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

Delegations will find in annex a courtesy translation of the submission from Germany on the above subject, as issued in ST 12082/23 INIT, concerning questions and comments on the proposal for a Regulation on new genomic techniques (NGT) and on the accompanying impact assessment.

19 July 2023

Initial questions from the Federal Republic of Germany on the Proposal from the EU Commission for the regulation of new genomic techniques following up on the meeting of the Working Party on Genetic Resources and Innovation in Agriculture (meeting on 10 July 2023)

As announced during the above-mentioned meeting, the ESP Presidency has invited questions and comments on the EU Commission's Proposal for a Regulation on new genomic techniques (NGTs) and the accompanying impact assessment (to be submitted by 19 July 2023). We are grateful to be given this opportunity, which we will make use of by submitting the questions below. We trust you will appreciate that at this early stage, immediately after the presentation of the proposal, these initial questions are not conclusive and are, in addition, of a purely technical nature, i.e. they do not represent any positioning by the Federal Government. We look forward to the coming deliberations.

I. Category 1 NGTs (cat-1 NGTs)

Criteria

1. In terms of the verification of cat-1 NGT plants, the proposal envisions an examination based on the criteria defined in Annex I. These refer exclusively to the plant's DNA sequence.

   What scientific foundations or insights are the criteria for the classification under category 1 (Annex I) based on, particularly the restriction to 20 base pairs for substitutions or insertions and to 20 genetic modification events, considering the fact that a mutation caused by chemical agents or radiation is likely to cause multiple mutational events?

2. On what is the assumption based that progeny of cat-1 NGT plants are also cat-1 NGT plants (Article 4 (1) (b))? Do plants obtained through crossbreeding cat-1 NGTs not need to meet the requirements of Annex I (Article 3 (7) vs. Article 4 (1))?

3. Does the Commission consider first-generation cat-1 NGT plants to be part of the breeder's gene pool for generating second-generation cat-1 NGT plants?

4. Annex I (5): In this part of Annex I, what genetic modifications does "*any other targeted modification of any size*" refer to, particularly in distinction from cisgenesis? Does Annex I encompass intragenesis?

5. Annex I (3): How is "*does not interrupt an endogenous gene*" defined? Does a gene in this context only include the coding sequence or are other up- and downstream elements such as promoters, terminators, cis-regulatory elements, trans-regulatory elements, introns etc. included as well?

6. Due to the very general nature of Annex I (3), this regulation is likely to prevent the inactivation of genes/proteins which confer certain unfavourable characteristics to plants. This applies, for example, to certain surface proteins that are known to serve as entry points for certain pathogens, either fungi or bacteria. Was this taken into consideration while drafting this Article?

7. In contrast to the leaked version, herbicide tolerance is not specified as an exclusion criterion with regard to the classification in category 1. Are other approaches envisaged to prevent or limit any potential impact of the cultivation of herbicide-tolerant plants on biodiversity?

Verification

8. To what extent does the current proposal envisage applicants to submit complete sequence information of their NGT plants when applying for their classification in category 1 or authorisation in category 2?

9. What options for action do national authorities have if, during their assessment, they gain the impression that in an individual case – taking into account the precautionary principle – a more in-depth examination is necessary, which would, for example, also consider any potential traits resulting from sequence modifications?

Coexistence and labelling

10. Article 24 obligates Member States to draw up coexistence rules in relation to cat-2 NGT plants. However, the proposal does not contain any information on coexistence measures for cat-1 NGT plants.

    What options for Member States' coexistence measures in relation to cat-1 NGT plants and non-GMO – especially organic farming – does the Commission see if only seeds must be labelled, the applicants are not required to provide any detection or identification options and opting out is precluded?

11. Within the scope of its impact assessment, did the Commission account for the economic and socioeconomic costs of repealing the coexistence rules for the organic farming sector – for which a prohibition of the use of cat-1 NGT plants is envisaged – as well as for the conventional farming sector? How high are these and how do they compare to the costs of maintaining coexistence along the entire value chain? Were potential effects on the objective of achieving a proportion of 25 % organic farming by 2030 taken into account?

12. According to our understanding of the current proposal, the use of NGTs would have to be indicated in the common catalogue of varieties and on the packaging; however, there is no obligation to label such use on the level of seed companies/distributors, i.e. in their catalogues, on their websites etc. Is this correct?

13. What additional measures does the proposal envisage to ensure freedom of choice and transparency for everyone in terms of cat-1 NGT products?

Market relevance

14. Is the Commission aware of how many of the plants under development, being researched, or already commercially available and being cultivated by means of NGT, have met or are meeting the criteria compiled in Annex I?

    In the Commission's opinion, how large is the market share of cat-1 NGT plants estimated to be in comparison to cat-2 NGT plants?

II. Category 2 NGTs (cat-2 NGTs)

15. The term *"risk profile"* is key to the extent of the (environmental) risk assessment for cat-2 NGT plants. What different risk profiles are there, and how are they defined? What requirements result from these risk profiles according to Annex II, parts 2 and 3?

16. What will the requirements be for a notifier's or applicant's sufficient justification that it is not technically possible to provide an analytical method that detects, identifies and quantifies the NGT plant?

17. A re-authorisation generally only needs to be applied for once, after which the authorisation would be valid indefinitely. In this context, what does the term "proportionality" refer to in preliminary remark (30)?

18. Annex II: Are *"putative traits"* not listed under parts 1 or 2 excluded or included when it comes to incentives?

19. Annex III: What are the requirements for demonstrating that any modified traits contribute to the sustainability of the plant?

20. Why are NGT plants featuring herbicide-tolerant traits not eligible for incentives under this framework – especially in comparison to NGT plants featuring herbicide-tolerant traits produced through conventional plant breeding or classical mutagenesis?

Monitoring

21. What are the requirements for monitoring experimental releases? (Chapter III, Article 13 (c), (v))

    What alternative measures does the Commission see for establishing a system to monitor environmental impact if no detection method is required for the experimental releases of cat-2 NGT plants (Chapter III, Article 13 (c) in comparison to Article 14 (1) (l))?

    How can the results of such monitoring systems ensure that negative, cumulative, long-term and unexpected effects on human health and the environment are observed?

22. According to the Deliberate Release Directive, the monitoring of environmental impact should also reveal any environmental impact not predicted by the risk assessment. How is this ensured when the decision whether or not market authorisation requires monitoring to be conducted depends on the results of the risk assessment? (Reference to recital 29)

23. The Commission intends to establish indicator-based investigations in order to determine the effects on the environment and human health, among others. Are there any indicators yet that are suited to determine the effects of GMOs on the environment and on human health, and are there any baseline values? (Article 30 (1), (3) and (4)). Is there a scientific basis for the start of monitoring after 3 years at the earliest? (II Article 30 (1))

III. Additional questions

24. In accordance with Article 290 (1) TFUE, delegated acts may only refer to certain non-essential elements of the legislative act. Against this backdrop, how does the Commission justify having the power to amend Annex I as specified in Article 5 (3) (which defines the scope of application of the EU's genetic engineering legislation)?

25. The Commission's FAQs on the proposal state that a report concerning the effects of potential patenting of NGT breeding material is set to be presented by 2026. What are the reasons for this decision and scheduling? What will be the procedure for the development of this report and what content-related aspects – and taking into consideration which potential follow-up measures – will be evaluated? How will the Member States be involved?

26. When can we expect to receive definitions of key terms such as "*risk profile*", "*sequence similarity*", "*breeder's gene pool*" and "*similar plants*", which are missing at the moment but are crucial for a common understanding?