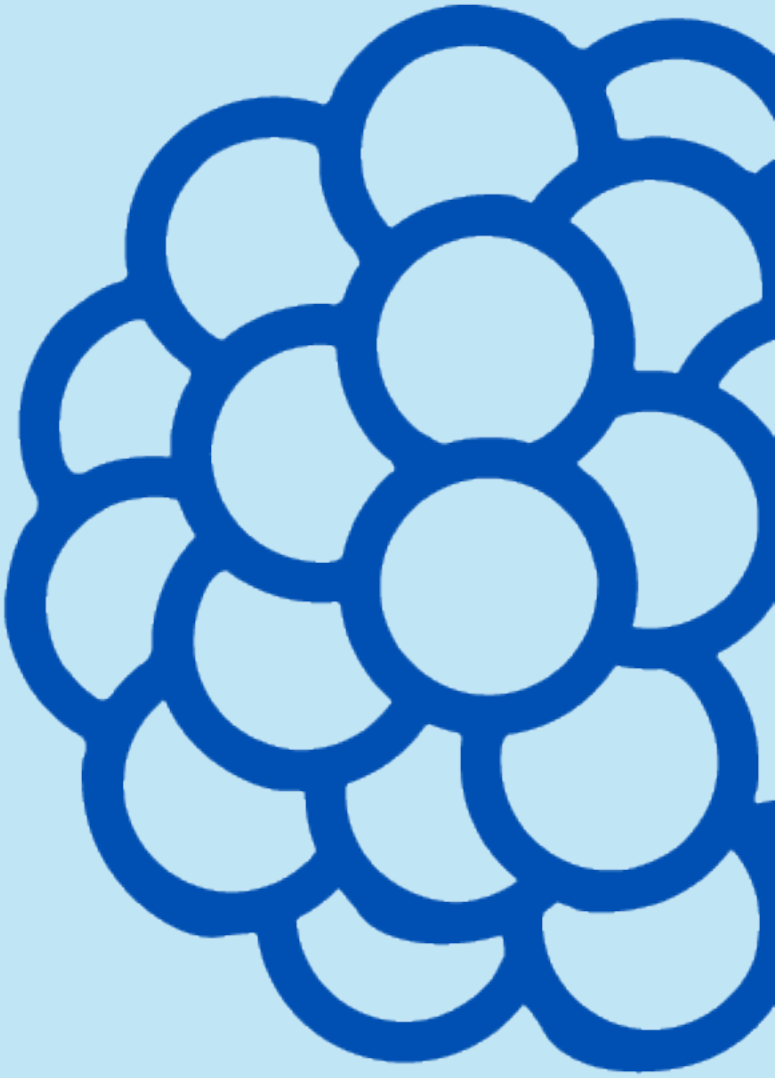
EU Biotech Act

Draft Input for the Public Consultation



hollandbio

Inhoudsopgave

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

1 General views on biotechnology

Q1. Considering biotechnology and biomanufacturing products overall, to what extent do you agree with the following:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Biotechnology and biomanufacturing products can positively impact the EU economy	( )	( )	( )	( )	(x)	( )
*Biotechnology and biomanufacturing can positively impact the EU society	( )	( )	( )	( )	(x)	( )
*Biotechnology and biomanufacturing can positively impact the environment	( )	( )	( )	( )	(x)	( )
*Biotechnology and biomanufacturing products that reach the EU market are safe and secure	( )	( )	( )	( )	(x)	( )
*Information to users and consumers on biotechnology and biomanufacturing is available and accessible	( )	( )	(x)	( )	( )	( )
*Consumes are willing to pay a price premium for biotechnology and biomanufacturing products	()	(x)	( )	( )	( )	()

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

2 The regulatory environment in the EU

Q1. Taking into account recent initiatives and legislation adopted or under discussion at EU level, to what extent do you agree with the following statement: EU rules lead to regulatory barriers for biotechnology and biomanufacturing products to reach the market in the following phases:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*In early-stage or pre-clinical development	( )	( )	( )	(x)	( )	( )
*In product development	( )	( )	( )	(x)	( )	( )
*In pre-commercial testing or clinical trials	( )	( )	( )	(x)	( )	( )
*In the assessment and in obtaining authorisation to market products	( )	( )	( )	( )	(x)	( )
*In techno-economics (outside of health) or health technology assessment	( )	( )	( )	()	(x)	( )
*In commercialising products	( )	( )	( )	( )	(x)	( )
*In scaling-up production or manufacturing	( )	( )	( )	()	(x)	( )
*In post-market activities, including monitoring and surveillance	( )	( )	( )	(x)	( )	( )

Q2. Please indicate other phases of the innovation and manufacturing cycle where there are regulatory barriers caused by EU rules. 600 character(s) maximum

European biotech companies face a complex, fragmented, and inconsistent regulatory framework, causing delays, high costs, and hampered access to the EU market. In addition to the factors already listed, barriers occur in translation, scale-up, and uptake due to fragmentation between Member States, duplicative requirements, lack of regulatory sandboxes, limited conditional approval routes, restrictive state aid rules, weak spin-out/tech-transfer pathways and non-uniform procurement, HTA and reimbursement. A single, harmonised EU route from lab-to-market would remove these frictions.

