Additional input to the EC public consultation on the Biotech Act

SECTION 3 – Access to capital

Question 3a – Please indicate other relevant private and public financial instruments

The EU bioeconomy needs an ambitious CBE JU to deliver on EU's Bioeconomy, competitiveness and resilience ambitions, with a bigger budget to back the efforts required to fill the 'innovation commercialization' gap effectively.

Examples of funding instruments already used and still in development or proposed:

- EIC Accelerator – Blended finance (grant + equity) for high-risk biotech SMEs.
- InvestEU – Guarantees and equity via the European Investment Fund (EIF) to de-risk biotech investment.
- InnovFin – Legacy Horizon 2020 tool offering loans, equity, and guarantees for biotech innovation.
- CBE-JU / IHI – Public-private partnerships supporting industrial and health biotech scale-up.
- Innovation-oriented public procurement – EU and national levels to create early markets for biotech (not enough explored).
- TechEU Platform (EIB Group) – to simplify access to €250bn in equity, loans, and guarantees for innovation.
- European Tech Champions Initiative (ETCI) – Pools EU and Member State capital to support late-stage biotech scale-ups.
- European Competitiveness Fund (MFF 2028+) – Proposed to support critical technologies, including biotech, across the innovation cycle.
- Scale-Up Europe Fund – Proposed €10bn public-private fund to address the growth-stage funding gap in biotech and deep tech.

Question 5 - Please indicate other factors that drive investment in a biotechnology and/or biomanufacturing company

The EU enzymes market is worth 2 billion EUR with significant benefits for performance and sustainability across industries: Enzymes add value for food & feed, laundry & homecare with a huge untapped potential. Yet, outdated regulations, such as restrictions on enzymes under the GRA of REACH or the current GM framework for microorganisms, jeopardise continued EU innovation and growth. A simplified & streamlined regulatory framework based on risk, not hazard, can lead to sustainable growth & further investment.

Question 8 – Please substantiate your statement with additional evidence on the challenges related to access to finance in the EU

The EU capital markets are fragmented and risk-averse and require deeper integration (as underlined in the Letta and Draghi reports). This limits access to finance for innovative sectors such as biotechnology. Integration is key to mobilise private investment at scale, spread risk more effectively across EU and strengthen Europe's global competitiveness. As highlighted by Letta and Draghi, a truly integrated capital market would provide long-term funding needed to accelerate innovation and sustainable growth.

Specifically on biopolymers, EIB and other funding programs do not support innovations using plant sugars as feedstock on the unfounded grounds of food security.

The problem is appropriate support along the development chain. Many promising innovations are supported up to TRL 5-7 (e.g. by Horizon Europe). But especially in biotechnology, the investment in the TRL 7+ technology maturity is particularly risky. There is a lack of suitable funding programs (e.g. similar to the Innovation Fund for low carbon technologies) and the linking of these so that the entire development chain is mapped.

Question 9 – In your view, what actions at EU level are necessary for the public sector to attract/ derisk private investments in biotechnology and/or biomanufacturing?

- Enhance regulatory clarity,
- Increase incentives,
- Establish a Biotech for Europe Initiative,
- Establish a Biotech and Life Sciences Index (EU biotech NASDAQ),
- Maintain strong intellectual property rights, and accelerate the roll-out of the Unified Patent System,
- Expand the scope of public procurement for bio-based products and biotech applications outside of healthcare.

Besides a predictable regulatory framework to accelerate scale-up of biotechnology and biomanufacturing, public intervention is needed to de-risk advanced TRL innovations and capacity investments, for example, through financial guarantees.

Setting up dedicated market pull measures to grow this sector is also critical. These could include public procurement, as well as the setting of targets to further develop the market and incentivize companies.

- Coordinate EU and national funding under a single framework to align eligibility, timelines, and ensure national public grants do not distort competition by requiring companies to withdraw operations from other Member States.
- Expand InvestEU guarantees and EIF risk-sharing to support biomanufacturing scale-up.
- Use innovation-oriented public procurement to create early demand, guided by sustainability and technological sovereignty criteria.
- Maintain robust IP protection and complete implementation of the Unitary Patent Court to strengthen investor confidence and cross-border enforcement.

Question 10 – In your view, what actions at the EU-level are necessary to prioritise funding for high-risk and high-reward biotechnology research and innovation?

The Strategic Technologies for Europe Platform (STEP) is a good platform for highlighting high-risk and high-reward biotechnology research and innovation. Combined with a funding strategy covering the whole development chain and evaluation steps at critical points in the innovation process, it could help to prioritize and speed up biotechnology research and innovation.

