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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?

International Biocontrol Manufacturers Association (IBMA)

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

- [x] Industry association (EU level, country level, or other)
- [ ] 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?

1995

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

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

- [x] Belgium
- [ ] Bulgaria
- [ ] Croatia
- [ ] Cyprus
- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [x] France
- [x] Germany
- [x] Greece
- [ ] Hungary
- [ ] Iceland
- [ ] Ireland
- [x] Italy
- [ ] Latvia
- [ ] Liechtenstein
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Malta
- [x] Netherlands
- [ ] Norway
- [ ] Poland
- [ ] Portugal
- [ ] Romania
- [ ] Slovakia
- [ ] Slovenia
- [x] 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
- [ ] 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
- [x] Fertilising products & biocontrol
- [ ] Food/feed
- [ ] Other (please specify)

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

Biocontrol

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)

Members of IBMA face challenges linked to biocontrol plant protection products authorisation process, related to Regulation (EU) 1107/2009 on the placing on the market of plant protection products

* 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)

An unnecessarily lengthy and complex authorisation process for biocontrol products leads to time to market constraints and competitive disadvantages. Regulation (EU) 1107/2009 on the placing on the market of EU Plant Protection Products (PPPs) has been designed for chemical pesticides and is not well adapted to biological PPPs, leading to unnecessary delays in their evaluations (up to 10 years from submission to market, compared to 2-3 years in other global jurisdictions). With the current regulatory framework, requests for authorisation of biocontrol products submitted between 2023-28 will not reach the market until 2033-38. These delays are holding back an innovative sector of the European crop-protection industry with leading companies increasingly deciding to invest outside the EU; as well as leading to fewer biocontrol solutions available to European farmers to control pests and diseases, putting them in a competitive disadvantage compared to other leading agricultural nations such as USA and Brazil.

Main regulatory bottlenecks related to Reg (EU) 1107/2009 include:
-Lack of provisional authorisation for biocontrol PPPs: Emergency authorisations are currently used by Member States as interim solution to the current lack of alternatives for farmers. However, they only last 120 days and have to be resubmitted each year until the final authorisation is granted in the Member State (likely 7-8 years), creating uncertainty and significant administrative burden for Member States. Article 30 of the Reg (EU) 1107/2009 provides for provisional authorisation (which as opposed to emergency authorisations, is not renewed annually) but remains dormant since 14 June 2016.
-Periodic re-registration for biocontrol: EU and Member States workload is dominated by re-registration, consuming much of the valuable evaluation resources and reducing available time for new authorisations. Moreover, Member States choose not to evaluate any label amendment, mutual recognition or other authorisation during this time period which lasts between five to seven years ('frozen period').
-Restriction of biocontrol use by crop: the current restriction of biocontrol use by crop means that every time biocontrol wants to be used for a different crop, a new application needs to be started; which creates significant backlog.
-Poor implementation by Member States of mutual recognition provisions: a lot of resources are often required to obtain product authorisations in different Member States. The zonal system and mutual recognition was developed to facilitate this process but current Member States practices mean mutual recognition is at best slow and at worst not performed by many Member States, further delaying farmers access to biocontrol already approved at EU level and authorised in some Member States. As a consequence, there is no single market for biocontrol in the EU.

* 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?

1. Immediate simplification measures should be introduced in any upcoming legislative initiative from the European Commission to make biocontrol solutions available to farmers now, including (i) a harmonised EU-wide legal definition of biocontrol PPPs (please read IBMA one online https://ibma-global.org/wp-content /uploads/2025/02/What-is-biocontrol.pdf), accompanied with (ii) measures to amend the treatment of this defined group of PPPs within Regulation (EU) 1107/2009 outlined below.