Q3. Please substantiate your statements with additional evidence on the challenges resulting from the EU regulatory environment. 600 character(s) maximum

As many reports have shown, EU biotech lags due to slow, unpredictable, and fragmented regulations (GMO, Novel Foods, clinical trials, HTA). Politicized or two-step authorisations - where EU-level approval is followed by separate national authorisation - plus fragmented Member State implementation create duplication, inconsistent requirements, high costs and multi-year delays. As an example: Novel Food procedures often take 5-7y versus 12-24m for US GRAS, resulting in biotechs to launch/scale elsewhere. And the visible result of that is investment flight and brain drain to US/Asia.

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Q4. In your view, what actions at EU level are necessary to improve the regulatory environment for biotechnology and biomanufacturing in the EU? Please substantiate your statements with views and evidence on the ways forward. 600 character(s) maximum

To reap the benefits of biotech, the EU should transition from its current precautionary principle to a proactionary or innovation principle. Sticking to today's status quo is more harmful than swiftly allowing biotech products with a positive risk/benefit profile to enter market. In addition, we must stop discriminating products based on the tech they are made with and instead look at the characteristics of the product. Finally, assign a EU Life Sciences & Biotech Office to guide harmonisation, end fragmentation and implement best practices, i.e. sandboxes, fast-tracks or early access routes.

Q5. To what extent do you agree that the EU regulatory environment in comparison with some of the countries outside of the EU…:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
… is more predictable	( )	(x)	( )	( )	( )	( )
… is less complex and clearer	( )	(x)	( )	( )	( )	( )
… leads to lower costs for complying with the regulation	(x)	( )	( )	( )	( )	( )
… enables biotechnology and biomanufacturing products to reach the market faster	(x)	( )	( )	( )	( )	( )
… ensures a higher level of safety and security	( )	(x)	( )	( )	( )	( )

Q5a. Regarding predictability: Please indicate the reasons why, and in which third- country(ies) this applies. 600 character(s) maximum

Procedures in countries such as the US, UK, and Switzerland are more predictable due to transparency about processes and close collaboration between industry and regulators. Assessors are knowledgeable and understand industry needs. There is relevant information and guidance available and opportunities for early and ongoing consultation, such as case examples and room for stakeholder input, objections, and advance meetings.

Q5b. Regarding complexity and clarity: Please indicate the reasons why, and in which third-country(ies) this applies. 600 character(s) maximum

In the EU, installing new or revising regulations often results in more complexity rather than less. F.e. many innovators find the MDR/IVDR route impossible, seeking national goat trails instead. Other legislation fails to reach goals due to political pressure that has nothing to do with safety or effectivity: pressure to reduce GPL incentives framework by MS affordability concerns, sustainability & patentability criteria in NGT legislation, and the overarching GM deadlock itself. In contrast, countries like the US, UK & Switzerland focus on clarity, streamlining & reducing regulatory burden.

Q5c. Regarding compliance costs: Please indicate the reasons why, and in which third-country(ies) this applies. 600 character(s) maximum

In the EU, the drive to eliminate risk raises the bar to become and remain compliant. Regulations such as Cybersecurity, IVDR/MDR, CSRD, and the CMA add complexity, measures and demands from industry, raising costs. Companies must perform more studies and hire external expertise, such as consultants or additional staff, to meet requirements. In contrast, countries like the US and Singapore have more proportionate requirements and lower compliance costs.

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Q5d. Regarding speed of reaching the market: Please indicate the reasons why, and in which third-country(ies) this applies. 600 character(s) maximum

In the EU, numerous review steps, under-resourced agencies, and involvement of several bodies (Commission, EMA, EFSA, notified bodies) cause long timelines and high costs. For novel foods, missing EFSA pre-notification can mean a 6-month pause and the total process often takes 3-7 years. By contrast, the US (GRAS) and Singapore offer faster, simpler, and cheaper procedures, e.g., 6-12 months for approval, one main authority handling the process and lower to no fees, reducing bureaucracy and enabling quicker market access.

Q5e. Regarding the level of safety and security: Please indicate the reasons why, and in which third-country(ies) this applies. 600 character(s) maximum

Thorough assessment for the purpose of health, safety and security is important, but the EU's current one-sided and extreme focus on safety hinders innovation. Assessment often depends on the technology used, or the novelty of product or method, not the properties of the final product. A strict risk-avoidance approach ignores the risk of inaction and missing out on benefits or improvements, keeping the status quo, such as fossil industry, in place. In contrast, regions outside of the EU focus on risk-benefit and assess the product, enabling responsible innovation.

Q6. Please indicate any other relevant factors that characterise the regulations in non-EU countries and that are applicable to biotechnology and biomanufacturing products. 600 character(s) maximum

Non-EU countries often have science-based safety regulation, rather than the EU's politicised frameworks. General legislation to bring safe products to the market suffices, building on producer's responsibility & liability instead of the EU approach to fit in innovation in outdated legislation or engage in lengthy, tech specific revisions that are too slow to catch-up. Flexible, adaptive regulatory frameworks, i.e. fast tracks, conditional approvals, sandboxes & dedicated guidance increase clarity & adaptability, fostering a innovation-savage environment & speed to market.

