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Public Questionnaire informing the European Biotech Act

Fields marked with * are mandatory.

Introduction

The European Biotech Act

Biotechnology and biomanufacturing hold great promise for advancing competitiveness and innovation within the European Union (EU). As previously acknowledged in the Communication on Biotechnology and Biomanufacturing (March 2024) and the reports by Enrico Letta (April 2024) and Mario Draghi (September 2024), it is necessary to address the challenges faced by European companies, users and consumers, and all stakeholders involved to boost the technological advancement, competitiveness and economic growth of the EU.

To this end, the Commission has announced in the 2024-2029 political guidelines a new European Biotech Act, aimed at creating an enabling environment to make it easier to bring biotech products from the laboratory to the factory and then onto the market, while maintaining the highest safety standards for the protection of the population and the environment.

EU policy initiatives relevant for this sector are for example the Strategy for European Life Sciences, the Competitiveness Compass, new EU Bioeconomy Strategy, the AI in science Strategy, the Vision for Agriculture and Food, the European Innovation Act, the EU Start-Up and Scale-up Strategy, the Union of Skills and the Savings and Investment Union. Some of these are currently still under development and the European Biotech Act will be defined in synergies with them.

The public consultation

The European Commission is launching a **public consultation** on the European Biotech Act in the form of an online questionnaire. The aim is to gather evidence and views from stakeholders across all relevant sectors of biotechnology and biomanufacturing, including the medical and pharmaceutical, agricultural, food and feed, industrial, environmental and marine sectors. Your feedback is crucial for identifying the most important challenges and barriers that could be addressed by the Act and for shaping targeted policy actions.

Instructions

The first section of the questionnaire contains questions about you or the organisation you represent, which is then followed by questions on the regulatory and non-regulatory environment in the EU to inform the policy-

making process of the European Biotech Act.

Whenever possible, please substantiate your replies with data and sources of information or practical examples.

This questionnaire is available in all EU official languages and you can reply in any EU official language. You can pause at any time and continue later. You can download your contribution once you have submitted your answers.

About you

* Language of my contribution

- Bulgarian
- Croatian
- Czech
- Danish
- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian

- ○ Spanish
- ○ Swedish

* I am giving my contribution as

- ○ Academic/research institution
- ◉ Business association
- ○ Company/business
- ○ Consumer organisation
- ○ EU citizen
- ○ Environmental organisation
- ○ Non-EU citizen
- ○ Non-governmental organisation (NGO)
- ○ Public authority
- ○ Trade union
- ○ Other

You have identified yourself as a business association or a company/business.
Please indicate whether you belong to one of the following areas:

- ☐ Company conducting research and/or development in biotechnology and/or biomanufacturing
- ☐ Company supplying materials or equipment to the biotechnology manufacturing sector (e.g. strains, bioreactors)
- ☐ Biotechnology manufacturer
- ☐ Biotechnology distributor or retailer
- ☑ Other

Do you identify yourself as a private investor (e.g. venture capitalist, business angel)?

- ○ Yes
- ◉ No
- ○ I don't know/I'd rather not say

Are you or the organisation you represent part of a **cluster** or of a **cluster organisation**?

'**Clusters** are groups of firms, related economic actors, and institutions located near each other and with sufficient scale to develop specialised expertise, services, resources, suppliers and skills.' [**link to definition of clusters**]

'**Cluster organisations** are the legal entities that support the strengthening of collaboration, networking and learning in innovation clusters and act as innovation support providers by providing or channelling specialised and customised business support services to stimulate innovation activities, especially in SMEs. They are usually the actors that facilitate strategic partnering across clusters.' [**link to definition of cluster organisations**]

- ○ Yes
- ◉ No
- ○ I don't know/Not applicable

* This questionnaire covers **all areas of biotechnologies.** Please indicate the **sector s** that are relevant to you or the organisation you represent, or which you have most knowledge on.

You can select multiple sectors.

Please note that your answers to the questionnaire will be analysed in relation to the sector(s) you have selected.

- ☑ Medical/pharmaceutical
- ☑ Agricultural
- ☑ Food/feed
- ☑ Industrial
- ☑ Environmental
- ☑ Marine
- ☑ Bioinformatics
- ☑ Biotechnology for defence and security

- [x] Other areas of biotechnology
- [ ] Not applicable

If a different sector of biotechnology is relevant to you or the organisation you represent, please specify.

*First name

Anne-Gaelle

*Surname

Collot

*Email (this won't be published)

ag.collot@europabio.org

*Organisation name

255 character(s) maximum

EuropaBio, the European Association for Bioindustries

*Organisation size

- ( ) Micro (1 to 9 employees)
- (•) Small (10 to 49 employees)
- ( ) Medium (50 to 249 employees)
- ( ) Large (250 or more)

Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

1298286943-59

*Country of origin

Please add your country of origin, or that of your organisation.