- **Prioritise translational research, tech transfer, and commercialisation**, in line with the Knowledge Valorisation Framework, to bridge the gap between discovery and deployment.
- **Expand shared technology infrastructures** (e.g. pilot biomanufacturing facilities) to reduce capital intensity and scale-up risk for SMEs.
- **Leverage CBE-JU** to support industrial biotech translation, particularly in sustainable materials and bio-based processes.
- **Use IPCEI** to address market failures in strategic biotech areas, enabling coordinated national and EU-level funding.
- **Deploy STEP** to identify and label breakthrough biotech projects with the STEP Seal, enabling access to pooled EU funding from Horizon Europe, InvestEU, and national programmes.
- **Ensure STEP enables cluster integration** across biotech, clean tech, and digital tech, such as AI, supporting cross-sectoral innovation and shared infrastructure.
- **Align national innovation policies** with STEP priorities through a European Forum structure.

- **Support regional biotech ecosystems** through initiatives like the Baltic Biotech Action Plan and Regional Innovation Valleys.

Question 11 – In your view, what other actions are necessary at the EU-level?

- **Complete the Single Market** by harmonising market, product and services regulations to remove non-tariffs trade barriers within the EU and deliver innovation on a European scale.
- **Complete and leverage the Savings and Investments Union** to unleash capital into innovative projects.
- **Establish an EU Innovation Forum**

  A permanent coordination platform should be created to align EU and national R&I programmes, pool investments, and monitor implementation. This would build on the Commission's coordination role under the Strategic Technologies for Europe Platform (STEP).
- **Harmonise procurement, tax, and IP practices**

  Fragmentation in procurement rules, tax incentives, and IP enforcement limits biotech scale-up. The Commission's Innovation Procurement Guidance and benchmarking of national frameworks highlight the need for harmonisation.
- **Standardise licensing and spin-off terms**

  The EU should promote model agreements for licensing and spin-offs, inspired by ETH Zürich. A recent Commission report recommends simplifying IP frameworks and aligning university equity stakes with those of investors.
- **Improve talent mobility and incentives**

  Improve the EU Blue Card scheme to attract global biotech talent, offering clear timelines for visa application status updates to companies. Promote best-practice employee stock ownership plans (ESOPs), exploring, for example, the Non-Optional initiative. These are essential to retain founders and incentivise scale-up teams, especially in deep tech sectors.
- **Complete the Single Market and advance the Savings and Investment Union:** Market fragmentation and underdeveloped capital markets remain major barriers.

Section 4 - Biotechnology clusters and/or cluster organisations

Question 1 – 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?

Considerations not fully captured in the tabled answers:

- **Insufficient industrial presence**

  SMEs often relocate to the US for commercialisation, as large industrial players tend to invest there rather than in EU biotech clusters. More visible opportunities for both SMEs and larger companies.

- **Incubators and business support infrastructure limited visibility and fragmentation**

  While incubators and regulatory affairs support exist, they are fragmented and poorly visible. Some Member States excel, while others lack access entirely.

- **Cluster collaboration gaps**

  Biotech clusters collaborate actively among themselves but lack strong integration with other strategic sectors such as AI, medtech, and manufacturing.

- **Technology transfer office (TTO) challenges:**
  - Many TTOs exist but often lack biotech-specific expertise.
  - Commercialisation is hindered by rigid institutional policies (e.g. mandatory royalties, founder share allocations).
  - Cross-border collaborations face delays due to incompatible frameworks across Member States.
  - Successful models like VIB (Belgium) or ETH Zürich (Switzerland) offer scalable best practices for replication across EU regions.
  -

Section 5 - Biotechnology manufacturing

Question 1 – To what extent do you agree that biotechnology manufacturing in the EU faces the following challenges?

Additional input and considerations not fully reflected in the tabled responses:

- **Member State fragmentation**

  Energy, **logistics**, and **infrastructure** costs vary widely across the EU. Some Member States offer low energy prices and strong infrastructure, while others face high costs and limited access creating uneven conditions for biomanufacturing.

- **Taxation and customs barriers**

  Tax credits and import duties are often shaped by external dependencies, including US policy frameworks Global instability and shifting trade dynamics introduce uncertainty into supply chains, investment planning, and regulatory alignment.

Section 6 - Availability, upskilling and reskilling the biotechnology workforce

Question 5 – Please substantiate your statements with additional evidence on the challenges faced by the workforce for biotechnology in the EU.

Examples of additional evidence and references:

- **Skills Gaps in Regulatory Affairs and Bioprocessing**

  Reports from OECD highlight persistent shortages in regulatory affairs expertise and bioprocessing capabilities. SMEs also report difficulties in recruiting for quality management and dossier preparation.

- **Weakening of Basic Science Skills**

  Sector feedback indicates declining proficiency in microbiology, biochemistry, and chemistry, as training emphasis shifts toward molecular biology and data processing.

- **Talent Retention and ESOP Fragmentation**

  A European Parliament study (June 2025) confirms that tax fragmentation across Member States creates high compliance costs and barriers to cross-border mobility, undermining retention strategies like stock options.

- **Regional Disparities and Training Gaps**

  The European Innovation Scoreboard 2025 shows persistent divides between innovation hubs and lagging regions, with biomanufacturing training particularly underdeveloped in moderate and emerging innovator countries.

