechnology products. Recognised projects are then granted access to a coordinated package of regulatory, administrative and financial support measures:

- Access to single points of contact (SPOCs) to coordinate the permit-granting process and provide information on administrative, technical and financial support.
- Administrative support, including: (a) assistance to ensure compliance with administrative, regulatory and reporting obligations; (b) support and facilitation

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of permitting and authorisation procedures; and (c) assistance to inform the public and those in the vicinity of the project.

- Permit-granting deadlines - 10 months from acknowledgement that the application is complete, with a possible extension of up to 3 months in duly justified complex cases.
- Priority status / public interest: considered as contributing to strengthening biomanufacturing capacity and supply resilience of biotechnology products in the Union and therefore considered in the public interest.
- Accelerated procedures.
- Highest national significance status available in national law and ensure the most rapid permit-granting and licensing procedures possible, including environmental and spatial-planning procedures.
- Urgent treatment for dispute resolution and judicial remedies relating to such projects, to the extent national law allows.
- National support eligibility: Member States may use relevant frameworks for providing public support, including national promotional banks and other public support instruments, in line with State aid rules, to support health biotechnology strategic projects.
- Union-level financial support: Projects can be supported under Union programmes, funds and financial instruments, but without an explicit priority label.
- Access to EU Health Biotechnology Support Network and related services: project promoters receive support for identifying Union-level funding opportunities, liaison with investors. They are also directed by SPOCs to national and regional antennas of the Network.

7.2 Baseline and counterfactual scenario

Under the baseline, the following conditions are expected to persist:

- project delivery in health biotechnology remains characterised by slow and fragmented administrative pathways, with complex procedures and uncertain timelines. The burden is expected to be disproportionate for SMEs, start-ups and scale-ups, with barriers to scaling up production linked to complex and fragmented permitting, overlapping legislative requirements and uneven implementation across Member States.

- no dedicated EU-level priority-project recognition or fast-track governance track exists under the baseline, meaning there is no recognised strategic project pipeline and no project-specific signal or coordinated “front door” for investors and public financiers to identify, diligence and prioritise strategic-scale projects.

- structural finance constraints at scale-up and industrial deployment stages persist, reflecting fragmented capital markets and limited depth of pan-European late-stage funds, while access to public and private investment instruments (including debt and equity) remains difficult and is often perceived as not worth applying for.

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- biotechnology ecosystems remain fragmented, with clusters, infrastructures and support schemes often operating in isolation, limiting critical mass, cross-border collaboration and EU-scale value chain formation.

- investment decisions for strategic-scale deployments remain constrained by a combination of the wider financing environment and project-level execution risk, including permitting uncertainty and time-to-revenue risk.

2025 baseline (status quo)

In 2025, the baseline issue was that health biotechnology projects were materially affected by fragmented administrative pathways and limited predictability. Stakeholder inputs pointed to duplication and uncertainty, with repeated calls for a one-stop shop for regulation and permitting and for maximum timelines and accelerated approval concepts to reduce friction, particularly for SMEs and start-ups. Public consultation[257] results reinforced the salience of permitting as a bottleneck: 61.6% (286 out of 464) agreed or strongly agreed that the length and or complexity of permitting processes for new facilities is a challenge for biotechnology manufacturing in the EU, rising to 75.4% (153 out of 203) among industry respondents.

The core conduct-of-business baseline metric concerned permit-granting duration and predictability, measured from acknowledgement of completeness to the final decision, including the share completed within a 10-month benchmark and the use of extensions. Health-biotechnology-specific permitting duration statistics are not available, but comparable strategic industrial project evidence indicated that permitting timelines can vary from months to multiple years, with substantial outliers and with environmental assessment durations ranging widely across Member States.

Competitiveness and investment conditions reflected a pronounced scale gap. As background context on the wider financing environment. Over the last 10 years, US biopharma start-ups received around nine times more late-stage funding than EU biopharma start-ups, with around EUR 219 billion of venture capital focused on health biotechnology invested in the US compared to EUR 25 billion in the EU between 2015 and June 2025[258]. At project level, the baseline constraint for strategic-scale deployments was not only the general funding gap, but also the absence of a recognised project pipeline and associated project-specific signal for investors and public financiers, with projects remaining exposed to permitting uncertainty and execution risk, delaying financing decisions and extending time-to-close.

Public consultation[259] evidence further indicated persistent hurdles in accessing finance. Only 18.8% (87 out of 464) agreed or strongly agreed that it is easy to access EU grants and subsidies such as Horizon or EU4Health, while 45.9% (213 out of 464) disagreed or strongly disagreed. For debt and equity instruments such as the EIC, EIB or STEP, only

[257] European Commission 'Have Your Say', European Commission website, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act/public-consultation_en.
[258] Landscape analysis study
[259] European Commission 'Have Your Say', European Commission website, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act/public-consultation_en.

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5.2% (24 out of 464) agreed or strongly agreed that access is easy, compared with 46.3% (215 out of 464) who disagreed or strongly disagreed, while neutral and not applicable or I do not know responses together accounted for 48.5% (225 out of 464). This reinforced the perception that companies do not see a clear, coordinated pathway to identify and access relevant instruments and that the expected costs of applying can outweigh perceived benefits.

Innovation performance combined strong science with weaker translation. The EU produced more biotechnology publications than the US, yet the US consistently filed more IP5 biotechnology patent families since the mid-1980s and China had almost reached EU patenting levels by 2020. Over the last decade, US biotech companies raised around 870% more Series C capital and around 945% more in IPO proceeds (EUR 45.4 billion versus EUR 4.28 billion). US business sector biotech R&D intensity rose to over 0.4% of GDP compared to 0.04-0.12% in the EU[260]. This translation gap was reinforced by perceived ecosystem fragmentation, including reported barriers linked to insufficient collaboration among clusters (45.9% agreement) and incapacity to reach a critical mass of stakeholders (46.3% agreement).

Baseline evolution 2025-2030 (near term)

Over 2025-2030, baseline evolution implies continuity of regulatory and administrative complexity, with limited automatic compression of permitting durations in the absence of sector-specific streamlining. Any improvements in permitting predictability are expected to be gradual and uneven, driven mainly by horizontal measures such as administrative digitalisation and modernisation rather than a step-change in governance. Under this trajectory, the distribution of permit durations is expected to remain wide, with only limited improvement in the share of complex projects permitted in under one year.

Administrative costs for promoters are expected to remain case-specific and potentially significant, particularly where technology novelty increases interpretative uncertainty and reliance on external consultants and legal support.

On finance and competitiveness, near-term evolution implies continued policy attention but persistent structural constraints in late-stage capital availability. Time-to-financial-close for capital-intensive projects is expected to remain constrained and sensitive to bankability and execution risk, with continued dispersion across Member States and project types. Aggregate mobilisation through transversal instruments is expected to continue, but without generating a traceable cohort of projects benefiting from a common governance track and without creating a project-specific signal or coordinated pathway that could systematically accelerate investment decisions. Ecosystem fragmentation and limited inter-cluster collaboration are expected to continue to constrain EU-scale collaboration and diffusion effects.

Baseline evolution 2030-2038 (medium term)

Over 2030-2038, baseline evolution implies gradual modernisation and some learning effects from parallel strategic-project approaches in other sectors, but not systematic

[260] Bridging the Gap – Transforming EU Biotech Policy, ADC, DANSK BIOTEK, 2025.

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convergence towards predictable, capped permitting timelines for health biotechnology. In comparable strategic-project settings, the impact of introducing permitting provisions has been framed as potentially reducing average permitting duration materially, for example using a one-third reduction assumption derived from other infrastructure contexts. Under baseline conditions, such a structural reduction would not be expected to materialise at scale, meaning permitting uncertainty would continue to weigh on bankability and time-to-revenue, especially for multi-site and multi-purpose industrial projects.

Administrative uncertainty is expected to sustain material economic exposure for large strategic deployments. Delay and uncertainty remain economically material for capital-intensive investments, with an indicative benchmark suggesting that regulatory delays of more than 12 months beyond initial projections have been associated with an average 34% increase in total development costs, alongside a high incidence of additional funding rounds and some programme abandonment, highlighting the potential magnitude of delay-related economic exposure for capital-intensive, timeline-sensitive innovation investments [261].

In the medium term, competitiveness and investment flows are expected to improve only gradually and unevenly, with continued sensitivity of investment timing and location decisions to execution risks and persistent late-stage funding asymmetries. The baseline continues to lack a recognised project pipeline, a project-specific signal and a coordinated support pathway that would, in itself, reduce time-to-close for large strategic projects or produce a traceable uplift in public-private co-investment and leverage associated with a recognised portfolio. In parallel, ecosystem fragmentation and uneven collaboration across clusters are expected to remain a structural constraint on EU-scale value chain development and on stronger links between innovation outputs and industrial deployment decisions.

7.3 Expected impacts

Conduct of business

The strongest effects are expected to arise at project level through a reduction in administrative uncertainty and execution risk. More specifically, the framework changes the operational conditions under which project promoters organise permitting and project preparation. Instead of dealing with multiple, partly sequential interfaces, promoters would benefit from coordinated case management through single points of contact, combined with a legally anchored maximum permit-granting timeline and associated facilitation measures. The practical importance of this change lies not only in the potential shortening of average timelines, but in the reduction of variability and unpredictability across cases.

This distinction is important. For strategic industrial projects, the main business effect of administrative streamlining is often a reduction in the volatility of project schedules rather than a uniform shortening of every phase. Lower volatility improves planning horizons, contracting and procurement sequencing, and the alignment of financing drawdowns with

[261] https://www.boyle-associates.com/the-hidden-costs-of-regulatory-delays

project milestones. In other words, the effect is not limited to "faster permitting" in a narrow sense, but extends to more reliable project execution.

A key caveat is that the size of the benefit remains sensitive to project complexity and to the use of justified extensions. In practice, more complex projects, especially those involving multiple sites or interfaces with environmental procedures, are likely to continue to require more intensive handling. The expected gain is therefore best understood as a structured reduction in uncertainty and schedule risk, not as the elimination of all timing frictions.

Administrative costs on businesses, including SMEs

Reduced transaction costs and avoided delay costs are the core administrative-cost effects that are expected, based on several mechanisms:

First, the framework creates a predictable recognition stage. This is analytically relevant because, under business-as-usual, there is no equivalent standardised entry point. A recognition decision within a defined period provides earlier certainty for promoters on whether a project qualifies for the support architecture and can therefore benefit from the related facilitation measures. This reduces the search and coordination costs associated with navigating fragmented support arrangements.

Second, administrative burden is expected to fall through fewer parallel interfaces, lower duplication of exchanges and reduced reliance on external consultants and legal support. This is expected to matter in particular for SMEs, start-ups and scale-ups, which tend to have a more limited internal regulatory capacity. This is confirmed by stakeholder consultation responses calling for one-stop-shop arrangements, simplified evidence requirements and dedicated channels for smaller operators.

Third, the regulatory design contains specific features that support lower compliance costs over time. These include electronic submission and the possibility to reuse existing data, studies and authorisations where the evidence remains applicable and up to date. This is important because, for complex projects, repeated preparation of similar documentation across procedures is a significant source of administrative burden.

The monetisation of avoided delay costs can be illustrated on the basis of indicative project values, for which a range of EUR 60–200 million is considered reasonable, noting that the strategic-project portfolio is expected to be heterogeneous and may include smaller-scale deployments. On the basis of indications from a closely regulated medical technology context that regulatory delays of more than 12 months beyond initial projections may be associated with an average increase in total development costs of 34%[262], the implied cost exposure in the event of a major delay would be roughly EUR 20.4–68.0 million per project. Assuming, for illustration, that the framework reduces the probability of such a delay by 25%, the expected avoided delay cost is estimated at around EUR 5.1–17.0 million per mature project. Combined with the assumption that roughly 70–80% of

[262] https://www.boyle-associates.com/the-hidden-costs-of-regulatory-delays/

recognised projects reach sufficient maturity for this exposure to be economically material, this underpins the cumulative ranges reported in the main text.

The main caveat is that these values are illustrative and highly sensitive to project size, maturity and implementation conditions. They should therefore be interpreted as showing the scale of the mechanism, not as a fixed per-project saving. The largest gains can be expected to be concentrated in the most capital-intensive projects, where schedule adherence lies on the critical path.

Competitiveness, trade and investment flows

The central impact channel for competitiveness is the creation of a more "investable" project pipeline. Recognition as a strategic project matters not only because it is linked to administrative streamlining, but because it provides a structured signal to investors and public financiers that a project is strategic, publicly relevant and embedded in a coordinated support architecture. This signalling effect is expected to interact with lower execution risk resulting from more predictable permitting and support services.

The framework for strategic biotechnology projects is expected to affect both the speed from recognition to funding decision and financial close and the amount of total investment mobilised. In practical terms, the reduction in permitting uncertainty is expected to lower risk premia and reduce the probability that financing is delayed pending administrative milestones. This supports shorter time-to-close and improves the likelihood that large-scale industrial deployment takes place in the Union rather than being relocated elsewhere.

To give substance to the mobilisation estimates, indicative capital values for biopharma manufacturing and related infrastructure can be used as a proxy for the investment envelope of relevant industrial deployments. Evidence from recent investments suggests that large-scale manufacturing facilities typically fall in the range of approximately EUR 316–428 million[263], while smaller-scale or modular facilities and specialised production units may require lower investment levels, for example in the range of EUR 60–200 million as used elsewhere in this analysis.

Taken together, this supports the use of a broad investment envelope spanning medium to large-scale deployments. Combined with the assumption that approximately 70–80% of recognised projects would reach financial close (the point at which a project's financing is fully secured, contractually committed, and ready for disbursement) under standard project-development conditions, this provides a plausible basis for the mobilisation ranges set out in Section 5.

The main caveat is that competitiveness impacts are especially sensitive to uptake and project maturity. Under low uptake, the effects may be economically meaningful but remain localised to a relatively small portfolio. Under medium and high uptake, the project pipeline becomes more visible and more likely to generate crowding-in effects. The

[263] Based on reported values for a syringe manufacturing facility and a vaccine manufacturing facility transaction: https://apnews.com/article/north-carolina-syringes-plant-jobs-5a69d78d39973fb59eaf6e4da167bc2c; https://www.wsj.com/business/wuxi-biologics-to-sell-irish-vaccine-facility-to-merck-for-500-million-4d6684dc

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measure therefore improves the conditions for investment but does not remove broader structural financing constraints in the Union.

Functioning of the internal market and competition

The key effect is not harmonisation of national permitting systems as such, but the creation of a more visible, comparable and coordinated pipeline of strategic projects. In that sense, the measure reduces information asymmetries and lowers dispersion in execution risk across Member States.

A particularly important operational feature is cross-border recognition for projects located in two or more Member States. Where one designated authority issues a recognition decision, that recognition is then to be acknowledged by the designated authorities of the other Member States concerned. This does not eliminate differences in national procedures, but it does reduce duplicative recognition steps and supports greater consistency of treatment for genuinely cross-border projects.

The report also provides a plausibility benchmark by referring to other EU priority-project mechanisms operating across many jurisdictions, including the first Union list of Projects of Common Interest and Projects of Mutual Interest, which comprised **166 projects**[264]. While health biotechnology is narrower in scope, the comparison is used to support the proposition that a sufficiently large recognised pipeline could, over time, begin to reduce perceived fragmentation and strengthen contestability of investment across the internal market.

The corresponding caveat is that the effect should not be read as implying uniform convergence of national permitting outcomes. The relevant signal is improved transparency and comparability, particularly for multi-country projects, rather than complete alignment of administrative regimes. The size of the effect remains dependent on uptake, cross-border footprint and implementation capacity.

Innovation and research

The measure is expected to support faster translation of scientific and technological capabilities into industrial deployment by facilitating projects that strengthen industrial capacity, scale up or upgrade research and technology infrastructures, and support collaboration across actors.

As a rough comparator for portfolio effects, benchmarks from other sectors can be considered, such as the microelectronics IPCEIs, which comprise 100 projects across 14 Member States[265]. The point of the comparison is not to equate the sectors, but to support the logic that a sufficiently large portfolio of recognised projects can generate visible infrastructure and collaboration outputs over time.

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[264] https://cinea.ec.europa.eu/news-events/news/first-pcispmis-list-data-available-transparency-platform-managed-cinea-2024-05-14_en

[265] https://competition-policy.ec.europa.eu/state-aid/ipcei/approved-ipceis/microelectronics-value-chain_en

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The main caveat is that innovation impacts are expected to be strongly dependent on project composition. If the recognised portfolio contains relatively few projects with material research and innovation, pilot or testing components, the effect on this category will remain limited. The framework therefore contributes incrementally to innovation and research by strengthening late-stage translation conditions, rather than by directly altering the broader research system.

Public authorities

Impacts for public authorities are expected to be front-loaded because implementation requires the establishment or designation of single points of contact, the operation of recognition processes and the provision of structured support services. However, this should not be interpreted as requiring entirely new administrative bodies in all Member States, given that such bodies have already been set up in other frameworks for EU strategic-project regimes, including the Net-Zero Industry Act, the Critical Raw Materials Act and the European Chips Act, all of which allow Member States to designate or adapt existing authorities and coordination mechanisms rather than build new institutions from scratch. This supports the conclusion that the main public authority cost is likely to arise from process design, workload reallocation and service standards rather than from the creation of wholly new structures.

As regards workload implications, it should be underlined that impact can be expected to scale with uptake because recognition decisions, coordination and support functions are workload-driven. Using illustrative assumptions on project activity and active case management over a 2–3 year period, and assuming that one FTE can manage around 10–15 active cases per year, indicative capacity ranges can be calculated as indicated in section 5. These ranges should only be considered as indicative illustrations of scale rather than staffing forecasts.

The key caveat is that implementation effects are highly context-dependent. Where Member States already have strong coordination structures, incremental resource needs may be relatively modest. Where baseline coordination is more fragmented, implementation may be more demanding. Over time, however, routinised handling, digital tools and reduced duplication are expected to improve efficiency per case.

Public health and safety

The key impact mechanism is that faster and more predictable project delivery enables earlier commissioning of EU-based capacity for selected strategic biotechnology products, which can then contribute to supply resilience.

At the same time, public health and resilience outcomes depend on wider market and system conditions and cannot be inferred mechanically from project recognition alone. For that reason, the scenario logic remains outcome-oriented and attribution-aware: uptake and earlier capacity commissioning may be linked to observable resilience proxies, but the effect on realised health outcomes will still depend on product mix, external shocks and broader supply conditions.

This means that the value of the measure in this category is best understood as improving the conditions under which resilience-enhancing capacity can materialise earlier, rather than as guaranteeing a given health-system result.

Cross-cutting drivers, caveats and limitations

Across all categories, the magnitude of impacts depends primarily on uptake, project maturity and implementation capacity. Uptake matters because the framework is voluntary and the aggregate effect is proportional to the number of projects entering the recognised pipeline. Project maturity matters because the most material business, administrative-cost and investment effects are concentrated in projects that are sufficiently advanced to face economically relevant delay exposure and to reach financial close. Implementation capacity matters because the effectiveness of single points of contact and coordinated support will vary across Member States.

In terms of limitations of the analysis, it should be noted that quantified effects rely on illustrative assumptions rather than observed implementation data, because the framework does not yet exist. Comparisons with other EU strategic-project regimes and other industrial sectors are analytically useful, but they are not one-to-one proxies for health biotechnology. Finally, some categories, in particular innovation and public health, are inherently more difficult to quantify.

For these reasons, the quantified results in section 5 of the SWD should be interpreted as orders of magnitude that support the plausibility and direction of impacts, rather than as precise forecasts.

8 INTERVENTION N°10: RECOGNITION AND SUPPORT OF HIGH IMPACT STRATEGIC HEALTH BIOTECHNOLOGY PROJECTS

8.1 Detailed description of the proposed measures

The measure establishes a framework for the recognition and support of high impact strategic health biotechnology projects, i.e. projects with the potential to contribute to the Union's biotechnology objectives in a systemic manner and to generate catalytic effects across the Union biotechnology ecosystem. High-impact projects may cover different types of interventions defined in the Regulation, including biotechnology development accelerators, centres of excellence for advanced therapies, projects linked to late-stage financing, AI-enabled innovation infrastructures and biodefence capabilities.

For the purpose of this analysis, the measure focuses on two categories of high-impact projects: biotechnology development accelerators and centres of excellence for advanced therapies (as impacts expected from projects linked to late-stage financing, AI-enabled innovation infrastructures and biodefence capabilities are assessed in the respective sections). Biotechnology development accelerators are shared infrastructures providing trusted testing and demonstration facilities that replicate real-world biomanufacturing conditions, including GMP-compliant processes, and support process testing, validation and small-batch manufacturing, including for investigational medicinal products. They combine state-of-the-art equipment, applied research, training activities and partnerships

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between industry, academia and public authorities to integrate research, innovation and skills development.

Centres of excellence for advanced therapies are specialised infrastructures aimed at strengthening the Union's capabilities in advanced therapies, including cell and gene therapies. They provide or coordinate advanced manufacturing and downstream processing infrastructures, integrate regulatory science, quality and safety functions, and support the transition from laboratory research to commercial manufacturing. They offer services such as acceleration and incubation programmes, access to GMP facilities, partnership facilitation and connections to clinical and hospital settings for testing and validation. A key feature is cross-border accessibility, enabling users from all Member States to access their services and supporting Union-wide development and deployment of advanced therapies.

As regards the general support architecture, high impact strategic health biotechnology projects benefit from the same package of regulatory, administrative and financial support measures as strategic health biotechnology projects, as described under Intervention n°9. This includes, in particular, access to single points of contact, administrative support, priority treatment in relevant procedures, access to the EU Health Biotechnology Support Network and eligibility for national and Union support instruments.

In addition, high impact projects benefit from enhanced treatment reflecting their systemic relevance and expected multiplier effects. In particular:

- they are recognised at Union level, either at the request of Member States or following dedicated calls for proposals;
- they benefit from priority access across procedures, in the context of the administrative support measures that strategic projects benefit from;
- they are subject to a shorter permit-granting timeline of 8 months, instead of 10 months for strategic projects, with a possible extension of up to 3 months in duly justified complex cases;
- they are given particular consideration for Union financial support, including where relevant in the form of blended financing.

8.2 Baseline and counterfactual scenario

Key assumptions:

- Late-stage translation in health biotechnology remains constrained by limited availability and uneven distribution of advanced testing, validation and scale-up infrastructures, particularly for complex modalities such as advanced therapies. Existing infrastructures are fragmented, vary in capability and scale, and are not organised as a visible or coordinated Union-level portfolio.
- No dedicated EU-level framework exists to identify, recognise and support a limited number of catalytic, system-relevant infrastructures with cross-border accessibility, resulting in weak signalling to investors and users and limited ability to prioritise or coordinate support for such projects.

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- Project development for capital-intensive infrastructures remains exposed to administrative complexity and permitting uncertainty, with no differentiated fast-track or priority handling for projects with systemic relevance.
- Investment mobilisation for large, shared infrastructures remains constrained by execution risk, time-to-revenue uncertainty and the absence of a clearly identifiable pipeline of investable flagship projects, limiting the speed and scale of financing decisions.
- Cross-border access to late-stage translation and manufacturing capabilities remains uneven and largely dependent on geographical proximity to established clusters, with limited transparency on available services and access conditions.
- The translation of research into clinical development and scalable manufacturing remains constrained by bottlenecks in late-stage testing, validation, GMP capacity and regulatory integration, particularly for advanced therapies.

2025 baseline (status quo)

In 2025, the baseline is characterised by the presence of relevant infrastructures and initiatives across Member States, including pilot facilities, testing platforms and specialised centres, but without a coordinated Union-level framework to identify and support a limited portfolio of high-impact, system-relevant projects. As a result, the key baseline issue is not the absence of capacity as such, but its fragmentation, uneven accessibility and limited visibility at Union level.

