



17 February 2026

(26-1108)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<p>1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved (Articles 3.2 and 7.2):</p>
<p>2. Agency responsible: European Commission EU-TBT Enquiry Point, Fax: +(32) 2 299 80 43, E-mail: grow-eu-tbt@ec.europa.eu Website: https://technical-barriers-trade.ec.europa.eu/en/home</p>
<p>3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [X], 5.7.1 [], 3.2 [], 7.2 [], Other:</p>
<p>4. Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): 11.120 Pharmaceuticals; 11.220 Veterinary medicines 67-Food technology</p>
<p>5. Details of notified document(s) (title, number of pages and languages, means of access): 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; (258 page(s), in English), (20 page(s), in English) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://members.wto.org/crnattachments/2026/TBT/EEC/26_00950_00_e.pdf https://members.wto.org/crnattachments/2026/TBT/EEC/26_00950_01_e.pdf European Commission EU-TBT Enquiry Point Fax: + (32) 2 299 80 43 E-mail: grow-eu-tbt@ec.europa.eu The text is available on the Website: https://technical-barriers-trade.ec.europa.eu/en/home</p>
<p>6. Description of content: The proposal consists of measures targeted to strengthen the competitiveness of the biotechnology, structured in the following chapters: <i>Chapter I – Subject Matter, Scope and Definitions</i>, sets out the subject matter of this proposal, which consists of measures that articulate its overall objective to improve the functioning of the internal market by establishing a framework to strengthen the competitiveness of the biotechnology sector and specifies the scope of the proposal, which applies to health biotechnology products and services during their entire lifecycle,</p>

Chapter II – Union health biotechnology and biomanufacturing, introduces the concepts of health biotechnology strategic projects and high impact health biotechnology strategic projects and establishes a framework for the recognition and the support of such projects aimed at strengthening the EU's industrial biomanufacturing capacity and value chains.

Chapter III – Access to funding, establishes an EU health biotechnology investment pilot in partnership with the European Investment Bank Group and other implementing partners.

Chapter IV – Extension of the supplementary protection certificate, introduces an extension of 12 months of the Supplementary Protection Certificate (SPC) for medicinal products developed by means of biotechnology processes and for Advanced Therapy Medicinal Products.

Chapter V – Enhancing competitiveness in biosimilars, supports EU competitiveness in the field of biosimilars by encouraging the development of EMA guidelines on facilitating the authorisation of biosimilar medicinal products

Chapter VI – Artificial intelligence and data as biotechnology enablers, encourages the adoption and integration of AI in actions supporting biotechnology, to foster innovation, efficiency and technological sovereignty in biotechnology and biomanufacturing.

Chapter VII – Regulatory tools for novel health biotechnology products, sets out a flexible, collaborative and anticipatory approach to regulate novel health biotechnology products by reinforcing and complementing existing mechanisms in Union law,

Chapter VIII – Biodefence and preventing biotechnology misuse, establishes a framework for preventing the misuse of biotechnology products of concern.

Chapter IX – Amendments to Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938, introduces amendments to EU legislative frameworks in the areas of health and food and feed safety with the aim of simplifying procedures and accelerating time to market that are necessary to ensure the effectiveness of the substantive provisions established in this proposal by creating legislative frameworks conducive to innovation. Further, it establishes amendments to Regulation (EU) 2024/795 (STEP Regulation) regarding the status of health biotechnology strategic projects and of high impact health biotechnology strategic projects under that Regulation.

Chapter X – Final provisions, contains provisions on (i) monitoring; (ii) delegation of power; (iii) committee procedure, (iv) an obligation for the Commission to prepare regular reports to the European Parliament and to the Council for the evaluation of this Regulation; (v) handling of confidential information, and entry into force and application.

Annexes to the proposal:

Annex I- Biotechnology Products of Concern

Annex II- Amendments to Regulation (EU) 536/2014

Annex III- Amendments to Regulation (EU) 2019/6

7. Objective and rationale, including the nature of urgent problems where applicable: National security requirements; Consumer information, labelling; Prevention of deceptive practices and consumer protection; Protection of human health or safety; Protection of animal or plant life or health; Protection of the environment; Quality requirements; Harmonization; Reducing trade barriers and facilitating trade; Cost saving and productivity enhancement

8. Relevant documents:

[-EUR-Lex - 52025PC1022 - EN - EUR-Lex](#)

9. Proposed date of adoption: To be determined

Proposed date of entry into force: The Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

10. Provision of comments

Final date for comments: 18 April 2026

[X] 60 days from notification

Contact details of agency or authority designated to handle comments regarding the notification:

European Commission,
EU-TBT Enquiry Point,
Fax: + (32) 2 299 80 43,
E-mail: grow-eu-tbt@ec.europa.eu