This list does not represent the official position of the European institutions with regard to the legal status or policy of the entities mentioned. It is a harmonisation of often divergent lists and practices.

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Saint Martin
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka

- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu

- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

Anonymous

Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

Public

Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

☑ I agree with the personal data protection provisions

Questions regarding a future European Biotech Act

*Mandatory questions are indicated with an *.*

Please note that the answers to the questionnaire will be analysed in relation to the area(s) you have selected in the 'About you' section.

Section 1 - General views on biotechnology

Biotechnology can be defined as the application of science and technology to living organisms, as well as parts, products and models of them, to alter living or non-living materials for the production of knowledge, goods and services.

Biomanufacturing is the use and conversion of biotechnology and biological resources into chemicals, products and energy.

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**	○	○	○	○	◉	○
* Biotechnology and biomanufacturing can **positively impact the EU society**	○	○	○	○	◉	○
* Biotechnology and biomanufacturing can **positively impact the environment**	○	○	○	◉	○	○
* Biotechnology and biomanufacturing products that reach the EU market are **safe and secure**	○	○	○	○	◉	○
* **Information to users and consumers** on biotechnology and biomanufacturing is available and accessible	○	◉	○	○	○	○
* Consumes are **willing to pay a price premium** for biotechnology and biomanufacturing products	○	○	◉	○	○	○

Section 2 - The regulatory environment in the EU

The following questions seek to collect views on the regulatory environment in the EU, in particular the perceived regulatory barriers.

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:**

Not all phases may be applicable to all biotechnology and biomanufacturing products.

This specific question covers EU rules, i.e. legislation stemming from the European Union.

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

Q2. Please indicate **other phases of the innovation and manufacturing cycle** where there are **regulatory barriers** caused by EU rules.

600 character(s) maximum

Regulatory barriers occur throughout the biotech cycle: fragmented IP and licensing in early R&D; overlapping Clinical Trials, GMO, and data protection rules; slow, unpredictable licensing and permits for scale-up; and no clear path for non-medical GM fermentation. Divergent GMO Food & Feed and HTA rules create legal uncertainty and market bias. Post-market, inconsistent pharmacovigilance and data-sharing limit evidence use. Lack of circularity and end-of-life pathways hinders sustainable bioproduct markets.

Q3. Please substantiate your statements with **additional evidence** on the **challenge s** resulting from the **EU regulatory environment**.

600 character(s) maximum

GM rules focus on technology rather than product, slowing down adoption of innovation (NGTs) and hampering market entry. For non-plant, non-healthcare applications using microorganisms, the current GMO reg framework results in no genetically modified microorganisms being marketed for deliberate release, e.g. biofertiliser, biocontrol, microbial cleaning products, environmental remediation. Sustainable biomass: see nova-Institut study: https://renewable-carbon.eu/publications/product/benefits-of-using-first-generation-biomass-for-food-fuels-chemicals-and-derived-materials-in-europe-pdf/

The following questions seek to collect views on possible ways forward to simplify and streamline the EU regulatory environment applicable to biotechnology and biomanufacturing products.

* **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

Simplified permitting, clearer guidance, and risk-based regulation would reduce delays and costs. Align GMO, environmental, and clinical rules, introduce fast-track pathways for sustainable bioprocesses, including through regulatory sandboxes, and ensure consistent implementation across Member States. Shift to a product-focused framework for microorganisms and adapt existing regulations to enable broader use of microbial solutions. Align DSI and genetic-resources practice under the CBD/Nagoya Protocol. Expand IPR-backed finance with EIF de-risking.

The following questions refer to views or experience with regulatory environments in countries outside of the EU and of the EEA (Norway, Iceland and Liechtenstein).

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

For each statement, you will have the possibility to indicate the third country(ies) your answer refers to.

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

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

600 character(s) maximum

Predictability means knowing requirements and timelines upfront, an area where the EU has opportunity for improvement. EU biotech regulation lacks predictability due to fragmented implementation, legal ambiguity, and retroactive EFSA guidance. Examples include Reg. 1829/2003 triggering RASFF alerts even for authorised products; product renewal often requiring new data. In contrast, Brazil (CTNBio), the US (SECURE rule), and the UK (ILAP) offer clear, time-bound pathways.

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

600 character(s) maximum

In contrast to the EU, the US coordinates FDA–USDA reviews, Singapore uses a single-window regulatory system and Canada and Australia apply product-based frameworks with clear criteria for biotech traits. Better pre-application advice is common outside the EU. The EU Transparency Regulation adds burden via study prenotification and penalties. Greater consistency and regulatory streamlining are urgently needed.

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

600 character(s) maximum

Lower costs are associated with better coordinated authorities and defined datasets, along with limited duplication. For ex, the US Coordinated Framework aligns FDA, USDA and EPA. Timing-wise, EU novel-food evaluations under Regulation 2015/2283 are sequential and often paused (clock-stops) whereas US SECURE and Singapore's guidelines (https://www.sfa.gov.sg/regulatory-standards-frameworks-guide) keep defined routes and typical timelines. EU costs are similar to the US, China, and Brazil; whilst in India, Singapore, and Vietnam, regulatory compliance tends to be less costly.

