

EN
E-004209/2025
Answer given by Mr Várhelyi
on behalf of the European Commission
(17.12.2025)

1. The Commission's proposal on plants produced by certain new genomic techniques (NGTs)¹ aims at maintaining a high level of protection of human, animal health and the environment, in accordance with the precautionary principle and the Treaty on the Functioning of the European Union. It would set two distinct regulatory pathways adapted to different risk profiles of NGT plants.

NGT plants equivalent to naturally occurring or conventionally bred plants in terms of modifications introduced and, therefore, of potential risks (i.e. category 1 NGT plants) would be subject to the same safety and environmental rules as conventional plants. This is underpinned by scientific opinions of the European Food Safety Authority² and by the opinion of many other scientific bodies³. In the context of the legislative negotiations, the European Parliament and the Council did not adopt amendments to introduce risk assessment for category 1 NGT plants.

NGT plants with complex modifications that would not be equivalent to conventional plants (i.e. category 2 NGT plants) would remain subject to a GMO risk assessment including environmental considerations.

2. The Commission cannot directly harmonise risk assessment internationally, but contributes actively to various international fora on biosafety⁴.

An increasing number of non-EU countries regulate certain NGT plants as conventionally bred plants. In this context, the NGT proposal would help reduce regulatory divergence and protect the international competitiveness of European products.

¹ COM(2023) 411 final.

² EFSA Panel on Genetically Modified Organisms, Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. *EFSA Journal* 2012;10(10):2943: <https://doi.org/10.2903/j.efsa.2012.2943>; EFSA Panel on Genetically Modified Organisms, 2012. Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. *EFSA Journal* 2012;10(2):2561: <https://doi.org/10.2903/j.efsa.2012.2561>; EFSA Panel on Genetically Modified Organisms, 'Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using SDNs type 1 and 2 and oligonucleotide-directed mutagenesis', *EFSA Journal* 2020;18(11):6299: <https://doi.org/10.2903/j.efsa.2020.6299>; EFSA Panel on Genetically Modified Organisms, 2022. Updated scientific opinion on plants developed through cisgenesis and intragenesis. *EFSA Journal* 2022;20(10):7621, 33 pp: <https://doi.org/10.2903/j.efsa.2022.7621>; EFSA Panel on Genetically Modified Organisms, 2022. Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. *EFSA Journal* 20(10):7618, 12 pp: <https://doi.org/10.2903/j.efsa.2022.7618>; EFSA Panel on Genetically Modified Organisms, 2024. Scientific opinion on the ANSES analysis of Annex I of the EC proposal COM (2023) 411 (EFSA-Q-2024-00178). *EFSA Journal*, 22(7), e8894: <https://doi.org/10.2903/j.efsa.2024.8894>; EFSA, 2025. Literature horizon scan for new scientific data on plants and their products obtained by new genomic techniques (January 2022 to May 2025). *EFSA Journal*, 23(8), e9619: <https://doi.org/10.2903/j.efsa.2025.9619>.

³ SWD(2023) 412 final, Section 1 and Annex 6.

⁴ Such as the Cartagena Protocol to the United Nations Convention on Biodiversity or relevant working groups of the Organisation for Economic Co-operation and Development (OECD).