- **Skills Shortages as Investment Barriers**

  The EIB Investment Report 2024/25 identifies workforce skills shortages as a top obstacle to biotech investment, especially in less competitive regions.

- **Call for Upskilling in Biomanufacturing**

  Initiatives such as those from EIT Manufacturing emphasise the urgent need for targeted upskilling and reskilling pipelines to support industrial biotech growth.

Section 7 – Data and Artificial Intelligence

Question 1a – If yes, what barriers are you currently facing?

EuropaBio's member companies face barriers including fragmented data sources, inconsistent access rules across Member States, and lengthy or unclear approval processes for secondary data use. Limited interoperability, variable data quality, and uncertainty around the protection of commercially sensitive information also hinder effective use. Greater harmonisation, transparency, and legal clarity are needed to enable responsible, innovation-driven data use in biotechnology and biomanufacturing, including addressing:

- **Fragmented data ecosystems**

  Health, genomic and environmental datasets remain siloed under incompatible formats and consent rules.

- **GDPR and AI compliance uncertainty**

  Differing national interpretations slow access to pseudonymised or secondary-use data. AI Act obligations (risk classification, transparency) are complex and resource-intensive for startups and SMEs.

- **Limited AI-ready datasets for life sciences**

  Few structured, annotated, high-quality life-science datasets for model training.

- **High compute costs**

  SMEs lack affordable infrastructure to develop or validate AI tools.

- **Talent shortage**

  Shortage of data scientists and AI engineers with biotech domain expertise. Academia-industry mobility remains low.

Moreover, the inclusion of digital sequence information (DSI) under national access and benefit-sharing (ABS) frameworks in several countries (e.g. Brazil, India, Kenya) poses a growing challenge for research and innovation. Many biotechnology applications rely on reference sequences originating from multiple countries, and bilateral approval procedures would significantly delay or even prevent access. In addition, around half of the DSI entries in public databases lack clear information on geographical origin, making compliance with bilateral ABS frameworks practically unworkable. This underlines the need for a multilateral, transparent, and practicable solution that ensures benefit sharing while safeguarding open access to genetic data. The framework conditions agreed at COP16 are a first step, but further clarification and harmonisation are necessary to ensure legal certainty and continued data use for innovation.

Fragmented and non-interoperable data infrastructures, divergent GDPR interpretations, and uneven AI Act implementation hinder data access and reuse. The European Health Data Space could improve secondary use of health and genomic data, but inconsistent national rules and slow setup of access bodies risk further fragmentation. Harmonised governance and trusted intermediaries are vital for secure, innovation-friendly data use.

Question 3 – To what extent do you agree that data synthetisation is a viable mean to overcome data scarcity in the EU?

EuropaBio's pharma members view data synthetisation as a promising complementary tool to help address data scarcity and support research, particularly when access to real-world or patient-level data is limited. However, synthetic data should not replace high-quality, real-world datasets. Its usefulness depends on transparency of methods, validation standards, and regulatory acceptance to ensure reliability for research and innovation.

Question 4b – What are the specific challenges related to the implementation of the EHDS that you or the organisation you represent encounter?

EuropaBio's members support the EHDS goal of enabling secure and interoperable health data use but face challenges including unclear access conditions for industry, inconsistent implementation across Member States, and lack of harmonised data standards. Stronger protection for commercially sensitive information, proportional administrative processes, and alignment with GDPR and other EU data laws are essential to ensure innovation, legal certainty, and patient benefit.

- **Legal clarity and data access conditions**

  There remains significant uncertainty regarding how "data users" such as pharmaceutical and biotechnology companies will be granted access to health datasets. The draft framework lacks sufficient clarity on access criteria, permitted purposes, and the process for secondary use authorisations. Ambiguity risks creating uneven implementation across Member States and discouraging cross-border research.

- **Protection of commercially sensitive information (CSI)**

  The proposed data sharing obligations must ensure robust safeguards for trade secrets, proprietary methods, and pre-commercial data. Without clear guarantees for CSI protection, innovation incentives and EU competitiveness could be undermined.

- **Data quality, interoperability, and standardisation**

  The current fragmentation of health data infrastructure and the absence of harmonised data quality and interoperability standards pose major challenges. The EHDS will only deliver value if datasets are consistent, high-quality, and usable for research and regulatory purposes.

Lack of fully harmonised technical and semantic standards for health, genomic, and clinical trial data delays cross-border exchange.

- **Governance and implementation consistency**

  The roles and capacities of national health data access bodies may vary widely, potentially leading to inconsistent application, timelines, and costs across Member States. A centralised EU coordination mechanism and clear operational guidance will be essential.

- **Proportionality and administrative burden**

  The administrative and compliance obligations for data access requests, documentation, and reporting could become disproportionate, especially for SMEs and early-stage biotech companies. Streamlined and digitalised procedures are needed to avoid deterring participation.

- **Alignment with existing frameworks**

  The EHDS must be coherently aligned with the GDPR, Clinical Trials Regulation, Data Governance Act, and Data Act. Divergent interpretations or overlapping obligations risk creating legal uncertainty and additional compliance complexity.

