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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

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

* 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

- [x] Environmental
- [ ] Marine
- [ ] Bioinformatics
- [ ] Biotechnology for defence and security
- [ ] 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

*Surname

*Email (this won't be published)

*Scope

- ( ) International
- ( ) Local
- (•) National
- ( ) Regional

*Level of governance

- ( ) Parliament
- (•) Authority
- ( ) Agency

*Organisation name

255 character(s) maximum

From the Dutch government on behalf of the Dutch Ministry of Economic Affairs

* 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.

* 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
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Saint Martin
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles

- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- 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
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia

- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d’Ivoire
- Croatia
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam

- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- 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

There are multiple examples where biotech innovations have to comply with more than one regulations. The Netherlands calls for a coherent, flexible EU framework that aligns overlapping rules and eliminates contradictions. For instance regarding GMO and Novel Food legislation. In the assessment and in obtaining authorization to market products, an specific example is green pesticides as market product. The Commission could provide more guidance and support to applicants, through a contact point that they can approach for general questions and specific questions about and during the procedure.

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

600 character(s) maximum

Currently EU plant protection product regulations are primarily designed for chemical substances and are ill-suited for biological alternatives, resulting in unpredictable and excessively long lead times. The approval of low-risk biological substances and authorization of corresponding market products can take up to 10 years. The approval procedures for novel foods, sometimes produced with GMOs such as cellular food production or precision fermentation, are currently perceived by companies as non-transparent, costly and slow, and therefore hampering commercializing products.

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

Given the rapid developments in biotechnology and new insights in safety, regulations should be forward-looking and resilient: developing adaptable regulations while ensuring harmonisation and maintaining the highest safety standards. Especially the 2009/41 (CU) and 2001/18 (DR) could merit from more adaptability to the latest scientific developments. For example, revising the GMO-definition should help to properly assess new applications and whether they fall under the scope of the GMO legislation. Also, the differentiation in procedures should be risk- instead of containment-based (CU/DR).

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**	○	○	○	○	◉	○

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

Where the EU applies the precautionary principle – meaning that if there is scientific uncertainty about potential risks, approval is withheld until safety can be assured – non-EU countries like the US/Canada regulate using a product-based approach regardless of whether the product is a GMO. This means GMO's in the phase before market-authorisation are not assessed and possibly dangerous when released into the environment. GMOs can spread uncontrollably and irreversibly and may cause lasting damage and severe diseases in humans and the environment – GMOs multiply and may grow exponentially.

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

It is important that national and EU regulations should align with the latest scientific findings. The regulatory framework within Europe should be harmonised and forward-looking. The procedures associated with legislation and regulations must be transparent, effective and predictable.

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

Seed capital

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

In order to offer a level playing field and prospects to developers and financiers of biotechnological innovations in Europe the Netherlands calls for proportional and future-oriented European legislation and regulations with transparent, efficient and predictable approval procedures. Thereby Europe can optimally use these innovations in our society, while maintaining a high level of safety guarantee. In the field of green and industrial biotechnology a factor that drives investment is market demand. Without market demand for green and sustainable products, the business case is not competitive. Creating market demand on a EU-level green and circular biotech products will improve the business case.

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

600 character(s) maximum

As an example, there is a medical company in the Netherlands that wants to build a new plant and has the ambition to make their process circular. This is because they are using a rare earth metal in their process. They need to use mercury, a metal that is phased out, in order to make it circular. They asked for a 'exception position' at DG ENV. However, there is no specific reaction period to take this into consideration. Companies that want to start a plant can experience this (possibly long waiting time) as a bottleneck. Additional evidence on challenges can be found in section 9.

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

Availability of public-private research and technology infrastructure and access to facilities for experimentation and scaling are important prerequisites for SME, start-up and scale-up for strategic innovation. (Long term) funding for pilot- to -demo infrastructure is a prerequisite for exploitation of these facilities. The Netherlands are in favor for public support mechanisms to derisk and attract private capital. The Netherlands also promotes to make existing shared facilities better accessible for innovative SMEs, start-up and scale-up.

* **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 Netherlands calls for tailored instruments in the next MFF to close funding gaps for scaling and commercialization of innovations, because SMEs in industrial biotech or cultivated meat often lack access to late-stage finance and must rely on foreign investors to grow. Therefore, the ECF and the new Horizon Europe must offer tailored instruments - such as grants, direct and indirect equity, venture debt, guarantees, and blended finance – as well as the right framework conditions such as focus on the most strategic technologies and sectors, including biotech, based on excellence and impact.