From a conduct-of-business perspective, access to late-stage capabilities remains case-specific and often dependent on informal networks or bilateral arrangements. While some infrastructures operate at high technical standards, access conditions, service scope and pricing structures vary significantly, and utilisation is not systematically optimised at Union level. Metrics such as number of firms served, service engagements or utilisation rates are not consolidated across facilities, limiting transparency over bottlenecks and capacity gaps.

From an administrative perspective, project promoters of capital-intensive infrastructures face standard permitting and authorisation pathways, without systematic priority treatment or capped timelines linked to the systemic relevance of the project. Permit-granting duration remains variable across Member States and project types, and compliance costs remain case-specific, with particular challenges for smaller operators lacking internal regulatory capacity.

From a competitiveness and investment perspective, the baseline is characterised by the absence of a clearly identifiable pipeline of flagship projects. While financing instruments exist at Union and national level, projects are not systematically packaged or signalled as strategic investment opportunities. This contributes to longer time-to-financial-close, fragmented financing structures and continued exposure to execution risk. Public consultation evidence points to persistent perceived difficulties in accessing support for capacity expansion and scaling.

For the internal market, cross-border access to specialised infrastructures remains uneven and largely driven by proximity to established ecosystems, with limited comparability of

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access conditions and limited data on cross-border usage. For innovation and research, strong upstream scientific performance is not consistently matched by efficient late-stage translation into clinical development and manufacturing, particularly for advanced therapies. For public authorities, administrative handling remains dispersed across authorities and projects, with no dedicated framework for the selection, monitoring and coordination of a limited flagship portfolio.

Baseline evolution 2025–2030 (near term)

Over 2025–2030, the baseline implies gradual expansion of late-stage infrastructures through existing national initiatives, Union programmes and private investment, but without structural coordination at Union level. Improvements in access and capacity are expected to remain uneven and cluster-driven, with limited convergence in access conditions or service availability across Member States.

Administrative processes may benefit from incremental digitalisation and learning effects, but no systematic reduction in permitting timelines for catalytic infrastructures is expected in the absence of a differentiated high-impact track. Investment mobilisation is expected to continue through existing channels, but remains opportunistic rather than pipeline-driven, with time-to-close continuing to depend on project-specific risk profiles and administrative readiness.

Cross-border collaboration and usage of infrastructures may increase gradually, but without a coordinated framework, barriers related to information asymmetries, access conditions and fragmentation are expected to persist. Innovation outcomes are expected to improve incrementally, but bottlenecks in late-stage translation and scale-up remain a structural constraint.

Baseline evolution 2030–2038 (medium term)

Over 2030–2038, the baseline implies continued maturation of the EU biotechnology ecosystem, with incremental improvements in infrastructure capacity, skills and collaboration. However, in the absence of a mechanism to identify and support a limited number of high-impact, system-relevant projects, fragmentation is expected to persist and convergence towards a coherent, Union-wide late-stage translation layer is not expected to materialise.

Conduct-of-business conditions for users of advanced infrastructures remain heterogeneous, with continued variability in access, cost and service scope. Administrative uncertainty for large, capital-intensive infrastructures remains economically relevant, with delays and coordination challenges continuing to affect project timelines and investment decisions.

Competitiveness and investment flows are expected to improve gradually but remain constrained by the absence of a visible flagship project pipeline capable of generating strong signalling and crowding-in effects. Internal market integration remains partial, with continued uneven access to specialised capabilities. Innovation performance continues to be shaped by strong upstream research but constrained by persistent bottlenecks in late-stage development and industrial deployment, particularly for advanced therapies.

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8.3 Expected impacts

Conduct of business

The high-impact designation is expected to facilitate development and use of specialised testing, validation and small-batch GMP services and related scale-up support for a wider set of firms than the project promoters themselves, thereby reducing coordination frictions and dependence on bespoke, network-based sourcing. The incremental effect relative to strategic projects is that high-impact projects are expected to generate benefits that extend beyond the project boundary, through a structured service offer with cross-border accessibility, clear access conditions and a deliberate orientation towards broader ecosystem users, including SMEs, start-ups and scale-ups.

These impacts are expected to be most observable through increased utilisation of the supported infrastructures and services, measured through the number of firms served (including SMEs), the number of service engagements delivered (such as testing, validation and small-batch GMP runs) and the utilisation rate of relevant facilities. The expected direction of change is an increase in both breadth of access and intensity of such service provision, reflecting reduced entry barriers, clearer access conditions and stronger coordination of demand for late-stage translation services at Union level. For recognised projects taking the form of biotechnology development accelerators and centres of excellence for advanced therapies, conduct-of-business effects are expected to concentrate on improved planning horizons for development and scale-up activities, with less time spent on searching for suitable capacity, negotiating bespoke arrangements and managing discontinuities between development stages.

Under a low uptake scenario (around 6-8 recognised projects by 2038), the portfolio would plausibly include around 2 promoter-led shared translation infrastructures with a service offer aimed at broader ecosystem users. On an illustrative utilisation assumption of around 30-60 firms served per year per infrastructure, with around 2-4 service engagements per firm[266], the order of magnitude would be around 60-120 firms served per year and roughly 120-480 service engagements per year once facilities are operational and demand stabilises. Under medium uptake (around 12-15 projects), assuming around 4-6 such infrastructures, the corresponding order of magnitude would increase to around 120-360 firms served per year and around 240-1,440 engagements per year. Under high uptake (around 20-25 projects), assuming around 8-10 infrastructures, the order of magnitude would rise to around 240-600 firms served per year and around 480-2,400 engagements per year.

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[266] The utilisation assumptions are calibrated using observed throughput of comparable late-stage translation and biomanufacturing support infrastructures. For example, the Cell and Gene Therapy Catapult reports collaborating with 70 companies in a single year and delivering 127 collaborative projects (https://ct.catapult.org.uk/about/annual-review/annual-review-2025), implying close to two projects per company per year. In addition, a bioprocessing research, development and demonstration facility (Verschuren Centre, https://www.canada.ca/en/atlantic-canada-opportunities/news/2022/06/verschuren-centre-expansion-will-help-cleantech-entrepreneurs-find-solutions-to-environmental-challenges.html) reports working with more than 40 companies. Against these benchmarks, an illustrative range of 30-60 firms served per year per infrastructure is conservative, but suitable for a specialised, high-impact facility, while 2-4 service engagements per firm reflects that firms typically interact through more than one structured work package (such as testing, validation, GMP-mirroring runs and associated quality control activities) rather than a single one-off interaction.

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These ranges should be interpreted as project-level throughput rather than market-wide effects. The incremental impact of the high-impact designation would be evidenced by the extent to which utilisation is cross-border, repeat usage is sustained and service offers reduce reliance on bespoke sourcing, relative to a baseline where comparable capacity, where it exists, is less visible and less structured as a Union-facing service layer.

Administrative costs on businesses, including SMEs

The key additionality in terms of administrative cost impacts attributable to the high-impact designation stems from the tighter time cap for permit granting and prioritised access to facilitation support for the recognised project cohort. This is expected to reduce schedule uncertainty for a small number of capital-intensive catalytic projects, which is economically material given their exposure to delay-related costs and knock-on effects on financing and procurement sequencing.

The principal quantification and monetisation route remains avoided delay costs for capital-intensive investments, as the high-impact designation reduces time-to-decision relative to what would otherwise be achieved.

For SMEs, the expected incremental benefit is concentrated in reduced indirect transaction costs, including fewer iterations and lower reliance on external advisory support when interacting with a prioritised facilitation pathway for the small cohort of recognised high-impact projects, rather than a general reduction of administrative burden across the sector.

With an illustrative project value range of EUR 60-200 million for capital-intensive catalytic projects, calibrated against biotechnology-relevant infrastructure proxies[267], combined with the assumption that regulatory delays of more than 12 months beyond initial projections can be associated with an average 34%[268] increase in total development costs, delay-related economic exposure can be material even for a small flagship portfolio. Under low uptake (6-8 projects), assuming around 4-5 projects reach sufficient maturity for delay-related exposure to be economically material, the order of magnitude effect is that a small subset of projects would benefit from reduced probability and duration of material delays. In this scenario, the implied cost exposure per project is EUR 20.4-68.0 million. If it is assumed, for illustration, that the high-impact pathway reduces the probability of such a >12-month delay by 25%, the resulting expected avoided delay costs are around EUR 20.4-85.0 million cumulatively for the low uptake case.

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[267] The lower bound is anchored in published orders of magnitude for bioprocessing translation and training infrastructures. For example, the NIBRT facility in Ireland was reported as a EUR 57 million build (https://www.rte.ie/news/business/2011/0609/302171-research-business/) and NIBRT's 2022 annual report states that IDA Ireland has invested over EUR 80 million in NIBRT since 2011, with a further EUR 21 million cell and gene therapy related investment referenced (https://www.nibrt.ie/wp-content/uploads/2023/01/NIBRT-Annual-Report-2022.pdf). The upper bound reflects that more GMP-intensive advanced-therapy capability and manufacturing facilities can move into the low hundreds of millions, depending on scope and industrial intensity, for example UCB announced an investment of more than EUR 200 million in a gene therapy development and clinical manufacturing facility (https://www.ucb.com/newsroom/press-releases/article/ucb-expands-innovation-footprint-with-new-state-of-the-art-gene-therapy-facility). Additional reference points indicating variation in scale include a EUR 14 million hospital-linked ATMP facility investment (https://www.uzleuven.be/en/news/uz-leuven-and-ku-leuven-invest-14-million-euros-new-cell-and-gene-therapy-facility) and public investments in ATMP ecosystem capability at regional level (https://www.wallonia.be/en/news/advanced-therapy-wallonia-invests-eu81-million-atmp).

[268] See footnote 279.

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Under medium uptake (12-15 projects), assuming around 10-12 projects reach this maturity, the expected avoided delay costs scale proportionately to around EUR 51.0-204.0 million cumulatively under the same assumptions. Under high uptake (20-25 projects), assuming around 18-20 projects reach maturity, the expected avoided delay costs increase to around EUR 91.8-340.0 million cumulatively, with the largest benefits concentrated in the most capital-intensive projects where schedule adherence is on the critical path and financing resilience is most sensitive to delay risk. Any reductions in routine administrative compliance costs (staff time and external advisory costs) are expected to be smaller than this delay-exposure channel and concentrated in the recognised project cohort, with proportionately larger relative benefits for SMEs where reduced iteration and clearer process milestones reduce reliance on external support.

Competitiveness, trade and investment flows

The high-impact designation is expected to increase the probability that a small portfolio of flagship projects reaches financial close and proceeds to implementation in the Union by strengthening the credibility of delivery plans, improving comparability of project propositions and reducing perceived execution risk for investors and public financiers.

Relevant indicators to assess this include the volume of public financing mobilised for recognised high-impact projects and time to disbursement, including the share delivered as blended finance and the time profile from recognition to first disbursement, complemented by private capital mobilised alongside public support and the associated leverage ratio. The expected direction of change is faster progression from recognition to first disbursement and stronger mobilisation and leverage for sufficiently mature projects, reflecting improved signalling effects and a more “investable” project narrative.

Evidence from cross-border flagship initiatives indicates that EU-level co-financing can be catalytic in expanding the scale of financing packages even where it does not determine initial participation decisions, and may encourage participation by Member States with limited prior engagement in such initiatives[269]. This supports the expectation that high-impact designation, and in particular the particular consideration for Union financial support that high impact projects would be given, can help unlock larger financing packages for a small number of capital-intensive projects with multiplier effects.

Public consultation evidence further indicates that access to public support for capacity expansion is widely perceived as difficult, particularly among industry respondents, reinforcing the relevance of mechanisms that improve packaging and “investability” for a targeted flagship portfolio rather than dispersing support thinly across many initiatives.

Comparator evidence from strategic-tech infrastructure programmes also supports the plausibility that concentrating resources into a small number of shared, state-of-the-art infrastructures can strengthen visibility and perceived credibility of flagship assets and

[269] Case study on cross-border and multi-country projects, with specific focus on Important Projects of Common European Interest (IPCEIs), https://commission.europa.eu/document/download/30a28e5a-a052-4f49-9c79-f5ec35f10527_en?filename=case-study-on-cross-border-and-multi-country-projects.pdf

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support investment mobilisation, without implying an economy-wide solution to structural financing constraints[270].

Under low uptake (6-8 projects), the expected incremental competitiveness effect would be concentrated in a small flagship portfolio. For scenario purposes, if recognised projects mobilise total investment (public and private) of around EUR 300-800 million per project once they reach financial close[271], the implied order of magnitude would be around EUR 2-6 billion of total investment mobilised over the period, with the public component and leverage ratio dependent on the instrument mix and project risk profile.

Under medium uptake (12-15 projects), the order of magnitude would rise to around EUR 4-12 billion. Under high uptake (20-25 projects), the order of magnitude would rise to around EUR 6-20 billion.

Functioning of the internal market and competition

Internal market and competition effects attributable to the high-impact designation are expected to arise from improved transparency and comparability of a limited flagship project pipeline and from strengthened cross-border accessibility of the services and capabilities delivered by recognised projects. The key element is the explicit systemic orientation of the high-impact cohort, which is expected to be selected and supported on the basis of Union-level added value, including cross-border relevance and broader ecosystem benefits, rather than on purely local or national considerations. This is expected to reduce information asymmetries for promoters, users and investors regarding where relevant capacity exists, what services are available and under what conditions access can be obtained.

Relevant indicators to assess progress in this area include take-up of the high-impact recognition framework, alongside cross-border usage patterns, including the share of users accessing supported services from a different Member State than the service location and the share of supported projects implemented across two or more Member States. The expected direction of change is increased cross-border usage and multi-country implementation for the recognised high-impact cohort, reflecting more contestable access conditions and reduced dependence on informal networks or proximity to established clusters.

Experience from cross-border initiatives in the medical device domain suggests that such initiatives can help address fragmentation and support investment mobilisation, including for SMEs, by creating cross-border synergies, strengthening the internal market and building a structured ecosystem around priority innovation areas. This supports the logic that a small number of catalytic flagship initiatives can function as a practical lever to

[270] https://digital-strategy.ec.europa.eu/en/policies/european-chips-act

[271] The assumed investment range per project is based on indicative evidence from comparable large-scale biopharmaceutical research and manufacturing investments, as analysed in the Rapid Assessment Scenario Study (forthcoming), where examples of such investments are featured.

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reduce fragmentation and generate observable cross-border ecosystem integration effects[272].

Under low uptake (6-8 projects), assuming for scenario purposes that around 2-3 projects are implemented across two or more Member States and the subset of shared-capability projects supports cross-border users at a rate of around 20-40% of total users[273], the order of magnitude of cross-border users supported would be around 12-48 firms per year once services are operational, based on the low-uptake throughput assumptions in conduct of business.

Under medium uptake (12-15 projects), assuming around 4-6 multi-country projects and 20-40% cross-border usage, the order of magnitude would increase to around 24-144 cross-border users per year. Under high uptake (20-25 projects), assuming around 7-10 multi-country projects and a similar cross-border share, the order of magnitude would increase to around 48-240 cross-border users per year.

Innovation and research

The high-impact designation is not expected to improve the innovation system in general. Rather, it is expected to generate systemic translation effects by supporting promoter-led projects that provide shared infrastructures and services that directly de-risk and accelerate late-stage development steps, including specialised testing, validation and small-batch GMP activities, and, where relevant, integration with regulatory science and early engagement pathways.

The materialisation of such effects could be observable through proxies linked to the recognised project portfolio, including clinical pipeline activity (applications and authorisations and median time from submission to authorisation decision) and knowledge creation and transfer outputs (patent families, licences and spin-offs attributable to supported projects and associated capabilities). The expected direction of change is improved throughput and timeliness for development and translation activities linked to the recognised portfolio, with the strongest effects expected where the supported assets address known late-stage bottlenecks and operate with broad user access.

The materiality of this translation focus is reinforced by the structural characteristics of advanced biomedical innovation, where development cycles are cited at 10-15 years and investment needs at EUR 1.28-1.71 billion to bring a new drug to market, with around half

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[272] Decision for the Important Project of Common European Interest (IPCEI) – Innovative medical devices and support software (Tech4Cure).

[273] The 20-40% range is a conservative proxy for the share of users expected to originate from a different Member State than the service location once EU-wide access is operational, recognising that facility-type infrastructures will typically continue to serve a material domestic user base alongside cross-border users. The calibration draws on established practice in EU-funded Transnational Access schemes, where access is explicitly reserved for external user groups and eligibility commonly requires that the user group leader and the majority of users work in a country other than the country where the installation is located (for example ChETEC-INFRA eligibility criteria: https://www.chetec-infra.eu/ta/application/; JERICO access rules referencing the EC grant agreement: https://www.jerico-ri.eu/ta/access-rules/; SERA-TA transnational access conditions: https://sera-ta.eucentre.it/transnational-access/). Given that such "transnational-only" access rules imply a much higher cross-border share within the funded access stream, applying 20-40% as the cross-border share of total users is intended as an order-of-magnitude assumption that allows for continued national usage alongside a substantial but not dominant cross-border component.

of time and investment occurring in clinical trial phases. In this context, catalytic late-stage assets can be expected to generate disproportionate value by reducing iteration cycles, improving readiness and shortening time-to-clinic and time-to-scale for a subset of high-potential programmes, even if broader innovation system dynamics remain unchanged[274].

Under low uptake (6-8 projects), if for scenario purposes it is assumed each such capability project supports around 10-20 development programmes per year with de-risking steps that shorten iteration cycles and improve readiness, and if around 2-4 programmes per infrastructure per year translate into clinical trial applications attributable to the supported capability, the order of magnitude would be around 4-8 clinical trial applications per year linked to the capability layer in steady state.

Under medium uptake, assuming 4-6 capability projects, the order of magnitude would be around 8-24 such applications per year and under high uptake, assuming 8-10 capability projects, around 16-40 per year. Knowledge creation and transfer effects would be expected to scale in a broadly similar way, with the most policy-relevant signal being improved throughput and timeliness in late-stage translation steps rather than system-wide shifts in patenting or publication trends.

Public authorities

Impacts for public authorities attributable specifically to the high-impact designation are expected to be limited and not driven by more demanding selection and monitoring requirements for the high-impact cohort, to ensure that the designation is reserved for projects with credible Union-level added value and measurable multiplier effects. Cost drivers associated with general project delivery facilitation, including standard administrative support arrangements and routine permitting operations, should not be attributed to the high-impact category again.

Experience from multi-country flagship initiatives underlines the importance of early, inclusive Member State engagement, a designated coordinator with sufficient administrative capacity and a jointly managed timeline and workplan to maintain manageability. It also highlights that overly large project portfolios are harder to coordinate, design and assess, supporting an approach that concentrates effort on a limited number of high-leverage projects. These lessons are directly relevant to the design and implementation of the high-impact designation and the associated governance model[275].

Under low uptake (6-8 projects), impacts for public authorities would imply a small steady-state workload for processing applications, documenting decisions and collecting performance information, with the incremental burden broadly scaling with the number of recognised projects and the share that are multi-country.

Under medium uptake (12-15 projects) and high uptake (20-25 projects), incremental workload would rise proportionately, but the scale would remain bounded by design, since

[274] Decision for Important Project of Common European Interest (IPCEI) on health (Med4Cure).
[275] DG COMP Code of good practices for a transparent, inclusive, faster design and assessment of IPCEIs, https://competition-policy.ec.europa.eu/system/files/2023-05/IPCEIs_DG_COMP_code_of_good_practices.pdf. See also Joint European Forum (JEF-IPCEI) workstreams and related guidance, including IPCEI factsheets, templates and the IPCEI Design Support Hub: https://competition-policy.ec.europa.eu/state-aid/ipcei_en

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the high-impact category is intended to remain a limited portfolio. The relevant quantification would therefore depend on the number of applications processed per year, the number of monitoring cycles completed, and the intensity of cross-border coordination required, rather than on general costs related to permitting and single point of contact operations that are not specific to the high-impact designation.

Public health and safety

Public health and safety impacts, expected to be positive but indirect and in the medium term, would be driven by the potential of the high-impact project framework to facilitate the development and operation of shared capabilities that enable faster, safer and more efficient development of innovative therapies, in particular advanced therapies, through improved access to specialised testing, validation, small-batch GMP and quality-control services. This is expected to reduce late-stage bottlenecks and iteration cycles, support earlier identification and mitigation of quality and safety risks and improve readiness for clinical development and scale-up.

In addition, where recognised high-impact projects are connected to relevant data and digital infrastructures, the framework can contribute to improved patient access across the Union by supporting more efficient development pathways and, indirectly, more consistent cross-border availability of innovative therapies.

Under low uptake (6-8 projects), if for scenario purposes it is assumed each capability project supports around 1-2 high-potential therapy programmes per year to progress more rapidly and with stronger quality assurance through specialised testing, validation, small-batch GMP and quality control, the order of magnitude would be around 2-4 programmes per year experiencing improved development pathways under low uptake, rising to around 4-12 under medium uptake and around 8-20 under high uptake.

These figures should be interpreted as indicative throughput effects rather than direct health outcomes, since patient access depends on downstream regulatory, reimbursement and health system conditions.

9 INTERVENTION N°11: HEALTH BIOTECHNOLOGY ECOSYSTEM SUPPORT FRAMEWORK

9.1 Detailed description of the proposed measures

This intervention includes four mutually reinforcing components: (i) strategic mapping of the Union's biotechnology ecosystem; (ii) networks of health biotechnology clusters; (iii) an EU Health Biotechnology Support Network; and (iv) a European Health Biotechnology Steering Group. Together, these measures aim to reduce information asymmetries, improve coordination across Member States, facilitate access to regulatory support and funding, and strengthen ecosystem connectivity around strategic and high-impact strategic projects.

First, the proposal provides for a strategic mapping of the Union's biotechnology ecosystem, to be carried out by the Commission in cooperation with Member States and maintained over time. The mapping is intended to deliver a comprehensive and up-to-date

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overview of capacities, infrastructures, dependencies, gaps and investment needs across biotechnology value chains. It covers in particular industrial and research infrastructures, access to risk-tolerant capital, clusters and ecosystems, skills needs, and the availability and use of data and AI infrastructures. The mapping serves as the evidence base for the identification and prioritisation of strategic and high-impact projects and informs Union and national policy and funding decisions, as well as the work of the Steering Group.

Second, the proposal promotes the development of networks of health biotechnology clusters, facilitated by the Commission and Member States. These networks are intended to provide the structural connectivity layer of the ecosystem by linking regional and national clusters and supporting cross-border collaboration. Their activities may include facilitating interregional value chains, pooling resources and infrastructures across Member States, enabling cross-border access to research and biomanufacturing facilities, supporting scale-up from research to industrial deployment, and promoting knowledge transfer, standardisation and inter-cluster cooperation. Where appropriate, such networks may adopt dedicated governance structures or legal entities to implement joint actions and investments.

Third, the proposal establishes an EU Health Biotechnology Support Network, coordinated by the Commission and composed of national and regional antennas. The Network provides a single entry point for biotechnology developers and project promoters—particularly SMEs, start-ups and scale-ups—to navigate the Union's regulatory and funding landscape. Its functions include providing information on applicable Union and national rules and authorisation procedures, supporting access to relevant regulatory pathways and support mechanisms, and facilitating identification of funding, scaling-up and collaboration opportunities. The Network is designed to build on and complement existing structures and may be supported by digital tools to enhance accessibility and efficiency.