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

600 character(s) maximum

The EU process is often slowed by limited guidance, unpredictable timelines (e.g. 'stop the clock'), and retroactive requirements. Authorities tend to re-analyse data rather than verify it. In contrast, countries like Brazil prioritise market access, rely on producer liability, and conduct faster dossier reviews. Singapore also offers clearer routes and faster timelines for biotech approvals.

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

The EU's regulatory system reflects a strong commitment to safety, with process-based triggers and detailed oversight. However, this does not necessarily result in higher safety outcomes compared to countries like the US or Singapore, which use product-based approaches. The US SECURE Act focuses on traits, while Singapore centralizes biosafety oversight. Comparative analyses show that product-based approaches can achieve equivalent safety with greater predictability and efficiency.

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

Flexible pathways like the US GRAS system, facilitate innovation of safe products. Higher digital tools and AI integration readiness accelerate regulatory decisions. Better public opinion and political dynamics, especially around GMOs, influence approval timelines and market acceptance. Harmonised international standards (Codex, OECD, WTO SPS) vary in enforcement, affecting global interoperability and recognition. Regulatory sandboxes, for instance, support higher risk tolerance and innovation.

Section 3 - Access to capital

The following questions seek to collect views on access to public and private capital and related barriers.

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)	○	○	◉	○	○	○
* Debt and equity instruments (e.g. European Innovation Council, European Investment Bank, Strategic Technologies for Europe Platform)	○	◉	○	○	○	○
* Commercialisation support	○	◉	○	○	○	○
* Support to capacity expansion	○	◉	○	○	○	○

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	○	◉	○	○	○	○
* Venture capital: Start-up/early stage (Series A)	○	◉	○	○	○	○
* Venture capital: Expansion stage (Series B)	◉	○	○	○	○	○
* Venture capital: Growth stage (Series C, etc)	◉	○	○	○	○	○
* Debt financing	○	◉	○	○	○	○
* Private equity	○	◉	○	○	○	○
* Strategic research or sales partnerships and collaborations	○	◉	○	○	○	○
* Publicly listing (Initial Public Offering (IPO))	◉	○	○	○	○	○
* Capital markets/shareholders	○	◉	○	○	○	○
* Corporate funding (from other companies in the market)	○	○	◉	○	○	○

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

- (●) Yes
- ( ) No
- ( ) I don't know

Q3a. Please indicate **other relevant private and public financial instruments**.

600 character(s) maximum

Key instruments include the EIC Accelerator (blended finance for high-risk biotech SMEs which needs to be significantly larger), InvestEU (EIF-backed guarantees and equity), and CBE-JU/IHI partnerships supporting industrial and health biotech. The EU needs a stronger, better-funded CBE-JU to close the innovation–commercialisation gap. New tools like the TechEU Platform, European Tech Champions Initiative, Scale-Up Europe Fund, and proposed Strategic Autonomy Fund can expand late-stage and strategic biotech financing. Innovation procurement remains underused. (*see annex)

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	( )	( )	( )	(●)	( )	( )
* 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)	( )	( )	( )	(●)	( )	( )
* Scientific evidence, including data, concerning innovation	( )	( )	(●)	( )	( )	( )
* Access to data held by public sector bodies	( )	( )	(●)	( )	( )	( )
* Experienced management team	( )	( )	( )	(●)	( )	( )
* Robust supply chain	( )	( )	( )	(●)	( )	( )
*						

Regulatory certainty (e.g. length and predictability of authorisation process)	○	○	○	○	◉	○
* Sufficient protection of intellectual property	○	○	○	○	◉	○
* Financial health and projections	○	○	◉	○	○	○

Q5. Please indicate **other factors that drive investment** in a biotechnology and/or biomanufacturing company here.

1000 character(s) maximum

- Positive perception of GM products - Track record of commercialised innovations - Access to shared infrastructure (e.g. pilot-scale biomanufacturing facilities), which reduces capital intensity and accelerates scale-up. - Proximity to a national or regional biotech cluster (with access to other critical technology clusters, such as AI, academia, research centres and tech transfer offices) - Availability of blended finance (e.g. EIC Accelerator, InvestEU) to de-risk early-stage investment. - Regulatory innovation mechanisms available (e.g. sandboxes, adaptive pathways) that shortens time-to-market. - Public procurement opportunities - IP valorisation mechanisms, including patent pooling and EIF-backed IP-based lending. - Risk-based regulatory reform is vital. For example, the €2 billion EU enzyme market drives sustainability across sectors, but outdated REACH and GM rules hinder innovation (*see annex).

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

Q8. Please substantiate your statements with **additional evidence** on the **challenge s** related to **access to finance in the EU**.