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

3 Access to capital

Q1. To what extent do you agree it is easy to access the following types of public investments in the EU:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Grants and subsidies (e.g. at EU level: HORIZON, EU4Health)	(x)	()	( )	( )	( )	( )
*Debt and equity instruments (e.g. European Innovation Council, European Investment Bank, Strategic Technologies for Europe Platform)	(x)	( )	( )	( )	( )	( )
*Commercialisation support	(x)	( )	()	( )	( )	( )
*Support to capacity expansion	(x)	()	( )	( )	( )	( )

Q2. To what extent do you agree it is easy to access the following types of private investments in the EU:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Angel investors	(x)	( )	( )	( )	( )	( )
*Venture capital: Start-up/early stage (Series A)	( )	(x)	( )	( )	( )	( )
*Venture capital: Expansion stage (Series B)	(x)	( )	( )	( )	( )	( )
*Venture capital: Growth stage (Series C, etc)	(x)	( )	( )	( )	( )	( )
*Debt financing	(x)	( )	( )	( )	( )	( )
*Private equity	(x)	( )	( )	( )	( )	( )
*Strategic research or sales partnerships and collaborations	( )	(x)	( )	( )	( )	( )
*Publicly listing (Initial Public Offering (IPO))	(x)	( )	( )	( )	( )	( )
*Capital markets/shareholders	(x)	( )	( )	( )	( )	( )

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*Corporate funding (from other companies in the market)	( )	(x)	( )	( )	( )	( )

Q3. In your views, are there other financial instruments relevant for the biotechnology sector in the EU?

(x) Yes ( ) No ( ) I don't know

Q3a. Please indicate other relevant private and public financial instruments. 600 character(s) maximum
Other relevant instruments include crowdfunding, philanthropic capital, innovation vouchers, milestone-based grants, export credit insurance, and government-backed guarantees. However, the greatest impact comes from creating large, broad and flexible funding opportunities with innovation-driven criteria that fit multiple business stages, rather than many niche instruments. This approach allows more companies to access support, reduces administrative burden, and better matches the dynamic needs of biotech.

Q4. Based on your experience, to what extent do you agree that the following factors drive investment in a biotechnology company?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Innovative science	( )	( )	( )	( )	(x)	( )
*Groundbreaking technology (e.g. health biotech: a breakthrough that significantly improves upon existing therapies or addresses unmet medical needs; food biotech: solution that can boost food security)	( )	( )	( )	( )	(x)	( )
*Scientific evidence, including data, concerning innovation	( )	( )	( )	( )	(x)	( )
*Access to data held by public sector bodies	( )	( )	( )	(x)	( )	( )
*Experienced management team	( )	( )	( )	( )	(x)	( )
*Robust supply chain	( )	( )	( )	(x)	( )	( )
*Regulatory certainty (e.g. length and predictability of authorisation process)	( )	( )	( )	( )	(x)	( )
*Sufficient protection of intellectual property	( )	( )	( )	( )	(x)	( )
*Financial health and projections	( )	( )	( )	( )	(x)	( )

Q5. Please indicate other factors that drive investment in a biotechnology and/or biomanufacturing company here. 1000 character(s) maximum
The most decisive driver of investment in biotechnology and biomanufacturing is return on investment (ROI). Investors are ultimately seeking financial upside, whether through revenue growth, acquisition, licensing deals, or public offerings. If a company demonstrates a credible path to profitability or a

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lucrative exit, it becomes significantly more attractive, regardless of its scientific base. In addition to the factors already listed, key factors influencing ROI include speed, costs and certainty to reach market, clear exit opportunities (most EU biotechs IPO at Nasdaq), positive market trends (large exits in EU biotech will attract more investors) and competition with others (heavily subsidized) sectors. For investors to invest, science and innovation must be paired with a compelling, bankable business case, which is heavily influenced by the overall innovation climate.

Q6. When seeking investments, is the EU a priority region under the growth strategy of the organisation you represent?

- **Yes**
- No
- I don't know

The EU is a priority for European biotech companies, as the total EU market is quite significant. Moreover, EU biotechs initially prefer to grow and scale locally, benefit from proximity to key partners, and align with EU regulations and networks.

Q7. Is the EU a priority region under your investment strategy?

- **Yes**
- No
- I don’t know

Q7a. If you would like to indicate why, you can do so here. 600 character(s) maximum

While the EU is a priority for European biotech companies seeking to grow and invest locally, the world often is their oyster. Like water, they will find the route that is the easiest to follow. If investment opportunities are lacking in the EU, or come with stricter or restricting conditions, they will seek funding elsewhere. The same goes for the regulatory climate. Currently, foreign capital is often easier to secure, and regions like the US or Singapore offer faster, more predictable approval and better returns. As a result, the EU is not always able to grow their local gamechangers.

Q8. Please substantiate your statements with additional evidence on the challenges related to access to finance in the EU. 600 character(s) maximum

EU biotech faces a persistent investment gap, especially in scale-up (“valley of death”). EU has fewer large investors (>€1B AUM) and fragmented capital markets (Boston vs. EU-wide). Large funding rounds are hard to do in the EU with EU Capital. There is a difference in ticket sizes between EU and abroad. For example, the average US round is almost $100M, and in the EU its closer to $50M (e.g. Upside $161M versus Meatable $35M & Xaira $1B versus Cradle $24M, https://www.drugdiscoverytrends.com/biotech-funding-landscape-2023/). European biotechs often list on Nasdaq not EU exchanges (e.g. Genmab, Pharming, New Amsterdam, UniQure, Merus). This limits growth, innovation, and global competitiveness.

