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NOTE

From: General Secretariat of the Council
To: Delegations
Subject: Regulation on new genomic techniques (NGT) – non-paper submitted by Hungary and supported by Austria, Poland, Romania and Slovakia

Delegations will find in annex a non-paper submitted by Hungary and supported by Austria, Poland, Romania and Slovakia on the above subject, with a view to the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 27-28 November 2023.

Non-paper supported by Hungary, Austria, Poland, Romania and the Slovak Republic

On 5 July 2023 the Commission proposed a legislative draft¹ on plants obtained by certain new genomic techniques and their food and feed. The negotiations are ongoing in the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture). The following three subjects of the draft are crucial in order to proceed further with the proposal.

1. Maintenance of the opt-out possibility for category 2 NGT plants

This proposal explicitly excludes the possibility for Member States to decide themselves on restricting or prohibiting the cultivation of category 2 NGT plants on part or all of their territory. In 2015, after more than four years of negotiations this opportunity was provided to the Member States with regard to the cultivation of GMOs by the amendment of the EU GMO Directive². The current draft regulation would *de facto* take this right enshrined in the *acquis* away from Member States; furthermore it would not take into account the regional, national specificities of EU countries in this context. This would contradict the principle of subsidiarity and Member States' acquired rights.

Directive 2015/412³ provided EU Member States greater flexibility to decide during or after the authorisation procedure whether or not to cultivate GMOs on their territory. The possibility given to the EU Member States in Article 26b of the GMO Directive is in line with the principle of subsidiarity, as supported by recitals 6 and 8 of Directive 2015/412.

The proposal constitutes a *lex specialis* complementing the EU legislation on GMOs in case of category 2 NGT plants, so where there are no specific provisions in the proposal; these plants and products should remain subject to the requirements of the Union GMO legislation. One of the specific provisions is that the draft regulation would not allow for Member States the restriction or prohibition of the cultivation of these plants despite the fact that the effects of the cultivation of NGT plants might not be different from the cultivation of classical GMOs. Issues related to the placing on the market and the import of classical GMOs or category 2 NGT plants should certainly remain regulated at Union level to preserve the internal market. However cultivation requires more flexibility in certain instances not only for classical GMOs but also for category 2 NGT plants as it is an issue with strong national, regional and local dimensions, given its link to land use, to local agricultural structures and to the protection or maintenance of habitats, ecosystems and landscapes.

¹ 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

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

³ Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory

It is also important to note that the possibility for opt-out is not an obligation, it is only an option.

Based on the above mentioned reasons we would like to maintain the possibility for Member States for the restriction or prohibition of the cultivation of category 2 NGT plants, thus we suggest to amend Article 25 of the current proposal as follows:

Article 25

Cultivation

Article 26b of Directive 2001/18/EC shall ~~not~~ apply to category 2 NGT plants.

2. Labelling of category 1 NGT food and feed products

Labelling of products is essential to ensure traceability, keep consumer trust by providing sufficient information and the freedom of choice for consumers.

According to the current proposal only seeds and propagating material of category 1 NGT plants are subject to the labelling requirement. As regards the breeding and farming sector this provides insufficient transparency. Traceability of category 1 NGT plants and products from operator to operator until the end consumer can only be ensured if all the products are labelled along the whole food chain.

The use of new genomic techniques is incompatible with the concept of organic production and with consumers' perception of organic products. Therefore, according to the current proposal, the use of category 1 NGT plants remains prohibited in organic production, however the implementation of this in practice raises questions. Organic farming does not only use seeds and propagating material for its production, but also food and feed products. Consequently the exclusion of category 1 NGT plants of organic farming can only be guaranteed, if not only seeds and propagating material, but also food and feed products are labelled.

Based on the above mentioned arguments, the labelling requirement for category 1 NGT plants should be extended to food, feed and other products in order to ensure transparency along the entire production chain, thus we propose to amend Article 10 of the proposal as follows:

Article 10

Labelling of category 1 NGT plant reproductive material, including breeding material

Plant reproductive material, including for breeding and scientific purposes, **food, feed and any other products** that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

3. The issue of patents in relation to NGT plants and products

A number of concerns were already expressed by Member States in relation to patentability of NGT plants and products. Similar concerns had already been raised during several consultation phases of the preparation of the impact assessment, which accompanied the proposal. In the impact assessment itself *“the Commission has taken note of the concerns brought forward by certain stakeholders on the need to ensure in particular the accessibility of farmers to patented seeds and of breeders to patented genetic material, and will carefully consider them.”* The Commission also stated that an evaluation of this issue will be conducted until 2026; however, we believe that there is high probability that by that time any resulting statutory measures come into force, the most important traits and new techniques will already have been patented. Therefore we would like to see assurances in the proposal that patents will not increase market concentration, will not have a negative effect on small breeders and farmers and will not restrict their access to genetic resources.