Fourth, the proposal creates a European Health Biotechnology Steering Group, composed of Member State representatives and the Commission, to provide the governance and coordination layer of the framework. The Steering Group facilitates the exchange of information and best practices, supports the effective recognition and implementation of strategic projects, and provides advice on ecosystem development, including cluster networking and funding coordination. It also contributes to identifying and addressing systemic challenges faced by biotechnology projects and supports broader coordination across Member States.

Taken together, these components form an integrated support architecture: the mapping provides the analytical foundation; the Steering Group ensures coordination and strategic guidance; the Support Network delivers operational support to firms and project promoters; and cluster networks strengthen cross-border linkages and access to infrastructures. The intervention therefore complements the strategic project framework by improving the functioning of the broader ecosystem in which such projects are developed and scaled.

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9.2 Baseline and counterfactual scenario

Core baseline assumptions (counterfactual without the ecosystem support measures)

- No single-entry point exists for health biotechnology innovators to navigate the EU regulatory and funding landscape; developers must independently engage multiple national and EU-level bodies without coordinated guidance.
- General support networks (EEN, national innovation agencies) lack health biotechnology-specific expertise and are not positioned to develop such specialisation without dedicated investment.
- No structured investor-innovator matchmaking mechanism exists at EU level for health biotechnology; connections remain ad hoc, network-dependent, and geographically concentrated in a few leading ecosystems.
- Support conditions for health biotechnology innovators vary significantly across Member States, creating an uneven playing field where a company's prospects depend substantially on location.
- Cross-border access to biomanufacturing facilities and research infrastructure is not systematically available; cluster cooperation remains fragmented with limited inter-cluster collaboration.
- No structured EU-level governance mechanism exists for coordinating health biotechnology ecosystem development; Member States set priorities independently without standardised mechanisms for discussing complementarity or identifying dependencies.

2025 baseline (status quo)

Health biotechnology SMEs and start-ups face substantial transaction costs when identifying applicable regulatory pathways, funding instruments, potential investors, and available infrastructure across the EU's multi-framework landscape. Companies seeking to scale across borders face engagement with national innovation agencies, regulatory authorities, funding bodies, and cluster organisations in each Member State, compounded by divergent national interpretations of EU frameworks[276]. SMEs struggle to identify available R&D capacity, testing facilities, GMP manufacturing slots, and scale-up infrastructure due to fragmented information and poor visibility of clusters and support services across the EU[277]. These burdens fall disproportionately on SMEs and start-ups lacking in-house regulatory affairs capacity.

Investor perception of the EU biotechnology ecosystem remains shaped by fragmentation, poor navigability, and absence of a transparent overview of EU capabilities and investment opportunities.

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[276] EuropaBio (2024). *Joint Statement on the EC Initiative: Boosting Biotechnology and Biomanufacturing in the EU*. Available at: https://www.europabio.org/joint-statement-on-the-ec-initiative-boosting-biotechnology-and-biomanufacturing-in-the-eu/.

[277] European Commission (2024). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and The Committee of the Regions: Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU*, COM(2024) 137 final.

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Regional disparities in support availability persist, with biotechnology SMEs' ability to navigate the system depending heavily on which Member State they are located in. Cross-border access to pilot plants, testing facilities, and GMP capacity is not systematically available. Cluster cooperation remains fragmented, with health biotech clusters poorly integrated and lacking strong cross-border collaboration.

The EU's strong basic research output does not translate proportionally into commercial innovation. OECD analysis confirms that structural ecosystem weaknesses, not scientific capability, are the primary cause of the EU's underperformance in translating research into innovation[278]. Weak academic-industry linkages persist[279], knowledge transfer between clusters remains ad hoc and project-dependent, and no systematic mechanisms exist to identify R&D capability gaps at EU level.

At public authority level, no structured EU-level governance mechanism exists specifically for coordinating health biotechnology ecosystem development.

Baseline evolution (medium to long term)

Without ecosystem support measures, current conditions are expected to persist or deteriorate. The navigational burden for SMEs is expected to increase as additional regulatory and policy frameworks become relevant, adding procedural steps and institutional contact points without corresponding enhancement in support capacity. General support networks will continue providing cross-sectoral SME services but are not positioned to develop health biotechnology-specific expertise given their mandate.

The competitive disadvantage relative to the other jurisdictions is expected to persist, as global competitors continue strengthening their positions: the US Biotechnology and Biomanufacturing Initiative provides coordinated federal support, while China deploys state-directed cluster development with substantial infrastructure investment[280]. The cumulative effect is continued high attrition in the EU health biotechnology pipeline, with projects failing not due to inadequate science but because developers cannot efficiently access the support, funding, and infrastructure needed to progress.

The intra-EU innovation divide is expected to persist, with leading ecosystems (Netherlands, Denmark, Germany, France) continuing to benefit from established clusters, stronger investor networks, and more developed support structures, while less developed ecosystems in Central and Eastern Europe and Southern Europe lack these foundations. Incompatible national frameworks will continue to limit cross-border value chain development.

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[278] OECD (2026). *A comparison of the innovation and regulatory environments for biotechnology and biosolutions across the EU and the United States*. Available at: https://www.oecd.org/en/publications/a-comparison-of-the-innovation-and-regulatory-environments-for-biotechnology-and-biosolutions-across-the-european-union-and-the-united-states_1ec20342-en.html.

[279] European Commission (2024). *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and The Committee of the Regions: Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU*, COM(2024) 137 final.

[280] See https://www.bridgecross.bio/mapping-chinas-biotech-hubs-where-policy-capital-and-competition-collide/; https://merics.org/en/report/lab-leader-market-ascender-chinas-rise-biotechnology.

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The translation gap between EU research output and commercialisation is expected to persist or grow. The pipeline of frontier biotechnologies continues to expand (AI-enabled drug discovery, advanced therapies, precision medicine, synthetic biology), requiring increasingly sophisticated translation infrastructure that the current fragmented ecosystem is not positioned to deliver. EU-funded research projects will continue to produce high-quality science, but commercialisation will increasingly occur outside the EU.

Without a Steering Group or equivalent coordination mechanism, the risk of duplicative national investments will persist. As EU-level biotechnology investment grows, particularly under the European Competitiveness Fund, the coordination gap becomes increasingly costly, with larger volumes of funding channelled through fragmented national systems increasing the probability of duplication and suboptimal resource allocation.

9.3 Expected impacts

Conduct of business

The ecosystem support measures assessed may indirectly influence companies' conduct of business, but these effects are difficult to isolate, as changes in companies' behaviour are likely to result from the combined effect of several measures under the European Biotech Act as well as other factors. The relevant pathways through which the intervention may affect conduct of business are captured under other impact areas. Given the difficulty of attributing conduct of business effects specifically to the ecosystem support measures, impacts on this category are considered neutral in the multi-criteria analysis scoring.

Administrative costs on businesses, including SMEs

The EU Health Biotechnology Support Network, acting as a single entry point with health biotechnology-specific support and navigation capacity, is expected to reduce the transaction costs currently borne by businesses and SMEs in particular. The proposal envisages that national and regional antennas may build on existing structures such as the European Enterprise Network (EEN) where appropriate.

Evidence from comparable support networks indicates the potential scale of impact. The EEN impact evaluation shows that supported businesses report substantially higher knowledge levels across relevant areas compared to unsupported businesses: how to access funding and finance (57% vs 40%); the market in which they operate (88% vs 78%); regulation and standards (78% vs 72%)[281]. Among EEN-supported businesses reporting positive impacts, improved knowledge was cited by 57% regarding finance access, 50% for market knowledge, and 35% for regulations and standards. Similarly, evidence from the EMA SME office survey found over 80% of respondents rated assistance services as

[281] Innovate UK (2023). *Enterprise Europe Network impact evaluation*. Available at: https://www.ukri.org/publications/enterprise-europe-network-impact-evaluation/.

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relevant to their needs – suggesting that the Support Network's advisory functions would be utilised and deliver value to the target population[282].

Together, accessible single entry points and health biotechnology-specific advisory capacity are assumed to reduce FTE days spent on identifying applicable regulatory pathways, funding instruments, and scaling-up opportunities.

Competitiveness, trade and investment flows

The competitiveness effect of the intervention is expected to operate primarily through the EU Health Biotechnology Support Network's matchmaking function. In addition, better ecosystem navigation, targeted support, and improved infrastructure access are expected to contribute to reduced time-to-market for health biotechnology products.

Evidence from existing EU-level networks indicates the potential scale of impact on investor access and matchmaking. The EEN impact evaluation shows that supported businesses report higher capability in investment-related areas compared to unsupported businesses: investment readiness (57% vs 42%) and ability to access funding or finance (52% vs 44%)[283]. The Single Market Programme evaluation found that over 84% of SMEs using EEN services reported either strong or reasonable impact on access to finance and funding opportunities – the strongest impact areas among all assessed[284]. This demonstrates that network antennas with matchmaking functions can result in improved access to investors and capital for developers. The European Innovation Council (EIC) provides further evidence that structured matchmaking can increase innovator-investor connections that translate into measurable funds raised. Since 2021, through its Business Acceleration Services, the EIC has facilitated over 20 000 one-on-one meetings between EIC awardees and corporates, procurers, and investors, resulting in 595 deals and EUR 350 million raised through investor outreach[285].

On time-to-market effects, several sources support the proposition that structured navigation and support in retrieving information systematically can reduce development timelines. EMA analysis of initial marketing authorisation applications indicates that applicant-side "clock-stops" represent a substantial portion of total procedure time, and in 2023, the average duration of clock-stops (198 days) was comparable to the assessment time itself (204 days)[286]. EMA reports that 42% of applicants requested extended clock-stops because their data was not mature enough at submission, suggesting that interventions improving submission readiness could reduce elapsed time. Evidence from the EMA SME Office indicates persisting demand for support services that help SMEs prepare for regulatory interactions. Surveys show high satisfaction with existing services (80-90% depending on the specific service), but also consistent calls from SMEs to expand

[282] European Medicines Agency (2025). *Outcome of SME office survey on the implementation of the SME regulation - Commission Regulation (EC) No 2049/2005*. Available at: https://www.ema.europa.eu/en/about-us/support-smes/sme-regulation-reports.
[283] Innovate UK (2023). *Enterprise Europe Network impact evaluation*. Available at: https://www.ukri.org/publications/enterprise-europe-network-impact-evaluation/.
[284] European Commission (2025). *Single market programme mid-term evaluation – Supporting study – Final report*. Available at: https://data.europa.eu/doi/10.2873/1307895.
[285] See https://eic.ec.europa.eu/eic-funding-opportunities/bas_en.
[286] See https://www.ema.europa.eu/en/news/improving-efficiency-approval-process-new-medicines-eu.

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regulatory assistance, training, and pre-submission support[287]. The Support Network would not itself provide regulatory advice. However, by helping SMEs navigate the complex landscape of documentation, requirements, and available pathways upstream of regulatory engagement, it could ensure that developers come better informed and prepared to their interactions with the EMA SME Office and, where eligible, with schemes such as PRIME[288]. This improved preparedness would address the submission readiness gaps that contribute to extended clock-stops, thereby contributing to reduced overall time-to-market.

The UK Regulatory Advice Service for Regenerative Medicine (RASRM) further offers a comparator to the proposed Support Network. RASRM operates as a "one-stop shop" providing a single point of access to coordinated expert responses, aiming to reduce the burden of navigating required standards and legislation for complex therapies[289]. The UK Government response notes that the service resolved concerns regarding the complexity of the regulatory environment and provides an early opportunity to help speed access[290]. Taken together, this evidence supports the expectation that the Support Network's function of helping navigate the system and retrieve relevant and timely information would contribute to reduced time-to-market.

Functioning of the internal market and competition

The EU Health Biotechnology Support Network is expected to reduce the effect of varying national support structures by providing comparable advisory services through antennas across all Member States. By establishing health biotechnology-specific antennas based on common criteria across the EU[291], the intervention would reduce the current dependence on national support structures that vary significantly in scope and capacity. This addresses the baseline condition where a health biotechnology SME's ability to navigate the system and access support depends on which Member State it is located in. Stakeholder consultations validated this approach, emphasising the importance of building on existing structures and instruments. Workshop participants noted that clusters already maintain connections across multiple levels, including innovation agencies, the ECCP, European Clusters Alliance, and industry associations, providing an established foundation for the proposed networks[292].

The cluster networks are intended to improve cross-border access to biomanufacturing facilities and research infrastructure. Although outcome-level data on facility access is limited, evidence on existing cluster initiatives supports the potential impact of this

[287] EMA 2020 and 2025 SME Office surveys. Available at https://www.ema.europa.eu/en/about-us/support-smes/sme-regulation-reports. See also https://somerville-partners.com/how-successful-are-the-emas-sme-initiatives/.
[288] PRIME is a scheme run by EMA to enhance support for the development of medicines that target an unmet medical need. This voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier.
[289] See https://www.hta.gov.uk/guidance-professionals/guidance-sector/human-application/regulatory-advice-service-regenerative.
[290] See https://assets.publishing.service.gov.uk/media/5a81f4bced915d74e3400f57/Government_Response_to__Inquiry_into_Regenerative_MedicineCm_9491.pdf.
[291] As per the Proposal for the European Biotech Act (Section 4, Article 19(5)) "The Commission shall select the members of the Network based on criteria made public pertaining to the expertise and capabilities required to fulfil the missions referred to in paragraph 3".
[292] Workshop on strengthening biotechnology clusters: current landscape and potential impacts of the European Biotech Act proposal.

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mechanism. The ECCP Cluster Panorama underlines the role of cluster networks as facilitating economic resilience and market integration by enabling firms to pool infrastructure and operate shared resources including testbeds, GMP facilities, and data spaces, and can arrange access to pilot lines and form cross-border consortia from demonstration to manufacturing[293]. The importance of cluster collaboration for infrastructure access is recognised in other strategic sectors. For example, the Silicon Europe cluster alliance, connecting over 2 500 companies and research institutions in the electronics sector, acts as a single entry point with aligned shared infrastructures.

Innovation and research

The cluster networks and Support Network measures are expected to contribute to innovation and research through complementary functions. The cluster networks bring together projects, research organisations, and market actors in cross-border collaborations, pooling resources and strengthening research-industry linkages that support the translation of research into market applications. The Support Network helps individual actors navigate the ecosystem and connect with relevant cluster networks and cooperation opportunities, thereby increasing the uptake of research collaboration.

Cluster networks: Evidence from other EU initiatives demonstrates that cluster-based approaches can generate measurable partnership activity and research-market connections. The 2021 evaluation of EU cluster initiatives under COSME and Horizon 2020 found that INNOSUP-1 supported 1,687 SMEs, bringing together companies and research organisations in cross-border consortia; ESCP-4i facilitated 64 partnerships across 32 countries; and ESCP-S3 strengthened interregional collaboration with 57 partners from 19 countries[294]. Stakeholder consultations confirm that cluster organisations possess deep ecosystem knowledge developed over many years of close interaction with industry and research actors, positioning them to identify bottlenecks and facilitate targeted connections[295].

Support Network: The Support Network is expected to contribute to innovation capacity at firm level by helping developers identify relevant research partnerships and access cluster networks. The EEN impact evaluation shows that firms receiving network support report higher capability across innovation-related areas compared to unsupported firms: knowledge sharing and collaboration (69% vs 55%), management of innovation (79% vs 66%), and culture of innovation (84% vs 74%)[296]. Among supported businesses, 55% reported positive impact on knowledge sharing and collaboration, 52% on management of innovation, and 43% on R&D spend. Workshop participants noted that current EU cluster instruments primarily attract early-stage start-ups, while mature scale-ups, whose priorities centre on industrialisation, regulatory acceleration, and market access, engage less

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[293] European Cluster Collaboration Platform (2025). *Clusters and Europe's Competitiveness ECCP Summary Report 2025*. Available at: https://www.clustercollaboration.eu/sites/default/files/document-store/ECCP_SummaryReport_2025.pdf.

[294] Prognos, CSES, Idea Consult (2021). *Evaluation Study of and Potential Follow-Up to Cluster Initiatives under COSME, H2020 and FPI*. Available at: https://data.europa.eu/doi/10.2873/977418.

[295] Workshop on strengthening biotechnology clusters: current landscape and potential impacts of the European Biotech Act proposal.

[296] Innovate UK (2023). *Enterprise Europe Network impact evaluation*. Available at: https://www.ukri.org/publications/enterprise-europe-network-impact-evaluation/.

frequently[297]. The Support Network's functions are expected to help these actors identify and access relevant cluster networks, extending ecosystem support for research collaboration and innovation across the full development lifecycle.

Public authorities

The intervention introduces several obligations for **Member State authorities**: participation in the European Health Biotechnology Steering Group (Article 20), data provision for strategic mapping upon Commission request (Article 17), facilitation of the Support Network's tasks (Article 19(7)), and designation of single points of contact for strategic projects (Article 11).

Comparable strategic project initiatives provide indicative benchmarks. The Net-Zero Industry Act estimates 1–2 FTEs for Member States to operationalise permitting one-stop shop functions, with potentially higher requirements depending on project volume and federal structures, and a maximum of 1 FTE per Member State for administrative support to strategic projects[298]. The Critical Raw Materials Act estimates 0.25 FTE per year for reporting on the state of strategic projects and 2 FTEs per year for participation in the governance structure[299]. Given that one-stop shop architectures will have already been established under these initiatives, Member States will have developed points of contact, coordination channels, and workflows, resulting in marginally lower set-up costs. Remaining incremental cost would primarily relate to scope extension – integrating health biotechnology strategic projects into existing workflows and developing sector-specific expertise. The costs associated with Steering Group participation, national coordination, and data submissions for strategic mapping will depend on the frequency of mapping requests and the intensity of Steering Group activity.

These initial obligations are expected to yield efficiency gains over time. Member States gain access to a systematic evidence base (strategic mapping) and a coordination forum (Steering Group) that do not currently exist for biotechnology specifically, improving national decision-making and reducing duplicative investments by providing comparable information on capacities, gaps, and funding priorities across the Union. The Support Network would also alleviate the burden on national administrations that bear the full load of guiding health biotechnology applicants through complex EU funding and regulatory landscapes (see section on competitiveness, trade and investment flows).

At **EU level**, administrative costs arise from operating the Steering Group secretariat, conducting and maintaining the strategic mapping, and coordinating the Support Network.

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[297] Workshop on strengthening biotechnology clusters: current landscape and potential impacts of the European Biotech Act proposal.

[298] European Commission (2023). *Commission Staff Working Document for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Europe's net-zero technology products manufacturing ecosystem (Net Zero Industry Act)*. Available at https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/swd/2023/0219/COM_SWD(2023)0219_EN.pdf.

[299] European Commission (2023). *Commission Staff Working Document Impact Assessment Report accompanying the document Proposal for a Regulation of the European Parliament and of the Council establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) 168/2013, (EU) 2018/858, 2018/1724 and (EU) 2019/1020*. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023SC0161.

The proposed act identifies relevant tasks including administrative and logistic support to Steering Group meetings, drafting calls for proposals for the Support Network, project selection and assessment for strategic projects, workflow management of Support Network queries, and promoting networking and cooperation among projects. Technical assistance appropriations of approximately EUR 2.6 million annually (EUR 18.4 million over the MFF period) include, among other tasks, financing the contract agents implementing these functions on the Commission side. The Critical Raw Materials Act estimates 2 FTEs for the governance structure secretariat plus EUR 75,000 per year in organisational costs, and 1 FTE for supporting strategic project selection. As with other EU-coordinated support structures, the long-term sustainability of the Support Network and its antennas will depend on the development of sustainability strategies and funding diversification approaches.

Public health and safety

The ecosystem support measures do not directly affect public health and safety outcomes. Given the absence of a direct transmission mechanism and the difficulty of isolating any indirect effects, impacts on this category are considered neutral.

10 INTERVENTION N°12: BIOSIMILARS COMPETITIVENESS FRAMEWORK

10.1 Detailed description of the proposed measures

The proposal includes the update and development of **EMA guidelines** on tailored and risk-proportionate regulatory approaches for biosimilar development, reflecting manufacturing and analytical testing advances. Guidance will consider potential reduction of clinical data requirements for biosimilar development and approval without affecting quality, safety and efficacy. They will aim at shortening the development and facilitating the authorisation of biosimilar medicinal products.

The proposal also includes the establishment of a framework for the **recognition and the support health biotechnology strategic projects focused on biosimilar** research, development, manufacturing and marketing authorisation. The support package includes administrative, regulatory and financial and technical support at Member State level, also promoting international cooperation between economic operators and biotechnology clusters in this area.

10.2 Baseline and counterfactual scenario

Non-binding guidance by the European Medicines Agency for a tailored regulatory approach for biosimilar development, reflecting advances in analytical science and considering potential reductions in clinical data requirements (Article 28):

Biosimilar development currently entails costs of approximately EUR 85.6–257 million and timelines of 6–9 years[300]. A major cost and time driver is the comparative efficacy study (CES), which accounts for 20–50% of total development costs (approximately EUR

[300] McKinsey & Company. (2022, August 19). Three imperatives for R&D in biosimilars. https://www.mckinsey.com/industries/life-sciences/our-insights/three-imperatives-for-r-and-d-in-biosimilars

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14–46 million) and extends development timelines by 12–24 months[301,302]. Europe is the leading region for biosimilar clinical trials with 83 trials conducted between 2020–2025 and roughly EUR 4.9 billion biosimilar trials investments, 71% of which dedicated to CES.

Regulatory practice has already begun to evolve toward a risk-based approach. For well-characterised, simpler products with accepted pharmacodynamic biomarkers the EMA has accepted PK/PD-based clinical packages without Phase III CES for many years. From the EMA Medicines Database, 41 of 151 authorised biosimilars (27.2%) are simple biologics in this category[303]. For monoclonal antibodies and fusion proteins, Phase III CES with clinical efficacy endpoints was included in 100% of the 36 MAAs evaluated by EMA

between July 2012 and November 2022[304]. However, evidence shows that negative regulatory outcomes were linked to quality deficiencies rather than clinical efficacy results, indicating that CES has had limited regulatory impact in determining approval outcomes[305].

The European Medicines Agency draft Reflection Paper on a Tailored Clinical Approach in Biosimilar Development (2024) proposes formalised criteria for waiving CES requirements, marking a shift from case-by-case flexibility to a generalised scientific principle[306]. This approach aligns with international regulatory convergence. The U.S. Food and Drug Administration has removed switching study requirements and expanded flexibility in clinical evidence (2024–2025)[307], while Canada is consulting on CES elimination for most biosimilars[308]. South Korea already applies CES waivers in practice[309], and Japan is expected to adopt similar flexibility by 2028.

Under the baseline, the EMA continues a gradual shift toward tailored, risk-based approaches through non-binding guidance, without changes to formal regulatory standards for safety, quality, or efficacy. At the same time, global competitors streamline evidentiary requirements more rapidly. As a result, EU competitiveness in biosimilar development is

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[301] Moore, T. J., Mouslim, M. C., Blunt, J. L., Alexander, G. C., & Shermock, K. M. (2020). Assessment of availability, clinical testing, and US Food and Drug Administration review of biosimilar biologic products. JAMA Internal Medicine, 181(1), 52–60. https://doi.org/10.1001/jamainternmed.2020.3997

[302] IQVIA, The Impact of Biosimilar Competition in Europe, January 26, 2026, iqvia-the-impact-of-biosimilar-competition-in-europe-2026-01-26-forweb.pdf

[303] European Medicines Agency. (2026). Medicines output report [dataset]. Retrieved 2 March 2026 from https://www.ema.europa.eu/en/medicines/download-medicine-data

[304] Kirsch-Stefan, N., Guillen, E., Ekman, N., Barry, S., Knippel, V., Killalea, S., Weise, M., & Wolff-Holz, E. (2023). Do the outcomes of clinical efficacy trials matter in regulatory decision-making for biosimilars? BioDrugs, 37(6), 855–871. https://doi.org/10.1007/s40259-023-00631-4

[305] Kirsch-Stefan, N., Guillen, E., Ekman, N., Barry, S., Knippel, V., Killalea, S., Weise, M., & Wolff-Holz, E. (2023). Do the outcomes of clinical efficacy trials matter in regulatory decision-making for biosimilars? BioDrugs, 37(6), 855–871. https://doi.org/10.1007/s40259-023-00631-4

[306] European Medicines Agency. (2024). Reflection paper on a tailored clinical approach in biosimilar development (draft for consultation). Amsterdam: EMA.