Q9. In your view, what actions at EU level are necessary for the public sector to attract/derisk private investments in biotechnology and/or biomanufacturing? 600 character(s) maximum

Make biotech start- and scale-ups more attractive for private investors and institutions to invest in, for example by offering capital matching and tax incentives for private investments and creating a stable and predictable business climate with clear rules and regulations and a strong IPO market. Focus on reducing risk and increasing risk appetite instead of just injecting more public money. The more successful the investment climate and business ecosystem, the easier it will be to mobilize private capital and encourage long-term investor engagement.

Q10. In your view, what actions at EU level are necessary to prioritise funding for high-risk and high-reward biotechnology research and innovation? 600 character(s) maximum

Breakthrough biotech innovation is inherently risky. To attract high-risk, high-reward investments, the EU must and act on both levers it can influence: reduce external risk and increase potential returns. Ideally that means creating a climate where only technological risk remains. Think of expanding

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dedicated and flexible EU funds that fit the needs of biotech (e.g. EIC for deeptech), relaxing state aid and "undertaking in difficulty" rules so biotechs can qualify for subsidies and grants, and de-risking demand through innovation-oriented procurement (such as the COVID purchasing agreements).

Q11. In your view, what other actions are necessary at EU level? 600 character(s) maximum

The EU must ramp up its risk appetite to unlock biotech's full potential. Enable ambitious companies, and especially SMEs, to scale by making funding accessible, flexible, and innovation-driven and creating a globally competitive and EU-wide IPO market. Establish a central Life Sciences & Biotech Office to coordinate collaboration, simplify access to funding, and serve as a one-stop contact for investors, companies, and researchers.

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

4 Biotechnology clusters and/or cluster organisations

Q1. To what extent do you agree that biotechnology clusters and/or cluster organisations in the EU face the following barriers in order to reach their full potential?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Insufficient number of academic institutions with long standing expertise in the area of biotechnology	( )	(x)	( )	( )	( )	( )
*Insufficient presence of industrial players	( )	(x)	( )	( )	( )	( )
*Insufficient higher education or vocational training institutions	( )	(x)	( )	( )	( )	( )
*Insufficient startup incubators or business support infrastructure (providing for example regulatory affair support)	( )	( )	(x)	( )	( )	( )
*Lack of technology transfer offices	( )	( )	(x)	( )	( )	( )
*Incapacity to reach a critical mass of stakeholders	( )	( )	( )	( )	(x)	( )
*Insufficient public support	( )	( )	( )	( )	(x)	( )
*Insufficient collaboration among existing clusters	( )	( )	( )	(x)	( )	( )
*Insufficient financial support	( )	( )	( )	( )	(x)	( )

Q2. Please indicate other factors impacting biotechnology clusters and/or cluster organisations in the EU. 1000 character(s) maximum

The EU landscape is scattered with numerous cluster organisations, often subsidized by regional authorities and/or grants to focus on regional development rather than sector-wide priorities. While there are many incubators, business support infrastructures, and TTOs, their sector knowledge, quality and effectiveness are often not impactful. Most offer generic rather than specialised support that not always fits biotech needs. Lack of knowledgeable staff, short-term or insufficient funding, regional competition instead of collaboration and limited mandate restricts their impact. Subsidy criteria often prioritise collaboration over expertise and added value and focus on technology push rather than societal pull. Lack of coordination and benchmarking leads to duplication of efforts and missed opportunities for knowledge and best practises sharing, hindering growth and competitiveness. As a result, the effective support ecosystem lacks that we need to scale smart ideas to societal impact.

Q3. Please substantiate your statements with additional evidence on the challenges faced by biotechnology clusters and/or cluster organisations in the EU. 600 character(s) maximum

EU incentives often aim to strengthening weaker areas, rather than investing in strengths. Programs like EFRO and Interreg focus on regional development, and grants like Twinning aim to boost weaker regions, but support to sustain and build on excellent clusters is lacking, leaving flourishing science parks underfunded. The landscape is scattered: a small country like The Netherlands counts 12+ regional science parks, with their own regional development office, TTO and multiple cluster organisations that are often competing to attract companies, funding, talent etc, instead of collaborating. Regional funding schemes differ widely, causing unequal access and inefficiency. As a result, companies may miss out on funding if their activities don't fit local priorities.

Q4. In your view, what actions at EU level are necessary to enhance the impact of biotechnology clusters and/or cluster organisations in the EU? 600 character(s) maximum

To enhance the impact of biotechnology clusters and cluster organisations, the EC should promote an integrated, EU-wide approach with clear focus and strategic choices. Encourage knowledge sharing and benchmarking between support organisations to avoid duplication and raise quality. Prioritise quality and sector-specific expertise in incubators, support infrastructures, and TTOs. Align funding and policies to reward real innovation and leverage regional strengths, rather than spreading resources too thinly.