- **Secondary-use uncertainty**

  Unclear definitions of "public interest" and "scientific research" under EHDS vs. GDPR.

- **Limited human resources**

  Shortage of data-protection officers, health-data stewards, and AI specialists trained in biomedical data governance.

- **Interoperability gaps: Infrastructure gaps**

  Insufficient secure data-storage and compute nodes certified for EHDS use, especially in smaller Member States.

As evidenced above, major challenges include fragmented national implementation, differing interpretations of GDPR, and uncertainty around governance of secondary data use. Slow establishment of health data access bodies and limited interoperability between sectors hinder practical use. Clear guidance on data standards, consent management, and alignment with the AI Act are essential to ensure legal certainty and promote responsible innovation under the EHDS. Further barriers include insufficient compute and storage infrastructure, lack of data stewardship skills, unclear IP and trade secret safeguards, and limited stakeholder coordination at EU and national levels.

In summary, EuropaBio's members emphasise the importance of a transparent, harmonised, and innovation-friendly implementation of the EHDS that ensures both the protection of personal and commercial data and facilitates responsible access for research and innovation to improve patient care in Europe.

Question 8 – 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

- **Computer and cost barriers**

  The OECD *AI Policy Observatory* notes that European SMEs face disproportionate costs for compute and cloud resources, slowing AI scaling.

- **Regulatory complexity**
  The European Commission's 2024 *Study on the deployment of AI in healthcare* warns of overlapping legal frameworks (AI Act, GDPR, EHDS) and the absence of unified guidance: (Study on the deployment of AI in healthcare - Publications Office of the EU)
- **Validation & trust**
  EMA's *Reflection Paper on AI in the Medicinal Product Lifecycle* (2024) highlights the lack of harmonised validation standards and reproducibility criteria for AI models in medicine. (EMA Reflection Paper on the use of artificial intelligence in medicinal product life cycle)
- **Skills shortage**

  The *EIB Investment Report 2024/25* finds fewer than 20 % of EU life-science firms have in-house AI expertise, versus 45 % in the US. (EIB Investment Report 2024-25)

- **SME access & certification costs**

  Commission studies on *AI adoption in SMEs* (2024) show smaller biotech firms struggle with both cost and regulatory know-how to comply with high-risk AI provisions: (Commission launches AI innovation package)
- **Infrastructure gaps**

  The *EuroHPC Joint Undertaking Annual Report 2024* cites uneven access to high-performance computing and secure data spaces across Member States.

- **Validation & trust**

  No widely accepted, harmonised EU procedures to verify model performance/reproducibility in medicines. (EMA Scientific Guideline on the use of AI in the medicinal product life cycle)

- **Compute & secure infrastructure**
  Uneven access to certified HPC/secure data spaces. (EuroHPC JU Annual Activity Report 2024)

- **Skills gap**

  EU firms report shortages of AI talent in life sciences. Skills constraints are a top obstacle to investment. (EIB Investment Report 2024-2025)

- **SME burden & standards.** High cost of compliance/documentation for high-risk AI. Need for clearer technical standards. (OECD AI Policy Observatory)

- **Lack of AI-ready datasets**
  Fewer than 20% of EU life-science firms have in-house AI expertise, compared to 45% in the US, limiting capacity to prepare and curate high-quality, annotated datasets for model training. (EIB Investment Report 2024-2025)

Question 9 – In your view, what actions at the EU-level are necessary to enhance the use of AI in R&D biotechnology in the EU?

To enhance the use of AI in biotech R&D, the EU should focus on creating a clear and supportive ecosystem that reduces uncertainty and provides the necessary resources.

Establish EU-Wide "Regulatory Sandboxes" for Health Data: Inspired by other successful models, the EU should launch well-resourced regulatory sandboxes. These should provide researchers and companies with lawful access to large, high-quality, and diverse anonymized health datasets for training and testing AI models. This would significantly lower the barrier to entry and accelerate the development of robust and unbiased algorithms.

We acknowledge the existing recommendation to establish EU-wide regulatory sandboxes as a call to accelerate, harmonize, and adequately resource the network that is currently being built in a fragmented way. However, while the legal basis exists, the practical reality for a biotech company today is that widespread, easy access to a compliant environment for testing AI models with high-quality health data is not yet a reality. The recommendation, therefore, remains highly relevant and urgent.

Harmonize and Clarify Rules for Secondary Use of Health Data: The EU should issue clear, harmonized guidelines under GDPR for the secondary use of health data for AI R&D. This guidance should provide legal certainty for researchers on requirements for anonymization, de-identification, and patient consent, addressing the current fragmentation and legal ambiguity that stifles innovation.

Promote "Transparency-by-Design" in Funding and Grants: EU research funding programs (e.g., Horizon Europe) should incentivize or require "transparency-by-design." This would mean that projects developing AI for biotech must integrate algorithm and data transparency, bias detection, and ethical risk management into their R&D process from the outset, rather than as an afterthought.

