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**Committee on Sanitary and Phytosanitary Measures**

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**THE EUROPEAN COMMISSION STUDY ON THE STATUS OF  
NEW GENOMIC TECHNIQUES IN THE EUROPEAN UNION**

COMMUNICATION FROM THE EUROPEAN UNION

The following document, received on 12 July 2021, is being circulated at the request of the Delegation of the European Union.

1. On 29 April 2021, the European Commission published a study on the status of New Genomic Techniques (NGTs) under European Union law. The New Genomic Techniques (NGTs) term is used to refer to techniques of genetic modification that have emerged or have been developed since 2001, when the current EU legislation on genetically modified organisms (GMOs) was adopted.
2. The study found that NGTs and their products have been rapidly developing in the last 20 years in many parts of the world, with some applications already on the market of some EU trade partners. More applications in various sectors are expected in the years to come; while there is considerable interest for NGT-related research in the European Union, the large majority of applications are being developed outside the European Union.
3. The study also observed that NGT products have the potential to contribute to sustainable agri-food systems in line with the objectives of the European Green Deal and Farm to Fork Strategy. In the pharmaceutical sector, these techniques would allow faster, more affordable development of medicines, with potential to tackle unmet medical needs. NGTs can be used for the production of useful substances from microorganisms, with applications in cosmetics, biofuels, food ingredients and pharmaceutical substances.
4. The main concerns raised in the consultation are related to possible safety and environmental impact of NGTs, among others, on biodiversity, coexistence with organic and GM-free agriculture, as well as labelling and consumers' right to information and freedom of choice.
5. Based on the available scientific evidence, the European Food Safety Authority (EFSA) concluded that plant products with similar risk profiles can be obtained with conventional breeding techniques, targeted mutagenesis and cisgenesis. For these techniques, EFSA did not identify new hazards compared with conventional breeding methods. EFSA also concluded that these techniques can induce off-target mutations (i.e. modifications in other genomic locations than the intended target) but these would be of the same type and fewer than those occurring with conventional breeding techniques. For other NGTs or for applications in animals and microorganisms, the necessary scientific knowledge is still limited or lacking, especially on safety aspects.
6. The study concluded that the current GMO legislation, adopted in 2001, is not fit for purpose for certain NGTs and their products, and that it needs to be adapted to scientific and technological progress.
7. The European Commission believes that new genomic techniques can contribute to the Green Deal and Farm to Fork objectives of innovation and sustainability of the food systems, as well as to a more competitive economy, which are at the centre of current priorities of the European Union.

8. Based on the information available and the outcome of the study, the European Commission has concluded that there is sufficient evidence and scientific basis to initiate a targeted policy action on plants derived from targeted mutagenesis and cisgenesis.

9. For other organisms (animals and microorganisms) and other new genomic techniques, the Commission intends to continue to build up the required scientific knowledge, in view of possible further policy actions.

10. Considerations related to the use of NGTs in medicinal products will be addressed separately, in the context of the Commission's Pharmaceutical Strategy.

11. The policy action on plants will aim at a proportionate regulatory oversight, which would maintain a high level of protection of human and animal health and the environment and allow reaping benefits from innovation, in particular to achieve the goals of the European Green Deal and Farm to Fork Strategy.

12. In 2022, an impact assessment, including a public consultation, will be carried out in accordance with the EU Better Regulation rules, to examine potential policy options. The impact assessment will also examine the concerns expressed about NGTs during the consultation on the study, and how they can be addressed.

13. More information:

a. Documents:

- EC study on new genomic techniques:  
[https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques\\_en](https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en)

b. Website:

- New techniques in biotechnology:  
[https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology\\_en](https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology_en)
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