Q5. In your view, what actions at EU level are necessary to create more synergies between existing clusters and/or cluster organisations and facilitate pooling of expertise and resources in the EU? 600 character(s) maximum

To create more synergies and pool expertise, the EU should implement integrated biotech policy with clear leadership, such as a dedicated EU Life Sciences and Biotech DG and Office. Avoid adding new layers or complexity; instead, coordinate existing clusters and support organisations, promote knowledge sharing and benchmarking, and focus resources on quality and region-specific strengths to maximise impact. National biotech strategies, such as the one in The Netherlands, can help to guide regional support along national ambitions, reduce disparities, and boost sector-wide success.

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

5 Biotechnology manufacturing

Q1. To what extent do you agree that biotechnology manufacturing in the EU faces the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Length and/or complexity of permitting processes for new facilities	( )	( )	( )	( )	(x)	( )
*High cost of raw material and/or of the operations	( )	( )	( )	( )	(x)	( )
*High energy costs	( )	( )	( )	( )	(x)	( )
*Other operational costs	( )	( )	( )	(x)	( )	( )
*Limitations in logistics and physical infrastructure	( )	( )	(x)	( )	( )	( )
*Vulnerabilities in supply chains and strategic dependencies	( )	( )	( )	( )	(x)	( )
*Labour costs	( )	( )	( )	(x)	( )	( )
*Inconsistent environmental and sustainability policies or lack of a policy	( )	( )	( )	( )	(x)	( )
*Taxation and customs barriers (e.g. tax credits, import duties)	( )	( )	( )	(x)	( )	( )
*Global competition	( )	( )	( )	( )	(x)	( )
*Difficulty scaling up from pilot to industrial production	( )	( )	( )	( )	(x)	( )
*Maintaining product quality and consistency at scale	( )	( )	( )	(x)	( )	( )

Q2. Please indicate other challenges impacting biotechnology manufacturing in the EU. 600 character(s) maximum

Other challenges impacting biotechnology manufacturing in the EU include fragmented and unpredictable regulatory implementation across Member States, lack of harmonised standards for new bioprocesses, insufficient support for technology transfer and scale-up, limited access to pilot and demonstration facilities, inadequate and scattered funding, slow policy adaptation and a shortage of targeted demand-

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

side incentives (such as public procurement or CO_2-based pricing) to stimulate market uptake of innovative biotech products.

Q3. Please substantiate your statements with additional evidence on the challenges impacting biotechnology manufacturing in the EU. 600 character(s) maximum

Sector leaders and reports confirm that fragmented and unpredictable regulation, slow and misaligned funding, and lack of infrastructure for scale-up and pilot production are key barriers. These missing preconditions drive manufacturing to more attractive regions outside the EU. Well-known companies have relocated production due to high costs and regulatory hurdles.

Q4. In your view, what actions at EU level are necessary to enhance the impact of biotechnology manufacturing in the EU? 600 character(s) maximum

To enhance biotechnology manufacturing in the EU, all essential preconditions must be in place: harmonized and simplified regulation, access to resources (affordable energy, feedstock, human capital), sufficient pilot and demonstration infrastructure, sufficient and suitable financing, and targeted market incentives. Only when these conditions are met, will Europe remain attractive for biotech manufacturing. Without them, companies will continue to relocate production to regions where these preconditions are present.

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

6 Availability, upskilling and reskilling the biotechnology workforce

Q1. To what extent do you agree that the EU workforce for biotechnology faces the following challenges?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Shortage of vocational skills especially for biotechnology and biomanufacturing (e.g. lab technicians, operators, etc.)	( )	( )	( )	(x)	( )	( )
*Insufficient STEM education graduates (STEM: Science, Technology, Engineering, Mathematics)	( )	( )	( )	(x)	( )	( )
*Insufficient research and technical skills	( )	( )	( )	(x)	( )	( )
*Insufficient regulatory and quality assurance expertise	( )	( )	( )	(x)	( )	( )
*Insufficient digital and data science skills	( )	( )	( )	(x)	( )	( )
*Insufficient intellectual property skills	( )	( )	( )	(x)	( )	( )
*Limited financial, entrepreneurial skills and mindsets	( )	( )	( )	( )	(x)	( )
*Other	( )	( )	( )	(x)	( )	( )

* Limited knowledge of career opportunities (e.g. lack of role models and (entrepreneurial) career examples, unclear career paths, limited outreach to students and young professionals)

Q2. Please indicate other challenges faced by the workforce for biotechnology in the EU. 600 character(s) maximum

In addition to the challenges already mentioned, other challenges include limited opportunities for hands-on training at commercial-scale facilities, fragmented education and training ecosystems, slow adaptation of curricula to new technologies, and difficulty attracting and retaining talent due to global competition. There is insufficient collaboration between academia and industry to align skills with actual workforce needs and entrepreneurship is rarely recognized as a valid career path during academic training, which discourages scientists from pursuing opportunities in biotech industry.

Q3. To what extent do you agree that the following factors lead to the EU workforce facing the above-mentioned challenges?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Difficulty in attracting, developing and retaining global talent	( )	( )	( )	(x)	( )	( )
*Misalignment between education and industry needs	( )	( )	( )	(x)	( )	( )
*Regional disparities in the availability of skilled workers in the EU (for example as a result of brain drain or lack of availability of training courses)	( )	( )	( )	(x)	( )	( )
*Insufficient public and private investment in skilled workforce	( )	( )	( )	(x)	( )	( )

Q4. Please indicate other factors leading to the EU workforce facing the above-mentioned challenges. 1000 character(s) maximum

Key factors include limited collaboration and siloed approaches between academia and industry, and especially SMEs, which hinder the alignment of training with real-world needs. Careers in industry are often undervalued compared to academic paths, making biotech R&D and manufacturing less attractive. The sector is often only known within specific circles, and there is a lack of inspiring, realistic, and visible career perspectives for young people and career switchers, leading to talent shortages.

