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Stakeholder Questionnaire – Regulatory framework for biotechnology and biomanufacturing in the EU

Fields marked with * are mandatory.

Dear Participant,

This survey is part of the study **"Analysis of the regulatory framework for biotechnology and biomanufacturing in the EU"** and is performed on behalf of the **Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, the Directorate-General for Research and Innovation, and the Directorate-General for Health and Food Safety.**

The **thematic scope** of the study covers the application of biotechnology and biomanufacturing across multiple sectors, including medical, pharmaceutical, agri-food, industrial, environmental, and marine industries. However, bioenergy and any (future) EU legislation currently under negotiation are excluded, focusing solely on existing legislation within the previously mentioned sectors.

In terms of **geographical scope**, the study will consider legislation of all countries that are part of the European Economic Area (EEA).

The **main objectives of the study** are:

- To **gather evidence** on possible policy options provided by the European Commission, enabling an assessment and comparison of these options.
- To **collect data and information on challenges relating to EU and national legislation** applicable to biotechnology and biomanufacturing products and processes, their implementation, and enforcement, as well as any resulting impacts on the sector. This includes identifying areas where EU legislation could potentially be further streamlined or simplified or where implementation could be improved.

This survey takes place in the context of the second objective of the study.

The attached **privacy statement** will inform you how the European Commission will protect your personal data and respect your privacy. We would like to highlight that your views will be reflected and summarised in the study report that will be published on a Europa website, in an anonymised manner. The Commission only publishes your identity if you consent to the publication.

Your participation in this survey is crucial in gathering valuable insights that will contribute to the assessment and potential improvement of the regulatory framework for biotechnology and biomanufacturing in the EU.

Please note the **deadline for the survey is 25 April 2025.**

Thank you for your time and input!

1 Privacy Statement

Privacy_statement_Biotech.pdf

1 Profiling Questions

* 1.1 What is the name of your organisation?

Plants for the Future European Technology Platform

* 1.2 Which category best describes your organisation? (select all that apply)

- [x] Industry association (EU level, country level, or other)
- [x] Academia or research organisations
- [ ] Start-up
- [ ] Spin-off
- [ ] Scale-up
- [ ] Other SME
- [ ] Large enterprise
- [ ] Civil Society
- [ ] NGO

* 1.3 What is the total number of employees in your organisation ?

- (•) 1-10 Employees
- ( ) 11- 50 employees
- ( ) 51-250 employees
- ( ) >250 employees
- ( ) Do not know

* 1.5 Since when has your organisation been active?

2004

* 1.6 In which country is your organisation active? (Multiple options are possible.)

- [ ] All EU Member States
- [x] All EEA countries
- [ ] International (non-European countries)
- [ ] Austria

- [ ] Belgium
- [ ] Bulgaria
- [ ] Croatia
- [ ] Cyprus
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Hungary
- [ ] Iceland
- [ ] Ireland
- [ ] Italy
- [ ] Latvia
- [ ] Liechtenstein
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Malta
- [ ] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia
- [ ] Spain
- [ ] Sweden

* 1.7 At which stage(s) of the value chain is your organisation involved (Please select all that apply)

- [x] Research
- [x] Development
- [x] Manufacturing
- [x] Commercialisation and/or market placement
- [x] Advocacy / Consulting
- [ ] Other (please specify)

* 1.9 Which biotechnology and/or biomanufacturing sectors is your organisation involved in? (Please select all that apply)

- [ ] Health/pharmaceuticals
- [ ] Chemicals
- [ ] Personal care & household (cosmetics, detergents etc.)
- [ ] Plastics & polymers
- [ ] Packaging
- [ ] Automotive

- [ ] Construction
- [ ] Fibres & textiles
- [ ] Furniture
- [x] Agriculture/environment
- [ ] Fertilising products & biocontrol
- [x] Food/feed
- [ ] Other (please specify)

* 1.11 Please specify the type of product or service your organisation is involved in.

tools and technology for research and the development of improved plant varieties

2 Challenges and Potential areas for simplification

This section aims **to identify the regulatory challenges and impacts faced by stakeholders across the biotechnology and biomanufacturing value chain** (i.e. research, development, manufacturing, commercialisation and/or market placement).