While the EHDS regulation entered into force in 2025, its framework is not yet operational. The legal foundation has been laid, but the complex infrastructure required to make it a reality is still being built.

Transitional Period: The regulation includes a multi-year implementation period. Key provisions and the national Health Data Access Bodies that will grant access to data are still in the process of being set up.

Practical access is not yet available, which means that for a researcher or a biotech company today, a streamlined, pan-EU system to apply for and receive access to health data for R&D does not exist yet. They must still navigate the current fragmented landscape of national laws.

- **Create European AI-Biotech Testbeds**

  Joint EU–national facilities for model validation, data sharing, and regulatory sandboxes to accelerate clinical and industrial use.

- **Enable cross-cluster collaboration**

  Link biotech, digital, and manufacturing clusters across Member States through Horizon Europe and the European Innovation Council; co-fund shared data spaces and AI pilot projects.

- **Standardise data access**

  Ensure EHDS and research infrastructures adopt harmonised, FAIR data models for training and testing AI tools.

- **Support SME adoption**

  Provide compute vouchers, simplified conformity-assessment guidance under the AI Act, and shared cloud/HPC access.

- **Invest in skills**

  Expand Erasmus+ and Pact for Skills programmes for AI–biotech training, integrating technical and regulatory modules.

- **Public procurement incentives**

  Include AI-driven bioprocess optimisation and health-data analytics in EU innovation procurement roadmaps.

- **Ensure regulatory coherence**

  Align AI Act, EHDS, and Data Act requirements to streamline compliance for biotech applications.

Strengthen biotech-AI capabilities within the EDIH network: Leverage and expand the existing network of 163+ European Digital Innovation Hubs by establishing dedicated biotech-AI specialisation tracks within strategically selected EDIHs, co-funded through Horizon Europe and the Digital Europe Programme. These specialised hubs can deliver tailored, one-stop-shop services for biotech SMEs and startups, including: streamlined access to EuroHPC AI Factories and high-performance computing resources; practical regulatory guidance on AI Act and EHDS compliance; federated access to health and genomic datasets; AI model validation and testing facilities; and integrated business acceleration and scale-up support. This approach maximises

the impact of existing EU infrastructure while addressing the unique convergence challenges of AI and biotechnology.

Support the development of FAIR-compliant, AI-ready biodata repositories for genomic, proteomic, metabolomic, clinical, and imaging data, with standardised annotation, quality labels, and federated access mechanisms. These repositories should enable lawful secondary use of health and research data under EHDS and GDPR frameworks, providing researchers and biotech companies with streamlined, privacy-preserving access to diverse, high-quality datasets for AI model training, validation, and benchmarking across borders. Integrate these repositories with existing EU research infrastructures (ELIXIR, BBMRI-ERIC, Euro-BioImaging) to maximize interoperability and coverage.

Launch a dedicated Pact for Skills initiative targeting AI-biotech convergence, including joint academic-industry PhD programmes, short-term AI upskilling for biotech professionals, and mobility schemes to retain and attract global AI-biotech talent.

Question 10 – In your view, what actions at EU-level are necessary to enhance the use of AI in R&D in biotechnology in the EU?

To enhance AI use in biotech R&D, the EU should incentivize adoption of FAIR data principles—making data Findable, Accessible, Interoperable, and Reusable. This includes funding for structured data infrastructure, harmonized metadata standards, and secure data-sharing frameworks. Support for cross-sector collaboration and AI-ready datasets will accelerate innovation and deployment of biotech solutions

- **Establish AI-biotech testbeds and sandboxes** under the *Digital Europe Programme* and *Horizon Europe Cluster 1 & 4* to test AI in clinical research, manufacturing, and regulatory decision-support with competent authorities.
- **Interconnect EU clusters**

  Foster cross-cluster collaboration among biotech, digital, and manufacturing ecosystems through the *European Cluster Collaboration Platform* and EIC networks, enabling the co-development of datasets, algorithms, and standards.
- **Harmonise data standards and access**

  Ensure the *European Health Data Space (EHDS)* and *European Research Data Commons* adopt interoperable, FAIR-compliant metadata and access procedures for AI model training.
- **Support SMEs through infrastructure and cost relief**

  Expand *EuroHPC* access and launch compute vouchers for SMEs. Provide simplified conformity assessment and guidance for AI Act compliance.
- **Public procurement for AI adoption**

Include AI-enabled biomanufacturing, diagnostics, and sustainability applications in EU innovation procurement roadmaps (as done under "Buy Social" and "Green Deal" frameworks).

- **Strengthen digital skills and AI literacy in the biotech workforce**

  Develop cross-disciplinary training programmes integrating AI, regulatory science, and biotechnology under initiatives like *EU4Health* and *Horizon Europe Partnerships*. Upskilling researchers, clinicians, and SMEs will accelerate responsible AI adoption and improve collaboration between digital and life sciences experts.