[307] U.S. Food and Drug Administration. (2024). Considerations in demonstrating interchangeability with a reference product: Update (draft guidance). Silver Spring, MD: FDA.

[308] Smart & Biggar. (2025, July 4). Update on biosimilars in Canada – June 2025. https://www.smartbiggar.ca/insights/publication/update-on-biosimilars-in-canada-june-2025

[309] Kang, H. N., Thorpe, R., Knezevic, I., *et al.* (2020). The regulatory landscape of biosimilars: WHO efforts and progress made from 2009 to 2019. Biologicals, 65, 1–9. https://doi.org/10.1016/j.biologicals.2020.02.005

expected to weaken, with developers prioritising earlier submissions in jurisdictions with lighter requirements, potentially delaying EU market entry.

Europe and the United States combined hold over 80% of the global biosimilar market by revenue. However, the EU's relative share is declining as the US market expands rapidly. The US biosimilar market grew from EUR 6.1 billion in 2020 to an estimated EUR 10.1 billion in 2024, while the Asia-Pacific region - driven primarily by China - grew from EUR 1.5 billion to approximately EUR 4.5 billion over the same period[310]. The EU biosimilar market projected to grow at a compound annual growth rate (CAGR) of approximately 17%, increasing from EUR 13.2 billion in 2025 to EUR 62.9 billion by 2035[311] driven primarily by patent expiries and expanding therapeutic applications. The estimated cumulative savings of EUR 75 billion from biosimilar competition since 2006 with EUR 13 billion in 2024 continues to grow.

Advances in analytical sciences are expected to further strengthen the scientific consensus that Phase III CES provides limited additional value for well-characterised biosimilars. However, as development shifts toward more complex products (e.g. monoclonal antibodies, bispecific antibodies, antibody–drug conjugates), a proportion of applications will continue to require clinical data, particularly for immunogenicity assessment.

Biosimilar strategic projects recognition and support (Article 29 -30)

Conduct of business

Assumption

The Chapter II strategic project support infrastructure (Articles 3–14) is operational for general health biotechnology projects, providing single points of contact (Art. 11), priority permit-granting (Art. 12), compliance assistance (Art. 13), and pathways for financial and technical support (Art. 14). However, biosimilar-specific eligibility criteria under Article 29 do not exist in the baseline. Biosimilar companies may compete for general industrial support but lack dedicated recognition.

Administrative costs on businesses, including SMEs

Assumption

Chapter II administrative support infrastructure (single points of contact, compliance assistance, priority permitting under Articles 11–14) is operational for general health biotechnology projects but not accessible to biosimilar-specific projects absent Article 29 recognition.

Competitiveness, trade and investment flows

[310] Precedence Research. (2025, August 13). Biosimilars market size to hit USD 175.99 billion by 2034. https://www.precedenceresearch.com/biosimilars-market

[311] Precedence Research. (11 Mar 2026). Biosimilars Market Size, Share and Trends 2026 to 2035. https://www.precedenceresearch.com/biosimilars-market

Biosimilar-specific investment data (venture capital, FDI) disaggregated from the broader health biotechnology sector is not publicly available. However, what can be stated with biosimilar-specific evidence is:

- The EU retains significant biosimilar manufacturing capacity. Of the top five global biosimilar companies by revenue in 2024, two are EU-based (Sandoz, Austria/Germany; Fresenius Kabi, Germany) and two operate major EU manufacturing facilities despite non-EU headquarters (Samsung Bioepis, Netherlands operations; Celltrion, Hungarian operations).[312]
- Despite 77% of innovative biologic active ingredients being sourced within Europe[313], dedicated biosimilar manufacturing is increasingly migrating to Asia, particularly South Korea and India.[314]
- Recent studies identified an increasing number of partnerships involving ex-EU biosimilar companies that collaborate with European manufacturers to launch products in Europe. Historically, these partnerships were relatively uncommon, but their prevalence has increased. Between 2006 and 2013, ex-EU partnerships represented 30% of all approvals, but more recently this figure increased to 45% (2014–2024).

Assumption

EU-based companies hold approximately 49% of EU biosimilar authorisations, with South Korean companies (Samsung Bioepis, Celltrion) at 16% and US/global pharma at 17%. While international cooperation among biosimilar economic actors is an increasing trend, there is increasing competitive pressure from developers from India, China, and Korea that expand their EU market presence.[315]

Functioning of the internal market and competition

Assumption

Biosimilar strategic project measure's implementation depends on Member State establishment of Chapter II infrastructure. Differences in administrative capacity across Member States can be a potential implementation uncertainty for strategic projects, as with other EU industrial support frameworks. This risk is mitigated by the European Biotech Act's institutional design: the European Health Biotechnology Steering Group provides implementation guidance and facilitates best-practice exchange (Article 20); the Commission's strategic mapping identifies capacity gaps and investment needs (Article 22); and Member States may designate or adapt existing coordination mechanisms as single points of contact rather than creating new structures.

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[312] Alira Health. (2025, November 6). Key players in the biosimilars market 2025. https://alirahealth.com/key-players-biosimilars-market-2025/

[313] Why Europe is Becoming a Global Hub for Biologics Manufacturing. Mabion Science Hub: https://www.mabion.eu/science-hub/articles/why-europe-is-becoming-a-global-hub-for-biologics-manufacturing/

[314] Cohen, H. P., Turner, M., McCabe, D., & Woollett, G. R. (2023). Future evolution of biosimilar development by application of current science and available evidence: The developer's perspective. *BioDrugs*, *37*(5), 583–593..

[315] European Medicines Agency. (2026). Medicines output report [dataset]. Retrieved 2 March 2026 from https://www.ema.europa.eu/en/medicines/download-medicine-data

Innovation and research

Assumption

Innovation in analytical science continues to advance, enabling increasingly precise characterisation of biosimilar products. Modern mass spectrometry, high-resolution chromatography, and functional assays can now characterise protein structures with extraordinary precision[316]. In absence of biosimilar strategic project recognition these advancements continue but are not candidates for potential support under Article 29's measure.

Public authorities

Assumption

Chapter II infrastructure (single points of contact, priority permitting, compliance assistance under Articles 11–14) is operational for general health biotechnology projects but not accessible to biosimilar-specific projects absent Article 29 recognition.

10.3 Expected impacts

Non-binding guidance by the European Medicines Agency for a tailored regulatory approach for biosimilar development, reflecting advances in analytical science and considering potential reductions in clinical data requirements (Article 28)

Administrative burden

The administrative burden and associated costs of preparing marketing authorisation applications (MAAs) for biosimilars, with or without a Phase III comparative efficacy study (CES) follows the methodology follows the Standard Cost Model (SCM) from the Better Regulation Toolbox, where administrative cost is calculated as person-days multiplied by labour rate and quantity. Labour rates are based on two Eurostat scenarios: €400 per person-day as a baseline and EUR 600 per person-day for specialised regulatory affairs or external consultancy. Task decomposition draws on common technical documentation (CTD) structure requirements, industry benchmarks for MAA team size and timeline (typically 20–30 people over 18–24 months), and EMA biosimilar-specific guidance on clinical data requirements.

The administrative burden differs depending on whether a CES is included. Category A, representing a tailored clinical package (PK/PD plus immunogenicity, no CES), requires approximately 253 person-days, whereas Category B, representing a full Phase III CES

[316] Guillen, E., *et al.* (2023). A data driven approach to support tailored clinical programs for biosimilar mAbs. Clinical Pharmacology & Therapeutics, 113(1), 108–123. https://doi.org/10.1002/cpt.2785

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package, requires approximately 328 person-days, giving a difference of 75 person-days (range: 50–100). This difference arises from three main workstreams:

- First, CES-specific clinical modules—including clinical study report drafting, efficacy analysis, and extended safety narratives—account for 40–80 person-days. These modules exist only in Category B, so if CES is eliminated, these sections are no longer required.
- Second, immunogenicity assessment contributes 5–10 person-days of additional effort. While both categories require immunogenicity data, Category A generates it within a combined PK/immunogenicity study (~100–400 subjects), whereas Category B generates it within the Phase III CES (~500–1,500 patients), producing a larger dataset requiring more documentation.
- Third, eCTD publishing and submission accounts for 5–10 person-days difference. Without CES modules, the electronic common technical documentation is smaller, reducing formatting, cross-referencing, and quality control efforts. All other workstreams—including regulatory strategy, quality/chemistry/manufacturing/control (CMC) comparability, non-clinical comparability, and PK/PD modules—are identical between Categories A and B.

Applying the SCM formula, the 75 person-day difference translates into an administrative cost saving of EUR 30,000–45,000 per MAA (75 PD × EUR 400–600/PD). This saving applies only to dossier preparation labour and is deliberately separate from, and much smaller than, the CES trial execution cost saving, estimated at EUR 19–26 million per product. Both savings are additive but operate at very different scales.

Table 11. Cost and efficiency impacts of CES implementation (2025–2038)

INDICATOR	2025 (BASE)	2025–2030	2030–2038	EMA GUIDELINES FOR CES WAIVERS	BIOSIMILAR STRATEGIC PROJECTS SUPPORT
CES execution cost saved per product	EUR 19–26 million (USD 20–28 million) per CES	EUR 222–467 million/year (aggregate, 12–18 MAAs)	EUR 463 million–1.0 billion per year (25–40 MAAs)	Direct: full trial elimination for qualifying products	—
Development timeline saving	0	~24 months per product	~24 months per product	Direct: shorter pipeline, later start, reduced commercial risk	—
MAA dossier preparation (person-days per MAA)	253–328	253 for 50–75% of mAb MAAs	253 for 70–80% of all MAAs	~75 person-days saved per transitioning MAA; EUR 30–45 thousand	—
Aggregate annual dossier saving (EUR)	—	EUR 0.4–0.8 million/year	EUR 1.0–2.5 million/year	12–18 MAAs near-term; 25–	—

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				40 medium-term	

***Sources**: Annex I (dossier preparation, Nevens et al., 2019); Annex II (CES execution, Ranbhor & Kulkarni, 2026); Cakić (2026);*

Biosimilar strategic projects recognition and support (Article 29 -30)

Table 12 presents the illustrative order-of-magnitude impacts for biosimilar strategic projects under Article 29, derived by proportional scaling from the Strategic Projects of chapter II (intervention Nº 9)

Table 12. Overall strategic project impact adapted for the biosimilar case

Impact category	Low uptake (3–5 projects)	Medium uptake (8–12 projects)	High uptake (15–20 projects)
Conduct of business *Projects completing permit-granting within 10 months (Article 12)*	~2–4	~6–10	~11–17
Administrative costs on businesses, including SMEs *Avoided delay costs (cumulative, EUR million)*	~EUR 13–60 million	~EUR 33–147 million	~EUR 57–260 million
Competitiveness, trade and investment flows *Total investment mobilised (cumulative, EUR billion)*	~EUR 0.9–1.7 billion	~EUR 2.3–4.3 billion	~EUR 4.0–7.6 billion
Functioning of the internal market and competition *Cross-border projects (≥2 Member States)*	~0–1	~1–2	~2–4
Innovation and research *Projects with material R&I or analytical innovation outputs (Article 29(1)(b))*	~1–2	~2–4	~3–6
Public authorities *Biosimilar recognition decisions per year; incremental single point of contact capacity*	~0.3/year; negligible incremental FTE (absorbed within Chapter II SPoC)	~1/year; ~0.1–0.2 incremental FTE	~1.5/year; ~0.2–0.3 incremental FTE
Public health and safety *Capacity-relevant biosimilar manufacturing deployments*	~1–2	~3–5	~5–10

***Source:** Derived by proportional scaling from the Strategic Projects IA (Cakić, 2026), applying biosimilar-specific uptake scenarios to the same per-project impact parameters. Scaling ratios: Low = 4/27.5 (0.145); Medium = 10/65 (0.154); High = 17.5/110 (0.159). Figures rounded to reflect order-of-magnitude precision.*

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Expected impact of both biosimilar measures (Article 28-30)

Competitiveness, Trade and Investment Flows

By adopting CES waiver guidelines, the EU aligns itself with leading global jurisdictions and strengthens its regulatory appeal, ensuring it remains a premier destination for developer investment, not losing terrain to the US and Asia-Pacific markets. The medium-term effect of biosimilar strategic projects support on EU-based MAH share depends on whether Article 29 provides sufficient incentive to offset lower manufacturing costs in other regions e.g., Korea, India, and China. The total investment mobilised by Article 29 varies by uptake hypothesis, ranging from EUR 0.9–1.7 billion in the low uptake scenario (3–5 projects) to EUR 4.0–7.6 billion in the high uptake scenario (15–20 projects) [see Table 12 above "overall strategic project impact adapted for the biosimilar case"].

Table 13. Global competitiveness and market position of the EU biosimilar sector (2025–2038)

INDICATOR	2025 (BASE)	2025–2030	2030–2038	EMA GUIDELINES FOR CES WAIVERS	BIOSIMILAR STRATEGIC PROJECTS SUPPORT
EU share of global biosimilar market (revenue)	~43–55% (~USD 13–18B depending on scope and methodology	38–43% (US growth erodes share; EU grows in absolute terms)	35–40% (global market reaches USD 150–175B; EU grows to USD 55–65B)	Indirect: faster entry maintains EU as preferred launch territory	Direct: manufacturing capacity retention in EU
EU-based MAH share of EU authorisations	49%	45–50% (Korean + Indian competition continues)	40–50% without strategic projects; 45–55% with strategic projects	—	Direct: Art. 29 support retains EU-based developers
Jurisdictions with CES waiver	2 (South Korea, UK)	4–5 (US, Canada, Japan formalise by 2028)	6–8 (global convergence toward tailored approach)	Direct: CES waiver ensures EU is in the leading group, not lagging	—

***Sources**: Alira Health (2025) for market size; EMA Medicines Database for MAH analysis; Precedence Research (2025) for market projections; Smart & Biggar (2025) and FDA (2024–2025) for jurisdiction CES status*[317,318].

Functioning of the Internal Market and Competition

The EMA guidance is expected to contribute to the increase of biosimilar competition in the EU market by reducing barriers to entry and accelerating time-to-market. Recent industry reports document that biosimilar competition typically drives prices down by 20–50% or more following market entry, with cumulative savings of approximately EUR 75 billion and roughly EUR 13 billion in 2024[319]. Faster and cheaper biosimilar development is expected to increase the number of competitors per reference product and reduce the time from patent expiry to first biosimilar entry, strengthening competition and price pressure. Biosimilar strategic projects support can also boost faster and cheaper biosimilar

[317] Alira Health. (2025). 2025 global biosimilars report. https://alirahealth.com/biosimilars-market-2025-market-size-growth-drivers-regional-dynamics/

[318] Precedence Research. (2025). Biosimilars market size to hit USD 175.99 billion by 2034. https://www.precedenceresearch.com/biosimilars-market

[319] Medicines for Europe. (2024). The impact of biosimilar medicines in Europe. Brussels.

development, the impact on internal market functioning will depend on how many member states will prioritise strategic projects in this domain.

Table 14. Impact of EMA guidelines for CES waivers and biosimilar strategic projects: health savings, price reduction and operational infrastructures

INDICATOR	2025 (BASE)	2025–2030	2030–2038	EMA GUIDELINES FOR CES WAIVERS	BIOSIMILAR STRATEGIC PROJECTS SUPPORT
Cumulative EU biosimilar savings (EUR)	~EUR 75 billion (since 2006); ~EUR 13 billion in 2024	EUR 130–160 billion cumulative by 2030; EUR 16–22 billion/year	EUR 300–450 billion cumulative by 2038; EUR 22–35 billion/year	Indirect: faster entry + more competitors = greater savings	Indirect: EU supply security supports access continuity
Average price reduction post-entry	20–50%	25–60% (more competitors per molecule)	30–70% (mature competition + next-generation procurement)	Indirect: more entrants = deeper competition	—
MS with operational Ch. II single points of contact	0 (not yet operational)	15–20 MS (larger MS first)	22–27 MS (full rollout)	—	Direct: depends on how many member states take up the measure

***Sources**: IQVIA (2025) for baseline savings; Medicines for Europe (2024) for price reduction range. Savings projections assume 17% CAGR in biosimilar market + CES waiver acceleration*

Public Health and Safety

The upper bounds of the therapeutic area and authorisation projections are constrained by the 'biosimilar void': of approximately 100 biologics expected to lose exclusivity by 2032, 79% have no biosimilars in development and only 10% are likely to face biosimilar competition in Europe (IQVIA, 2026). The EMA guidance and the biosimilar strategic project support are designed to address this gap:

- the first by reducing per-product development costs (EUR 19–26 million for CES elimination), making lower-value biologics commercially viable for biosimilar development;
- and the second by providing investment support through the Chapter II strategic project framework (see table 13 above "overall strategic project impact adapted for the biosimilar case").

The principal risk is to perceived safety, not actual safety. If prescribers or Health Technology Assessment bodies lose confidence in biosimilars approved with less clinical data, uptake could decrease, offsetting the access benefits of faster entry. Effective communication strategies and transparent post-marketing monitoring are prerequisites. The 2030–2038 projection assumes that the first decade of tailored-approach approvals (2025–2035) generates sufficient pharmacovigilance evidence to confirm that the safety profile is equivalent regardless of the clinical data package at authorisation.

Table 15. Impact of EMA guideline for CES waivers and biosimilar strategic projects on public health and safety

INDICATOR	2025 (BASE)	2025–2030	2030–2038	EMA GUIDELINES FOR CES WAIVERS	BIOSIMILAR STRATEGIC PROJECTS SUPPORT

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Biosimilars authorised (cumulative)	151	250–350	450–650	Indirect: accelerated authorisations	—
Therapeutic areas covered	~27 reference products	~35–45 reference products	~55–75 reference products	Indirect: lower barriers open new areas	—
Annual healthcare system savings (EUR)	~EUR 13 billion (2024)	EUR 16–22 billion/year by 2030	EUR 22–35 billion/year by 2035–2038	Indirect: more biosimilars = deeper competition = greater savings	Indirect: EU supply security supports access continuity
Safety: biosimilars withdrawn on safety grounds	0 (in 19 years)	0 expected	0 expected	No change: CES waiver modifies evidence type, not safety standard	—
EudraVigilance identifiability rate	91.5% (2011–2019; downward trend)	Requires monitoring — CES waiver must not exacerbate decline	Target: >90% maintained through strengthened traceability policies	Risk: more biosimilars may dilute identifiability if not managed	—

11 INTERVENTION N°13: SPC EXTENSION FOR BIOTECHNOLOGY MEDICINES

11.1 Additional information on baseline and assumptions

Conduct of business

Baseline

Market authorisation holders in the EU benefit from several layers of protection from generic and biosimilar competition. Regulatory data and market protection lasts ten years from the date of market authorisation (MA) in the current system. This will however change when the revision of the pharmaceutical legislation will come into force, introducing a modular system of market protection that will allow to obtain an extra year of market protection in certain cases. Application is foreseen by the second half of 2028 at the earliest.

Patents last twenty years from filing and therefore may expire before or after the end of the regulatory protection (RP) depending on the time it took to bring the product to market. SPCs currently provide up to five and a half years (the additional half year being conditional on a paediatric investigation plan (PIP)) of protection beyond the expiry of the primary patent lasting a maximum of fifteen and a half years beyond the market authorisation date. The actual length of the SPC is conditional to the time lasted from the patent filing to the marketing authorisation of the product.

The evaluation of the pharmaceutical legislation found that on average medicines for which SPC is the last protection to expire (around 30-35% of the medicinal products) have higher revenues and longer lifecycles than RP-reliant medicines and shorter lifecycles than patent-reliant medicines. The modular length of market protection that will apply when the pharmaceutical reform comes into force might affect the pool of products for which SPC is the last protection to expire. However, while it is impossible to estimate in advance the impact of the changes of the regulatory protection, it is expected that there will not be an impactful change in the overall duration of RP. Most of the newly authorised products will be expected to reach the maximum of 10 years RP bringing consequently also benefits to the patients and the society. Consequently, it is not expected that the modular system of

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market protection introduced in the pharma reform will have a significant impact on which is the last protection to expire.

The economic importance of SPCs is reflected in the revenue profiles of protected products. Looking at the cohort of 198 products analysed for this assessment, we see confirmed the trend observed in previous literature and studies, i.e. that SPC reliant medicines generate substantially higher revenues in the final year before expiry compared to products relying on regulatory data protection or patents.

Table 16. Average protection duration and pre-expiry revenues by last line of protection (all products, n=198)

Last line of protection	Number of products	Avg. protection duration	Avg sales in year before expiry
Regulatory protection	68	10.1	EUR 151 m
Market Exclusivity	12	10.7	EUR 36 m
SPC	96	14.4	EUR 320 m
Patent	22	16.9	EUR 173 m
Grand Total	**198**	**13.0**	**EUR 227 m**

***Source**: author analysis based on IQVIA MIDAS and IQVIA Patent Intelligence* [320]

When focusing specifically on the subset of biological medicines in our 198-product cohort, the difference becomes even more pronounced, with SPC-reliant products exhibiting significantly higher pre-expiry sales.

Table 17. Average protection duration and pre-expiry revenues by last line of protection (biological products, n=31)

Last line of protection	Number of products	Avg. protection duration	Avg sales in year before expiry
Regulatory protection	10	10.1	EUR 83 m
Market Exclusivity	6	10.7	EUR 42 m
SPC	12	14.8	EUR 743 m
Patent	3	16.7	EUR 395 m
Grand Total	**31**	**12.7**	**EUR 361 m**

***Source**: Author analysis based on IQVIA MIDAS and IQVIA Patent Intelligence*

Key Assumptions

- Protection profiles remain decisive: differences in revenue outcomes across products continue to reflect the last layer of protection and the associated effective regulatory protection period.

[320] Analysis using IQVIA MIDAS® quarterly sales data 2008-2024. Geographical coverage: EU27 without Cyprus, Malta and Denmark which were obtained under license from IQVIA and reflect estimates of real world activity. Copyright IQVIA. All rights reserved. Last layer of protection was determined through analysis of *IQVIA Patent Intelligence.*

- Lifecycle management unchanged: originator firms continue to concentrate commercial strategies on the final years of effective regulatory protection, reflecting persistent expectations of steep post-expiry revenue losses. This includes a continued focus on pricing, contracting and market coverage during the remaining period of regulatory protection.
- ATMPs follow distinct dynamics: commercial performance remains primarily driven by clinical adoption, reimbursement and manufacturing scale-up. Given their technical complexity and the current lack of established follow-on competition, ATMPs have, in practice, faced limited exposure to post-expiry competitive erosion to date. Accordingly, commercial outcomes are less strongly linked to predictable post-expiry dynamics under the baseline. Nevertheless, we include ATMPs in our assessment of eligible products for SPC extension not to exclude that in the future biosimilar versions of these products might be approved.