Q5. Please substantiate your statements with additional evidence on the challenges faced by the workforce for biotechnology in the EU. 600 character(s) maximum

Breakthroughs in biotechnology are often realized outside the EU due to missed opportunities for valorisation and entrepreneurship. While academic research in biotech is strong, the industry faces shortages of skilled talent due to fragmented and outdated training that adapts too slowly to new technologies. Limited collaboration between academia, industry, and government means workforce skills often do not match industry needs, hampering innovation and talent retention.

Q6. In your view, what actions at EU level are necessary to enhance specialised training programmes/curricula? 600 character(s) maximum

To enhance specialised training programmes and curricula, the EU should support hybrid learning environments, hands-on internships, and close collaboration between industry and (academic) education. Programmes must be regularly updated to reflect new technologies and industry needs. Public-private partnerships and exchange between academia and industry are essential to ensure skills match real-world biotech challenges and to strengthen long-term career perspectives.

Q7. In your view, what actions at EU level are necessary to enhance support for scientists to launch a business (e.g. through incubators, pilot facilities for knowledge transfer and idea testing, etc.)? 600 character(s) maximum

To enhance support for scientists launching a business, the EU should provide targeted business skills training, mentorship, and access to incubators and pilot facilities. Programmes should include entrepreneurship, IP management, regulatory affairs, and funding strategies. Facilitating industry-academia exchange and offering hands-on experience in business development will empower scientists to successfully translate ideas into biotech ventures.

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

Q8. In your view, what actions at EU level are necessary to support programmes to attract talent from other geographical areas? 600 character(s) maximum

To attract talent from abroad, the EU should create favourable conditions for working, earning, and living, such as streamlined visa processes, competitive salaries, and support for relocation. Promoting Europe as a leading biotech hub through international campaigns and showcasing success stories will boost its appeal. Making career opportunities visible and accessible helps attract and retain global biotech talent.

Q9. In your view, what other actions at EU level are necessary for the availability, upskilling and reskilling of the biotechnology workforce? 600 character(s) maximum

To strengthen the biotech workforce, the EU should invest in a compelling, sector-wide narrative that showcases biotech's societal impact and realistic career opportunities, similar to the approach in the semiconductor sector. Targeted campaigns, relatable success stories, and visible role models can inspire young people and international talent to choose biotech.

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

7 Data and Artificial Intelligence

Q1. Are you or the organisation you represent having difficulties in accessing or using relevant data for the development of biotechnology or biomanufacturing products?
(x) Yes ( ) No ( ) Partially ( ) Not applicable/I don't know

Q1a.If Yes - What barriers are you currently facing? 600 character(s) maximum
Access to relevant health and biotech data is hindered by fragmentation, lack of interoperability, and restrictive data-sharing policies. Researchers and SMEs face difficulties obtaining clinical, genomic, and real-world data due to unclear ownership, high costs, and limited public-private collaboration frameworks. Inadequate digital infrastructure and secure data platforms further limit the ability to store, process, and share large-scale biotech datasets.

Q2. Are you or the organisation you represent relying on data sourced from outside of the EU/EEA for the development of biotechnology and biomanufacturing products and services?
(x) Yes ( ) No ( ) Not applicable/I don't know

Q2a. If YES - What are the main reasons for relying on data sourced from outside of the EU/EEA?
The main reason is that the EU lacks a unified, accessible, and interoperable data infrastructure. There is data available in the EU, but these are often fragmented across multiple systems, making it difficult to access and combine for research and innovation. As a result, organizations turn to non-EU sources that provide more comprehensive, better structured, and readily available datasets, especially for clinical and genomic research.

Q2b. Please specify what the other reasons are. 600 character(s) maximum
Other reasons include restrictive data-sharing policies for industry compared to academic institutes, high administrative burden, and unclear data ownership within the EU. Technical barriers and the absence of central coordination further complicate data use. Unrestricted access and minimal bureaucracy are essential to facilitate the use of high-quality datasets. Non-EU sources often offer lower barriers and better access for researchers.

Q3. To what extent do you agree that data synthetisation is a viable means to overcome data scarcity in the EU?
(x) Strongly disagree ( ) Disagree ( ) Neutral ( ) Agree ( ) Strongly agree ( ) Not applicable/I don't know

Q4. Regarding the health biotechnology sector, are you or the organisation you represent actively preparing for the entry into application of the EHDS?
() Yes **(x) No** ( ) Not applicable/I don't know

Q4a. If YES - In what capacity does your organisation expect to be involved in the European Health Data Space? Please select the capacity(ies) that is/are most relevant for you.
N/a

Q4b. What are the specific challenges related to the implementation of the EHDS that you or the organisation you represent encounter? 600 character(s) maximum
N/a

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Q5. Which types of services of research and health data infrastructures (e.g. biobank research infrastructures) are currently used in the biotechnology sector? 600 character(s) maximum

Biotech companies can benefit a lot from i.e. data of biobanks, disease registers, use of (competitor) medicines and outcome-data. However, access to this data is often limited. Data may exist, but that doesn't immediately grant companies access for secondary use. Access may for example depend on the question of a company, its size and/or its willingness and ability to pay for access. This creates barriers for innovation. For reference, an overview of the available health (research) data for the Netherlands can be found in HealthRI's National Health data catalogue.