The following targeted amendments to Reg (EU) 1107/2009 are imperative:
-Re-instatement of provisional authorisation (art 30) for PPPs containing only biocontrol active substances. This is the primary route to accelerating biocontrol and is an alternative mechanism for temporary registration. Provisional authorisation would minimise rework (annual rework needed for emergency authorisation) and provide a more stable, legally based framework. The process of provisional authorisation follows the initial evaluation procedure to ensure a robust safety evaluation has been made and can be re-instated for biocontrol PPPs allowing their immediate access for farmers.
-Removal of re-registration process for biocontrol: Removal of biocontrol renewal programme reduces EU and Member States workload and allows focus on new innovations. On application the approval of biocontrol active substance shall be for an unlimited period of time. Safety of existing authorisations can be ensured through existing provisions under Articles 21 and 56 of EU Reg 1107/2009. The change proposed may also require changes in the Commission Implementing Regulation EU 2020/1740.
-Facilitate label expansion for biocontrol PPPs: where biocontrols are pest or disease specific, the label extension to other crops where the same pest or disease are present, is possible with minimal concerns of efficacy, phytotoxicity or crop residues, allowing extension of use with minimal additional data. In this way new uses of existing authorised products are more rapidly available to farmers. Biocontrol PPPs are frequently first authorised in fruit and vegetable crops where the demand for sustainably grown produce is strongest - there is now an urgent need to extend these authorisations to arable crops and facilitation of label expansion of biocontrol PPPs can increase their availability in arable crops.
The tendency of Member States to not review label extensions during any review of the active substance approval should not apply to biocontrol active substances so that label extensions of currently authorised biocontrol PPPs can be accelerated.
-A system of mutual recognition 'automatically' applied to all Member States could ensure the single market for biocontrol within the EU. Member States can opt out but only with a serious reason as indicated in the seed treatment (art. 49.1).
-Establishing a priority lane for biocontrol solutions will also allow Member States to deliver these alternatives to the market faster. Prioritisation of biocontrol evaluations within the authorisation procedure in Brazil greatly increase the number of biocontrol products on the market within one year.

2. Post 2035, biocontrol is expected to be the dominant type of pest control. In this situation, a future-proof new regulatory framework adapted to biocontrol is needed to maintain the competitiveness and resilience of the agricultural and crop protection markets in Europe. In doing so, the Commission shall assess the need to establish a dedicated Single Agency for biocontrol active substances and products; as well as other key features such as (i) moving away from the current zonal system established under 1107/2009 so that there would be instead one single zone for biocontrol products ('one market, one assessment') and (ii) developing a risk assessment procedure fully adapted for all types of biocontrol products.

-Please read more online in IBMA’s proposal of immediate targeted amendments to Regulation No 1107 /2009, to be included in any pertinent immediate legislative initiative - https://ibma-global.org/wp-content /uploads/2025/04/IBMAs-proposal-of-immediate-targeted-amendments-to-Regulation-No-1107-2009-to-be-included-in-any-pertinent-immediate-legislative-initiative.pdf -

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

- (●) Yes
- ( ) No

* 2.1.9 If yes, please explain the success story and how authorities could replicate the approach and repeat the success.

Brazil is a biocontrol powerhouse. In the last 2 years, around an additional 100 biological products registered which continues to grow annually.Brazilian authorities responded to farmer demand for biocontrol by prioritizing it in the authorization process. To achieve that they acted by:
-Raising awareness of biocontrol. In Brazil, 90% of farmers know about biocontrol whereas in the US, 86% of farmers don't know about it.
-Providing training on how to assess biocontrol.
-Helping farmers use biocontrol. Make biocontrol available, invite farmers to demonstrations, show them how it works. Farmers will then make their own choices. In Brazil, this choice is for biocontrol.
In addition,he advancement of biocontrol in Brazil was not driven by a goal of reducing chemical pesticides. Brazilian farmers favored biocontrol solutions because of their effectiveness and attractive cost. Without major changes to the legislation, but by systematically prioritizing biocontrol products in the approval system, the required authorization time was significantly reduced. As a result, the number of authorizations increased significantly, and farmers enthusiastically adopted these solutions, as evidenced by their impressive growth rate.

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

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.

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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

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