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To whom it may concern

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In its "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", the Commission wants to weaken or abolish various long-standing and reliable principles of European gene technology law. In this respect, a set of so-called "criteria of equivalence to conventional plants" (Art. 3 para. 7 lit. a) of the proposal) plays a central role, which is intended to ensure that no further risk assessment is carried out for category 1 GMO and their progeny. The equivalence criterion understood in this way is open to criticism from various points of view.

Firstly, it should be noted that the assumption on which this approach is based, whereby "small changes" only harbour small and, above all, negligible regulatory risks, has not been scientifically

proven. Instead, number and type of genetic change are not a proxy for how risky a NGT plant might be. It is necessary to consider the genetic change in the NGT plant itself and its effects on plant traits, may it be intended or unintended (cf. Kawall, The Generic Risks and the Potential of SDN-1 Applications in Crop Plants, in: Plants 2021, 10; DOI: 10.3390/plants10112259; Eckerstorfer/Grabowski/Lener/Engelhard/Simon/Dolezel/Heissenberger/Lüthi, Biosafety of Genome Editing Applications in Plant Breeding: Considerations for a Focused Case-Specific Risk Assessment in the EU, in: BioTech 2021, 10; DOI: 10.3390/biotech10030010). Therefore, from a biological perspective, Annex I is not suitable to decide whether an NGT plant should be authorised without a risk assessment. Above all, the Commission´s approach is incompatible with the findings of the European Court of Justice. In particular, in Case C-688/21, the Court stated that even the smallest changes to supposedly established methods can lead to a completely different risk profile: “It cannot be ruled out that the application of a technique/method with such characteristics may lead to genetic modifications of the organism concerned which differ, by their nature or by the rate at which they occur, from those obtained by the application of that second technique/method of mutagenesis” (Case C-688/21, para 52).

Secondly, the Commission's proposal assumes that equivalence can be assumed for up to "20 genetic modifications" - whereby some "single modifications" in turn include an unlimited number of alterations (cf. Annex I of the proposal). For example, the "deletion of any number of nucleotides" would constitute a single genetic modification, as would the "targeted reversal of a sequence of any nucleotides". In this way, even massively genetically modified plants are to be constructed as category 1 plants, which results in an incompatibility with the precautionary principle. The ECJ has ruled that the correct application of the precautionary principle enshrined in Art. 190 para. 2 TFEU “presupposes, first, identification of the potentially negative consequences (…), and, second, a comprehensive assessment of the risk (…) based on the most reliable scientific data available and the most recent results of international research (Case C-616/17 para 46; see, by analogy, Case C-343/09, para. 60, and Case C-77/09, para 75). Since the comparison between NGT plants and conventional plants is not suitable for a comprehensive assessment of the risks of NGTs and is neither based on the most reliable scientific data and nor takes into consideration the most

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recent results of international research, Annex I is not in line with the necessary legal standard to properly apply the precautionary principle. The ECJ has permanently highlighted the importance of this European primary law principle for the interpretation of European gene technology law, including the case by case analysis of potential risks (Case C-528/16, para 50 ff; Case C-688/21, para. 44 et seq.). This is all the more dramatic, therefore, as the Commission does not implement any kind of regulatory follow-up and instead assumes that once equivalence has been certified, this justifies the assumption of "eternal stability" of the genetic modifications made.

Furthermore, the Commission wants to introduce the possibility for itself to amend the equivalence criteria by means of delegated acts (Art. 5 para 3 of the proposal). This authorisation violates Art. 290 para. 1 subpara. 1 TFEU, which only allows the completion of provisions that are primarily manifested in the detailing and concretisation of the regulations contained in the respective legislative act. As can be seen from the case law of the ECJ, "the parameters for the assessment and authorisation" of food-related products and the "essential safety requirements" are among the key aspects that the legislator itself must regulate (Case C-66/04, para 53 et seq.). However, since the equivalence criteria are not refinements of the applicable law, but rather, according to the Commission's intention, the only relevant points for the (non-) applicability of gene technology law, Art. 290 TFEU prohibits the Commission's planned approach.

With kind regards,

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