



31 October 2023

(23-7321)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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| 1. Notifying Member: <u>EUROPEAN UNION</u> 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): Plants obtained by certain new genomic techniques; Food and feed containing, consisting of, or produced from these plants; Other products containing or consisting of these plants |
| 4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries: |
| 5. Title of the notified document: Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 (Text with EEA relevance). Language(s): English, French, Spanish. Number of pages: 70+Annex https://members.wto.org/crnattachments/2023/SPS/EEC/23_13232_00_e.pdf https://members.wto.org/crnattachments/2023/SPS/EEC/23_13232_01_e.pdf https://members.wto.org/crnattachments/2023/SPS/EEC/23_13232_00_f.pdf https://members.wto.org/crnattachments/2023/SPS/EEC/23_13232_01_f.pdf https://members.wto.org/crnattachments/2023/SPS/EEC/23_13232_00_s.pdf https://members.wto.org/crnattachments/2023/SPS/EEC/23_13232_01_s.pdf |
| 6. Description of content: On 5 July 2023, the European Commission adopted a legislative proposal for a Regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. The proposal is part of a package of proposals to ensure resilient and sustainable use of the EU's natural resources. The proposal sets out specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by targeted mutagenesis and cisgenesis (including intragenesis) and for the placing on the market of food and feed containing, consisting of, or produced from such plants, and of products, other than food or feed, containing or consisting of such plants ('NGT plants and products'). It is supported by an impact assessment and takes account of the scientific work from the European Food Safety Authority, the Commission's Joint Research Centre and other scientific bodies (for further information see impact assessment, section 1.1. and Annex 6). The objectives of the proposal are to: <ol style="list-style-type: none">1. Maintain a high level of protection of human and animal health and of the environment;2. Enable the development and placing on the market of plants and plant products contributing to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies;3. Ensure the effective functioning of the internal market and enhance the competitiveness of the Union agri-food sector at the Union and global levels. |

The main measures of the proposal include:

1. The proposal (in Chapter I) makes the deliberate release and placing on the market of NGT plants and products subject to one of two procedures: verification procedure to establish equivalence with conventional plants/products or authorisation in accordance with EU legislation on GMOs;
2. Chapter II of the proposal provides for a verification procedure and criteria to verify whether NGT plants/products obtained by targeted mutagenesis or cisgenesis could also have been obtained naturally or by conventional breeding techniques, based on the criteria laid down in Annex I ('category 1 NGT plants'). Category 1 NGT plants/products are exempted from the requirements of the GMO legislation, and subject to the rules on conventionally bred plants. Transparency is ensured in a public database, through labelling of the seeds and through the relevant registers on plant varieties;
3. Chapter III of the proposal applies to NGT plants/products which do not meet the criteria to consider that they could also be obtained naturally or by conventional breeding ('category 2 NGT plants'). They remain subject to the rules on GMOs with adaptations as regards risk assessment, detection method, monitoring and renewal requirements. They are made subject to traceability and labelling requirements of the GMO legislation, with the possibility of a voluntary label to indicate the purpose of the genetic modification. The proposal includes regulatory incentives for Category 2 NGT plants/products featuring traits that could contribute to the overall performance of varieties as regards sustainability (Annex III to the proposal);
4. The proposal provides that NGT plants/products are prohibited in organic production;
5. The proposal includes provisions for the monitoring of economic, environmental and social impacts of NGT plants and products, supporting implementation reports and the future evaluation of the legislation.

This Proposal for a Regulation will also be notified under the TBT Agreement

- 7. Objective and rationale:** food safety, animal health, plant protection, protect humans from animal/plant pest or disease, protect territory from other damage from pests.

- 8. Is there a relevant international standard? If so, identify the standard:**

Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):

World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):

International Plant Protection Convention (e.g. ISPM number):

None

Does this proposed regulation conform to the relevant international standard?

Yes No

If no, describe, whenever possible, how and why it deviates from the international standard:

- 9. Other relevant documents and language(s) in which these are available:**

Impact assessment – executive summary (English, French, Spanish)

English:

https://food.ec.europa.eu/system/files/2023-09/gmo_biotech_ngt_ia_report_swd-2023-413_en.pdf

French:

https://food.ec.europa.eu/system/files/2023-09/gmo_biotech_ngt_ia_report_swd-2023-413_fr.pdf

Spanish:

https://food.ec.europa.eu/system/files/2023-09/gmo_biotech_ngt_ia_report_swd-2023-413_es.pdf

Impact assessment - English:

https://food.ec.europa.eu/system/files/2023-07/gmo_biotech_ngt_ia_report.pdf

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| 10. Proposed date of adoption (dd/mm/yy): 5 July 2024 Proposed date of publication (dd/mm/yy): 5 July 2024 |
| 11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): The proposal is currently under discussion by the EU legislative bodies following the relevant EU legislative procedure ("ordinary legislative procedure"). After its adoption, the proposal would enter into force on the 20th day following the publication in the Official Journal of the European Union. It would apply two years after the entry into force. <input type="checkbox"/> Trade facilitating measure |
| 12. Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 30 December 2023 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: 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 |
| 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: 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 |