Q6. To what extent do you agree that the use of AI in R&D is facing the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Technological challenges, access and use of data (e.g. outdated infrastructure to support the integration of AI tools, lack of interoperability, lack of local validation (performance testing), lack of post-deployment monitoring mechanisms, lack of AI transparency and explainability etc)	( )	( )	( )	(x)		( )
*Challenges in the implementation of regulatory frameworks (e.g. complex regulatory landscapes for AI users and/or deployers, concerns over liability, concerns surrounding data security and privacy etc)	( )	( )	( )	(x)	( )	( )
*Organisational and business challenges (e.g. lack of end-user involvement in the development and deployment of AI tools, lack of added value assessment in deploying AI, lack of AI strategy for use/deployment in the entity)	( )	( )	( )	(x)	( )	( )
*Social and cultural challenges (e.g. lack of trust in AI tools, lack of digital literacy among users/deployers/the public, concerns on job security, concerns surrounding overreliance on AI tools, etc	( )	( )	( )	(x)	( )	( )

Q7. To what extent do you agree that the deployment of AI-based biotech products is facing the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Technological challenges, access and use of data (e.g. outdated infrastructure to support the integration of AI tools, lack of interoperability, lack of local validation (performance testing), lack of post-	( )	( )	( )	( )	(x)	( )

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deployment monitoring mechanisms, lack of AI transparency and explainability etc)						
*Challenges in the implementation of regulatory frameworks (e.g. complex regulatory landscapes for AI users and/or deployers, concerns over liability, concerns surrounding data security and privacy etc)	( )	( )	( )	( )	(x)	( )
*Organisational and business challenges (e.g. lack of end-user involvement in the development and deployment of AI tools, lack of added value assessment in deploying AI, lack of AI strategy for use/deployment in the entity)	( )	( )	( )	( )	(x)	( )
*Social and cultural challenges (e.g. lack of trust in AI tools, lack of digital literacy among users/deployers/the public, concerns on job security, concerns surrounding overreliance on AI tools, etc	( )	( )	( )	( )	(x)	( )

Q8. Please substantiate your statements with additional evidence on access to data, the use of AI in R&D, and deployment of AI-based biotech products in the EU biotechnology sector here. 600 character(s) maximum

Regarding data access: we follow EHDS developments closely and believe it holds promise for better data access, though we have a feeling that many of the the biotech companies in our network are not yet actively engaged. Regarding use and deployment of AI: biotech companies embrace AI in R&D when it improves speed, quality, or reduces risk. The sector is agile in adopting new tools, but deployment faces hurdles, especially in clinical use, where regulation (e.g. AI Act) adds complexity. Therefore, the EU must ensure proportionate rules and support uptake across the full value chain.

Q9. In your view, what actions at EU level are necessary to enhance the use of AI in R&D in biotechnology in the EU? 600 character(s) maximum

Use of new technologies, such as AI, in biotech R&D is driven by competitive advantage: companies adopt it when it improves outcomes. Therefore, EU action should focus on enabling responsible use, not mandating adoption. The AI Act introduces risk-based regulation similar to MDR/IVDR, which may deter launches due to increased complexity to reach the market. To stay competitive, the EU must ensure proportionate rules and monitor global developments to avoid falling behind.

Q10. In your view, what actions at EU level are necessary to enhance the deployment of AI-based biotechnology products in the EU? 600 character(s) maximum

To enhance deployment of AI-based biotech products, the EU must ensure proportionate, innovation-friendly regulation. The EU AI Act should avoid excessive burdens and make sure AI-based biotech products can reach the European market, especially for SMEs. Support for clinical validation, access to health data, and harmonised standards can accelerate adoption. It is important that the EU monitors global developments to stay competitive and avoid regulatory deadlocks.

Q11. In your view, what other actions should be prioritised at EU level related to data and AI in the field of biotechnology and biomanufacturing (e.g. on data, on use of high-performance computers (HPC), etc.)? 600 character(s) maximum

The EU should prioritise secure access to high-quality health and research data, support interoperable data infrastructures, and invest in HPC capacity tailored to biotech needs. Facilitate cross-border data

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sharing and AI training on real-world datasets. Ensure SMEs can access data, computing power and expertise. Align data governance with innovation goals to avoid overregulation and unlock AI's full potential in biotech and biomanufacturing.

Q12. The European Commission is supporting the creation of AI Factories to accelerate trustworthy AI development. AI Factories are dynamic ecosystems bringing together computing power, data, and talent to create cutting-edge AI models and applications across various sectors (e.g. health, manufacturing, climate etc.). In your views, how can the AI factories be leveraged to advance biotechnology innovation in Europe?