Please note that the survey allows you to add challenges individually, enabling a deeper exploration of each **individual legislation-related challenge.**

2.1 Legislation-related challenge 1

* 2.1.1 Is there any legislation or connected implementation or enforcement measure at the EU and/or national level that is posing challenges to you or your member's activity?

- (•) Yes
- ( ) No

* 2.1.2 Which legislation-related challenge do your organisation or your members face? (if possible, please refer to the specific legislation(s) at either EU or national level, to which this challenge is connected)

Barriers for approval for cultivation and/or commercialisation of plant varieties developed using new breeding techniques (GMO Directive 2001/18/EC). Challenges for obtaining approval for field trials for research purposes.

* 2.1.3 What impact does this challenge have on your organisation or your members (e.g. costs, time spent, competitive disadvantages, time to market issues, etc.)? (if possible, please provide a quantification and examples to the identified impacts)

- For approval for field trials: not possible to conduct field trials in all countries. Costs and administrative burden very high, with limitations in size of trials due to practicalities.
- For approval for cultivation: major barriers for approval of new plant varieties for cultivation. Legal uncertainty due to no plant variety having been approved for cultivation since the direction was adopted. The majority of member states have opted out of growing GMO varieties.
- For approval for commercialisation (of imported products): high costs and long approval process, limiting the diversity of imported products and characteristics, and reducing the potential of SMEs to participate.

* 2.1.4 Is this challenge affecting your organisation's or your member's competitiveness at the national, EU or international level (please select all that apply)?

- [x] National level
- [x] EU level
- [x] International level
- [ ] No impact

* 2.1.5 Are you aware if similar organisations (outside the biotechnology/biomanufacturing sectors) face the same challenge?

- ( ) Yes (please specify)
- (•) No

* 2.1.7 How would you like to see the identified challenge addressed by legislators or public administrations?

> Moving from a risk focused assessment of new technology and considering the benefits as well. Focusing less on the technology used and more on the end product. Acknowledging and leveraging data from the last decades on the proven safety of cultivating GMO plants.

* 2.1.8 Are you aware of instances where the regulatory challenge was resolved with the support of authorities?

- ( ) Yes
- (•) No

2.2 Legislation-related challenge 2

* 2.2.1 Is there any additional legislation or connected implementation or enforcement measure at the EU and /or national level that is posing challenges to your or your member's activity?

- ( ) Yes
- (•) No

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3 Closing questions

Thank you very much for your time, participation and feedback. Your responses are very valuable for the success of the study.

* 3.1 Do you agree to be contacted for clarification purposes or to participate in further consultation activities?

- (•) Yes
- ( ) No

* 3.2 Would you be interested in participating in a 1-hour interview (online)? The purpose of this interview is to gain a deeper understanding of how these regulatory challenges impact your business / organisation and explore how potential solutions could address them.

- ○ Yes
- ◉ No

* 3.3 As part of our study, we are seeking real-life cases to illustrate the regulatory challenges identified. Would you be willing to participate as a case study?
A one-page overview will be developed for each case, and any sensitive information can be anonymised to ensure confidentiality.

- ○ Yes
- ◉ No

* 3.4 If you agreed to participate in one or more of our data collection activities (clarification consultation, interivew and/or case study), please provide your contact information.

secretariat@plantetp.eu

Note to the respondent: To enhance stakeholder engagement, to help gather additional responses and to support our study with qualitative data, the study team would greatly appreciate if you could share this survey with your network.
If you have any questions or comments, please feel free to contact us at BEBiotechStudyEU@deloitte.com.

Contact

bebiotechstudyeu@deloitte.com