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From: General Secretariat of the Council
To: Delegations
Subject: Regulation on new genomic techniques (NGT) – comments from Slovenia

Delegations will find in annex submissions from delegations on the above subject, concerning comments on the revised Presidency compromise text for a Regulation on new genomic techniques (NGT) put forward after the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (Innovation in Agriculture) on 14 November 2023.

SLOVENIA**Slovenia's comments on Articles 1-11 with related introductory statements and Annex I****Recital (3):**

Republic of Slovenia notes the absence of more detailed sustainability criteria. We believe that the inclusion of comprehensive and clear sustainability criteria is essential for the regulation, which serves as one of the fundamental aspects.

Recital (7):

We kindly seek clarification on the suitability of patenting NGT 1 when the European Network of GM Laboratories asserts that a clear separation is unattainable. If this assertion holds true, it raises questions about the compatibility of such patents with the stipulations of patent law. We appreciate your insights on this matter.

Recital (38):

In view of the changed definition of NGT plant (the text "genetically modified" («NGT plant» means a genetically modified plant) has been deleted), we suggest adding «NGT» plant to this introductory statement. With the proposed amendment, the text would read as follows:

*»...That renders necessary for Member States' public authorities to define coexistence measures to balance the interests of producers of conventional, organic, **GM genetically modified and NGT plants** and thereby allow producers a choice between different types of production, in line with the Farm to Fork Strategy's target of 25 % of agricultural land under organic farming by 2030...«.*

Article 3(2):

- From a scientific standpoint, the Republic of Slovenia expresses reservations regarding the proposed modification and cannot provide its full endorsement. As established during the working group meetings of the Council (for instance on 30th of October) NGT products are classified as genetically modified organisms, but are intended to be exempted from GMO legislation based on predefined criteria outlined in this Regulation.
- Regrettably, the proposed criteria fail to adequately differentiate these products based on considerations of safety, environmental impact, and potential risks to human and animal health. Instead, the criteria employ an equivalence-based approach.
- It's important to mention that the Regulation doesn't include a clear definition for new genomic techniques. The proposal currently addresses only two techniques, namely cisgenesis and targeted mutagenesis. Consequently, the title of the Regulation may be deemed potentially misleading in its limited coverage of the broader spectrum of new genomic techniques.

Article 5(2):

Should the proposed compromised text involve the removal of the term «*genetically modified*» from the second paragraph of Article 3 in this regulation, the Republic of Slovenia deems it's necessary to incorporate a prohibition on use of GMOs in organic production.

With the proposed incorporation, the text would read as follows:

*»For the purposes of Regulation (EU) 2018/848, the rules **on prohibition of GMOs in organic production** set out in its Articles 5 (f) (iii) and 11 shall **also** apply to category 1 NGT plants and to products produced from or by such plants.«.*

Article 5(3):

The Republic of Slovenia maintains the perspective that the criteria for differentiating the first and second categories of NGTs should not be the subject of a delegated act.

Article 9(1)(e):

We believe it would be sensible to improve clarity in this paragraph by incorporating the phrase »of the NGT plant.«. With the proposed incorporation, the text would read as follows:

»(e) an identification number **of the NGT plant**, and«.

Annex I:

Republic of Slovenia expresses significant reservations regarding the change, proposed in compromised text (addition of »*per monoploid genome*«).

The Republic of Slovenia would also like to present a broader commentary on the draft text, specifically addressing the provision allowing for potential changes to the criteria for classification of NGT categories based on emerging scientific discoveries. We recommend incorporation of a stipulation necessitating applicants to provide comprehensive information about the new plant. This information should encompass details such as whether it falls under NGT1 and will be treated as conventional, including sequences of altered genes and the methodologies employed for determination, with the latter being particularly pertinent for NGT2.

Additionally, we propose that reference materials be made available, and all information disclosed should be accessible through national reference laboratories, if not publicly accessible. This approach ensures transparency and facilitates distribution of crucial data related to NGT applications.

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