- **Facilitate investment and blended finance for AI-biotech innovation**

  Mobilise instruments from *InvestEU*, *EIC Fund*, and *European Innovation Council Accelerator* to co-finance scale-up of AI-based biotech startups and cross-sector innovation hubs. Encourage public–private partnerships that share risk and accelerate market entry of novel AI-enabled therapies, diagnostics, and biomanufacturing solutions

- **Embed sustainability and ethical frameworks** into AI-biotech development. Ensure that AI applications in biotechnology adhere to the *EU AI Act*, *Ethics Guidelines for Trustworthy AI*, and sustainability objectives under the *European Green Deal*. Promote lifecycle analysis, circularity in biomanufacturing, and transparent data governance to align innovation with societal values and environmental goals.

Question 11 – In your view, what other actions should be prioritised at the EU level related to data and AI in the field of biotechnology and biomanufacturing?

In addition to FAIR data and structured infrastructure, the EU should prioritize development of biosensing probes for high-resolution data capture in biotech processes. These tools are essential for generating fine-grained, real-time datasets that fuel AI models. At IFF, we pair legacy and new data with HPC and modern algorithms, supported by robust IT systems, to accelerate AI-driven biomanufacturing.

It is key for the European Union to secure harmonized EHDS implementation. Securing data can be accessed in an efficient manner in and across all Member States. EHDS Board can mandate standardized approaches across the EU.

Framework of the GDPR and EHDS can create a single, predictable data governance system for innovators. Finalizing this coherent framework is a top priority.

For HPC, consideration should be given to the fact that many models are trained on US based cloud infrastructure. This raises the question over how easy it would be to transfer models from cloud systems to HCPs, and we recommend that the European Commission reserves it its AI plan a central role for HPCs.

- **Develop an AI–biotech talent pipeline**

Integrate AI, bioinformatics, and regulatory training into *Erasmus+*, *Marie Skłodowska-Curie Actions*, and the *Pact for Skills*. Promote cross-sectoral fellowships that link academia, SMEs, and digital industries.

- **Cross-border cluster partnerships**

  Incentivise interregional alliances for shared training, data annotation, and compute access.

- **Investment and financing tools**

  Utilise the *InvestEU* and *EIC Fund* to mitigate the risks associated with private investment in AI-driven biotech platforms, and encourage blended finance and public procurement "pull" incentives.

- **Digital maturity diagnostics**

  Create an AI-readiness scorecard for biotech SMEs to identify gaps in data infrastructure, governance, and workforce capability.

- **Ethical and trust frameworks**

  Develop sector-specific codes of practice for the responsible use of AI in biomedical research and development, aligned with the *AI Act* and *the OECD Bioeconomy Principles*.

- **Promote open and secure data spaces**

  Fund European biofoundries and open genomic repositories with clear IP and access terms to reduce dependence on non-EU datasets.

- **Advance biosensing and data generation technologies**

  In addition to FAIR data and structured infrastructure, the EU should prioritise the development of advanced biosensing probes and analytical instruments for high-resolution data capture in biotechnological and biomanufacturing processes. These tools are essential for producing fine-grained, real-time datasets that fuel AI models and improve process control, optimisation, and sustainability assessment.

- **Leverage High-Performance Computing (HPC) for AI-biotech integration.**

  Ensure that Europe's *EuroHPC* infrastructure and related national facilities play a central role in the *EU AI and Data Strategy*. Many biotech AI models are currently trained on US-based cloud platforms, which poses interoperability and sovereignty challenges. The Commission should establish protocols to enable seamless transfer of trained models between commercial cloud systems and EU HPCs, ensuring scalability, data protection, and energy efficiency.

- **Ensure harmonised implementation of the European Health Data Space (EHDS)**

  It is crucial that data can be accessed efficiently across all Member States under common standards. The *EHDS Board* should mandate harmonised approaches to consent, data

quality, and interoperability. Within the frameworks of the *GDPR* and *EHDS*, a single, predictable data governance system for innovators must be finalised as a top priority.

- **Promote open and secure European data spaces.**

  Fund *European biofoundries* and *open genomic repositories* with transparent IP and access conditions to reduce dependence on non-EU datasets. Strengthen links with *EOSC*, *BBMRI-ERIC*, *ELIXIR*, and *EATRIS* to ensure secure cross-domain data sharing between research, industry, and healthcare.

- **Foster AI validation and benchmarking initiatives**

  Create shared EU facilities and datasets for validating AI models used in bioprocess optimisation, predictive toxicology, and omics data interpretation. These "AI validation hubs" could operate under *Horizon Europe Cluster 4* and the *Digital Europe Programme*, ensuring reproducibility and comparability of algorithms.

- **Enable digital-biological twins and simulation environments.**

  Support the development of virtual biomanufacturing platforms that integrate sensor data, process parameters, and biological models through AI-enabled simulation. These "digital twins" can reduce experimental costs, accelerate scale-up, and strengthen Europe's industrial resilience.

