(English version)

Question for written answer E-002341/26
to the Commission
Vytenis Povilas Andriukaitis (S&D)
(8 June 2026)

Subject: Biotech Act II

1. In the context of the preparation of the forthcoming Biotech Act II, and considering that agriculture constitutes the foundational input for a resilient and competitive European bioeconomy, how does the Commission intend to ensure that the proposal goes beyond a narrow focus on industrial biotechnology and biomanufacturing to fully integrate agricultural biotechnology, including plant and microbial innovations?

2. Can the Commission commit to undertaking a comprehensive assessment of the full horizontal biotechnology framework (notably Directives 2001/18/EC ([1]) and 2009/41/EC ([2]) and Regulation (EC) No 1829/2003 ([3])) and to identify and address regulatory bottlenecks to ensure a predictable, science-based pathway to market for these critical technologies?

3. Can the Commission also commit to simultaneously improving societal dialogue about these technologies and their benefits with a view to strengthening public trust?

Submitted: 8.6.2026

Answer given by Executive Vice-President Séjourné on behalf of the European Commission
(11 August 2026)

The Commission will ensure an ambitious proposal for the Biotech Act II, aiming to enhance the EU's industrial competitiveness in industrial biotechnology and biomanufacturing.

This includes increasing the resilience of the EU single market and promoting EU-based sustainable production. The exact scope of the act will be determined based on the impact assessment, including stakeholders' feedback ([1]).

The Commission proposed a regulation ([2]) and a directive ([3]) adopted on 16 December 2025 as the European Biotech Act, which covers food biotechnology by proposing amendments to the General Food Law ([4]), including some measures also applicable to genetically modified food and feed regulated under Regulation (EC) No 1829/2003 ([5]).

In addition, targeted amendments to Directive 2001/18/EC ([6]) are intended to reduce administrative burdens for microbial innovations in the agricultural and other sectors and enhance the EU's global competitiveness. The Commission remains committed to ensuring support for the scale-up of all biotechnologies.

A full mapping of regulatory bottlenecks related to biotechnology has been conducted in an external study commissioned by the Commission ([7]), which will be published on the website of the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs by the end of September 2026 ([8]) .

The Commission recognises the importance of an informed societal dialogue on new technologies and their potential benefits.

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1 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms (ELI: http://data.europa.eu/eli/dir/2001/18/oj).

2 Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (ELI: http://data.europa.eu/eli/dir/2009/41/oj).

3 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (ELI: http://data.europa.eu/eli/reg/2003/1829/oj).

([1]) The call for evidence closed on 10 June 2026, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/17394-Biotech-Act-II_en.

([2]) Proposal for a regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act), COM(2025) 1022 final.

([3]) Proposal for a directive of the European Parliament and of the Council amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs, COM(2025) 1031 final.

([4]) Regulation (EC) No 178/2002, OJ L 31, 1.2.2002, pp. 1-24. http://data.europa.eu/eli/reg/2002/178/oj.

([5]) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, https://eur-lex.europa.eu/eli/reg/2003/1829/oj.

([6]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, https://eur-lex.europa.eu/eli/dir/2001/18/oj.

([7]) 'Analysis of the Regulatory Framework for Biotechnology and Biomanufacturing in the EU', Deloitte, empirica et al., (forthcoming).

([8]) https://single-market-economy.ec.europa.eu/sectors/biotechnology_en.