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The European Commission is more attentive to biotech companies than to citizens

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Publié le 31/10/2025, modifié le 09/03/2026

In early August, the European Commission launched a multilingual online public consultation on its forthcoming "*Biotechnology Regulation*". Presented as an exercise in transparency and citizen participation, the questionnaire is in fact primarily designed to gather the industry's position. In particular, it does not address the ethical and civic dimensions raised by new genome editing techniques (NGTs), such as health risks, the appropriation of living organisms by industry, or the management of health data. This regulation could offer the Commission and multinationals a way out if current or past negotiations on other legislative acts fail to achieve their objectives.



The public consultation *on the* "*Biotechnology Regulation*"[i] launched in August by the European Commission (EC) is part of the European Union's (EU) 2024-2029 "*Competitiveness Strategy*", which aims to "*to create an enabling environment to accelerate the transition of biotech products from laboratory to factory to the market* "[ii]. Unsurprisingly, the key words that dominate this 47-page document are: competitiveness, economic growth, innovation, investment... On the other hand, biotech issues that are close to citizens' hearts, such as the assessment of health and

environmental risks, the artificialisation and appropriation of living organisms, and the potential impacts on biodiversity, are ignored. Furthermore, certain questions appear to have been formulated or chosen in such a way that answers can only be found within the industrial sector or among a seasoned audience, as evidenced by the titles of sections 1 to 7 of the document (see box). Is this to provide biotech companies with legislative tools that they would not have obtained elsewhere?

Questions that are not very accessible

The online consultation *on the Biotechnology Regulations* is intended for a very broad audience: "*citizens, innovators, entrepreneurs, industry, financial institutions, investors/venture capitalists, researchers/research organisations, civil society (including consumer, patient and environmental organisations), other users of biotechnology (e.g. farmers and foresters), trade unions, national and regional authorities and any other stakeholders*". The aim of this consultation is to ensure that "*all stakeholders have the opportunity to express their views and share insights on the main challenges faced by the [biotechnology] sector*". However, the majority of the questions asked remain fairly general and/or require significant prior knowledge[iii].

Not all of these questions are clearly accessible to the general public, particularly civil society and non-specialist citizens, even though they are the ones most directly affected. Even NGOs and small businesses may find it difficult to provide relevant answers. Take, for example, the first three questions in Section 1, which illustrate the very broad and sometimes abstract scope of the questions: "*Biotechnology and biomanufacturing products can positively impact the EU economy (Question 1), the EU society (Question 2) and the environment (Question 3)*". The expected responses (as for the entire questionnaire) are formulated on a Likert scale – from "*strongly disagree*" to "*strongly agree*" – which requires an overall assessment capacity that not all audiences necessarily have.

Another illustrative example concerns question Q1 in Section 2: *"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..."*. Several technical development phases (pre-clinical, pre commercial trials, clinical trials, etc.) for such products are then proposed, with the same Likert scale response options. The complexity of the exercise, or even the impossibility of completing it, is obvious for several profiles of the public surveyed.

These questions from the Commission also convey positive assumptions ("*positively impact the EU economy*"), as talking about *a* "*negative impact*" would be less in line with its initial objective of competitiveness. As we shall see, these choices of words, reflecting the stance of biotech companies, influence the responses.

Closed and leading questions

The questionnaire uses closed-ended questions that guide the responses. Question 3 (Section 1) above on *the* "*positive impact*" of bioproduction on the environment illustrates this logic. This is also the case for the following question (Question 4), which asks about the statement: "*Biotechnology and biomanufacturing products that reach the EU market are safe and secure*." The public surveyed must take a position on such very general statements. No questions address the conditions necessary to guarantee such safety, nor the scientific uncertainties or post-marketing monitoring mechanisms. Furthermore, a response of *"not applicable*" or "*I don't know*" to this type of question can be interpreted as a lack of opposition, a classic statistical bias in this type of

survey.