600 character(s) maximum

EU capital markets remain fragmented and risk-averse, as noted in the Letta and Draghi reports, limiting biotech financing. Deeper integration is needed to mobilise private investment and provide long-term capital for innovation. Funding gaps persist beyond TRL 7, where biotech scale-up becomes most capital-intensive. Unlike low-carbon sectors, biotech lacks dedicated high-TRL instruments. EIB programmes also exclude plant-sugar-based biopolymers over unfounded food-security concerns, further restricting sustainable investment.

The following questions seek to collect views on possible ways forward to support access to finance in the EU.

* **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**?

Please substantiate your statements with views and evidence on the ways forward.

You can provide references of successful schemes existing at EU level, national level or in other jurisdictions to attract private capital in biotechnology.

600 character(s) maximum

The EU should boost investor confidence through clear, predictable biotech regulation and strong IP protection under the Unitary Patent System. Expand InvestEU and EIF guarantees to de-risk high-TRL biomanufacturing projects and align EU–national funding for coherence. Launch a “Biotech for Europe” initiative and an EU Biotech Index (EU Biotech Nasdaq) to attract private capital. Use public procurement and market-pull measures to create early demand, modelled on US ARPA-style and Horizon Europe missions. (*see annex)

* **Q10.** In your view, what **actions at EU level** are necessary to prioritise **funding for high-risk and high-reward biotechnology research and innovation?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The EU should prioritise high-risk, high-reward biotech via CBE-JU and IPCEI to de-risk scale-up and translation. Use the STEP platform to label breakthrough projects with a “STEP Seal,” unlocking pooled EU and national funding. Expand pilot biomanufacturing facilities and tech-transfer hubs to bridge discovery and deployment. Align Horizon Europe, InvestEU, and regional funds to support cross-sector biotech innovation and ensure coherence across Member States under a unified EU biotech strategy. (*see annex)

* **Q11.** In your view, what **other actions** are necessary at EU level? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The EU should complete the Single Market and Savings & Investment Union to unlock capital and scale biotech innovation. Establish a permanent EU Innovation Forum to align national R&I programmes and pool investments under STEP. Harmonise procurement, tax, and IP rules, and promote standard licensing and spin-off models to ease tech transfer. Improve talent mobility via a stronger EU Blue Card and ESOP incentives to retain founders and attract global biotech expertise. (*see annex)

Section 4 - Biotechnology clusters and/or cluster organisations

The following questions seek to collect views on biotechnology clusters and/or cluster organisations in the EU.

'**Clusters** are groups of firms, related economic actors, and institutions located near each other and with sufficient scale to develop specialised expertise, services, resources, suppliers and skills.' [**link to definition**

of clusters]

'**Cluster organisations** are the legal entities that support the strengthening of collaboration, networking and learning in innovation clusters and act as innovation support providers by providing or channelling specialised and customised business support services to stimulate innovation activities, especially in SMEs. They are usually the actors that facilitate strategic partnering across clusters.' [**link to definition of 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	◉	○	○	○	○	○
* Insufficient presence of industrial players	○	○	○	◉	○	○
* Insufficient higher education or vocational training institutions	○	○	○	◉	○	○
* Insufficient startup incubators or business support infrastructure (providing for example regulatory affair support)	○	○	○	◉	○	○
* Lack of technology transfer offices	○	○	○	◉	○	○
* Incapacity to reach a critical mass of stakeholders	○	○	○	○	○	◉
* Insufficient public support	○	○	○	◉	○	○
* Insufficient collaboration among existing clusters	○	○	○	○	○	◉
* Insufficient financial support	○	○	○	◉	○	○

Q2. Please indicate **other factors impacting biotechnology clusters and/or cluster organisations** in the EU.

1000 character(s) maximum

National strategies across the EU remain fragmented, leaving biotechnology clusters without the scale or coordination needed to compete globally. Unlike the US, China, or Singapore, there is no consistent support for specialised hubs or pilot labs. Strategic foresight is sporadic, and integration with sectors like AI is still peripheral. Weak IP frameworks and inconsistent spin-off terms complicate commercialisation. Late-stage capital is scarce, and mobility schemes are slow and unattractive. These gaps prevent clusters from scaling, attracting investment, or retaining talent, and they continue to widen the distance between EU ambitions and global benchmarks. (*see annex for Q1)

Q3. Please substantiate your statements with **additional evidence** on the **challenge s** faced by **biotechnology clusters and/or cluster organisations** in the EU.

600 character(s) maximum

Fragmented support schemes (ECIPE), limited access to shared infrastructure (Shaping Bio, Pilots4EU), and weak links with strategic sectors (EuropaBio, EC foresight). Horizon and EIC projects confirm the value of cross-border collaboration, yet funding gaps (JRC, Nature Biotech), poor tech transfer (ETH Zurich), insufficient late-stage capital (Invest Europe, Draghi), and regulatory complexity (EC, EP, EFPIA, MedTech) continue to obstruct scale-up and deployment.