- **Strengthen coordination between European data and AI initiatives.**

  Align investments under *Horizon Europe*, *Digital Europe*, *EuroHPC JU*, and *HealthData@EU* to avoid duplication and ensure coherent progress. A joint *AI-for-Biotech Coordination Group* could streamline synergies and standardisation efforts across these programmes.

- **Hardware–software co-design initiatives**

  Launch joint programmes between semiconductor, biotech, and AI sectors to co-develop specialised architectures for molecular modelling, genomics, and fluid dynamics simulations.

- **Integration of sensing and computer hardware**

  Invest in next-generation smart bioreactor systems and lab-on-chip devices integrating sensors with local AI processing to achieve real-time optimisation and process control.

Question 12a – Indicate other factors

Interaction with quantum computing and Quantum AI initiatives should not be neglected as they will complement classical data and AI approaches soon, also for process modelling and hybrid approaches for non-AI compute (e.g. solving differential equations for flow simulations etc). This include also looking at potential impact of novel quantum sensors (e.g. NV centres for magnetoscopy), which produce a new category of data – early agreement on data standardization

and exchange is needed to avoid lack of coherence and fragmentation. The EU started to address liability concerns with the proposal for an AI Liability Directive and updates to the Product Liability Directive. However, as legislative processes are lengthy this creates unpredictability. Establishing a clear and predictable liability regime remains a crucial priority to de-risk the deployment of AI-based biotech products and build trust among users and investors.

The EU should prioritise digital and computer sovereignty in biotech by ensuring secure on-premise or federated data processing. Strategic dependencies on non-EU cloud providers risk data leakage, IP loss, and reduced competitiveness in AI-driven biomanufacturing.

Emerging AI-biotech convergence requires stronger oversight for dual-use risks and biosecurity. EU-level mechanisms for AI model verification, synthetic biology screening, and secure data sharing protocols should be advanced under Horizon Europe Cluster 3 and the AI Act.

Introduce EU guidance for long-term stewardship of biological and AI-generated datasets, covering lifecycle management, curation funding, and digital preservation to maintain interoperability and accessibility for future innovation.

Question 13a – To what extent do you agree that the following types of support would help biotech companies develop and deploy AI solutions more effectively?

Additional input and considerations not fully reflected in the tabled responses:

- **Cross-cluster collaboration mechanisms**

  Structured cooperation between biotech, digital, and manufacturing clusters to share datasets, algorithms, and talent pools.

- **Standardised data formats and ontologies**

  Enforce EU-wide technical standards for biological and bioprocess data interoperability.

- **Financial incentives for SME adoption**

  EU-backed tax credits, vouchers, or grants to offset the cost of AI integration and validation.

- **EU-level validation and certification frameworks**

  Harmonised procedures to assess the reliability and quality of AI models used in biotech processes.

- **Enhanced access to secure life-science data spaces**

  Enable SMEs to link with biobanks and clinical datasets with minimal cross-border legal complexity.

- **Integration into public procurement**

  Allow AI-driven biotech tools in health, environment, and manufacturing tenders to drive early market uptake.

- **International cooperation on standards**

  Align EU biotech-AI standards with those of the OECD, Switzerland, the UK, and other like-minded partners to ensure global compatibility and export readiness.

- **AI-on-chip and edge computing for biotech**

  Support the development and deployment of energy-efficient AI accelerators, neuromorphic chips, and embedded systems tailored to biotech and biomanufacturing environments. These will enable on-site analytics, lower data transfer needs, and improve compliance with data protection rules.

- **Cross-sector innovation vouchers**

  Enable SMEs to collaborate with digital or AI providers through targeted vouchers for data curation, model training, or integration.

Question 14 – 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.

To scale AI-driven biotech, the EU must foster interoperable standards—like APIs in computing or MCP for agentic workflows. IFF, as a biofoundry, struggles to scale external innovations due to incompatible design choices. A protein cloned in E. coli may not express in our production strains. Like semiconductors, biotech needs shared design standards and BioFAB models that protect IP yet enable seamless scale-up. Without this, much innovation remains siloed and inaccessible.

The example of Estonia's Biobank demonstrates how clear governance, integrated data, and public trust can accelerate the use of biotech and AI. Backed by the Human Genes Research Act, it connects genomic and health registry data for over 20 per cent of the population under one framework. Broad consent and strong digital infrastructure enable continuous updates and secure data access for research and startups. Its participant feedback model, MyGenome, builds trust. EU-wide replication with harmonised consent, interoperable registries and industry links would speed AI-driven biotech innovation.

The EU should launch federated learning pilots to train AI models across sensitive biotech datasets without data transfer, improving compliance and innovation. Joint AI–biotech regulatory sandboxes with EMA and EFSA could accelerate safe deployment. Linking life cycle and sustainability metrics to biotech AI models would align digitalisation with Green Deal objectives and measurable impact.