	Yes	No	Not applicable/I don't know
*Host public-private AI model development for biotech use cases	(x)	( )	( )
*Support validation and certification of AI tools in the biotech field	(x)	( )	( )
*Secure and high-performance processing of health data made available through the EHDS for development of innovative products and tools for the biotech sector	(x)	( )	( )
*Provide access and/or facilitate the use of high-quality datasets through 'data labs'	(x)	( )	( )
*Other	()	( )	(x)

Q12a. If you would like to indicate other factors, you can do so here. 600 character(s) maximum
Stimulate validation and uptake. AI Factories can support biotech by offering computing power, data access, and expertise, but building and funding these factories alone isn't enough. Focus should be on validating and qualifying AI applications for real-world use, not just academic pilots. Biotech provides the data fuel for AI, which in turn can provide ways to optimize biotech development. To set this collaboration off and make sure biotech becomes a favourable, priority sector for AI roll-out, AI factories must actively engage with biotech industry to translate innovation into deployment.

Q13. To what extent do you agree that the following types of support would help biotech companies, particularly SMEs, develop and deploy AI solutions more effectively in the EU?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Dedicated funding instruments for biotech-related AI research and development	( )	()	(x)	( )	( )	( )
*Access to annotated datasets (e.g. biological, clinical, genomic data)	( )	( )	( )	( )	(x)	( )
*Access to synthetic datasets	( )	( )	( )	(x)	( )	( )
*Regulatory sandboxes for testing biotech-related AI models	( )	( )	( )	( )	(x)	( )
*Partnerships with public research institutions or AI hubs/factories	( )	( )	( )	( )	(x)	( )
*Simplified IP and data-sharing frameworks	( )	( )	( )	(x)	( )	( )

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*Skills development and AI training for biotech personnel	( )	( )	( )	**(x)**	( )	( )
*Roadmaps for implementation and scalability of AI tools in the EU ecosystem	( )	( )	( )	**(x)**	( )	( )
*Other	( )	( )	( )	( )	(x)	**(x)**

Q13a. Please indicate other factors here. 600 character(s) maximum
General innovation funding is essential. If the right investment and business climate is in place, AI will naturally take off in biotech as it offers a clear competitive advantage.

Q14. If you would like to substantiate any of your statements with additional evidence on the ways forward to support the deployment and use of data and AI in biotechnology, you can do so here. 600 character(s) maximum
N/a

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8 Defence and security

Q1. To what extent do you agree that application of biotechnology in defence and security related areas faces the following challenges in the EU?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Threats related to biosecurity and biosafety, including misuse of biotechnology	( )	( )	( )	(x)	( )	( )
*Risks to strategic autonomy in biomanufacturing, and availability of medical and non-medical countermeasures	( )	( )	( )	(x)	( )	( )
*Vulnerabilities in the resilience of biotech supply chains	( )	( )	( )	(x)	( )	( )
*Insufficient civil military cooperation in biotechnology sector	( )	( )	( )	( )	(x)	( )
*Cybersecurity risks to biotech infrastructure and AI tools used in biotechnology	( )	( )	( )	( )	(x)	( )
*Other	( )	( )	( )	( )	(x)	( )

* Access to defense budgets: Biotech companies should be able to access defence budgets for dual-use innovation, as advanced biotech can contribute to both preparedness and security in many ways and increases strategic autonomy. Think of measures to treat wounds and infections, to counteract, detect and diagnose biological and chemical threats, ways to provide food security in crisis situations, new materials for protective gear, equipment and logistics.

Q2. Please indicate other challenges impacting biotechnology for defence and security in the EU. 600 character(s) maximum

Lack of expertise and knowledge of biotech, national compartmentalisation, limited room for experimental development, and scarce high-risk funding. Fragmented defence departments with rigid or ill-fitting specifications, complex procurement and small budgets create few opportunities, leading to low growth and commercial prospects. This negative feedback loop discourages new entrants and investments, as returns rarely match the risk profile, further limiting European innovation in biotech for defence and security.

Q3. To what extent do you agree that biotechnology for defence and security is creating the following opportunities in the EU?

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	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
*Facilitate detecting biological and chemical threats, including via availability of biosensors	( )	( )	( )	(x)	( )	( )
*Opportunity to revolutionise defence logistics with biotechnology products (including food) manufacturing close to its point of use	( )	( )	( )	(x)	( )	( )
*Development of new innovative medical countermeasures including vaccines and antidotes	( )	( )	( )	( )	(x)	( )
*Developments of materials with new functions and/or improved characteristic	( )	( )	( )	(x)	( )	( )
*Increased food security	( )	( )	( )	(x)	( )	( )
*Other	( )	( )	( )	(x)	( )	( )

* Biotech can also support bio-based energy solutions (biofuels), biometric security (DNA- or protein-based identification systems) and countermeasures against biological warfare (rapid response platform technologies like the mRNA vaccin).

Q4. In your view, what other actions at EU level are necessary to enhance the impact of biotechnology for defence and security in the EU? 600 character(s) maximum

Just like any application; to reap biotech impact for defence & security the EU must set up a Biotech Office to secure an integrated approach. Also, solid funding from lab to market, fitting routes to market entry, implementation and uptake are key. For defense & security purposes, learn from US organizations (ie DARPA, BARDA, Biomade) and establish an EU organization that removes hurdles & pushes a biotech for defense agenda, funding early science to scaling and implementation as well as securing end-to-end industrial biomanufacturing capabilities (technology, infrastructure, workforce).

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