



20 January 2026

(26-0422)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: EUROPEAN UNION

If applicable, name of local government involved:

2. Agency responsible: European Commission, Health and Food Safety Directorate-General

3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Genetically modified micro-organisms as or in products

4. Regions or countries likely to be affected, to the extent relevant or practicable:

All trading partners

Specific regions or countries:

5. Title of the notified document: 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. **Language(s):** English. **Number of pages:** 13

https://members.wto.org/crnattachments/2026/SPS/EEC/26_00402_00_e.pdf

6. Description of content: This proposal for a Directive covers two topics, the placing on the market of genetically modified micro-organisms (GMMs) and the processing of organs. This notification concerns only the part on GMMs (Article 1 of the proposed Directive), which is the relevant part under the SPS Agreement.

Amendment (as regards GMMs) to Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

Directive 2001/18/EC regulates the deliberate release into the environment of genetically modified organisms (GMOs) for any other purposes than placing on the market within the European Union (Part B of the Directive) and the placing on the market of genetically modified organisms as or in products within the European Union (Part C). This Directive does not apply to the market authorisation of food and feed containing, consisting of or produced from GMOs.

The proposed amendments introduce specific provisions in Part C of the Directive applicable to the placing on the market of GMMs as or in products (other than food and feed) with the aim of tailoring the requirements of the regulatory framework to GMMs while maintaining a high safety level for human health and the environment.

The provisions proposed relate to the risk assessment, to the validity of the consent granted for the placing on the market, and to detection methods applicable to all GMMs. In relation to a tailored risk assessment, provision is made for the information requirements in Annex III of Directive 2001/18/EC to be amended by the European Commission by way of delegated act in order to adapt them to the specificities of GMMs, respecting the general principles for the environmental risk assessment of Annex II of Directive 2001/18/EC. The validity of consent granted by the competent authorities would last for an unlimited period of time for GMMs. The modalities to comply with detection method requirements in cases where it is not feasible to provide a method that detects,

<p>identifies and quantifies are also adapted in the proposal.</p> <p>Further, the proposal would also introduce specific provisions for low-risk GMMs, including scientific criteria to establish this status, a streamlined authorisation procedure and adaptation of the requirement for post-market environmental monitoring.</p>	
<p>7. Objective and rationale: <input type="checkbox"/> food safety, <input checked="" type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input checked="" type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.</p>	
<p>8. Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>	
<p>9. Other relevant documents and language(s) in which these are available:</p> <p>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 and repealing Council Directive 90/220/EEC: EUR-Lex - 02001L0018-20210327 - EN - EUR-Lex</p>	
<p>10. Proposed date of adoption (dd/mm/yy): To be determined.</p> <p>Proposed date of publication (dd/mm/yy): To be determined.</p>	
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.</p> <p><input type="checkbox"/> Trade facilitating measure</p>	
<p>12. Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 21 March 2026</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: sps@ec.europa.eu</p>	
<p>13. Text(s) available from: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: sps@ec.europa.eu</p>	