The following questions seek to collect views on possible ways forward to support biotechnology clusters and/or cluster organisations in the EU.

* **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**? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The EU should align the Biotech Act with the Life Sciences and Bioeconomy Strategies. A “fermentation for all sectors” approach can unlock synergies across health, food, and industrial biotech. Coordinated R&I policies, expanded access to pilot and GMP infrastructure via CBE-JU/IPCEI, and support for convergence with AI and medtech are essential. Streamlined permitting, targeted funding, and a biotech skills agenda will enable scale-up and innovation deployment.

* **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? Please substantiate your statements with views and evidence on the ways forward here.

600 character(s) maximum

EU-level coordination should connect regional clusters via shared infrastructure, digital platforms, and joint training for upskilling/reskilling. A biotech data framework aligned with the European Health Data Space would enable structured exchange of clinical/process data. Multi-country investment pooling via IPCEI and a unified legal framework under the 28th regime would support strategic resource deployment and cross-border collaboration.

Section 5 - Biotechnology manufacturing

The following questions seek to collect views on biotechnology manufacturing in the EU.

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	○	○	○	○	◉	○
* High cost of raw material and/or of the operations	○	○	○	◉	○	○
* High energy costs	○	○	○	◉	○	○
* Other operational costs	○	○	○	◉	○	○
* Limitations in logistics and physical infrastructure	○	○	○	◉	○	○
* Vulnerabilities in supply chains and strategic dependencies	○	○	○	○	◉	○
* Labour costs	○	○	◉	○	○	○
* Inconsistent environmental and sustainability policies or lack of a policy	○	○	○	◉	○	○
* Taxation and customs barriers (e.g. tax credits, import duties)	○	○	○	◉	○	○
* Global competition	○	○	○	○	◉	○
* Difficulty scaling up from pilot to industrial production	○	○	○	○	◉	○
* Maintaining product quality and consistency at scale	○	◉	○	○	○	○

Q2. Please indicate **other challenges impacting biotechnology manufacturing in the EU**.

600 character(s) maximum

EU biotech manufacturing faces fragmented innovation policies and uneven access to infrastructure, talent, and funding. Unlike global peers, the EU lacks coordinated support for specialised hubs, shared pilot labs, and regulatory sandboxes. Weak IP frameworks, limited late-stage financing, and slow talent mobility further hinder scale-up and cross-sectoral innovation. (*see Annex for Q1)

Q3. Please substantiate your statements with **additional evidence** on the **challenges impacting biotechnology manufacturing in the EU**.

600 character(s) maximum

Biotech manufacturing in the EU faces scale-up constraints due to cautious EIB lending and unclear Taxonomy classification of biotech processes. GMO rules and permitting delays hinder facility upgrades and cross-border operations. Regional mismatches between biomass supply and processing capacity persist. Public misconceptions and IP risks from offshoring deter investment. These challenges are reflected in extensive biotech SME feedback.

The following question seeks to collect views on possible ways forward to support biotechnology manufacturing in the EU.

* **Q4.** In your view, what **actions at EU level** are necessary to **enhance the impact of biotechnology manufacturing in the EU?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The EU should establish a consistent legislative framework and clear vision for biotech. Fast-track permitting under the Industrial Emissions Directive would reduce delays. A revised microorganism framework and regulatory sandboxes are needed to support innovation. Connecting regional clusters via shared infrastructure and funding, alongside targeted education and IP enforcement, would enable scale-up and industrial deployment.

Section 6 - Availability, upskilling and reskilling the biotechnology workforce

The following questions seek to collect views on the needs of the workforce in biotechnology in the EU.

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.)	○	○	○	○	◉	○
* Insufficient STEM education graduates (STEM: Science, Technology, Engineering, Mathematics)	○	○	○	◉	○	○
* Insufficient research and technical skills	○	○	○	◉	○	○
* Insufficient regulatory and quality assurance expertise	○	○	○	◉	○	○
* Insufficient digital and data science skills	○	○	○	○	◉	○
* Insufficient intellectual property skills	○	○	○	◉	○	○
* Limited financial, entrepreneurial skills and mindsets	○	○	○	○	◉	○
* Other	○	○	○	◉	○	○

Q2. Please indicate **other challenges faced by the workforce for biotechnology in the EU**.

600 character(s) maximum

Biotech workforce challenges include gaps in technical, regulatory, and entrepreneurial skills, limited data tool literacy, and weak interdisciplinary links (e.g. AI, risk assessment). Fragmented training, and uncompetitive wages reduce sector appeal. Labour shortages are acute in rural areas, while visa delays for families, curriculum recognition and lack of a harmonised stock option regime hinder global talent access and retention.