Functioning of the internal market and competition

Key assumptions

- Biosimilar entry remains legally constrained by the expiry of the last applicable protection instrument. Although the revised pharmaceutical legislation is expected to enter into force from mid-2028 at the earliest, no systematic acceleration or delay of entry is assumed within the baseline, given long development timelines.
- Following expiry, biosimilar authorisations occur shortly thereafter, subject to standard regulatory procedures and Member State–level market access processes.
- Post-entry price erosion remains broadly consistent with historical EU patterns and continues to vary by product class, with faster erosion for small molecules and more heterogeneous outcomes for biologics and complex therapies**.**

Innovation and research

Key assumptions:

- Patent data as innovation proxy: patent-family counts are used as an indicator of innovation output, reflecting firms' expectations about the commercial value and appropriability of biotech inventions.
- Geographic anchoring: the earliest filing jurisdiction is used as a proxy for early protection and location preferences, recognising that it does not necessarily reflect the physical location of R&D or later commercialisation.
- Multi-jurisdiction filings: simultaneous filings are analysed separately, distinguishing between filings that include and exclude the EU, to capture the EU's relative prioritisation in global protection strategies.
- Cross-country comparability: patent volumes are interpreted cautiously, as filing behaviour is influenced by national policy and institutional factors; high patent counts do not translate one-to-one into globally oriented innovation.

Competitiveness, trade and investment flows

Key assumptions

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- Business as usual behaviour: Absent policy change, firms' decisions on the location of clinical development and manufacturing activities continue to reflect expected lifecycle revenues under protection, alongside market size, access conditions, regulatory predictability and operational considerations.
- Gradual evolution of EU activity: The presence and geographical distribution of EU-based clinical trials and manufacturing activity are assumed to evolve gradually over time, reflecting changes in technology and industrial conditions.

Administrative costs on businesses, including SMEs

Key assumptions:

- Under the baseline, administrative costs for businesses remain broadly stable over time, reflecting existing SPC procedures and routine IP management practices. No additional costs arise in the absence of an SPC extension.
- Firms continue to apply for SPC only where commercially justified, with no change in the frequency or scope of applications attributable to policy developments.
- Biotech SMEs continue to rely heavily on external legal and regulatory advisors due to limited in-house capacity, as under current practice.

Public authorities

Key assumptions:

- National authorities continue to process SPC applications under existing procedures, with assessment workload driven by case complexity rather than an increase in application volumes.
- Coordination between patent offices, medicines regulators and other bodies remain a structural feature of the SPC system, reflecting fragmented institutional responsibilities rather than inefficiencies.
- Administrative and legal costs borne by public authorities under the SPC system remain broadly in line with historical patterns, with year-to-year variation driven by individual cases.
- The baseline assumes no impact from the proposed unitary SPC system, which remains under discussion and is not affected by the proposed SPC extension under the European Biotech Act; national SPC procedures therefore continue to apply unchanged.

Public health

Key assumptions:

- Affordability outcomes are assumed to change primarily in response to the expiry of effective regulatory protection and the ensuing entry of biosimilar competition.
- Other determinants, including demand trends, prescribing behaviour and regulatory requirements, are assumed to evolve gradually and therefore do not generate discrete affordability effects over the period considered.

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11.2 Additional information on measures and expected impacts

The proposed measure introduces a 12-month extension of SPC protection for a limited subset of biotechnology-derived medicinal products and advanced therapy medicinal products that meet specific eligibility criteria. Eligible medicinal products will have to contain a new active substance which is effective via a mechanism of action distinctly different to that of any other product already authorised in the EU for prevention or treatment the same disease. The clinical trials supporting their marketing authorisation will need to have been conducted in more than two Member States and at least one manufacturing step, excluding packaging, quality and testing certification, will need to be performed in the Union.

Conduct of business, functioning of the internal market and competition

The proposed 12-month SPC extension is expected to entail limited short-term affordability and access pressures by delaying the entry of biosimilar competitors relative to the baseline. For biotechnology-derived medicines, biosimilar entry does not typically result in sharp reductions in average treatment prices; consequently, the difference in average prices between the extension scenario and the baseline is expected to be modest. Instead, the main effect of the extension relative to the baseline is the temporary postponement of additional product entry, implying fewer available treatment options and delayed expansion of supply for patients during the extension period.

By postponing competitive entry, the extension maintains higher average prices for an additional year and delays the expansion of supply associated with follow-on products. Our model estimate that an additional year of protection results in an additional direct cost to public payers of approximately EUR 70 million per product in the central case, corresponding to approximately EUR 210 million annually at aggregate level based on an average of three qualifying medicines per year. The aggregated cost in our model provides an approximation of the average annual EU wide impact on payers based on list prices from the IQVIA MIDAS[321] (see table 18).

Table 18. Impact of change of +1 SPC extension for biotechnology medicines

1 year increase in SPC	Per med	Annual (3 meds)
Originator gross profit	**230 m**	**690 m**
Biosimilar gross profit	-80 m	-240 m
Cost to public payer	70 m	210 m
Patients monetised gains/losses	135 m	405 m
Patients + payer monetised gain/loss	**205 m**	**615 m**

***Source**: Author analysis based on IQVIA MIDAS data*[322]

[321] Geographical coverage: EU27 without Cyprus, Malta and Denmark.
[322] Internal analysis by the authors using IQVIA MIDAS® quarterly sales data 2008-2024. Geographical coverage: EU27 without Cyprus, Malta and Denmark. which were obtained under license from IQVIA and reflect estimates of real world activity. Copyright IQVIA. All rights reserved

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Sensitivity analysis, applying stricter sample filters and modified parameters[323], yields a range of EUR 5 million to EUR 80 million per medicine (see table 19). The relatively contained magnitude of the payer cost impact reflects the shallow post-expiry revenue decline characteristic of SPC-reliant biologicals: unlike the sharp price erosion observed for small-molecule medicines upon generic entry, biosimilar competition produces more gradual and moderate price reductions, limiting the price differential between the extension scenario and the baseline.

Table 19. Sensitivity analysis on impact of change of +1 SPC extension for biotechnology medicines

1 year increase in SPC	Min per medicine	Max per medicine
Originator gross profit	140 m	290 m
Biosimilar gross profit	-60 m	-110 m
Cost to public payer	5 m	80 m
Patients monetised gains/losses	135 m	180 m
Patients + payer monetised gain/loss	170 m	260 m

***Source**: Author analysis based on IQVIA MIDAS data. NB. Because the maximum/minimum has been taken for each line, the combined cost will not equal the sum of the two components.*

Further distributional analysis of the SPC cost-benefit results

In this section, we argue that the total of the monetised cost to patients and the additional cost to payers can be interpreted as an approximation of the transfer of surplus from payers and patients to companies. In our analysis, we calculate the following costs:

Table 20. Patients + payer monetised loss of +1 SPC extension for biotechnology medicines

SPC+1	Per medicine
(1) Cost to public payer	70 m
(2) Patients monetised gains/losses	135 m
(3) Patients + payer monetised gain/loss	**205 m**

***Source**: Author analysis based on IQVIA MIDAS data*

For the purposes of this analysis, focussing on the distributional impacts as between patients/payers/society on the one hand and companies on the other hand, we will not distinguish between originators and biosimilars. In the diagram below, Q_B refers to the baseline quantity, P_B to the baseline price etc. Manufacturing, marketing and distribution costs are assumed to be constant and less than P_B (not shown on the diagram). For both scenarios, P_B/P_{SPC+1} can be thought of as the average price over the reference period. The willingness to pay (WTP) curve is depicted as steep, but not vertical, indicating a certain degree of price-sensitivity on the part of payers. This is confirmed empirically by the

[323] Namely removing products with lower than €50m revenue in the year before expiry and removing non-biotech products as well as including products with much shorter protection periods that are nonetheless SPC-reliant, and modified parameters for calculating profits

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trajectory of the total volume as can be seen in Figure 1 of Annex 4, with a marked uptick in growth coinciding with the decline in price that occurs upon loss of protection.

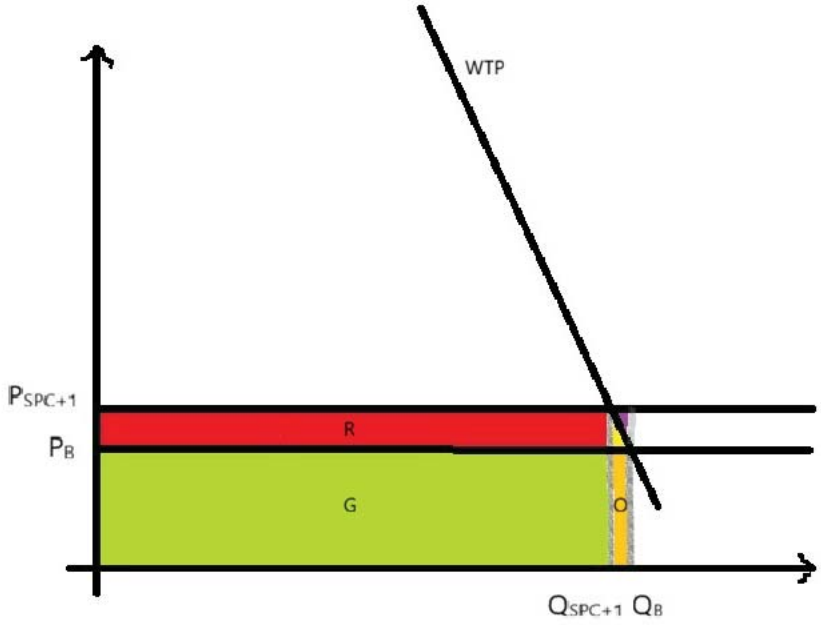

Figure 2. Illustrating the derivation of costs from prices and quantities in the model

Note that in the model, we calculate the price and quantity in both scenarios, so we are able to calculate:

(A) Baseline quantity at baseline prices = Q_B x P_B = G+O
(B) Baseline quantity at scenario prices = Q_B x P_{SPC+1} = R+G+O+Y+P
(C) Scenario quantity at scenario prices = Q_{SPC+1} x P_{SPC+1} = G
(D) Scenario quantity at baseline prices = Q_{SPC+1} x P_B = G+R

Using the initials R(ed), G(reen), O(range), Y(ellow), P(urple), we find that:

(1) is given by C - A = (R+G) – (G+O) = R-O
(2) is given by B - C = (R+G+O+Y+P) – (R+G) = O+Y+P
(3) is given by (2)+(1) = R+Y+P

In addition, assuming linear WTP with Y=P, we have B-A-C+D = (R+G+O+Y+P) – (R+G) – (G+O) + G = Y+P = 2Y, allowing Y+P to be estimated at EUR 10 million and Y at EUR 5 million.

(1) has clear policy relevance, being the change in spending by payers. As for (2), calculated at EUR 135 million, it has a common-sense interpretation – the amount we would have to pay to restore baseline coverage at policy scenario prices. The objective here is to argue that the combined amount (3) is also of economic significance, since it can be interpreted as an approximation of the transfer of surplus from payers/patients to companies (i.e. R, the red rectangle on the diagram). To give a more precise figure, we

would subtract Y+P, which can be estimated from the model at around EUR 10 million, giving EUR 195 million for the transfer of surplus. However, given that the difference is small, (3) remains a good approximation.

Impact on public health

As outlined in the previous section, delayed entry is associated with a reduction of coverage relative to the baseline, combining direct payer expenditure with the monetised cost of delayed patient access. Our model estimates this combined cost at approximately EUR 205 million per medicine in the central case (sensitivity range: EUR 170 million to EUR 260 million), corresponding to approximately EUR 615 million annually at aggregate level based on an average of three qualifying medicines per year. The cost is driven primarily by the delay in the expansion of patient coverage rather than by direct price effects: the modelling shows that coverage expands rapidly upon loss of protection, and the main social cost of the extension therefore consists in the temporary postponement of this expansion. The monetised cost of delayed patient access, estimated at approximately EUR 135 million per medicine (EUR 405 million annually based on an average of three qualifying medicines per year), substantially exceeds the direct payer cost, reflecting the fact that for SPC-reliant biologicals the volume effects of competition are at least as significant as the price effects.

To illustrate how this impact may translate across Member States, the EU total was allocated according to national shares of the EU pharmaceutical market (EFPIA 2023). This assumes that additional expenditure from delayed biosimilar entry broadly follows the existing geographic distribution of pharmaceutical consumption. Large pharmaceutical markets are therefore expected to account for the majority of the aggregate cost. Germany, France, Italy and Spain together represent around 65% of the EU pharmaceutical market, implying that they would bear a similar share of the additional expenditure. At the same time, these countries also exhibit relatively high healthcare spending capacity, with total health expenditure exceeding the EU average of around 9% of GDP[324]. This suggests that, while the absolute budgetary impact would be concentrated in these large markets, their health systems may be better positioned to absorb the additional costs compared with Member States with lower health spending levels.

Innovation output and geographic anchoring of biotech R&D

The extension of SPC protection is expected to improve the EU's relative attractiveness for SPC-eligible biotech innovation at the margin, by increasing the expected duration and predictability of post-authorisation exclusivity for highly innovative products.

In practical terms, the impact is expected to materialise mainly through early patenting and protection strategies, as these are among the first observable decisions influenced by changes in expected protection. Relative to the baseline, the SPC extension is expected to marginally increase the likelihood that the EU is included as an early filing jurisdiction for SPC-eligible biotech inventions, either as a first filing location or as part of simultaneous multi-jurisdiction filings. Effects are expected to be more pronounced for EU-based firms,

[324] European Federation of Pharmaceutical Industries and Associations. (2025). The pharmaceutical industry in figures 2025. https://www.efpia.eu/media/uj0popel/the-pharmaceutical-industry-in-figures-2025.pdf

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for which EU protection conditions directly affect portfolio and sequencing decisions, while impacts on non-EU firms are likely to be limited to a subset of globally oriented, high-value biotech projects.

Given the multiplicity of factors influencing innovation location decisions, the SPC extension is expected to contribute as one among several factors including national policies, tax regimes and regulatory procedures.

Competitiveness, trade and investment flows

The EU faces increasing global competition in the field of biotechnology. The problem drivers outlined in paragraph 2.2 - including in subparagraph 2.2.6 on SPCs -underscore the need for policy action to foster investment in clinical trials and biomanufacturing in the EU.

If we analyse the products authorised in the EU that would have been eligible for the SPC extension between 2016 and 2025, according to EMA data, almost half of those that met the "innovation" criteria (i.e. new active substance and mechanism of action) also conducted clinical trials in more than two member states and a part of their manufacturing in Europe. This means that on average, there were five medicines approved per year that meet all the criteria between 2016 and 2025. A further five meet the "innovation" criteria but fail on one or both of the geographical criteria (i.e. clinical trials supporting their marketing authorisation conducted in more than two Member States and at least one manufacturing step, excluding packaging, quality and testing certification conducted in the EU). The table below summarises this dynamic.

Table 21. ATMP and biotechnology product eligibility for 1+ SPC extension (2016-2025)[325]

	2016-25	Annual
a. Meeting all criteria	49	5
With distinct and different new active substance and mechanism of action and either:		
b. one manufacturing step in the EU other than packaging, labelling and testing (manufacturing criterion), but no Clinical Trials (CTs) in more than 2 Member States (MS)	14	1
c. CT in more than 2 MS, but manufacturing criterion not met	24	2
d. Neither b nor c met	13	1
Subtotal	*51*	*5*
Total	100	10

***Source**: author own calculation based on EMA data between 2016-2025*

[325] Annual values represent the average number of medicines per year over the 2016–2025 period (10 years), calculated as the total divided by 10 and rounded to the nearest whole number. As medicinal products cannot be meaningfully expressed in fractional units, results are presented in whole numbers. Minor discrepancies in totals may arise due to rounding.

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Out of the 31 biologics we analysed for assessing the cost of the SPC extension, 40% relied on SPC as their last effective protection. Assuming the proportion of products relying on SPC remains constant, the SPC extension would have an economic impact on **2-3 products per year**. These products represent marginal cases for which trial design and/or manufacturing decisions could plausibly be adjusted in response to the additional incentives.

Public Authorities

The proposed SPC extension would not materially increase administrative workload for national patent offices. Eligibility conditions would be assessed by the European Medicines Agency (EMA), with national authorities mainly verifying documentation rather than performing additional substantive assessment.

The measure introduces a new eligibility verification task for EMA, which would confirm whether applicants fulfil the conditions for the extension. The assessment would rely largely on regulatory information already available to the Agency, including clinical trial data, marketing authorisation documentation and manufacturing information. Based on comparable regulatory verification tasks, and consistent with the paediatric SPC experience at national patent offices, the assessment is estimated to require approximately one full-time equivalent working day per application.

Given the limited number of products expected to qualify, the resulting annual workload for EMA is expected to remain small. Between 2020 and 2025, EMA granted authorisations to between 15 and 28 biotech products annually. While not all of these would be eligible under the proposed European Biotech Act, they represent the total population of products potentially subject to assessment, implying a maximum workload of up to 28-30 working days per year.

Administrative costs on businesses, including SMEs

Under the current regulatory framework, companies applying for SPCs incur **administrative costs** associated with preparing and submitting applications, assessing eligibility, and interacting with patent and regulatory authorities. SPC applications require legal interpretation of patent scope, marketing authorisation timelines and regulatory status. They require internal legal and regulatory staff time and, in many cases, recourse to external legal advisors. For SMEs, SPC-related administrative and advisory costs can weigh more heavily, given their more limited in-house legal and regulatory resources and greater dependence on outsourced expertise.[326] Evidence from the impact assessment of the Commission proposals for a unitary SPC[327] shows that that overall administrative and

[326] European Commission (2023), Commission Staff Working Document – Impact Assessment accompanying the proposals on supplementary protection certificates, SWD(2023) 118 final, Brussels, 27 April 2023, Section 2.3.2 and Annex 6 (SME Test).

[327] European Commission (2023), Commission Staff Working Document – Impact Assessment accompanying the Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) and the Proposal for a Regulation on the unitary supplementary protection certificate for medicinal products, SWD(2023) 118 final, Brussels, 27 April 2023, Section 2.3.2 and Annex 5B.

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advisory costs for filing SPC extensions across multiple Member States typically range between approximately EUR 80,000 and EUR 150,000 per product.

Compared with the additional revenues linked to obtaining the SPC extension, the administrative costs associated with preparing and filing SPC applications represent a negligible fraction of the economic value generated by the extension. Even under the most conservative assumptions (maximum administrative cost of EUR 150,000 against the lower-bound profit estimate of EUR 203 million), administrative costs remain below 0.08% of additional gross profits.

The SPC system is subject to **disputes over eligibility, duration and scope**, which generate administrative and legal costs for companies, public authorities and courts[185]. The proposed SPC extension, by introducing novel eligibility criteria, could increase litigation risk and consequently administrative costs and burdens.

Conclusion

Overall, the SPC extension constitutes a targeted policy instrument that seeks to strengthen incentives for high-value biotechnology innovation while generating limited and time-bound costs for healthcare systems. Its impact is expected to be moderate in scale but strategically relevant in the context of broader efforts to enhance the competitiveness of the EU biotechnology sector.

Table 22. Summary assessment of the effects due to the policy measure

Policy interventions	COB	Admin	CTI	Int Mar	I&R	PA	H&S
MCA score	++	0/-	+	-	+	0	-
Justification for each category	Improved business certainty, reduced late-stage commercial risk, and enhanced predictability of returns for a limited but clearly defined subset of biotech and ATMP products	No new standalone administrative obligations introduced by the SPC extension itself. Possible minor adjustment costs	Incremental influence on: clinical trials location, late-stage manufacturing decisions, scale-up in the EU, inclusion of EU in global value chains	Competition is postponed but not distorted structurally	Operates mainly through: expectations of protection, early patenting and portfolio decisions, anchoring high-value biotech projects	No new standalone administrative obligations introduced by the SPC extension itself. Possible minor adjustment costs	fewer available products during extension period, prices remain somewhat higher for longer

12 INTERVENTION N°15: USE OF ARTIFICIAL INTELLIGENCE AND DATA

12.1 Detailed description of the proposed measures

The proposal establishes a framework to facilitate the safe, effective and scalable deployment of AI across the lifecycle of medicinal products, addressing regulatory uncertainty, infrastructure gaps and data limitations that currently constrain uptake.

First, the proposal introduces non-binding guidance to be developed and regularly updated by the European Medicines Agency (EMA), in agreement with the Commission, including the AI Office. This guidance covers the full lifecycle of medicinal products, including pre-

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clinical research, clinical development and trials, manufacturing, regulatory evaluation and approval, and post-authorisation monitoring. It aims to provide clarity on the development, deployment and validation of AI-enabled methodologies, including general-purpose AI models, while ensuring full coherence with the requirements of the AI Act and relevant sectoral legislation.

Second, the proposal provides for the recognition of high-impact health biotechnology strategic projects in the form of trusted AI-enabled biotechnology testing environments. These environments are designed to bridge the gap between research and market deployment by providing integrated infrastructures combining wet-lab, computational and data-driven capabilities. Operating under "trusted conditions" that ensure compliance with Union and national legislation, they aim to complement existing AI regulatory sandboxes and testing facilities established under the AI Act, while avoiding duplication.

These testing environments are intended to support experimentation, development and translational validation of AI-enabled biotechnology innovations, particularly in areas where AI can have a transformative impact, such as advanced therapies (e.g. ATMPs), immunology, and the development of new approach methodologies (NAMs). By enabling the joint use of advanced experimental systems and computational tools, they aim to optimise workflows, reduce development risks and accelerate validation processes.

Third, the proposal establishes a framework for biotechnology data quality accelerators as a distinct category of high-impact strategic projects, addressing a critical bottleneck for AI deployment in biotechnology: the limited availability of high-quality, interoperable and AI-ready datasets. These accelerators aim to support the curation, standardisation, annotation and provenance verification of datasets used for training, testing and validation of AI systems and models in health biotechnology applications.

12.2 Baseline and counterfactual scenario

In the absence of the enabling measures on AI and data, the EU biotechnology sector is expected to face a widening capability gap relative to global competitors, such as US or China. While the Union possesses strong fundamental research, the lack of integrated infrastructure and lifecycle guidance specifically for bio-AI creates a bottleneck that constrains the translation of into scalable industrial value. According to industry surveys, 82% of biopharmaceutical executives believe AI will fundamentally transform research and development within five years, and 63% consider that organisations failing to scale AI will fall behind in market relevance.[328] However, the Union is losing ground to faster-moving competitors in North America and Asia, who are scaling up through targeted policy interventions.[329]

Regulatory clarity

[328] Capgemini Research Institute. (2026). *Smart bet, only option, or both?: Biopharma R&D turns to AI*. Capgemini. https://www.capgemini.com/wp-content/uploads/2026/01/120126CRI_Gen-AI-in-Lifesciences-_Final-interactive.pdf
[329] Lowe, C. R., Minssen, T., & Skentelbery, C. (2024). Emerging biotechnologies in Europe: Foresight for policy (P.-M. Pélissier, Ed.). Publications Office of the European Union. https://doi.org/10.2760/4814109

AI-based methods are already widely used in pharmaceutical and biotechnology development, primarily to optimise processes, with outputs validated through conventional scientific methods[330]. However, the emergence of AI uses in the lifecycle of medicines is creating uncertainty regarding how AI-enabled approaches may be applied within existing regulatory processes. This uncertainty largely reflects the absence of specific guidance or established practice for the development, validation and acceptance of AI-enabled methodologies in across the medicines lifecycle. Developers must rely primarily on case-by-case regulatory interactions to obtain feedback on whether specific AI applications may be considered acceptable in regulatory submissions, in order to obtain clarity on whether internal governance and validation procedures will satisfy regulatory authorities[331].

The principal formal mechanism for obtaining regulatory clarity is EMA's Qualification Procedure for Novel Methodologies, costing EUR 89,000 per request (90% reduction for SMEs; no reduction for academic or non-profit developers) and taking 160–250 days[332]. Firms also use other forms of regulatory interaction, including scientific advice procedures, Innovation Task Force meetings, and other early-stage regulatory discussions, which serve distinct purposes within the regulatory framework, with AI-related interactions growing and concentrated at the pre-authorisation stage[333,334,335,336]. Crucially, all outcomes are confidential and non-reusable — each company must fund its own interaction, producing no cumulative public knowledge base[337].