Through these very broad and binary formulations, the questionnaire does not seek to shed light on the conditions under which these "*positive effects*" of biomanufacturing products are possible, nor on health risks, monitoring mechanisms, traceability or the management of scientific controversies. The phrase "*products are safe and secure*" (Section 1) is based on the assumption that safety has already been established. It is formulated as a statement to be approved or rejected, with a positive framing that may suggest that the statement is true. However, the issue of safety is precisely the subject of regulatory debate. Instead of asking whether the products are actually safe, the Commission is in fact asking whether we agree with its statement, which is not neutral. Above all, if the answer is yes, would the EC consider completely dispensing with risk assessment, since the assumption would be that there is no risk?

Furthermore, by referring *to "perceived regulatory* barriers" (Section 2), the Commission suggests that these rules are inherently problematic. The question is biased, as it invites respondents to consider existing regulations on "*market entry for biotechnology products and products derived from biomanufacturing*" as an obstacle, rather than neutrally assessing their role in protecting health and the environment, for example.

Missing or incomplete questions

Beyond the various complex, closed or biased questions, this questionnaire is also problematic due to its omissions and the fact that it ignores several important topics. This is particularly the case with the deregulation of GMOs obtained through certain new genome editing techniques, which is a crucial issue. Although the European Union has been debating this issue since July 2023, no specific questions are asked about labelling, traceability, let alone the possible effects of these technologies on agriculture, food and the environment. The same is true for the subject of biocontrol[iv], which is not mentioned at all. By diluting these topics into broad categories ("*agriculture*" and "*environment*"), the Commission is giving itself the leeway it needs to aggregate the responses and draw its own political conclusions.

Furthermore, although this is a genuine democratic issue, the section on health data is addressed in a partial manner and from a single perspective: its value for "*research and innovation"*. Section 7 of the questionnaire, devoted to the European Health Data Space (EHDS)[v], which came into force in March 2025, effectively highlights the usefulness of such data for biotechnology, without any specific questions on the overall democratic governance of this sensitive data, in particular the consent of the patients concerned or the protection of such data...

Among other illustrations of such gaps or omissions, we can also mention the subject of intellectual property in the biotechnology sector, which is presented as a "*factor driving investment*", an "*insufficient skills*" and therefore one to be strengthened within this sector... Nothing is said about confiscatory patents on living organisms, the challenges of equitable access to plant genetic resources, and the concerns this raises among citizens, farmers, seed producers, and others.

Excluding citizens from essential debates

Presented as an exercise in transparency, this consultation on the future "*Biotechnology Regulation*" resembles a survey designed to allow the results to be interpreted as reflecting European support. By favouring closed questions, avoiding certain sensitive topics and framing the debate from an essentially economic perspective, this consultation effectively excludes a significant portion of the public, namely those who are directly affected: citizens. Yet the topics covered are of

general interest: food security (and even sovereignty), public health, the appropriation of living organisms, the small-scale farming model, etc.

The consultation is open until 10 November 2025. It remains to be seen whether citizens, NGOs and other critical organisations will be able to make their voices heard in a framework that, for the moment, seems designed to reduce their influence rather than recognise it.

Summary of *the "Public questionnaire to gather data for the development of European legislation on biotechnology"*

Section 1 — General views on biotechnology
Section 1* — Presence of business in the EU market
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.
Section 3 — Access to capital
The following questions seek to collect views on access to public and private capital and related barriers.
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.
Section 5 — Biotechnology manufacturing
The following questions seek to collect views on biotechnology manufacturing in the EU.
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.
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.

i European Commission, Public Consultation on the "Biotechnology Act", 4 August 2025 - 10 November 2025.

ii Denis Meshaka, "The European Commission wants its *'biotech* revolution'", *Inf'OGM*, 11 February 2025.

iii European Commission, "Public questionnaire to gather data for the development of European legislation on biotechnology".

iv The use of GMOs to combat organisms considered harmful, but also RNA, for example. Christophe Noisette, "Le biocontrôle : un terme récent et problématique", *Inf'OGM, le journal*, no. 177, October/December 2024.

v Denis Meshaka, "The European Commission postpones its '*biotech law*' once again", *Inf'OGM*, 3 June 2025.

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