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	○	○	○	◉	○	○
* Misalignment between education and industry needs	○	○	○	◉	○	○
* 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)	○	○	○	○	◉	○
* Insufficient public and private investment in skilled workforce	○	○	○	◉	○	○

Q4. Please indicate **other factors** leading to the **EU workforce facing the above-mentioned challenges**.

1000 character(s) maximum

Misalignment between academic curricula and industrial needs leaves graduates underprepared for roles requiring GMP, QA, and entrepreneurship. Investment in reskilling is insufficient, and lifelong learning remains fragmented. Regulatory and qualification frameworks vary across Member States, limiting mobility and recognition. Industry-academia offer few structured pathways for hands-on experience. Rapid technological change outpaces training systems, while biotech remains underrepresented in career guidance. Visa delays, fragmented labour laws, and lack of a harmonised stock option regime hinder talent attraction.

Q5. Please substantiate your statements with **additional evidence on the challenges faced by the workforce for biotechnology in the EU**.

600 character(s) maximum

Reports from OECD-ICGB, EFPIA, and EuropaBio consistently highlight gaps in regulatory, bioprocessing, and quality management skills. SMEs report difficulty recruiting for dossier preparation and technical roles. Basic science skills are weakening as focus shifts to molecular biology. The European Parliament notes tax fragmentation hinders talent retention, while the EIB and Innovation Scoreboard confirm regional disparities and persistent training gaps. (*see annex)

* **Q6.** In your view, what **actions at EU level** are necessary to **enhance specialised training programmes/curricula?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The EU should promote specialised training via structured academia-industry partnerships. Standardised curricula for biomanufacturing and bioinformatics, modelled on best practices like BioMADE, would reduce fragmentation. Funding should support dual-degree programmes and placements. Expanding Erasmus+ and Horizon Europe to include technicians would boost workforce readiness across Member States.

* **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.)? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The EU should expand cross-border pilot facilities access and early-stage funding for biotech ventures. Scientists need access to IP advice, legal support, and commercialisation training. A one-stop platform for entrepreneurship services would reduce barriers. EU funding should target incubators with shared lab space and fast-track grants for spin-offs. Institutions with strong tech transfer records should be incentivised.

* **Q8.** In your view, what **actions at EU level** are necessary to support **programmes to attract talent from other geographical areas**? Please substantiate your answers with views and evidence on the ways forward.

600 character(s) maximum

The EU should streamline the Blue Card process and launch a fast-track permit system with parallel family processing. Fellowship schemes and trusted-university pathways can attract vetted cohorts. A single digital portal with standardised documentation and mutual degree recognition would simplify recruitment. Competitive salaries, career opportunities, and research funding are key to retention.

* **Q9.** In your view, what **other actions at EU level** are necessary for the availability, upskilling and reskilling of the biotechnology workforce? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The EU should support lifelong learning via online platforms and cross-border course sharing. Coordinated national investments would reduce duplication. A Biotechnology Skills Observatory could track supply and demand. CEDEFOP's index should guide training to high-need regions. Real-time labour data must inform curricula and funding. SMEs need simplified access to training funds and tailored programmes.

Section 7 - Data and Artificial Intelligence

The following questions seek to collect views on the challenges related to access to data and on the development, deployment and use of Artificial Intelligence (AI) in biotechnology.

* **Q1.** Are you or the organisation you represent having difficulties in **accessing or using relevant data** for the development of biotechnology or biomanufacturing products?

- (●) Yes
- ( ) No
- ( ) Partially
- ( ) Not applicable/I don't know

Q1a. What barriers are you currently facing?

600 character(s) maximum

Key barriers include fragmented and non-interoperable data infrastructures, divergent GDPR interpretations, and uneven AI Act implementation, hindering data access and reuse. Inclusion of digital sequence information (DSI) in national ABS frameworks creates delays and legal uncertainty, as many DSI records lack origin data. A harmonised, multilateral approach is needed to ensure benefit-sharing, open access, and legal clarity to enable innovation in biotechnology and biomanufacturing. (*see annex)

* **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?

- (●) Yes
- ( ) No
- ( ) Not applicable/I don't know

Q2a. What are the main reasons for relying on data sourced from outside of the EU /EEA?

- [x] Clear legal framework for access to data
- [ ] Less strict requirements for compliance with privacy and data protection
- [ ] More favourable IP rules
- [x] Available datasets are more reliable and of a higher quality
- [ ] Access to data is less costly
- [x] Other

Q2b. Please specify what the other reasons are.

600 character(s) maximum

Members depend on non-EU data to support global research, ensure diverse patient representation, and access large-scale clinical, genomic, and real-world datasets unavailable in the EU. Such data are vital for developing and validating biotech innovations, advancing precision medicine, and meeting global regulatory standards. Open, interoperable datasets and streamlined, low-bureaucracy governance via trusted data labs are essential for responsible, data-driven discovery.

Q3. To what extent do you agree that **data synthetisation** is a viable means to overcome data scarcity in the EU?