These timelines capture only the duration of the EMA Qualification Procedure for Novel Methodologies described above. The upstream period during which firms assess whether AI-enabled approaches are regulatorily viable before engaging EMA is unquantified but acknowledged as significant[338]. Workshop participants confirmed that R&D teams delay commitment to AI-enabled approaches pending regulatory clarity, particularly for patient-facing applications such as AI-driven clinical trial site selection and patient selection, where validation standards remain unclear (workshop). No regulatory standard, guidance, or accepted practice currently exists for validation of AI-generated evidence, generative

[330] Discussed during the stakeholder workshop on Data and AI – Rapid Assessment Scenario Study - forthcoming.
[331] Discussed during the stakeholder workshop on Data and AI – Rapid Assessment Scenario Study - forthcoming.
[332] European Medicines Agency. (2023). Qualification of novel methodologies for drug development: Guidance to applicants (EMEA/CHMP/SAWP/72894/2008 Rev. 5). https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-novel-methodologies-drug-development-guidance-applicants_en.pdf
[333] European Federation of Pharmaceutical Industries and Associations. (2024). EFPIA position on the use of artificial intelligence in the medicinal product lifecycle. https://www.efpia.eu/media/tzeavw1t/efpia-position-on-the-use-of-artificial-intelligence-in-the-medicinal-product-lifecycle.pdf
[334] European Medicines Agency. (2025). 2024 AI observatory report (EMA/76534/2025). https://www.ema.europa.eu/en/documents/report/2024-ai-observatory-report_en.pdf
[335] European Medicines Agency. (2025). 2024 AI observatory: Compilation of 2024 experience (EMA/154528/2025). https://bluepharm.fr/wp-content/uploads/2025/11/2024-ai-observatory-report-compilation-2024-experience_en.pdf
[336] European Medicines Agency. (2025). New approach methodologies EU-Innovation Network horizon scanning report (EMA/56850/2025 Rev. 1). https://www.ema.europa.eu/en/documents/report/new-approach-methodologies-eu-horizon-scanning-report_en.pdf
[337] European Medicines Agency. (2023). Qualification of novel methodologies for drug development: Guidance to applicants (EMEA/CHMP/SAWP/72894/2008 Rev. 5). https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-novel-methodologies-drug-development-guidance-applicants_en.pdf
[338] Lowe, C. R., Minssen, T., & Skentelbery, C. (2024). Emerging biotechnologies in Europe: Foresight for policy (P.-M. Pélissier, Ed.). Publications Office of the European Union. https://doi.org/10.2760/4814109

AI outputs, internal AI governance frameworks, or AI applications in clinical trials[339] (sentiment was also expressed in stakeholder workshop).

The measurable baseline is therefore EUR 89,000 and 160–250 days per formal interaction, with total pathway identification time substantially longer due to upstream deliberation[340,341].

Once developers have identified the applicable regulatory pathway, additional clarification and documentation efforts may arise when AI-enabled methodologies are used, due to the absence of specific guidance on their regulatory acceptance. The absence of codified evidence standards for AI-derived data[342] forces developers into repeated clarification requests and additional regulator engagement to confirm the acceptability of their approaches. Stakeholders note that without fit-for-purpose frameworks, developers cannot align with regulatory expectations early in the process[343], and the EMA's AI Workplan acknowledges that gaps in guidance require ongoing stakeholder engagement to prevent frameworks from lagging behind technological advances[344].

No specific guidance is yet available for lifecycle management of AI-based tools, including model retraining and updates, leaving "model change management" unresolved[345] and imposing ongoing post-approval costs as developers design and justify their own procedures without regulatory reference points. Public consultations confirm that a substantial share of administrative costs arises from the need to interpret how different regulatory frameworks interact when applied to emerging AI-enabled methodologies[346].

AI tools could accelerate regulatory submissions by approximately 19% through automation and predictive modelling[347]. However, this potential is limited by uncertainty regarding how systems based on advanced technologies, including AI, can be deployed and used within existing regulatory frameworks for medicinal products across the medicines lifecycle.

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[339] European Medicines Agency. (2024). Reflection paper on the use of artificial intelligence (AI) in the medicinal product lifecycle (EMA/CHMP/CVMP/83833/2023). https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf

[340] European Medicines Agency. (2023). Qualification of novel methodologies for drug development: Guidance to applicants (EMEA/CHMP/SAWP/72894/2008 Rev. 5). https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-novel-methodologies-drug-development-guidance-applicants_en.pdf

[341] Lowe, C. R., Minssen, T., & Skentelbery, C. (2024). Emerging biotechnologies in Europe: Foresight for policy (P.-M. Pélissier, Ed.). Publications Office of the European Union. https://doi.org/10.2760/4814109

[342] Lowe, C. R., Minssen, T., & Skentelbery, C. (2024). Emerging biotechnologies in Europe: Foresight for policy (P.-M. Pélissier, Ed.). Publications Office of the European Union. https://doi.org/10.2760/4814109

[343] "EFPIA Position on the Use of Artificial Intelligence in the Medicinal Product Lifecycle," EFPIA, 2024, https://efpia.eu/media/tzeavw1t/efpia-position-on-the-use-of-artificial-intelligence-in-the-medicinal-product-lifecycle.pdf.

[344] European Medicines Agency, "Multi - Annual AI Workplan 2023 - 2028," European Medicines Agency, 2023, https://www.ema.europa.eu/en/documents/work-programme/multi-annual-artificial-intelligence-workplan-2023-2028-hma-ema-joint-big-data-steering-group_en.pdf.

[345] European Medicines Agency, "Qualification Opinion for Artificial Intelligence-Based Measurement of Non-Alcoholic Steatohepatitis Histology in Liver Biopsies to Determine Disease Activity in NASH/MASH Clinical Trials," European Medicines Agency, 2025.

[346] Aggregated findings from the Public Consultation and Call for Evidence.

[347] Capgemini Research Institute. (2026). *Smart bet, only option, or both?: Biopharma R&D turns to AI*. Capgemini. https://www.capgemini.com/wp-content/uploads/2026/01/120126CRI_Gen-AI-in-Lifesciences-_Final-interactive.pdf

Under the business-as-usual scenario, these conditions are expected to worsen. AI-related regulatory queries are already increasing[348] and will accelerate as AI integration deepens. Each new entrant will face the same navigation costs, the confidential nature of outcomes will prevent any cumulative learning, and the growing complexity of the regulatory environment applicable to AI-enabled approaches will lengthen upstream deliberation further. For SMEs and academic developers, the barrier will become progressively more prohibitive, increasing the risk of project deferral, relocation outside the Union, or discontinuation.

Use of data for AI

In terms of data use, European AI models frequently rely on datasets originating from outside the Union, in particular for reference genetic sequences and multi-omics data.[349] The European Health Data Space will provide diverse health data for AI training, testing and validation. At the same time, datasets relevant for biotechnology innovation often lack the annotation, interoperability, metadata, and provenance needed to support the training of regulatory-grade AI models.[350] Health and genomic datasets remain siloed under incompatible formats.[351] Fewer than 20% of Union life-science firms possess the in-house AI expertise to curate high-quality datasets.[352] Industry surveys reveal that for eight out of eleven key data elements needed for AI in research and development, fewer than half of biopharma executives believe their companies are adequately prepared.[353]

The biotechnology sector faces challenges with both data quantity and quality; without standardising curation processes, the Union cannot leverage its data assets to compete with the massive, integrated datasets available to competitors in North America and Asia.[354] Fragmented metadata standards and inconsistent provenance documentation reduce interoperability across Member States, limiting the formation of large, regulatory-grade training datasets.

Databases with errors or incomplete data continue to result in imprecise outcomes.[355] AI models require large, high-quality, annotated datasets. Absent stronger initiatives for data curation processes, validation criteria and interoperability standards, high-value datasets are likely to remain dispersed across incompatible environments. This may limit the development of foundational biological AI models trained on European data and slow the emergence of shared reference datasets for regulatory use. Over time, the interaction between fragmented standards, delayed guidance and uneven data quality risks reinforcing a cycle in which innovation advances faster than harmonised oversight frameworks, constraining the effective functioning of the internal market.

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[348] European Medicines Agency. (2025). 2024 AI observatory report (EMA/76534/2025). https://www.ema.europa.eu/en/documents/report/2024-ai-observatory-report_en.pdf
[349] Submission to the Public Consultation by an European trade association.
[350] Submissions to the Call for Evidence.
[351] Submissions to the Call for Evidence.
[352] Submissions to the Call for Evidence
[353] Capgemini Research Institute. (2026). *Smart bet, only option, or both?: Biopharma R&D turns to AI*. Capgemini. https://www.capgemini.com/wp-content/uploads/2026/01/120126CRI_Gen-AI-in-Lifesciences-_Final-interactive.pdf
[354] Submissions to the Call for Evidence and Public Consultation.
[355] Submissions to the Call for Evidence and Public Consultation.

Under the baseline, data fragmentation, uneven standard adoption and regulatory variability are expected to persist. Their interaction increases cumulative compliance and integration costs for cross-border operations, effectively raising the marginal cost of scaling AI-enabled biotechnology within the Union. Over time, this dynamic may discourage multi-country deployment strategies, slow Union-wide diffusion of AI-enabled innovations and reduce the effective functioning of the internal market for advanced biotechnology.

Without the intervention of data quality accelerators, the lack of clear standards means that the uptake of enhanced datasets is expected to remain low, and the volume of data available for secondary use is not expected to increase significantly.[356]

Access to shared infrastructure and cross-border scale-up capacity

Under current conditions, severe capacity constraints limit scale-up opportunities for the wider ecosystem. Facilities such as the Bio Base Europe Pilot Plant report performing scale-up work for over 280 different companies, including large enterprises. However, public authorities note that most European fermentation and production capacity is already fully utilised.[357] The lack of available capacity creates a bottleneck for the entire sector.

When pilot and demonstration facilities operate at or near full capacity, project timelines lengthen and firms must queue for access, increasing opportunity costs and delaying commercial translation. While SMEs are financially excluded from access to industrial-grade infrastructure, larger firms also face delays due to the scarcity of open-access demonstration facilities required to generate scalable data.[358] This scarcity affects both entry and expansion, limiting the ability of smaller firms to transition from laboratory validation to industrial deployment.

Several examples of cross-border bio-AI scale-ups exist, including Biohm, MICROBS, and Kantify. Pilot facilities such as the Bio Base Europe Pilot Plant, Utrecht Science Park, and Estonia's Biobank facilitate effective scaling across borders.[359] In the medium and long term, capacity constraints are expected to persist. This may reinforce geographic concentration of industrial biotechnology in a limited number of hubs and reduce the ability of firms to scale operations across multiple Member States. Over time, constrained access to industrial-grade infrastructure risks slowing the translation of AI-enabled research into market-ready production within the Union.

The lack of investment in AI testbeds and innovation sandboxes limits opportunities for experimentation in realistic settings. Stakeholders stress that voluntary risk assessments are inadequate and call for mandatory safety evaluations for high-risk biological AI tools.[360] Workshop participants also emphasised that uncertainty regarding validation standards and lifecycle management increases the difficulty of designing effective test environments, as developers lack clarity on what constitutes acceptable regulatory-grade

[356] Submissions to the Call for Evidence and Public Consultation.
[357] Public authority submissions to the Call for Evidence and Public Consultation
[358] Submissions to the Call for Evidence and Public Consultation
[359] Submissions to the Call for Evidence and Public Consultation
[360] Submissions to the Call for Evidence and Public Consultation.

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evidence. An international regulatory stakeholder notes that innovation is hampered by the lack of structured, validated evidence from real-world testing environments. Without access to dedicated validation infrastructures, AI models cannot be effectively trained or tested against biological ground truth, limiting the accumulation of evidence that regulators need to issue fit-for-purpose guidance.[361]

Under the baseline, the transition from proof-of-concept to validation is expected to remain slow. Multiple digital policy frameworks addressing different aspects of AI and data and the lack of accessible validation infrastructure, including biobanks and high-performance computing, extend timelines. Regulatory requirements for rigorous validation are resource-intensive, and SMEs in particular face uncertainty about the level of proof required, leading to delays. Workshop stakeholders confirmed that ambiguity regarding evidentiary standards contributes to iterative clarification processes, increasing time-to-validation. The absence of integrated testing environments means that flaws in biological AI models are often detected only after significant investment, rather than during early-stage iterative testing. The research and development process remains linear and risk-heavy rather than iterative and agile. Public authorities are unable to accumulate the structured evidence needed to issue rapid, fit-for-purpose guidance.[362]

In the baseline, the Union's biotechnology sector faces a significant capability gap in AI expertise. Fewer than 20% of Union life-science firms possess in-house AI expertise, compared to 45% in the United States.[363] Industry surveys reveal that for eight out of eleven key data elements needed for AI in research and development, fewer than half of biopharma executives believe their companies are adequately prepared.[364]

This capability gap limits firms' ability not only to develop AI tools internally but also to critically assess, validate and integrate externally developed models into regulated workflows. In controlled tasks, AI demonstrates exceptional capability. The EMA's Scientific Explorer achieved F1 scores of 0.89 to 0.94 in information retrieval[365], and OpenAI's o1-preview model achieved 96% accuracy on medical licensing datasets[366]. However, a systematic review reveals a knowledge-practice gap: while models score high on knowledge benchmarks (61 to 79%), their performance drops in practice-based scenarios (45 to 69%)[367].

This knowledge–practice gap underscores the difference between benchmark performance and deployment readiness. Without integrated testing environments and clear validation

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[361] Submissions to the Call for Evidence; with references to ICMRA PQ KMS and Collaborative Hybrid Inspection Pilots.
[362] Submissions to the Call for Evidence and Public Consultation.
[363] Submissions to the Call for Evidence and Public Consultation.
[364] Capgemini Research Institute. (2026). *Smart bet, only option, or both?: Biopharma R&D turns to AI*. Capgemini. https://www.capgemini.com/wp-content/uploads/2026/01/120126CRI_Gen-AI-in-Lifesciences-_Final-interactive.pdf
[365] EMA, Scientific Explorer performance data
[366] Gong EJ, Bang CS, Lee JJ, Baik GH. Knowledge-Practice Performance Gap in Clinical Large Language Models: Systematic Review of 39 Benchmarks. J Med Internet Res. 2025 Dec 1;27:e84120. doi: 10.2196/84120. PMID: 41325597; PMCID: PMC12706444.
[367] Gong EJ, Bang CS, Lee JJ, Baik GH. Knowledge-Practice Performance Gap in Clinical Large Language Models: Systematic Review of 39 Benchmarks. J Med Internet Res. 2025 Dec 1;27:e84120. doi: 10.2196/84120. PMID: 41325597; PMCID: PMC12706444.

standards, high-performing models are expected to struggle to translate into reliable, regulatory-grade tools.

Workshop participants emphasised that uncertainty regarding evidentiary requirements and lifecycle management further complicates internal capability development, as firms lack clarity on the level of proof and documentation required for regulatory acceptance. This increases reliance on external consultants and technology providers, reinforcing capability asymmetries between large firms and SMEs.

Under the baseline, limited in-house expertise, ambiguous validation expectations and insufficient integrated experimentation environments are expected to reinforce each other. Firms with constrained AI capability may underinvest in lifecycle integration, while regulatory uncertainty discourages ambitious internal scaling strategies. Over time, these dynamic risks widening the capability gap between Union firms and global competitors with more mature AI integration ecosystems.

12.3 Expected impacts

Conduct of business

The non-binding guidance is expected to help reduce costly, one-off bilateral interactions by having a single publicly available reference point, reducing per-company transaction costs and enabling firms, to make development decisions with greater confidence[368]. The guidance would also reduce internal deliberation time within companies, where R&D teams currently delay commitment to AI-enabled approaches pending clarity on regulatory acceptability.

The guidance would disproportionately benefit SMEs, start-ups, and scale-ups by democratising access to regulatory intelligence that is currently available only through expensive formal procedures or informal networks with EMA. The potential cost relief is concrete. EMA's qualification procedure costs EUR 89,000 reduced by 90% for SMEs but not for academic or non-profit developers[369]. Even with the reduction, the procedure demands 160–250 days and produces confidential, non-reusable outcomes. Published guidance could help replace at least part of these procedures this with a free, publicly accessible reference point.

It is important to note, however, that the costs will not be fully eliminated. While the guidance is not binding, once EMA publishes this guidance it will become a de facto standard that assessors reference, so companies that deviate will bear the burden of justifying alternative approaches.

The testing environments are expected to generate significant structural impacts by addressing the current deficit of shared GMP-compliant pilot and scale-up infrastructure

[368] European Medicines Agency. (2023). Qualification of novel methodologies for drug development: Guidance to applicants (EMEA/CHMP/SAWP/72894/2008 Rev. 5). https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-novel-methodologies-drug-development-guidance-applicants_en.pdf

[369] European Medicines Agency. (2023). Qualification of novel methodologies for drug development: Guidance to applicants (EMEA/CHMP/SAWP/72894/2008 Rev. 5). https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/qualification-novel-methodologies-drug-development-guidance-applicants_en.pdf

in the Union. They would convert some firm-level fixed capital expenditure into pooled infrastructure accessible to multiple users. This is expected to reduce per-firm investment requirements for AI-enabled validation and scale-up activities. Where supported by predictable funding, comparable shared infrastructure models have demonstrated the capacity to crowd in private investment and accelerate the commercial translation of research outputs.

Time-to-access effects are likely to be material. SMEs may face delays of up to 18–24 months in securing pilot-GMP capacity under current conditions. Such delays reduce the effective duration of intellectual property protection and weaken competitiveness. Criteria-based access to shared facilities would reduce these delays by removing the need for individual firms to establish or negotiate bespoke infrastructure arrangements.

For SMEs and start-ups in particular, the expected impact extends beyond cost reduction. Limited access to pilot-scale infrastructure constrains the practical deployment of AI-enabled biotechnology and increases the risk that projects are delayed, outsourced outside the Union, or discontinued. Shared testing environments are therefore expected to function as an enabling condition for commercialisation, rather than merely as a cost-efficiency measure.

Administrative costs on businesses, including SMEs

Detailed guidance may function as a de facto standard, which means that if guidance is overly prescriptive or diverges from emerging international approaches, EU-based developers may face higher compliance burdens in global development programmes.

As regards testing environments and data quality accelerators, their recognition as high impact health biotechnology strategic projects entails that promoters must prepare applications, demonstrate eligibility against defined criteria, and operate under trusted conditions with ongoing reporting and knowledge-sharing obligations. This creates material implementation costs at firm level, the scale of which depends on the governance route chosen by Member States. For the recognition-and-coordination pathway the proposal establishes, cost estimates can be drawn from Horizon Europe experiences, where beneficiary administrative effort typically runs at 6–10% of project budgets, corresponding to approximately 0.5–1 FTE per project per year[370]. Scaled to reflect the additional requirements of a strategic project recognition framework, including dual reporting to national and EU authorities and longer monitoring periods, a reasonable central estimate is 1–2 FTE per project per year, corresponding to approximately 1–2% of total project value. Evidence from comparable EU funding instruments indicates that beneficiary administrative burden can absorb around 11% of eligible funding compared with 4% for

[370] The administrative burden observed in Horizon Europe projects (typically estimated at 6–10% of project budgets) is used as a reference point, corresponding to approximately 0.5–1 FTE of administrative effort per project per year. IPCEI reporting and compliance obligations are assumed to require approximately two to three times higher effort, reflecting additional State aid requirements, dual reporting to national and EU authorities, and longer monitoring periods. This implies an estimated administrative effort of 1–3 FTE per year per participant. When scaled to the larger investment volumes of IPCEI projects, this corresponds to approximately 1–2% of total project value. These figures should be interpreted as indicative orders of magnitude.

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managing authorities[371]; given the lighter governance structure of the Act's recognition pathway, this figure should be treated as an upper bound rather than a central estimate.

Where Member States choose to route funding under State aid rules, they are obliged to notify the envisaged aid to the Commission (for assessment and decision) before the public funding is granted. This should be factored in the overall procedure, while however it is not necessarily representative of the Act's default recognition-and-coordination pathway.

Competitiveness, trade and investment flows

OECD analysis confirms that investment increasingly concentrates in jurisdictions with specialised infrastructure: regions possessing advanced clusters and pilot facilities capture 78% of R&D-related FDI projects[372], and capital sorts towards jurisdictions with mature digital ecosystems[373]. These patterns underpin the rationale for trusted biotechnology testing environments and data quality accelerators as competitiveness-enhancing instruments.

Expected benefits of the testing environments that could be developed as high-impact strategic projects under the framework set out in the European Biotech Act proposal include:

- Addressing the principal R&D bottleneck. Firm-level evidence indicates that the most significant bottleneck for AI-biotech innovation lies in the validation phase, where computational models must be tested against biological data in regulated environments. The main causes of AI pilot failure are data quality and availability (55%) and IP, data security and compliance friction (50%)[374]. Firms with integrated "wet-dry" research environments are nearly twice as likely to attract investment (30% vs 18%)[375].
- Reducing offshore relocation of validation activity. By offering shared, regulatory-proximate validation capacity, Article 32 reduces the need for firms, particularly SMEs and startups, to build proprietary infrastructure or relocate validation activities to competing jurisdictions. The greatest expected impact is on the validation and translational stages of R&D, increasing the likelihood that AI-generated assets are developed within the Union rather than relocated to competing ecosystems.

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[371] European Commission, Spatial Foresight, & t33. (2018). New assessment of ESIF administrative costs and burden: Final report. European Commission, Directorate-General for Regional and Urban Policy. https://ec.europa.eu/regional_policy/sources/studies/assess_admin_costs.pdf

[372] Montegu, J., Saporito, N. F., & Polakiewicz, Z. (2026). *The evolution of the biotechnology sector: Implications for FDI and SME linkages across Europe* (OECD SME and Entrepreneurship Papers No. 75). OECD Publishing. https://doi.org/10.1787/420bb546-en

[373] Organisation for Economic Co-operation and Development. (2026). Connecting FDI and SMEs for productivity and innovation in Europe. OECD Publishing. https://doi.org/10.1787/9848e952-en

[374] Benchling. (2026). *The 2026 biotech AI report: Breakthroughs, bottlenecks, and the power shift shaping biotech's AI future*. Benchling. https://downloads.ctfassets.net/kzeezny59h5p/YpQPwDughrM22nvqp8pxl/ac49d590d9c9c74400dde6e6bf0657ea/2026-Biotech-AI-Report.pdf

[375] Benchling. (2026). *The 2026 biotech AI report: Breakthroughs, bottlenecks, and the power shift shaping biotech's AI future*. Benchling. https://downloads.ctfassets.net/kzeezny59h5p/YpQPwDughrM22nvqp8pxl/ac49d590d9c9c74400dde6e6bf0657ea/2026-Biotech-AI-Report.pdf

If access procedures are complex or facilities remain insufficiently integrated with regulatory pathways, the expected investment-attraction effect may be reduced despite public expenditure.

