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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?

Biocontrol Coalition

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
- [x] Civil Society
- [x] 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?

Officially active from January 2024

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

- [x] All EU Member States
- [ ] 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)

- [ ] Research
- [ ] Development
- [ ] 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.

The Biocontrol Coalition is a multistakeholder platform advocating for the European Union to rethink its framework for agriculture and food, particularly for biocontrol, to enlarge the farmer toolbox while ensuring safety and health and protecting the environment.

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)

Regulation EC 1107/2009

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)

If we start with the Biocontrol Coalition's FARMER MEMBERS, impacts include the following:

- Unequal access of EU farmers to biocontrol products. Despite the fact that all the food (and other crops) that farmers grow is sold into a Single Market, farmers do not have a Single Market for biocontrol products. This artificially induced fragmentation also changes their pricing dynamics, by making it more expensive to place products on the market, which disproportionately affects farmers in smaller markets.
- EU farmers have access to far fewer biocontrol products than farmers in other places, putting EU farmers at a competitive disadvantage on global markets. "[There] is…a 50% decrease in the number of approved active substances in pesticides over the last 25 years, according to the European Commission, the European Food Safety Authority (EFSA) and EU member states." (Source: https://www.ey.com/en_ch/insights/innovation/what-levers-should-be-used-for-a-better-eu-agriculture-system) The pesticide database reveals that the farmer toolbox for plant protection is 25% smaller than in 2017, with a net loss of 5 biocontrol active substances since 2019.
- It is not just a question of the number of products but how quickly EU farmers can access innovation. Since the approval process for biocontrol products is about three times longer in the EU than in countries like Brazil and the United States, it means two generations of innovation could be made available in other countries before EU farmers have access to them. That means that EU farmers will always be playing catch-up unless the problem is fixed.
- A sufficient choice of biocontrol products can also help farmers address various technical challenges, including the need to prevent pest and disease resistance to conventional plant protection.

The Coalition's CONSUMER MEMBERS want a wide range of choice when making purchasing decisions. While it is obvious that organic produce or zero-residue labels depend on farmers having access to biocontrol products, biocontrol is also increasingly important for the production of abundant, healthy, and affordable conventional agricultural products as well. Biocontrol is an essential tool for farmers to meet a multitude of societal expectations (including but not limited to reducing unwanted environmental impacts and proactively fostering positive impacts such as greater biodiversity) while farming profitably.

Last but not least are the Biocontrol Coalition's members who are PRODUCERS OF BIOCONTROL PRODUCTS:

- While the EU is fairly good at supporting innovation through Horizon, Life, and other research initiatives, too little attention is paid to ensuring that the innovations emerging from that research have a route to market. The current regulatory framework for biocontrol products is not fit-for-purpose:

1) The two-step system of registration of active ingredients, followed by national authorisations of products artificially inflates the number of dossiers and overwhelms competent authorities. If you assume that Mutual Recognition works seamlessly (which it does not), each active ingredient generates a minimum of 4 dossiers – one for the registration of the active ingredient and one for each of the EU's agroclimatic zones.
2) Although efforts are underway to adjust data requirements to the nature of biocontrol products, companies are too often asked to meet data requirements that were designed for novel, synthetic chemicals and which are not

appropriate for the nature of biocontrol active ingredients.
3) The result: it takes 7-9 years for biocontrol products to come to market in Europe, compared to 2-3 years in other key global markets. This is particularly problematic for start-ups under pressure from investors to start having revenue streams in five years or less. As a result, many EU-based innovators that have benefitted from European and Member State funds and tax credits to develop new products have chosen to place their innovations on the market in other countries where the time-to-market is shorter and to forego the laborious and costly process of placing products on the market in Europe. The result: much EU-funded innovation is available to farmers outside the EU but not here. This means that, in some case, EU research funds areundermining EU competitiveness.
4) These factors explain why the return on investment for placing biocontrol products on the market in Europe is 30% below the global average. Companies have limited resources for bringing products to market, so it is not surprising that companies deprioritise the EU market in their commercial strategies.
5) Because fewer plant protections products are available, Member States are using the Emergency Authorisation procedure more frequently and for longer durations that intended. This does not provide the predictability needed for business planning (neither for farmers nor for manufacturers). (Source: https://doi.org/10.1016/j.scitotenv.2024.174217)

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
- [ ] 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?

The European Commission has promised to propose several amendments to the existing regulation 1107/2009 before the end of 2025, which can bring some immediate relief, such as

- A harmonised EU definition
- Reactivating provisional registrations for biocontrol products
- Fast-tracking biocontrol products
- Exploring ways to ensure greater use of Mutual Recognition

These are important first steps that we support. However, several analyses, including the Commission's own Fit4Future panel (https://commission.europa.eu/document/download/f30d08c8-9054-467b-b2ff-3ddcc65d776c_en?filename=final_opinion_2022_sbgr3_08_biosolutions_fup.pdf) indicate that these improvements alone will be insufficient to deliver a future-proofed system that will ensure the competitiveness of EU farmers and ensure sustainability over time. While we all work to formalise the immediate fixes, it is therefore important to start discussing the critical next steps.