- ( ) Strongly disagree
- ( ) Disagree
- ( ) Neutral
- (•) Agree
- ( ) Strongly agree
- ( ) Not applicable/I don't know

The next set of questions specifically cover the implementation of the European Health Data Space (EHDS) and consequently focus on health data.

In the health domain, the EHDS aims to alleviate challenges in accessing data for secondary use by establishing a legal framework facilitating the reuse of health data for research and innovation, including in the biotechnology sector. The EHDS Regulation entered into force on 26 March 2025 and its key provisions will enter into application and be operational by March 2029.

Q4. Regarding the health biotechnology sector, are you or the organisation you represent **actively preparing for the entry into application of the EHDS?**

- (•) Yes

- ○ No
- ○ Not applicable/I don't know

* **Q4a.** 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.

- ☑ Data user
- ☑ Data holder
- ☐ Health Data Access Body
- ☑ Authorised participant to HealthData@EU infrastructure (e.g. as a health-related research infrastructure or other data-sharing infrastructure)
- ☑ Health Data Intermediation Entity
- ☑ Single Trusted Data Holder
- ☑ Cross-border registry
- ☐ Other

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

EuropaBio's members support the EHDS but face major implementation challenges: unclear access rules for industry, inconsistent national application, and fragmented data standards hinder cross-border use. Stronger safeguards for IP, trade secrets, and commercially sensitive data are needed, along with alignment to GDPR and the AI Act. Unclear anonymisation rules, slow setup of access bodies, and limited infrastructure and expertise risk delaying secure, innovation-friendly data sharing. (* see annex for Q3 & Q4b))

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

Biotechnology companies use diverse research and health data infrastructures, including biobanks, genomic and clinical data repositories, disease registries, and EU networks such as BBMRI-ERIC, ECRIN, ELIXIR, Cancer Image Europe and Euro-BioImaging. These provide access to samples, imaging, and real-world data for biomarker discovery, precision medicine, and regulatory science. Federated platforms, AI factories, and ELSI support ensure secure, ethical, and GDPR-compliant data use across research and innovation.

The following questions specifically concern the transformative potential of AI for biotechnology.

In the following questions, a distinction is made between two categories of AI use in biotechnology, representing different phases of the innovation cycle:

1. Use of AI in Research and Development (R&D): Biotech companies using AI toolsto support or accelerate their R&D processes (e.g. using AI to identify drug targets or design new molecules, applying machine learning to analyse omics data, etc).

2. Deployment and scale-up of AI-based Biotechnology Products: Biotech companies developing AI-powered products or services and deploying these products into real-world settings (e.g.AI-powered biomanufacturing platforms aimed to be integrated in production facilities, AI powered diagnostic tool that analyses blood based biomarkers to detect early stage cancer using a biological model of tumour progression, etc).

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)	○	○	○	○	◉	○
* **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)	○	○	○	○	◉	○
* **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)	○	○	○	◉	○	○
* **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	○	○	◉	○	○	○

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-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)	○	○	○	◉	○	○
* **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)	○	○	◉	○	○	○
* **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	○	○	◉	○	○	○

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

AI use in EU biotech faces key barriers. The EMA (2023) notes missing EU-wide validation standards for AI in medicines. The EIB (2024/25) reports only 20% of EU life-science firms have in-house AI skills (vs 45% in the US). OECD and EC studies (2024) cite high compute and certification costs limiting SME adoption. The EuroHPC JU (2024) highlights uneven access to HPC and secure data spaces. Regulatory overlap (AI Act, GDPR, EHDS) and fragmented datasets hinder AI-based biotech R&D and product deployment. (*see Annex)

The following questions seek to collect views on possible ways forward to support the deployment and use of AI and data in biotech.

* **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

To boost AI use in biotech R&D, the EU should establish well-resourced regulatory sandboxes and AI-biotech testbeds for lawful access to high-quality health data. Clear, harmonised guidance on GDPR, EHDS, and AI Act compliance is essential. Support SMEs with compute vouchers, simplified conformity rules, and HPC access. Invest in AI-biotech skills via targeted training and EDIH hubs. Develop FAIR, AI-ready biodata repositories to enable secure, interoperable, cross-border research and innovation. (*see annex)

* **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 deploy AI-based biotech products, the EU should establish AI-biotech testbeds and sandboxes to validate models with regulators, harmonise FAIR data and metadata standards under EHDS, and expand EuroHPC access with SME compute vouchers. Simplified AI Act compliance guidance, public procurement incentives, and blended finance through InvestEU and EIC will accelerate uptake. Cross-disciplinary AI-biotech training and strong ethical, sustainability, and transparency frameworks are essential for trusted, responsible deployment. (*see annex)

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 harmonised EHDS implementation to enable efficient, cross-border data access under clear GDPR rules. Invest in advanced biosensing and smart bioreactor systems to generate real-time, high-

resolution data for AI models. Strengthen EuroHPC's role by ensuring seamless interoperability with cloud platforms. Fund AI validation hubs, digital-biological twin development, and open genomic repositories. Build an AI–biotech talent pipeline and align EU data, AI, and biotech programmes for coherence and scale. (*see annex)

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	◉	○	○
* Support validation and certification of AI tools in the biotech field	◉	○	○
* Secure and high-performance processing of health data made available through the EHDS for development of innovative products and tools for the biotech sector	◉	○	○
* Provide access and/or facilitate the use of high-quality datasets through 'data labs'	◉	○	○
* Other	◉	○	○

Q12a. If you would like to indicate other factors, you can do so here.

