



17 February 2026

(26-1109)

Page: 1/2

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- Health care technology</p>
<p>5. Details of notified document(s) (title, number of pages and languages, means of access): 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; (22 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_00951_00_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: This proposal accompanies the 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, which establishes a legislative framework to strengthen the competitiveness of the health biotechnology sector. For the new framework to operate effectively within the existing acquis, targeted updates are required in two pieces of sectoral legislation. Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms The proposal amends Directive 2010/53/EU (organ processing) to expressly include processing alongside donation, testing, characterisation, procurement, transport and</p>

<p>transplantation, and to clarify that where organs are used for research purposes, the Directive applies only where they are intended for transplantation into the human body. A new Article 6a is introduced to require transplantation centres to obtain prior authorisation from the competent authority before applying a processed organ to a recipient, oblige transplantation centres to perform a benefit-risk assessment of the processing</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety; Quality requirements; Harmonization; Reducing trade barriers and facilitating trade; Cost saving and productivity enhancement</p>
<p>8. Relevant documents: -EUR-Lex - 52025PC1031 - EN - EUR-Lex</p>
<p>9. Proposed date of adoption: To be determined Proposed date of entry into force: The Directive shall enter into force on the twentieth day following that of its publication in</p>
<p>10. Provision of comments Final date for comments: 18 April 2026 <input checked="" type="checkbox"/> 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</p>