* **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 Netherlands welcomes the announcement in the Start-up and Scale-up strategy to revise the definition of Undertakings in financial Difficulty (UiD), which is also relevant for the biotechnology sector. The Netherlands calls on EC DG COMP, to collaborate with other EC DGs (CLIMA, SANTE, RTD, REGIO) to ensure that the State aid rules are fit fur purpose for aid measures for the biotechnology industry, particularly with respect to the definition of UiD, taking into account the specific characteristics of this sector.

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

Not applicable

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

600 character(s) maximum

Competition for national and international funding does not often encourage formation of (national) centres of excellence (and critical mass). There is insufficient integration of existing TTOs best practices on a national /international level. There is insufficient finance available for spinouts and young innovative companies arising from national biotechnology clusters. Seed finance is available. Availability of finances for growing companies is insufficient. For example, of corporate finance is limited, partly due to lack of critical mass on national level.

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 Netherlands calls for improvement of the knowledge and technology transfer between academia and industry and upscaling of innovations (specifically SMEs). To create centres of excellence and critical mass within Biotechnology, better collaboration between leading European biotech clusters is needed. The Netherlands offers several best practices such as: Leiden Bio Science Park hosts a high concentration of R&D-intensive companies and public-private research infrastructure, while the ecosystem around Wageningen University & Research foster innovation in agri-food and cellular agriculture.

* **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

The Biotech Booster is an example of a national cluster in The Netherlands. Effective ways to improve synergies in EU is to create networking opportunities (e.g. the EU Cluster Collaboration) and to finance strategic cross-border partnerships. Long-term investment is needed for sustainability. Successful pilots can be financed for longer periods (10 years), until such cross-border clusters can generate sustainable self-finance. Cluster formation should integrate of life sciences with emerging hi-tech.

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

Commercial producers/economic operators would like to have the opportunity to test their product in the development phase before applying for an authorisation. For these kind of 'taste tests', there is currently no possibility within the frame of the legislation. This concerns for example innovative fermentation products, or food produced by cellular agriculture. We are currently investigating the possibilities for facilitating taste testing for innovative fermentation products (on a national level). For cellular food production, the Netherlands has already facilitated some taste testing.

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

600 character(s) maximum

Market demand is lacking in the field of industrial biotechnology. Without market demand for green and sustainable products, the business case is not competitive. Creating market demand on a EU-level green and circular biotech products will improve the business case.

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 Dutch government welcomes the European Commission’s proposal to update the Bioeconomy Strategy and supports the objective to create and protect European lead markets for biobased products. Furthermore we support the Commission’s aim to secure the competitive and sustainable supply of biomass.

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

The demand for workers in general is high. Filling vacancies at the vocational and higher professional levels is becoming increasingly difficult in NL. This also applies to the biotechnology sector. In addition the enrollment of students in science and technology education is a factor that contributes to reducing labor market shortages in the Netherlands. We are committed to increasing the enrollment of students in science and technology education at universities of applied sciences and research universities and to reducing unnecessary student dropouts from these programs.

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

Continued and smart commitment to lifelong learning (LLD) is also necessary to reduce labor market shortages and increase labor productivity. LLD can increase the adaptability of individuals and companies, which is crucial in the context of rapid biotechnological developments. LLD requires structural and cultural changes, requiring both public and private commitment and investment. This should lead to a strong learning culture, in which it is clear to everyone that investing in learning and development is rewarding.

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

600 character(s) maximum

In Biotech Talent Unlocked, knowledge institutions from the Netherlands and Germany in the Eems Dollard Region (EDR) border region are committed to organizing sufficient and appropriately trained talent for the circular and biobased economy. The consortium focuses on increasing the visibility of career prospects in this region for young German and Dutch talent (MBO, BSc, MSc) with a background in biotech or related fields. Techkwadraat is a program that provides primary- and secondary schools with the opportunity to introduce their students to biotech, as part of the broader themes of STEM.

* **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 provision of research funds dedicated towards ecosystems that surround fundamental scientific questions which can be related to involved industries, similar to initiatives around quantum.

* **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

To accelerate innovation in new breeding techniques (genetic modification, synthetic biology), breakthroughs in biotechnological applications (such as the new DNA technology CRISPR/Cas9), robotization and virtualization, crop adaptations in response to climate change (including increased heat and salt tolerance), and shifts in food-producing regions worldwide. Staying ahead of the curve requires strong collaboration between businesses, education, and government, developing knowledge. Sufficient and highly trained personnel are essential.