Biocontrol products ultimately need a dedicated framework that is designed for their characteristics and that is adapted to the resource availability of competent authorities. To understand the changes that are needed, it is helpful to consider the historical context in which existing regulations were developed. When the regulatory framework for pesticides was first designed, regulators were largely dealing with synthetic, often novel, chemicals being introduced for the first time into agricultural landscapes. Knowledge about the characteristics and impacts of these substances was limited. Being derived from naturally occurring substances and modes of action, biocontrol product scome with more background information, including about their environmental fate. Therefore, a dedicated regulatory framework would take into account the different nature of these products and their modes of action (which can only be fully appreciated in the context of real-world use conditions, such as the expectation that the product may be used in a complementary fashion with another).

We also need to rethink the two-step registration/authorisation system, whereby the active ingredient is evaluated and approved by a Rapporteur Member State and EFSA, followed by multiple national dossiers for product authorisation. This framework artificially increases the total workload of authorities (as described above). Such duplication wastes the time and money of authorities by creating avoidable inefficiencies. The result is extremely slow registration/renewal, long wait times, and inefficient use of resources for public authorities and economic operators alike. The longer it takes to address the issue, the larger the backlog that will accumulate. At a time when public finances are under strain across the EU, rethinking the regulatory framework for biocontrol to have a more agile system that costs Member States less is common sense. Such an approach would also be better aligned with the principles of Better Regulation, which call for eliminating excessive administrative burdens on economic operators.

Guidance documents (adopted pursuant to Article 77) offer flexibility to improve the performance of the current framework for biocontrol products but have no legal authority. Furthermore, national competent authorities are still bound to evaluate applications against the provisions of Regulation 1107/2009, and in particular the benchmarks set by Articles 4 and 29, which

were designed for synthetic chemical plant protection products.

To give an example: hazard-based cut-off criteria may be triggered by plant extracts or secondary metabolites from microorganisms despite properties like biodegradability and a history of safe use history (one recent example is Tea Tree Oil). Such biocontrol products would be better evaluated by a pragmatic risk assessment scheme entailing a need-to-know principle in the context of problem formulation (e.g. no further assessment required if there is no hazard identified or no exposure expected).

Such an approach would deliver high levels of safety and environmental protection while preventing unnecessary, costly and lengthy data generation. This would be well aligned with the principles of Better Regulation. A fit-for-purpose regulatory framework for biocontrol products would demonstrate that there is no inherent tension between maintaining high levels of safety while incentivising investment in biocontrol products.

A dedicated legislative framework offers more legal certainty than workarounds within a framework that is not suited to the products being evaluated. As mentioned above a dedicated framework would use both EU and national resources more efficiently. It would also improve market functioning by harmonising interpretations of rules across the EU and reduce undue administrative burden on companies in line with the ambitions of Better Regulation.

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.

The Commission has previously proposed a separate legal act in areas where EU legislation was already in place in order to provide a framework that is fit-for-purpose. Three such examples are New Genomic Techniques (NGTs), veterinary medicines, and Advanced Therapy Medicinal Products (ATMPs).

In addition, feed materials moved from national authorisation to a centralised EU system over a decade ago.

Amending Regulation 1107/2009 to carve out biocontrol products does not inevitably mean that there will be a wholesale revision of the Regulation. It is possible to introduce targeted amendments to Regulation 1107/2009 via the separate biocontrol products act. (We will provide via e-mail a legal memo for details on how options for how that could be implemented, including "recasting".)

In the case of biocontrol, only micro-organisms and biocontrol products derived from nature would be removed from the Regulation's scope, with specific provisions for biocontrol active substances and products being consolidated into a separate act. This approach would likely beless burdensome and complex than a comprehensive overhaul of Regulation 1107/2009.

Regulation (EU) 2019/1009 on Fertilising Products provides a useful model whereby different product categories and component materials are subject to tailored essential requirements within a single framework. This regulation was designed under the New Legislative Framework, and the applicable conformity assessment module is also variable, depending on the characteristics of the different product categories.

Looking further afield, we can see where other countries such as Brazil and the United States have reduced the time-to-market by having dedicated rules and dedicated teams responsible for evaluating dossiers. Brazil went so far as to have a separate framework for all biological products used in agriculture. Recommendations from institutions such as the Organisation for Economic Co-operation and Development (OECD) and the Food and Agriculture Organization of the United Nations (FAO) are to assess biocontrol products differently from chemical pesticides and to regulate biocontrol products in standalone legislation.

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.

Kristen Sukalac, Secretary General, Biocontrol Coalition: TR 715938853121-73
mobile: +33 6 99 51 94 34 | kristen@prospero.ag

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 (mailto:BEBiotechStudyEU@deloitte.com).

Contact

bebiotechstudyeu@deloitte.com