600 character(s) maximum

The EU should integrate quantum computing and quantum AI into biotech strategies, ensuring early data standardisation for quantum sensor outputs. A clear, predictable liability regime is vital to de-risk AI-biotech deployment. Strengthen digital sovereignty through secure, federated data processing to reduce reliance on non-EU clouds. Advance oversight for dual-use biosecurity risks and establish EU guidance for long-term stewardship and interoperability of biological and AI-generated datasets. (* see annex)

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	○	○	○	○	◉	○
* Access to annotated datasets (e. g. biological, clinical, genomic data)	○	○	○	○	◉	○
* Access to synthetic datasets	○	○	○	◉	○	○
* Regulatory sandboxes for testing biotech-related AI models	○	○	○	◉	○	○
* Partnerships with public research institutions or AI hubs /factories	○	○	○	◉	○	○
* Simplified IP and data-sharing frameworks	○	○	○	○	◉	○
* Skills development and AI training for biotech personnel	○	○	○	◉	○	○
* Roadmaps for implementation and scalability of AI tools in the EU ecosystem	○	○	○	○	◉	○
* Other	○	○	○	◉	○	○

Q13a. Please indicate other factors here.

600 character(s) maximum

The EU should foster cross-cluster collaboration between biotech, digital, and manufacturing sectors; enforce standardised data formats and ontologies; and provide financial incentives for SME AI adoption. Establish EU-level validation frameworks for AI model reliability and expand secure life-science data spaces. Integrate AI-biotech tools into public procurement, align global standards, and support AI-on-chip and edge computing to enable efficient, privacy-preserving, on-site data analytics in biomanufacturing. (* see Annex)

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

Estonia’s Biobank shows how clear governance, integrated health–genomic data, and public trust accelerate AI use in biotech. EU-wide replication with harmonised consent and interoperable registries would unlock innovation. Federated learning pilots can enable AI training without data transfer, ensuring compliance. Joint EMA–EFSA sandboxes would speed validation, while linking AI-biotech models to sustainability metrics aligns deployment with the EU Green Deal and responsible innovation goals. (* see Annex)

Section 8 - Defence and security

Advanced biotechnological possibilities including development of synthetic pathogens, aided by AI-driven software systems, are creating new risks related to future health preparedness and potential of weaponisation by State or non-State actors (Sauli Niinistö report, October 2024).

The following questions seek to collect views on biotechnology for defence and security in the EU.

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	○	○	◉	○	○	○
* Risks to strategic autonomy in biomanufacturing, and availability of medical and non-medical countermeasures	○	○	○	○	◉	○
* Vulnerabilities in the resilience of biotech supply chains	○	○	○	◉	○	○
* Insufficient civil military cooperation in biotechnology sector	○	○	○	◉	○	○
* Cybersecurity risks to biotech infrastructure and AI tools used in biotechnology	○	○	○	○	◉	○
* Other	○	○	○	◉	○	○

* **Q2.** Please indicate **other challenges** impacting biotechnology for defence and security in the EU.

600 character(s) maximum

A unified framework linking health, defence, and research is needed to strengthen EU biotech security capacity. With that in mind, defence public actors should clearly communicate to industry the challenges they face in the EU and what they need from the biotech industry to successfully mitigate those challenges. This dialogue and coordination enable efficient action and the development and offering of feasible solutions for the defence. (* see annex)

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

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

The following questions seek to collect views on possible ways forward to support biotechnology for defence and security in the EU.

* **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**? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

Defence and security are best strengthened when the EU fosters an innovative, trusted and resilient biotechnology ecosystem. The EU Biotech Act should be positioned strategically to enhance resilience and technological sovereignty, building on models like the Chips and AI Acts. It should support innovation, safeguard biosecurity, capture synergies across biotech domains, and advance EU-wide investment, standards and infrastructure for civil and defence use. (* see annex)

Section 9 - Additional information

Is there anything else you would like to add that has not been covered by this consultation?

Lensch et al. 2024 “Safety aspects of microorganisms deliberately released into the environment “, EFB Bioeconomy Journal to underline the broad range of using of microbial solutions in applications beyond feed and food and addressing existing scientific knowledge regarding deliberate released of microorganisms. * see annex for additional information and references

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