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NOTE

From: Presidency

To: Permanent Representatives Committee/Council

Subject: Regulation on plants obtained by certain new genomic techniques and food and feed products

- *Presentation by the Commission*
- *Exchange of views*

Delegations will find in annex a Presidency background note for the exchange of views on the above-mentioned subject at the Council ("Agriculture and Fisheries") meeting on 25 July 2023.

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

Background note from the Presidency

On 5 July 2023, the European Commission has adopted a proposal for a Regulation on new genomic techniques (NGT)¹, as part of the ‘Food and biodiversity package’. The proposal aims to enable the EU agri-food sector to contribute to the innovation and sustainability objectives of the European Green Deal and Farm to Fork and Biodiversity strategies, and to enhance the sector’s competitiveness, while maintaining a high level of protection of health and of the environment.

Since the adoption of the current EU legislation on genetically modified organisms (GMO) in 2001, there has been substantial progress in the development of NGTs that enable more targeted, precise and faster changes in the genetic characteristics of plants, as compared to conventional breeding techniques. In addition, certain techniques do not introduce “foreign DNA”, i.e. DNA from species with which the plant cannot cross breed, and resulting products cannot be differentiated from those obtained by conventional methods.

In 2018, the European Court of Justice ruled that new mutagenesis techniques, that had appeared or had been mostly developed since Directive 2001/18/EC² was adopted, fall under the GMO legislation and are subject to the obligations laid down therein.

¹ 11592/23 + ADD 1

² 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

In order to clarify practical questions raised by the Court ruling, the Council adopted in 2019 a Decision based on Article 241 TFEU³, requesting the Commission to submit a study on the status of NGTs under EU law, and a proposal, if appropriate in the light of the study.

The Commission submitted that study to the Council in 2021⁴. On 27 May 2021, agricultural ministers exchanged views on the study's conclusions and generally agreed on the need to modernise the current legislation for NGT⁵.

Following extensive consultation of stakeholders and the public, and supported by the scientific work of its Joint Research Centre and of the European Food Safety Authority, the Commission has now also submitted the above mentioned proposal for a Regulation on NGT.

The scope of the proposal does not include all NGTs, only targeted mutagenesis and cisgenesis. Furthermore, plants obtained by any NGT that introduces genetic material from non-crossable species ("foreign DNA") are excluded from the scope of the proposal and remain fully regulated by the GMO legislation.

³ Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study

⁴ 8285/21

⁵ 9022/21

Two different categories of NGT plants are regulated in the proposal:

- NGT plants whose modification could also occur naturally or be obtained by conventional breeding (“category 1 NGT plants”). They are subject to a verification procedure prior to the deliberate release and placing on the market. Category 1 NGT plants and products are exempted from the requirements of the GMO legislation. They are regulated under applicable sectorial legislation and horizontal frameworks to ensure health and environment protection. In addition, to improve transparency and freedom to choose, they will be listed in a public database. Plant reproductive material will be labelled as category 1 NGT and this status will be referred to in the common catalogues of plant varieties.
- NGT plants other than category 1 NGT plants (“category 2 NGT plants”), with more complex modifications, on the condition that they do not contain “foreign DNA”. This category falls under the current GMO legislation with limited adaptations for detection methods, risk assessment methodologies and monitoring requirements. While category 2 NGT plants must be labelled as GMO, their labels may include information on the trait conveyed by the NGT modification to increase transparency and consumer’s information. Moreover, category 2 NGT plants containing traits with the potential to contribute to a sustainable agri-food system can benefit from certain incentives. Additional incentives have also been foreseen when the notifier or applicant is a SME. NGT plants featuring herbicide-tolerant traits are not eligible for these incentives. Member States cannot opt out of cultivation of category 2 NGT plants on their territory, in contrast to the GMO legislation.

Both category 1 and category 2 NGT plants and their products are prohibited in organic production.

The Presidency considers it useful to launch a discussion at the Council before starting the technical examination, to focus on the key parts of the proposal. In this regard, the Presidency puts forward the following questions for discussion:

Questions for the discussion:

What is your assessment of the proposal in the context of ensuring a sustainable and resilient agri-food system? Which aspects of the proposal do you consider most important?