As regards data quality accelerator projects, expected benefits include:

- Reducing "data friction" as a driver of R&D relocation. The binding constraint for AI-biotech is often not compute or algorithms but the availability of "AI-ready" datasets: 48% of healthcare respondents identify data quality and integration as the main barrier to AI adoption[376], and the OECD identifies access to large, high-quality datasets as a "key competitive differentiator" that effectively subsidises R&D costs in data-rich jurisdictions[377].
- Lowering material cost penalties from fragmented data. The Commission estimates the absence of FAIR data costs the EU economy at least EUR 10.2 billion annually in lost productivity and innovation spillovers[378]. Data engineering consumes 25–40% of total AI spend, with integration complexity adding a 2–3× labour-cost premium[379]. Jurisdictions that reduce these burdens improve their attractiveness for inward AI-biotech investment.
- Converting the EHDS into a distinctive competitiveness asset. Article 33 enables the EU to position EHDS secondary use across a 450-million population as an industrial competitiveness instrument. The Data Union Strategy projects EUR 11 billion in economic value over ten years from secondary use[380,381]. The phased implementation timetable provides a planning horizon for investment decisions, while Health Data Access Bodies as "one-stop shops" are intended to reduce fragmentation-related "push factors." The expected benefit is therefore not only increased data volume but improved data usability and predictability for cross-border, data-intensive R&D.

Both policy measures require non-trivial public CAPEX and sustained OPEX. Their intended functions are comparable to EU "meaningful scale" technology infrastructure interventions rather than small grants. The following EU instruments provide financial proxies for the order of magnitude required to make such environments globally credible:

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[376] IntuitionLabs. (2026). AI for biotech: A build vs. buy decision framework. IntuitionLabs. https://intuitionlabs.ai/articles/build-vs-buy-ai-biotech

[377] Montegu, J., Saporito, N. F., & Polakiewicz, Z. (2026). *The evolution of the biotechnology sector: Implications for FDI and SME linkages across Europe* (OECD SME and Entrepreneurship Papers No. 75). OECD Publishing. https://doi.org/10.1787/420bb546-en

[378] European Commission, Directorate-General for Research and Innovation, & PwC EU Services. (2018). Cost-benefit analysis for FAIR research data: Cost of not having FAIR research data. Publications Office of the European Union. https://doi.org/10.2777/02999

[379] IntuitionLabs. (2026). AI for biotech: A build vs. buy decision framework. IntuitionLabs. https://intuitionlabs.ai/articles/build-vs-buy-ai-biotech

[380] European Commission. (2025). Communication from the Commission to the European Parliament and the Council: Data Union strategy – Unlocking data for artificial intelligence (COM(2025) 835 final). European Commission. http://publications.europa.eu/resource/celex/52025DC0835

[381] European Commission. (n.d.). European Health Data Space regulation (EHDS). European Commission. https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space-regulation-ehds_en

Table 23. EU instruments providing financial proxies for the order of magnitude of investment in testing environments/data quality accelerators

Proxy instrument	Scale	Relevance to testing environments/data quality accelerators
IPCEI European Battery Innovation	EUR 2.9 billion public funding, unlocking EUR 9 billion private (≈1:3 leverage)	Upper bound; Act anticipates large-scale public-private investment for high-impact projects
Microelectronics IPCEI	~EUR 63 million per partner (2018) → ~EUR 145 million per partner (2021)	Illustrative proxy for the order of magnitude of support observed in selected strategic technology projects developed under the IPCEI framework,
Horizon Europe Large-Scale Service Pilot	EUR 35 million per pilot	Mid-scale proxy for individual Art. 32 nodes or Art. 33 accelerator configurations
Graphene Flagship	~EUR 1 billion over 10 years	Long-running network model illustrating OPEX exposure
IMI2 life-science PPP	EUR 3.276 billion (≈50/50 public-industry)	PPP proxy where Art. 32/33 projects pool public and private expertise

If implemented at the scale implied by their intended functions, budget impacts will materialise primarily through (i) prioritisation and mobilisation of existing Union programmes and (ii) Member State co-financing and/or State-aid compatible funding, rather than negligible incremental spending.

Infrastructure evidence suggests stable operation typically requires core funding covering 60–70% of operational costs as a "healthy" baseline, with user-fee-only models often unrealistic for research-grade infrastructures[382]. This is directly relevant because the Act's policy intent is to provide shared capability, particularly supporting SMEs and cross-ecosystem networking, rather than purely commercial facilities financed by full cost recovery.

A risk common to both articles is the potential for an "operation gap": facilities and data services are launched but cannot be sustained at the utilisation and quality level required to deliver the Act's competitiveness objectives. Unless long-term funding and governance arrangements are secured through Union programmes, Member State co-financing, and/or PPP co-investment significant public CAPEX may be deployed without the ongoing OPEX needed for credible, high-utilisation operation. This would reduce both the direct benefits (validation capacity, data quality uplift) and the indirect competitiveness signal to global investors.

Functioning of the internal market and competition

Impacts in this category are expected to be driven primarily by the measure on data quality accelerators.

The current EU health data landscape is characterised by heterogeneity in readiness. While the EU-27 composite eHealth maturity score stands at 83%, this aggregate masks a stark divide: "trendsetters" such as Belgium (100%), Estonia (100%) and Denmark (98%) operate near-universal digital coverage, while Romania (46%) and Ireland (44%) lag

[382] Organisation for Economic Co-operation and Development. (2017). Strengthening the effectiveness and sustainability of international research infrastructures (OECD Science, Technology and Industry Policy Papers No. 48). OECD Publishing. https://doi.org/10.1787/fa11a0e0-en

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significantly[383,384]. The divide is most acute in data depth: only 26% of Member States provide access to medical imaging through national infrastructures. The "meaningful use" of EHRs varies from 73% in Finland to 5% in Germany[385], and private provider connectivity lags at 59% versus 79% for public providers[386]. The data quality uplift that data quality accelerators would bring is therefore expected to expand the number of Member States where legally compliant AI development is practically feasible, enlarging the effective Single Market for data-driven biotech products.

These infrastructure disparities currently drive measurable innovation concentration. Medicon Valley (Eastern Denmark and Southern Sweden) alone attracted over EUR 2.5 billion in financing between 2023–2024, while for example, Romania's digital infrastructure contributes to "negligible" clinical trial activity[387]. In addition, industry stakeholders report that pharmaceutical companies "mainly use data from outside the EU, primarily from the US," because US datasets are larger, more streamlined and easier to access at scale[388]. Data quality accelerators are expected to reduce these location-based asymmetries and support a broader geographic distribution of AI-biotech activity, rather than further concentration in existing hubs.

On the risk side, three structural dynamics could partially offset these gains:
- The absorptive capacity gap (80% of large firms vs under 30% of SMEs using advanced analytics[389]) means data quality improvements may disproportionately benefit incumbents.
- Gatekeeping by data holders (52% of user obstacles linked to legal fragmentation[390]) may persist where the framework does not enforce transparent, non-discretionary access.
- The length of the implementation timeline may entail a prolonged transition during which the digital divide may widen before it narrows.

Innovation and research

Overall, the net R&I impact of the policy measures is expected to be positive:
- Testing environments have the potential to address the validation bottleneck that hampers SMEs from the AI-biotech pipeline, accelerating time-to-validation, regulatory submissions and boosting firm growth;

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[383] European Court of Auditors. (2024). Special report 25/2024: Digitalisation of healthcare. https://www.eca.europa.eu/ECAPublications/SR-2024-25/SR-2024-25_EN.pdf
[384] Capgemini Invent. (2025). 2025 Digital Decade eHealth indicator study: Final report. European Commission. http://espanadigital.gob.es/sites/espanadigital/files/2025-12/Estudio%20de%20Indicadores%20de%20eHealth%20de%20la%20D%C3%A9cada%20Digital%202025.pdf
[385] Organisation for Economic Co-operation and Development, & European Observatory on Health Systems and Policies. (2025). Synthesis report 2025: Health policy reform trends in the EU. OECD Publishing. https://doi.org/10.1787/1f6a8e9a-en
[386] Capgemini Invent. (2025). 2025 Digital Decade eHealth indicator study: Final report. European Commission. http://espanadigital.gob.es/sites/espanadigital/files/2025-12/Estudio%20de%20Indicadores%20de%20eHealth%20de%20la%20D%C3%A9cada%20Digital%202025.pdf
[387] Organisation for Economic Co-operation and Development, & European Observatory on Health Systems and Policies. (2025). Romania: Country health profile 2025. OECD Publishing. https://www.oecd.org/content/dam/oecd/en/publications/reports/2025/12/country-health-profile-2025-country-notes_7e72146d/romania_ca47b392/1269b371-en.pdf
[388] Collected through public consultations and workshop.
[389] Organisation for Economic Co-operation and Development. (2022). Data shaping firms and markets (OECD Digital Economy Papers, No. 344). OECD Publishing. https://doi.org/10.1787/7b1a2d70-en
[390] TEHDAS Joint Action. (2022). Report on secondary use of health data through European case studies. https://tehdas.eu/app/uploads/2022/08/tehdas-report-on-secondary-use-of-health-data-through-european-case-studies-.pdf

- Data quality accelerators have the potential to address the data usability deficit that currently renders 87% of publicly hosted biomedical datasets inaccessible for machine learning[391], with the EU losing an estimated EUR 10.2 billion annually from the absence of FAIR data[392] and targeted curation demonstrating savings of 5,000 researcher-hours and USD 1.4 million per year in a single use case[393].

The principal downside risk across all three instruments is that benefits are eroded by infrastructure capture (49–65% of funding concentrated in top partners[394]), technological obsolescence (15–20% annual CAPEX renewal requirement[395,396]), or administrative delay. If the EHDS delivers even a fraction of its projected EUR 11 billion in economic value over ten years at the scale of a 450-million population, the innovation return from data accelerator projects would be significant. The overall R&I impact depends less on the initial creation of infrastructure and guidance than on the sustained quality of governance, access design and technology refresh funding over the operational lifecycle.

The guidance on AI use is expected to generate positive effects on innovation by reducing the "wait-and-see" behaviour currently observed in AI-enabled drug development. While 68% of biopharma organisations plan to increase AI investment in R&D between 2025 and 2026[397], investment remains conditional on regulatory signals regarding the acceptability of AI-generated evidence. In analogous contexts, the provision of an operational framework has triggered measurable shifts in methodological uptake: under the EMA's Real-World Evidence framework, regulator-led RWD studies increased to 59 between February 2024 and February 2025, a 47.5% increase year-on-year, while study feasibility rose from 60% to 78% as the DARWIN EU network expanded to 30 data partners covering around 180 million patients across 16 countries [398,399].

Public authorities

The costs on EMA regarding the development of the guidance are difficult to quantify. However, it is known that implementation of coordinated systems (as it is with EHDS),

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[391] Fries, J. A., *et al*. (2022). Dataset debt in biomedical language modeling. https://edoc.mdc-berlin.de/id/eprint/22134/1/22134oa.pdf

[392] European Commission, Directorate-General for Research and Innovation, & PwC EU Services. (2018). Cost-benefit analysis for FAIR research data: Cost of not having FAIR research data. Publications Office of the European Union. https://doi.org/10.2777/02999

[393] Elucidata (2025), Data Mine to Data Minefield: The Hidden Costs of Poor Data Quality in Biopharma R&D. https://www.elucidata.io/blog/data-mine-to-data-minefield-the-hidden-costs-of-poor-data-quality-in-biopharma-r-d

[394] European Court of Auditors (2016), Special Report No 04/2016: The European Institute of Innovation and Technology must modify its delivery mechanisms and elements of its design to achieve the expected impact. https://www.eca.europa.eu/lists/ecadocuments/sr16_04/sr_eit_en.pdf

[395] Santos, F. M., & Mendonça, S. (2025), Innovation Intermediaries in the Digital Transformation Process, Technovation. https://doi.org/10.1016/j.technovation.2025.102902

[396] European Court of Auditors (2026), Opinion No 10/2026 on the proposal for a regulation establishing a budget expenditure tracking and performance framework. https://www.eca.europa.eu/en/publications/OP-2026-10

[397] Capgemini Research Institute. (2026). *Smart bet, only option, or both?: Biopharma R&D turns to AI*. Capgemini. https://www.capgemini.com/wp-content/uploads/2026/01/120126CRI_Gen-AI-in-Lifesciences-_Final-interactive.pdf

[398] European Medicines Agency. (2025, June 30). Real-world evidence framework to support EU regulatory decision-making: 3rd report on the experience gained with regulator-led studies from February 2024 to February 2025. European Medicines Agency. https://www.ema.europa.eu/en/documents/report/real-world-evidence-framework-support-eu-regulatory-decision-making-3rd-report-experience-gained-regulator-led-studies-february-2024-february-2025_en.pdf

[399] EMA Infosheet: https://www.ema.europa.eu/en/documents/other/infosheet-ema-review-real-world-data-studies-september-2021-february-2025_en.pdf

requires significant investment in capacity-building, training, and public engagement. The economic costs are borne at both Union and national levels, and additional resources are needed for healthcare systems, especially public ones.

Testing environments and data quality accelerators share the same recognition-and-support architecture as high impact health biotechnology strategic projects. The following incremental costs apply to both.

EU-level supervisory costs. EU-level supervisory tasks under Articles 32 and 33 cover recognition, monitoring, compliance verification and cross-border coordination for a limited portfolio of high impact projects. These are non-fiscal administrative functions and do not involve managing a direct funding portfolio. A bottom-up estimate of the staffing requirement suggests approximately 0.3–0.5 FTE per single-country project per year for ongoing supervision, rising to 0.5–1 FTE for multi-country projects given the additional coordination layer, plus a one-off recognition effort of approximately 1–1.5 person-months per project at initial designation[400]. On this basis, EU-level supervisory requirement is estimated at 1–3 FTE under low uptake (2–3 projects), 2.5–8 FTE under medium uptake (5–8 projects), and 5–15 FTE under high uptake (10–15 projects). The additional complexity of health biotechnology strategic projects, which span multiple regulatory frameworks (AI Act, Clinical Trials Regulation, EHDS, GMO legislation) and require coordination across a broader range of Union agencies (EMA, EFSA, national competent authorities) and sectoral stakeholders, supports placing estimates at the higher end of these ranges for multi-country projects. The Chips Joint Undertaking, where 18 FTE supervise a portfolio of approximately EUR 4.175 billion in EU funding involving direct programme management[401], provides a structural upper bound; the Act's recognition-and-coordination function is materially less resource-intensive than direct programme management.

Technological obsolescence and refresh costs. Both articles establish infrastructure that relies on AI-enabled digital components evolving significantly faster than traditional research equipment. Computational power required for frontier AI experiments doubles approximately every 3.5 months[402] and 30–40% of software stacks require replacement or major updates every 18–24 months[403]. Maintaining state-of-the-art status requires continuous reinvestment equivalent to 15–20% of initial CAPEX annually[404,405].The

[400] There is no database for these figures available, an assumption was made given the expected amount of work per project (see Rapid Assessment Study – forthcoming).
[401] In the current Chips JU, 18 FTE supervise a budget of around EUR 4.175 billion in EU funding. The Chips Act strategic project oversight model provides the closest available proxy for the administrative supervision function envisaged under Articles 32 and 33 of the proposed Biotech Act.
[402] Organisation for Economic Co-operation and Development. (2018). OECD science, technology and innovation outlook 2018: Adapting to technological and societal disruption. https://www.oecd.org/content/dam/oecd/en/publications/reports/2018/11/oecd-science-technology-and-innovation-outlook-2018_g1g98de3/sti_in_outlook-2018-en.pdf
[403] Santos, F. M., & Mendonça, S. (2025), Innovation Intermediaries in the Digital Transformation Process, Technovation. https://doi.org/10.1016/j.technovation.2025.102902
[404] European Court of Auditors. (2026, February 24). Opinion No 10/2026 (pursuant to Article 322(1) TFEU) on the proposal for a regulation establishing a budget expenditure tracking and performance framework. https://www.eca.europa.eu/en/publications/OP-2026-10
[405] Santos, F. M., & Mendonça, S. (2025). Innovation intermediaries in the digital transformation process. Technovation. https://doi.org/10.1016/j.technovation.2025.102902

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Hartree Centre evaluation illustrates the financial implication: EUR 35.3 million in active assets alongside EUR 31.9 million already retired or repurposed[406].

Human capital costs. Both types of projects require interdisciplinary profiles bridging medicine, data science and law, which are in critical shortage. AI talent concentration in hospitals remains below 2% of the workforce in most Member States[407]. Operating testing environments (Article 32) and data quality accelerators (Article 33) require permanent specialist roles (data stewards, cloud engineers, validation scientists) that represent new fixed costs for the public authorities hosting or co-managing these projects[408,409].

Beyond the shared strategic project costs, data quality accelerators potentially create incremental demands on public authorities that hold or govern health data. These costs arise not from the EHDS baseline (which mandates data access) but from the accelerator-grade quality uplift including curating, annotating, verifying provenance and standardising datasets to a level suitable for AI training, validation and testing.

This quality uplift is labour-intensive and costly. Making experimental results "AI-ready" by systematically recording metadata adds roughly 15% to experimentation costs [410]. For biobanks participating in accelerator-grade data provision, agreements range from EUR 100,000 to EUR 500,000 per project, reflecting the cost of providing "highly structured, harmonized data" capable of supporting computational cloud services [411]. This level of curation goes substantially beyond standard EHDS access obligations. Effective anonymisation at accelerator grade cannot be fully automated: "use case–specific anonymisation" requires deep domain expertise to preserve statistical utility while ensuring GDPR compliance[412].

Grant dependency risk. The public authorities are most likely to host or co-manage Article 33 accelerators (biobanks, registries) have funding structures incompatible with permanent service obligations. Core budgets cover only 16–17% of IT and development services, with 83–84% dependent on volatile project-based grants [413]. Article 33 imposes continuous curation, maintenance and data-holder support functions that require stable operational funding. Without structural budget allocation, accelerator projects risk the

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[406] Technopolis Group (2018), Hartree Centre Phase 1 & 2 Baseline Evaluation. https://www.technopolis-group.com/wp-content/uploads/2020/02/Hartree-Centre-Phase-12-Baseline-Evaluation.pdf

[407] Organisation for Economic Co-operation and Development. (2026). Progress in implementing the European Union coordinated plan on artificial intelligence (Volume 2): Uptake in high-impact sectors. OECD Publishing. https://doi.org/10.1787/3ac96d41-en

[408] BBMRI-ERIC. (2025). BBMRI-ERIC work programme 2025–2027. https://www.bbmri-eric.eu/wp-content/uploads/Work_programme_2025-2027_WEB.pdf

[409] European Commission, Directorate-General for Research and Innovation, & PwC EU Services. (2018). Cost-benefit analysis for FAIR research data: Cost of not having FAIR research data. Publications Office of the European Union. https://doi.org/10.2777/02999

[410] Organisation for Economic Co-operation and Development. (2023). Artificial intelligence in science: Challenges, opportunities and the future of research. OECD Publishing. https://doi.org/10.1787/a8d820bd-en

[411] EIT Health. (n.d.). Costs and agreements. https://biobankshealthdata.eithealth.eu/guide/costs-and-agreements/

[412] Pilgram, L.,et. al.., & GCKD Investigators. (2024). The costs of anonymization: Case study using clinical data. Journal of Medical Internet Research, 26, e49445. https://doi.org/10.2196/49445

[413] BBMRI-ERIC. (2025). BBMRI-ERIC work programme 2025–2027. https://www.bbmri-eric.eu/wp-content/uploads/Work_programme_2025-2027_WEB.pdf

same "project trap" cycle observed in existing biobank infrastructure: facilities built up for specific grant periods and subsequently degraded once funding expires [414].

Coordination needs with Health Data Access Bodies (an EHDS obligation) add an institutional coordination layer: accelerators must align their data quality standards, access procedures and governance with the HDAB framework operating in each participating Member State. For accelerators operating across borders, this involves navigating the heterogeneous implementation timelines and technical standards of multiple national systems, adding administrative complexity that scales with the number of Member States involved.

Overall, the incremental costs to public authorities for testing environments and data quality accelerators are driven primarily by three factors: EU-level supervision of the strategic project portfolio (25–30 FTE), continuous technology refresh to avoid obsolescence (15–20% of CAPEX annually), and, for data quality accelerators specifically, the accelerator-grade data curation burden that goes beyond baseline EHDS access obligations.

The critical sustainability risk is concentrated in data quality accelerators. The public authorities best positioned to operate data quality accelerators (biobanks, registries) are also the most financially precarious: 83–84% grant-dependent, with fee recovery models covering only a fraction of operational costs in comparable settings. In the context of data quality accelerators these entities would have to provide continuous, high-quality data stewardship as a permanent service, but their funding structures are designed for time-limited projects. Unless stable operational funding is provided, there is a material risk that accelerator projects are launched but cannot be sustained at the quality level required to deliver their intended innovation and competitiveness effects.

Public health and safety

Biotechnology testing environments are the main driver of impacts in this category, as they are expected to improve public health outcomes by enabling standardised, independent validation of AI-enabled biomedical tools before large-scale deployment. The expected effects operate through three channels.

Reducing the real-world performance gap. AI models validated through ad hoc firm-level processes suffer performance declines of 15–30% when deployed against heterogeneous patient populations and clinical workflows [415]. Shared testing environments providing access to diverse, representative datasets and standardised protocols are expected to narrow this gap before deployment, reducing the risk of clinical failures such as the Epic Sepsis Model case, where real-world AUC fell from 0.76–0.83 to 0.63, missing 67% of sepsis cases[416].

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[414] Towards the European Health Data Space (TEHDAS). (2022, April 1). TEHDAS identifies funding options for secondary use of health data. https://tehdas.eu/tehdas1/results/tehdas-identifies-funding-options-for-secondary-use-of-health-data/

[415] Li, Y., et. al. (2025). Reducing misdiagnosis in AI-driven medical diagnostics: A multidimensional framework for technical, ethical, and policy solutions. Frontiers in Medicine. https://doi.org/10.3389/fmed.2025.1594450

[416] Li, Y., et. al. (2025). Reducing misdiagnosis in AI-driven medical diagnostics: A multidimensional framework for technical, ethical, and policy solutions. Frontiers in Medicine. https://doi.org/10.3389/fmed.2025.1594450

Improving reliability through structured multi-system validation. Evidence from controlled testing architectures shows that where multiple AI systems cross-check outputs, the probability of achieving top-quartile safety performance increases 5.9-fold compared with single-model deployments [417]. Article 32 environments are designed to replicate such rigorous testing conditions at scale. This is particularly relevant given that frontier large language models in clinical settings produce severely harmful recommendations in up to 22.2% of cases, with a Number Needed to Harm of approximately 11.5 [418], and that by November 2024 the FDA had recorded 182 recall events involving 60 AI-enabled devices, with 43% occurring within one year of authorisation.

Reducing population-level bias. Testing against diverse datasets in shared facilities is expected to reduce bias arising from non-representative validation data, a documented patient safety risk where dermatology AI systems have shown false-negative melanoma rates 28% higher for darker-skinned patients and critical care misdiagnosis rates 31% higher for minority patients [419,420].

