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

Delegations will find in annex submissions from delegations on the above subject, concerning questions and comments on the proposal for a Regulation on new genomic techniques (NGT) and on the accompanying impact assessment.

CZECHIA

MINISTERSTVO ZEMĚDĚLSTVÍ

Prague, September 1, 2023

Technical comments by the Ministry of Agriculture of the Czech Republic to the 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 (EC) 2017/625

In general, the Czech Republic agrees with the wording of the draft Regulation. However, we consider it important to clarify and modify the equivalence criteria in ANNEX I and we have one question on the status of epimutagenesis.

GENERAL
Article 3

Is epimutagenesis the subject of this proposal? If so, we propose to add definitions of other new genomic techniques – intragenesis, epimutagenesis. It is not clear whether such plants can be considered equal to the products of conventional breeding or, on the contrary, fall into the GMOs legislation.

ANNEX1
Criteria of equivalence of NGT plants to conventional plants

Comments to the introductory paragraph:
- Limitation of the total number of changes in NGT category 1:
    a) does not reflect the situation in conventional breeding
    b) leads to an unclear classification of NGT plants into categories 1 and 2, since the classification depends not only on the nature of the genetic changes but also on the way of preparation or even formal aspects

The limitation on the number of genetic changes in NGT1 plants is unnecessarily restrictive - in the case of untargeted and spontaneous mutagenesis, the resulting number of mutations is up to several orders of magnitude higher. As a consequence of the numerical limit and the provision that the progeny of an NGT1 plant is again an NGT1 plant, an illogical situation arises that a plant in which more than 20 genetic changes have been accumulated by crossing can be classified as NGT1 or NGT2, depending on whether or not its parents were approved as NGT1 before the crossbreeding.

We suggest not to limit the number of changes allowed.

(c) makes it impossible to require a validated detection procedure for NGT2 as a tool for control authorities

If the reason for classifying NGT plant as Category 2 is only the presence of an excessive number of changes, all these changes may be difficult to detect and it is problematic to require a validated detection procedure. However, if NGT2 is defined on the basis of the presence of a more significant genetic change, then detection will not be a problem.

(d) requires the definition of the set of altered genomic sites that are the subject of the evidence and to which the limit applies (the proposed wording is complicated and ambiguous)

The current wording of Annex 1 limits the number of sites in the genome at which the applicant will analyse and document genetic modifications to DNA sequences that share sequence similarity with the target sites and are bioinformatically predictable. In our view, this approach has two pitfalls:
(i) the whole formulation could also be understood to imply that the types of listed changes are only permissible at the target sites and their similar sequences, and thus any change at any other site in the genome is a reason for non-equivalence!
(ii) if only changes in "bioinformatically predictable sites" are analysed and documented, such a definition results in problems with the limited availability of suitable tools, their reliability or the setting of probability measures in predicting possible (off) targets

Without a limit set for NGT1, there is no need to restrict changes to target sites and their off-targets.

-The regulation does not specify how to document the genetic changes present.

For unambiguous documentation and the possibility of follow-up, it would be appropriate to require whole-genome sequencing, with the condition that the subsequent bioinformatic analysis should be performed by a highly standardised procedure or at an operational cost by a dedicated EU authority.

Comments to paragraphs:
(1)
Single or multiple insertions/substitutions of up to 20 nt in length in the protein-coding region of a gene can increase the allergenic potential of the encoded protein.

The parameters of changes for NGT1 in some aspects do not guarantee equivalence with products of conventional breeding and the level of risk of NGT1 may be noticeably higher (comparable to GMO) when the prescribed parameters are met. 20 genetic changes per genome may be accumulated even within a single gene, which may encode a protein with dramatically changed sequence, function and allergenic potential. Even a single insertion or substitution of 20 nucleotides can easily create a new allergenic epitope.

(3)
The criteria for NGT category 1 are not uniform with regard to the permissibility of unplanned endogenous gene disruption.

The condition for insertion/substitution of a cisgene is the non-disruption of an endogenous gene. However, the regulation also allows for deletions/insertions/substitutions at target and non-target sites, where these changes may also result in gene disruption, but this is not regulated in any way. This can lead to illogical situations where insertion of a cisgene associated with a gene disruption at the target site is not allowed for NGT1, but insertion at a site where the gene was previously disrupted, for example by deletion, is already compatible with inclusion in NGT1.

In our opinion, the condition of no disruption of any endogenous gene is unnecessary. If it is an important gene, it will be reflected in a deterioration of the plant's characteristics and in result, such a plant will not be used by breeders. If it is an expendable gene, it does not matter that it has been disturbed in any way. A more stringent alternative would be to make also other types of genetic changes provided that there is no unplanned disruption of the endogenous gene.

(3) a)b); (4); (5)
The condition of targeted (intentional) changes is not uniform and not demonstrable.

Targeting of genetic changes is only required in points 3), 4) and 5) of Annex I, presumably to reach acceptability of insertions, deletions and substitutions in off-targets. However, such an approach is not internally consistent; it would be preferable not to require targeting at any point. Whether a cisgene was inserted at a particular point in the genome by targeting or by chance is not provable or demonstrable anyway.

(4)
The regulation does not address induced chromosomal translocations.

Under the point on inversions, it would be appropriate to include chromosomal translocations as well.

The first draft of an alternative text in Annex I (considering the above objections, comments or questions to clarify are highlighted):

ANNEX I
Criteria of equivalence of NGT plants to conventional plants

A plant prepared by new genomic techniques is considered equivalent to a conventional plant if it differs from the recipient/parental plant only by genetic modifications of the types referred to in points 1 to 4 which can be combined with each other:

1. **any modification of any size, on the condition that the resulting contiguous DNA sequence already occur in an analogous genomic context in a species from the breeders' gene pool**
2. **insertion of contiguous DNA sequence existing in the breeder's gene pool (one sequence to one locus);**
3. **deletion, inversion or translocation of any number of nucleotides;**
4. **substitution or insertion of no more than 20 (???) nucleotides on the condition that induced changes in protein sequences do not predictably decrease protein safety (???)**