* **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

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* **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

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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

* **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

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

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

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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

Generally, technological challenges are low (AI-)cloud adoption/a lack of compute, fragmented data systems and a lack of standardization, which combined undermine data utility and the machine-learning readiness of data models. A challenge in the implementation of regulatory frameworks is the lack of adequate security controls for the protection of intellectual property (IP) as well as sensitive personal data. Social challenges faced include the lack of digital skills and the competitive labor market for hiring AI/ML talent.

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?

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* **Q10.** In your view, what **actions at EU level** are necessary to enhance the **deployment of AI-based biotechnology products** in the EU?

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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

- Promoting availability, sharing of and access to high quality data - Support for the biotechnology and biomanufacting field connecting with EuroHPC and new high performance computing facilities in Europe (e.g. AI factories)

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	○	○	◉

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	○	○	○	○	○	◉

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

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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

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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

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Section 9 - Additional information

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

To add on actions at EU level that are necessary to improve the regulatory environment for biotechnology and biomanufacturing: The biotech-regulations could merit from an integrated-approach by taking all related legislation into account. Having different legislation and involved bodies at different levels within the EU and between Member States can lead to overlapping or conflicting requirements, which further complicates the permitting process. An example of conflicting rules is the over pressure that must prevail in clean rooms according to Good Manufacturing Practice (GMP), while the GMO regulations require negative pressure. Another example is the Working Conditions Act. We have several attachments: - To support our suggestions at Section 2 Q4 on forward-looking and resilient legislation. COGEM (Dutch Commission on Genetic Modification) research report: “Towards resilient regulations for rapid technological change.”: which can be found on the following website https://cogem.net/app/uploads/2025/02/CGM-2025-1-Grijze-gebieden-in-de-regulering-van-groene-en-rode-biotechnologie.pdf - Dutch government-wide vision on biotechnology: https://www.rijksoverheid.nl/documenten/rapporten/2025/04/11/kabinetsvisie-op-biotechnologie, we also uploaded the english translation in the attachment. - Dutch non-paper in relation to the EU Biotech Act, - Notes to section 8, - Notes to section 6. For additional evidence on the challenges related to access to finance in the EU we kindly refer to: - (Dutch) https://www.rijksoverheid.nl/documenten/rapporten/2024/06/26/kies-voor-baten-ibo-bedrijfsfinanciering - Meta analysis of dutch risk capital policy instruments https://www.rijksoverheid.nl/documenten/rapporten/2024/07/17/eindrapportage-meta-evaluatie-risicokapitaalinstrumentarium - State of European tech https://www.stateofeuropeantech.com/ Section 2 - Q2 additional information: There are multiple examples where biotech innovations have to comply with more than one regulation. For example, if a food additive contains, consists or is produced from GMOs, two regulatory frameworks apply: one for food additives (Regulation 1333/2008) and a second for genetically modified food and feed (Regulation 1829/2003). Each regulation requires a case specific risk assessment, which do not necessarily align. Section 2 - Q3 additional information: EU regulation cannot only be seen as a barrier, but serves a purpose. For example: GMO legislation ensures environmental safety. Another example: novel food regulation ensures food safety. Acquiring approval can take a long time which may cause for promising innovations a struggle to secure the necessary funding for large-scale implementation. The legislation on genetically modified food and feed has a broader scope of products than those commercially intended at the time of writing of the legislation. In the early 2000's GMO plants were the primary focus of this

legislation, though nowadays other type of GMO's are seen as part of the scope of this legislation (e.g. GM micro-organisms - GMMs). This raises questions/differences in interpretations between member states, which makes it difficult for food safety authorities to enforce the legislation and for commercial producers it threatens their current licence to operate. Section 2 – Q4 additional information: Regulatory procedures should be rendered more transparent and predictable. The Commission could provide more guidance to applicants, through a contact point that they can approach for general questions and specific questions about the procedure. For the legislation on genetically modified food and feed in order to solve interpretation issues, it would be beneficial to review the scope of the legislation, specifically on definitions of a GMO and the limitation of use of detection results. Section 6 - Q4 additional information: It remains crucial that training programs meet the needs of the labor market and society. Educational institutions have the authority to further develop and adjust their training programs (where necessary). Labor market relevance and the distribution of training programs are key principles. We continue to offer educational institutions, in collaboration with companies, the opportunity to broaden and renew current training programs where possible to accommodate new technological developments (and consideration for ethical aspects). Where necessary, they can launch new programs. In the context of training for the labor market of the future, we encourage and, where possible, make agreements about training programs focused on societal challenges and strategic shortage sectors such as technology.

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