[417] Goh, E. (2025). New Stanford–Harvard study: Widely used AI models can cause severe clinical harm in up to 22% of cases [LinkedIn post]. LinkedIn. https://www.linkedin.com/posts/ethan-goh_new-stanfordharvard-study-widely-used-activity-7402030275485962240-ywkw

[418] Goh, E. (2025). New Stanford–Harvard study: Widely used AI models can cause severe clinical harm in up to 22% of cases [LinkedIn post]. LinkedIn. https://www.linkedin.com/posts/ethan-goh_new-stanfordharvard-study-widely-used-activity-7402030275485962240-ywkw

[419] Abu-Mahfouz, N. (2026). Bias in medical AI: Algorithmic fairness and ethics challenges. Journal of Young Investigators, 29(1), 1–3. https://www.jyi.org/2026-january-1/2026/1/8/bias-in-medical-ai-algorithmic-fairness-and-ethics-challenges

[420] Abu-Mahfouz, N. (2026). Bias in medical AI: Algorithmic fairness and ethics challenges. Journal of Young Investigators, 29(1). https://www.jyi.org/s/202601-RA-Abu-Mahfouz-Bias-Medical-AI.pdf

ANNEX 8: COMPETITIVENESS CHECK

1 OVERVIEW OF IMPACTS ON COMPETITIVENESS

Dimensions of Competitiveness	Impact of the initiative (++ / + / 0 / - / -- / n.a.)	References to sub-sections of the main report or annexes
Cost and price competitiveness	+	Section 6 and Annex 7
International competitiveness	++	Section 6 and Annex 7
Capacity to innovate	++	Section 6 and Annex 7
SME competitiveness	++	Section 6 and Annex 7

2 SYNTHETIC ASSESSMENT

Cost and price competitiveness improves moderately across the biotech ecosystem, driven primarily by the reduction of regulatory compliance costs for innovators and the acceleration of competitive price dynamics in the biologicals market. The amendments to the EU rules on clinical trials, ATMPs, GMMs, and to the General Food Law collectively reduce duplicative procedural requirements, shorten authorisation timelines, and lower administrative expenditure per product. Quantified savings range from tens of thousands of euros per ATMP clinical trial application to EUR 112 to 225 million over 15 years from clinical trial digitalisation alone. The biosimilar measure reinforces competitive pricing by lowering development cost barriers for new market entrants. This builds on a baseline of EUR 6 billion in annual European healthcare savings achieved in 2024. By enabling faster entry and greater competition, the measure ensures this savings trajectory continues to deepen. These gains are partially offset by the SPC extension and biosecurity screening obligations. The SPC extension maintains higher originator prices for an additional year for eligible biotechnological medicines at an estimated EUR 210 million annual cost to public payers. Biosecurity screening obligations introduce compliance costs for synthetic nucleic acid providers and their customers. Some cost disadvantages, including the still-fragmented EU clinical trial landscape and persistently high manufacturing costs for advanced biologicals, limit the overall scale of improvement.

International competitiveness strengthens substantially across several key dimensions of the EU biotech sector. The proposed revision of the EU rules on clinical trials reverses the EU's declining attractiveness as a location for globally mobile trial investment, addressing the fall in the EU's share of global commercial clinical trials from 22% in 2013 to 12% in 2023, while China's share rose from 8% to 29% over the same period. The biosimilars measure prevents the EU from becoming the last major jurisdiction without CES flexibility, at a time when the US, Canada, and South Korea are already moving toward waiver or elimination of this requirement, thereby defending the EU's position as the world's largest biosimilar market at approximately 43% of a EUR 25.9 billion global market. The GMMs intervention enables the EU to compete in high-growth global markets

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such as biofertilisation, biocontrol and bioremediation, from which it has been effectively absent under the existing framework. Remaining barriers to venture capital availability, late-stage financing depth, and manufacturing cost levels relative to Asian competitors are not addressed by the European Biotech Act proposal, limiting the ceiling of achievable improvement.

Capacity to innovate is significantly enhanced through measures that collectively address the EU's persistent structural failure to translate its strong scientific base into commercial biotech innovation. The novel health products instruments (regulatory status repository, regulatory sandbox, foresight panel) directly reduce the regulatory uncertainty that currently suppresses high-risk, frontier research in the EU, with sandbox evidence from comparable frameworks indicating 20 to 40% faster time-to-market, a 15 to 50% increase in funding probability, and 20 to 30% gains in firm survival and patenting, with the potential to accelerate 10 to 20 novel products per cohort. The revision of the EU rules on GMMs unlocks an entirely blocked innovation pathway, enabling the EU to begin developing commercial products in bioremediation markets projected to grow at a CAGR of approximately 10 to 13% and bioleaching markets at approximately 9%, with biofertilisation and biocontrol representing further high-growth opportunities, sectors where the EU currently holds zero authorised products despite significant global market momentum. The ATMPs and clinical trial revisions remove procedural barriers to innovative trial designs, including adaptive, decentralised, and combined studies, enabling the EU to support cutting-edge development modalities that its current framework structurally hinders. The strategic projects and high-impact projects measures strengthen the EU's translation infrastructure by supporting pilot, testing and demonstration facilities and biomanufacturing innovation assets that convert research outputs into industrial deployment, complemented by the access to funding pilots, which target the EU's EUR 40 billion annual investment gap by improving late-stage capital continuity and reducing financing-round attrition. The Data and AI related policy measures further broaden innovation capacity by establishing trusted AI testing environments and data quality accelerators as high-impact strategic projects, and tasking EMA with guidance on AI integration across the medicinal product lifecycle.

SME competitiveness is expected to improve strongly across the biotech ecosystem, as SMEs and start-ups are the primary beneficiaries of the package's regulatory simplification, infrastructure access, and support provisions. SMEs are disproportionately burdened under the current system, lacking in-house regulatory affairs capacity, relying heavily on costly external consultants, and facing compliance costs that consume a structurally larger share of their resources than for large firms. Multiple interventions directly address these conditions. The clinical trial revision reduces per-trial administrative costs by EUR 2,714 to EUR 4,496 and introduces more predictable timelines that benefit resource-constrained sponsors. The GMMs low-risk pathway lowers market entry barriers for start-ups that would otherwise be unable to absorb the costs and timelines of the current process. The ATMP ERA simplification removes a compliance burden that industry identifies as particularly severe for smaller developers, who constitute the majority of the ATMP pipeline. The General Food Law amendments provide expanded scientific pre-submission advice that is of greatest value precisely for SMEs and first-time applicants most likely to submit incomplete dossiers. The strategic projects and high-impact projects measures create new market opportunities by opening shared pilot, testing, and small-batch GMP infrastructure with systematic cross-border accessibility, with 82% of SMEs

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currently unable to self-finance comparable validation infrastructure. The biotech ecosystem support network and access to funding pilots target the structural financing gap that constrains SME scaling, with the Investment Pilot explicitly designed to support the full company lifecycle including start-ups and scale-ups, addressing a broader annual investment gap estimated at EUR 40 billion.

3 COMPETITIVE POSITION OF THE MOST AFFECTED SECTORS

Health biopharmaceutical, biologics and ATMP developers benefit most directly. Regulatory simplification across clinical trials, ATMPs and GMMs reduces time-to-market, lowers development costs, and improves the EU's attractiveness as a location for late-stage clinical research and advanced therapy development. Strategic project recognition and access to funding measures strengthen the translation infrastructure connecting research to commercial deployment, partially closing the financing and scale-up gap with the US and China.

Biosimilar developers gain from both regulatory modernisation and supply-side support. Alignment of the EU's evidentiary requirements with the emerging international standard preserves the EU's position as the world's leading biosimilar market and removes the risk of regulatory disadvantage relative to the US, South Korea and Canada. Strategic project support for EU-based biosimilar manufacturing reinforces the domestic developer base against growing competition from South Korean and Indian producers.

Industrial biotechnology firms, particularly those active in biofertilisation, biocontrol, bioremediation and bioleaching, gain access to a viable EU market authorisation pathway for GMMs where none currently exists. This represents a qualitative shift in competitive position rather than an incremental improvement, enabling EU-based firms to begin competing in fast-growing global markets from which the current regulatory framework has effectively excluded them.

Veterinary medicine companies benefit from a single regulatory pathway for GMO-containing VMPs, reduced administrative burden on lifecycle management, and a new sandbox instrument for next-generation animal health technologies. These measures improve the EU's competitiveness in a sector where it holds the second-largest global market share and where the pipeline is increasingly reliant on GMO-based vaccine platforms.

Food and feed chain operators, including SMEs and first-time applicants, benefit from a more supportive and timely EFSA authorisation process. Reduced stop-the-clock incidents and earlier access to scientific guidance strengthen the EU's ability to bring innovative food and feed products to market without sacrificing the quality standards that underpin its international reputational advantage.

Synthetic nucleic acid synthesis providers operating responsibly gain from the levelling of competitive conditions across the sector. Mandatory screening removes the cost advantage currently enjoyed by non-compliant providers and positions EU suppliers more credibly in international markets where biosecurity standards are increasingly expected by customers and regulators alike

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ANNEX 9: SME CHECK

OVERVIEW OF IMPACTS ON SMES

Relevance for SMEs
Yes

(1) IDENTIFICATION OF AFFECTED BUSINESSES AND ASSESSMENT OF RELEVANCE[421]
Are SMEs directly affected? *(Yes)* **In which sectors?**
The health biotechnology and pharmaceutical sector is the most heavily affected sector, given that over 60% of ATMP developers in Europe are SMEs, and that EU biotech firms are structurally smaller on average and less likely to scale than their US counterparts. This sector includes developers of advanced therapy medicinal products (ATMPs: gene therapies, cell therapies, tissue-engineered products), biological medicinal products, and biosimilars. Biomanufacturing and scale-up services, including firms providing GMP-compliant pilot and testing infrastructure, for whom reduced permitting timelines and access to shared late-stage infrastructure are directly relevant to their conduct of business and commercial viability. Clinical research, including small sponsors (both commercial SMEs and academic innovators and non-commercial trial sponsors) conducting clinical trials for novel biotechnology products, who face disproportionate administrative and regulatory burdens relative to larger firms with dedicated regulatory affairs capacity. Industrial and environmental biotechnology, including start-ups and SMEs developing genetically modified micro-organism (GMM)-based products in areas such as biofertilizers, biocontrol agents, bioremediation, and bioleaching, for whom the absence of a workable and proportionate regulatory pathway has effectively blocked market entry under the current framework. Veterinary biotechnology and animal health, including SMEs and emerging developers of next-generation veterinary vaccines and biotechnology-derived animal health products, who are directly affected by the GMO exemption and regulatory sandbox provisions under the amended Veterinary Medicinal Products Regulation. Food and feed biotechnology, including first-time and one-time applicants to EFSA pre-market authorisation processes, disproportionately SMEs, who bear the highest relative cost of incomplete or non-compliant dossiers and who stand to benefit most from extended pre-

[421] The structural characterisation of the SME population in the EU biotechnology sector, including firm size distribution, sector composition, startup ecosystem data, and employment figures, is drawn from the Market Analysis (Technopolis Group, Orbis IP dataset, 2025) and the Final Report of the Landscape analysis study (forthcoming).

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submission advice covering both regulatory and scientific aspects, as well as from regulatory sandboxes for food, feed and GMO-related products.

AI-enabled health biotechnology and digital health, including SMEs developing AI-based tools for drug discovery, genomic analysis, and clinical development, who currently cannot self-finance validation infrastructure (with 82% of SMEs unable to do so) and who face delays of up to 18 to 24 months in accessing pilot-GMP capacity under current conditions.

Regenerative medicine and cell processing, including smaller SoHO entities and biotech firms operating at the interface of SoHO, ATMP and medical device frameworks, for whom regulatory sandboxes reduce the multi-framework compliance burden that currently falls disproportionately on entities without large in-house regulatory affairs capacity.

Estimated number of directly affected SMEs

The estimated number of directly affected SMEs falls in a range of **approximately 3,000 to 4,500,** based on the available firm-level data for the EU biotechnology sector across the health biotechnology, industrial biotechnology, food and feed biotechnology, veterinary biotechnology, and AI-enabled health technology sectors. This figure is likely a conservative estimate, as it does not fully capture SMEs in food, feed and veterinary biotechnology that are subject to the relevant legislative amendments but are not classified as biotechnology companies in standard firm-level databases.

Estimated number of employees in directly affected SMEs

Direct employment in the EU biotechnology sector stands at approximately 137,000 (Technopolis Group, Prodcom-based, 2024) to 238,000 (WifOR Institute, 2025). Since manufacturing activities, which are the most labour-intensive, are structurally concentrated in large firms while SMEs predominantly specialise in R&D and early-stage development, their share of direct employment is estimated at approximately 40 to 50% of the sector total, pointing to an indicative figure of approximately **55,000 to 120,000 employees**[422] in directly affected SMEs.

Are SMEs indirectly affected? *(Yes)* **In which sectors? What is the estimated number of indirectly affected SMEs and employees?**

SMEs are indirectly affected across a broad range of upstream and downstream sectors that are economically linked to biotechnology activity.
Upstream: this includes providers of laboratory equipment, analytical instruments and reagents; specialised contract research organisations (CROs); regulatory, legal and IP advisory service firms; bioinformatics and digital health technology providers; and raw materials and biological input suppliers.
Downstream: it encompasses medical devices and diagnostics firms supplying complementary products, logistics and cold chain operators handling biological products, food processing and manufacturing businesses affected by the food law amendments, agricultural input suppliers

[422] Figures estimated by PPMI (see Rapid Assessment Study – forthcoming) based total number of companies according to the Technopolis and Wifor reports,applying an assumed 40 to 50% SME employment share to the two total employment figures from those sources.

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linked to the GMM and VMP value chains, and healthcare service providers benefiting from improved availability of advanced therapies and biosimilars.
The total employment effects linked to the EU biotechnology industry, including upstream and downstream value chain linkages, amount to approximately 913,000 jobs (WifOR Institute, 2025), implying a spillover multiplier of 2.8 on approximately 238,000 direct biotech jobs. A disaggregated figure for employees in indirectly affected SMEs specifically is not available

(2) CONSULTATION OF SME STAKEHOLDERS

How has the input from the SME community been taken into consideration?

SME input was gathered through multiple consultation channels. The call for evidence (May to June 2025, 222 contributions) gathered additional input from companies and business associations representing SME interests. The public consultation (August to November 2025, 464 contributions) received submissions from 63 SMEs (comprising 28 micro-enterprises, 19 small enterprises and 16 medium-sized enterprises). Targeted stakeholder interviews were conducted (see annex 2 for more details) including with representatives of SMEs, start-ups and scale-ups across health, industrial, food and veterinary biotechnology. The assessment of impacts incorporated SME-specific views directly into the analytical frameworks: SME disproportionate burden is established as a core baseline assumption in the Biotech Ecosystem, Novel Health Products, ATMPs, Clinical Trials, GMMs and SPC Extension IAs. The European Biotech Act proposal itself explicitly lists support to SMEs, start-ups and scale-ups among its objectives in Article 2(2)(c).

Are SMEs' views different from those of large businesses? *(Yes)*

The consultation evidence documents several substantive differences between SMEs and large enterprises. On regulatory burden, both groups cited fragmentation as a problem, but small companies specifically highlighted high regulatory costs while large companies focused on the unpredictability of authorisation procedures. On access to funding, large companies pointed to public R&D under-investment as their primary concern, while also acknowledging the lack of financial and administrative capacity of SMEs to access EU-level funding or protect their intellectual property. On AI and data, large companies cited fragmented data ecosystems and lack of data access, whereas SMEs raised a more foundational concern: a lack of information and knowledge within companies about AI implementation and compliance. On biosecurity, SMEs and NGOs specifically raised dual-use risks, a concern not prominently voiced by large companies.

At intervention level, the assessment of impacts further document that SMEs face higher per-unit compliance costs across clinical trials, IP management and biosecurity screening relative to their size, reflecting their limited in-house regulatory and legal capacity compared to large firms.

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(3) ASSESSMENT OF IMPACTS ON SMEs[423]
What are the estimated direct costs for SMEs of the interventions?[424]
Qualitative assessment
The European Biotech Act proposal does not impose new mandatory costs on the general biotechnology SME population. The one exception which is biosecurity screening is targeted at a specific, narrow sub-sector of SME operators (nucleic acid synthesis providers) where the obligation is proportionate to the public security objective, and where many providers already screen voluntarily. For all other SMEs, the Act generates either net cost reductions through regulatory simplification or access to new voluntary support instruments.
Quantitative assessment
The only new mandatory direct cost falling on SMEs is biosecurity screening for nucleic acid synthesis providers: EUR 7.3 to 22.2 million per year across the approximately 77 EU custom synthesis providers not currently screening (approximately EUR 95,400 per provider per year). Customer-side compliance costs for SME research organisations ordering synthesis services add a further EUR 16.4 million per year across the user base. All other cost items under the interventions are either voluntary or generate net reductions relative to the baseline.
What are the estimated direct benefits/cost savings for SMEs of the interventions[425]?
Qualitative assessment
The European Biotech Act proposal delivers benefits to SMEs across four channels. First, regulatory simplification reduces per-unit compliance costs that fall disproportionately on smaller firms lacking in-house regulatory affairs capacity: ATMP framework reforms, biosimilar CES removal, VMP GMO pathway consolidation, and clinical trial harmonisation all reduce the absolute cost and time burden of regulatory engagement for SME sponsors and developers. Second, shared infrastructure under Articles 32 and 33 converts prohibitive firm-level capital expenditure (currently unaffordable for 82% of SMEs) into pooled access to GMP-compliant pilot and testing environments, addressing delays of up to 18 to 24 months in accessing pilot-scale capacity. Third, Article 31 AI guidance has the potential to reduce costly bilateral EMA qualification interactions by providing freely accessible public guidance, a measure whose value is asymmetrically concentrated in smaller actors that cannot absorb bilateral engagement costs. Fourth, the EU Health Biotechnology Support Network reduces search and navigation costs for SMEs across regulatory pathways, funding instruments and investor connections, with comparable network support associated with a 14-percentage point advantage in knowledge sharing and collaboration capability over unsupported firms.
Quantitative assessment

[423] The costs and benefits data in this annex are consistent with the data in annex 3. The measure include the mitigating measures listed in section 4 of this annex.
[424] Direct costs as well as direct benefits and cost savings for SMEs resulting from the different interventions are quantified in Annex 3 (Who is affected and how) and in the sections assessing the impact of respective interventions (see also the sections analysing impact per policy measure in the Rapid Assessment Study – forthcoming).
[425] The direct benefits for SMEs can also be cost savings.

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Clinical trial administrative savings: EUR 2,700 to 4,500 per multinational trial (15 to 25% through alone a reduction in the staff time for regulatory interactions. On an aggregated level, cost savings of EUR 1.5 to 3.1 billion per year across EU sponsor expenditure are expected, with administrative costs currently representing 11 to 29% of total trial costs, a burden falling proportionally harder on SMEs.

ATMP framework reforms: elimination of the additional 50-day assessment period and reduction of substantial modification timelines from 96 to 47 days; ERA exemptions remove 0.15 to 0.3 FTE-years per clinical trial application across a developer base of which over 60% are SMEs.

Biosimilar CES removal: EUR 19 to 26 million in direct trial cost savings per product, shortening development timelines by 12 to 24 months; aggregate annual savings of EUR 222 to 467 million across 12 to 18 marketing authorisation applications per year.

VMP VNRA batching: staff time saving of 14,930 to 29,859 hours per year sector-wide, equivalent to EUR 0.97 to 1.94 million per year; VMP GMO exemption saves approximately EUR 7,000 per marketing authorisation dossier.

Article 31 AI guidance: where individual EMA qualification interactions are replaced by relying on the free public guidance, 160 to 250 days could be saved per interaction, with benefit asymmetrically concentrated in SMEs.

Shared testing environments and data accelerators (Articles 32 and 33): 1,100 to 3,400 data users and 100 to 200 companies could be served per year in a medium uptake scenario (5–8 recognised testing environments and 5–8 data quality accelerators); of the 100 to 200 companies served through shared testing environments, approximately 60% are SMEs; delays of up to 18 to 24 months in accessing pilot-GMP capacity eliminated for qualifying firms.

Removed administrative burdens: EUR 1.50 to 3.32 million per year across the SME population from ATMP, VMP and biosimilar simplification measures combined.

What are the indirect impacts of this initiative on SMEs?[426]

Positive: ecosystem investment and market expansion. The strategic project recognition framework and associated investment instruments are expected to mobilise EUR 15 to 28 billion in total investment at medium uptake, generating a broader market expansion from which SMEs benefit as ecosystem participants, through increased demand for specialist services, testing, regulatory consulting, logistics and supply chain inputs.

Positive: improved competitive conditions and time to market. The cumulative effect of clinical trial harmonisation, ATMP simplification, biosimilar CES removal and VMP reforms is to compress development timelines and reduce the cost of translation from research to market across the sector. For SMEs not directly subject to these regulatory obligations but

[426] Indirect impacts on SMEs are based on the sections assessing the impact of respective interventions (including Strategic Projects, High Impact Projects, Biosimilars, SPC Extension, and Data and AI, as well as in the Access to Funding IA). See also the sections analysing impact per policy measure in the Rapid Assessment Study – forthcoming.

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participating in the value chain as contract service providers, testing laboratories, bioinformatics firms, or suppliers of inputs to larger development programmes, faster and cheaper development activity among their clients translates into increased demand and more stable revenue flows.

Positive: biosimilar market expansion. The EU biosimilar market is projected to grow at a CAGR of 17.3% from 2025 to 2034, reaching approximately EUR 55.4 billion by 2034, driven by ongoing patent expires on major biological medicines and increasing uptake of biosimilar prescribing across Member States. The biosimilar CES removal accelerates EU competitive positioning within this expanding market by reducing barriers to entry and shortening timelines. SME biosimilar developers, which form part of the EU-headquartered developer base currently holding 49% of EU biosimilar authorisations, stand to benefit from improved commercial conditions within a growing market.

Adverse: SPC extension delay for biosimilar developer SMEs. The 12-month SPC extension creates a directly adverse indirect impact for SME biosimilar developers. For marginal development programmes targeting smaller markets or carrying higher development costs, this reduction in expected return on investment may affect commercial viability at the margin. The measure benefits originator SMEs while imposing a revenue delay on biosimilar developer SMEs. Development programmes that have already advanced substantially are unlikely to be discontinued solely due to a one-year delay, but the effect on investment decisions at the margin is nonetheless to be taken into account.

(4) MINIMISING NEGATIVE IMPACTS ON SMES

Are SMEs disproportionately affected compared to large companies? (Yes)

If yes, are there any specific subgroups of SMEs more exposed than others?

Smaller firms may feel the impacts (in particularly linked to biosecurity screening requirement) more acutely due to fixed costs representing a higher share of turnover. This reflects structural characteristics of smaller firms rather than a differential obligation created by the Act, as the obligations introduced by the interventions are size-neutral by design. The biosecurity screening requirement applies uniformly to all custom nucleic acid synthesis providers, and the adverse indirect effect of the SPC extension on biosimilar developers applies equally regardless of firm size. For the broader SME population, the Act reduces rather than increases existing compliance burdens, and no provision of the preferred option imposes obligations specifically or more heavily on SMEs than on large companies. SMEs benefit proportionately more from the policy measures overall.

Have mitigating measures been included in the proposal?

EU Health Biotechnology Support Network, single points of contact with dedicated SME channels, shared infrastructure access provisions, voluntary participation design, and the proportionate scope of the biosecurity obligation.

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CONTRIBUTION TO THE 35% BURDEN REDUCTION TARGET FOR SMES
Are there any administrative cost savings relevant for the 35% burden reduction target for SMEs?
The preferred option introduces several simplification measures that generate administrative cost savings for SMEs and contribute to the EU's 35% burden reduction target. Clinical trial harmonisation reduces sponsor administrative costs by EUR 2,700 to 4,500 per multinational trial (a 15 to 25% reduction in staff time under the Standard Cost Model), aggregating to EUR 1.5 to 3.1 billion per year across EU sponsor expenditure, with SMEs benefiting disproportionately given that administrative expenses represent 11 to 29% of their total trial costs. The elimination of the ERA requirement for qualifying GMO-ATMPs removes 0.15 to 0.3 FTE-years of administrative workload per clinical trial application across a developer base of which over 60% are SMEs. The VMP VNRA batching reform saves 14,930 to 29,859 staff hours per year sector-wide (EUR 0.97 to 1.94 million per year), and the biosimilar MAA dossier simplification reduces per-application preparation costs by EUR 30,000 to 45,000 for each product transitioning to a tailored clinical package. Electronic submission and digitalisation measures contribute a further EUR 112 to 225 million cumulatively over 15 years. The establishment of single points of contact with dedicated SME channels and the EU Health Biotechnology Support Network further reduce navigational and compliance costs for smaller firms that lack in-house regulatory capacity, supporting compliance efficiency across the sector.

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