Dear [Name],

Subject: Your email and position paper of 6 November 2023 on the proposed regulation on plants obtained by certain new genomic techniques and their food and feed

I refer to your email of 6 November 2023 and the accompanying position paper regarding your concerns about the Commission proposal on plants obtained by certain new genomic techniques (NGTs). Having carefully read your letter, I would like to react to the following points.

You express doubts that these techniques can contribute to achieving the objectives of the Green Deal and the Farm to Fork Strategy. In the Commission’s view, the ambitions and targets of the Green Deal and the Farm to Fork Strategy need to rely on a wide range of solutions, including new technologies and innovation. Plant varieties with specific traits developed using NGTs can be a tool to contribute to social, environmental and economic sustainability, as shown in the impact assessment accompanying the Commission’s proposal. The impact assessment provides an overview of the NGT applications currently in research and development as well as case studies illustrating the potential impacts of NGTs.

In your position paper you claim that the use of the term NGT is misleading and that the Commission is abandoning the current GMO definition by not recognising that NGT products are covered by that definition as stated in the rulings of the European Court of Justice of 25 July 2018 and 7 February 2023.

Based on the 2021 Commission study - which was requested by the Council following the Court’s ruling of 25 July 2018 concluding that organisms obtained by new mutagenesis techniques are subject to the requirements of the GMO legislation - the

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1. Our reference number Ares(2023)7547101
Commission concluded that it was necessary to adopt a specific legal framework for GMOs obtained by targeted mutagenesis and cisgenesis and related products when deliberately released into the environment or placed on the market. The proposed Regulation constitutes a *lex specialis* with regard to the Union GMO legislation, introducing specific provisions for NGT plants and NGT products and adapting the legal framework to technical and scientific progress.

The Commission’s proposal does not modify the definition of GMO as laid down in Article 2(2) of Directive 2001/18/EC. With regard to the use of the term “NGT”, the Commission follows a broad scientific consensus that this and similar terms describe a well-defined group of diverse techniques – different from established genomic techniques (i.e. transgenesis) – characterised by their ability to generate in most cases more precise and targeted genetic alterations than conventional breeding or established genomic techniques, and which can lead to a wide diversity of products.

Your position paper also claims that all NGTs encompass cisgenesis and intragenesis and that NGT plants cannot be distinguished from transgenic plants. I would like to clarify that the proposal does not concern plants obtained by transgenesis. The existing GMO legislation will continue to apply to transgenic plants. The proposal only concerns plants obtained by targeted mutagenesis and cisgenesis, which introduce genetic modifications without permanently inserting genetic material from non-crossable species. In this regard, the proposal requires showing that NGT plants do not contain any genetic material originating from outside the breeders’ gene pool where such genetic material has been temporarily inserted during the development of the plant.

In your paper you also consider that, in particular concerning safety of NGTs, the proposal deviates from European Food Safety Authority (EFSA) opinions. We do not agree with this assessment. EFSA has concluded that there are no new hazards specifically linked to the genomic modification produced via certain NGTs as compared with conventional breeding or established genomic techniques. EFSA has considered that certain types of modifications introduced with NGTs can also take place naturally or through conventional breeding, and that on a case-by-case basis, a lesser amount of data might be needed for the risk assessment.4

The findings from EFSA’s work, widely shared in the scientific community, are an essential part of the evidence underpinning the impact assessment. These conclusions warrant a proportionate approach based on the different risk profiles that result from the diversity of NGTs and of the plants obtained with them, while ensuring that all NGT plants on the EU market will be as safe as conventionally bred varieties. On the basis of these findings, the Commission’s proposal establishes two categories of plants obtained by NGTs, each category subject to different requirements, adapted on a case-by-case basis to their characteristics and risk profile. I would also like to clarify here that there is no derogation of human health risk assessment for category 2 NGTs (those entailing complex modifications that remain subject to risk assessment and authorisation as GMOs).

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EFSA has also clarified how unintended modifications were taken into account in assessing potential risks and hazards of NGT plants. EFSA concluded, based on the available scientific evidence, that such unintended modifications are not specific to NGTs, but may well occur also with conventional breeding techniques or with physical and chemical mutagenesis and do not entail new and specific hazards compared to mutations naturally occurring or generated by conventional methods. Also, the increased speed of development associated to these techniques is not a hazard in itself. EFSA also concluded that due to the higher precision of NGTs compared to conventional breeding techniques the frequency of unintended modification is expected to be lower compared to the one obtained by conventional breeding techniques.

Views challenging the conclusions of its opinions were also addressed by EFSA, including the scientific paper that you mention in your position paper.

You also express concerns about freedom of choice for consumers, due to the fact that category 1 NGT plants would be treated like conventional plants and would not feature a GMO label. Imposing the GMO label for such plants would not accurately reflect the fact that the same product can be obtained conventionally. Please note also that the same rules apply already today to plants obtained by random mutagenesis, which have always been exempt from GMO labelling requirements. It is the Commission’s view that plant products with similar genetic modifications should not be subjected to different labelling and traceability requirements, depending on the technique that was used to obtain them. Nevertheless, the Commission proposes to label the seeds of such NGT plants, allowing GM-free supply chains to exclude them. Consumers wanting to avoid NGT plants can rely on the organic label as the organic sector will not be allowed to use plants obtained by NGTs. In order to minimise the risks of adventitious presence of NGT plants, the organic sector can rely on the organic traceability requirements and the preventive measures provided for in the Organic Products Regulation.

Category 2 NGT plants, which contain more complex modifications than category 1 NGT plants, would remain subject to risk assessment and authorisation, to the current traceability and labelling rules of the GMO legislation, as well as to coexistence measures, which all Member States would need to adopt.

The points made above are based on the proposal presented by the Commission, which is currently in the legislative process involving both the European Parliament and the Council, and therefore may be amended by them.

Yours sincerely,

Klaus Berend

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