Section 8 – Defence and Security

General comments

To scale AI-driven biotech, the EU must foster interoperable standards—like APIs in computing or MCP for agentic workflows. Some of our members (biofoundries) struggle to scale external innovations due to incompatible design choices. A protein cloned in E. coli may not express in our production strains. Like semiconductors, biotech needs shared design standards and BioFAB models that protect IP yet enable seamless scale-up. Without this, much innovation remains siloed and inaccessible.

Question 2 – Please indicate other challenges impacting biotechnology in defence and security in the EU

EU biotech for defence faces major challenges: dependence on non-EU raw materials, reagents, and components weakens resilience. Mapping and reducing these dependencies, and investing in scarce technologies, are essential factors that should be properly considered.

Moreover, negative public perception of biotechnology can limit support and funding. The EU thus needs to be clear on the role biotechnology can play in both defence and offense and educate the public accordingly. Moreover, rapid technological advances often outpace standardization and regulatory frameworks, creating further challenges for acceptance and use in a security context.

While the focus of recent EU action on security is on manufacturing capacity for critical medicines and stockpiling, those are only short-term solutions. The EU should focus on no longer being dependent on raw materials and key components on a single source to produce medicines and ensure self-sustainability as much as possible.

Europe should map biotech manufacturing dependencies for raw materials and key components as well as which technologies are scarce within the Union and invest in reducing real/structural dependency. International partnership should focus on addressing this vulnerability rather than primarily focus on API and finished products. Focus on advanced biotech (as for certain lipids produced during the pandemic) created a stronger and more resilient EU which successfully delivered for itself and the world.

- **Fragmented governance**
  The lack of a unified EU framework coordinating health, defence, and research actors on dual-use biotech policy.
- **Limited crisis coordination mechanisms**
  The absence of rapid data and resource-sharing protocols for cross-border biological incidents or pathogen detection.
- **Dependence on non-EU reagents and components**
  Critical raw materials, enzymes, and lab consumables are often sourced abroad, creating vulnerability in emergencies.
- **Slow public procurement processes**

Limited flexibility to quickly mobilise biotech manufacturing or testing capacity during security crises.

- **Lack of scenario-based planning**
  Few coordinated EU exercises linking biotech industries with civil protection and defence preparedness systems. ’

Please also refer to the April 2025 paper entitled **Charting the Future of Biotechnology**

Question 4 – In your view, what other actions at EU level are necessary to enhance the impact of biotechnology for defence and security in the EU?

To enhance the impact of biotechnology for defence and security, the EU should raise public awareness through education, emphasizing its positive contributions and clarifying its importance in the fight against natural and man-made threats. Also, the crucial role played by biotechnology in the fight against climate change, should be recalled, particularly in protecting food supply chains and food security. This includes both decarbonization, as well as promoting climate resilience.

Moreover, a pragmatic exploration of the use of biotech-generated products for novel computing paradigms (neuromorphic, quantum (bio)), paired with novel biotech produced sensors should be done, these technologies can be used to better protect critical infra structure or include novel ways of secured communication channels beyond digital.

Bio-labelling should also be enforced (e.g. synthetic DNA) - “know your customer” to prevent fraud and/or label authenticity for e.g. packaging, invest in a sovereign biomanufacturing network to secure supply chain resilience should also be properly explored.

Concrete measures should include:

- **Establish an EU Biosecurity and Defence Coordination Platform** to align research, preparedness, and crisis response.
- **Invest in dual-use R&D infrastructure**, such as secure high-containment manufacturing and rapid-scale bioproduction sites available to civilian and defence purposes.
- **Develop interoperable data and genomic surveillance systems** linking national labs, biobanks, and early-warning networks for faster threat detection and attribution.
- **Promote secure supply autonomy** through an EU programme for critical biotech inputs (enzymes, reagents, cell lines) sourced or manufactured within Europe.
- **Fund cross-sector training programmes** bringing together biotech experts, defence planners, and biosecurity professionals to build shared risk-assessment capabilities.
- **Create rapid contracting and procurement mechanisms** enabling biotech SMEs to respond swiftly to security or bioemergency needs.

- **Strengthen export-control and IP management guidance** to protect sensitive technologies while enabling responsible collaboration with trusted partners.
- **Support scenario-based preparedness exercises** that integrate biotech industries into EU civil protection and defence simulations.

Section 9 – Additional Information

Currently, the interplay between the legislation on Substances of Human Origin and Advanced Therapy Medicinal Products (also in view of the current revision of the pharma package) is unknown. In the EU, there is fragmentation between organisations collecting human biomaterial and those developing ATMP for the market, which creates issues as ATMPs are mostly developed from biomaterial. Therefore, European policymakers wishing to support EU-based ATMP innovation should give greater consideration to building better links between organisations collecting biomaterials and ATMP developers (Nature 2025).

Additionally, regulatory 'grey zones' with regard to Member States competencies and their impact on ATMP developers within the EU, particularly with regard to borderline products leave developers with increased uncertainty and less predictable regulatory pathways (Bird and Bird Bio Talk 2024).