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European Union

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NOTE

From: General Secretariat of the Council
To: Delegations

Subject: Regulation of plants obtained by new genomic techniques – need for coordinated action

- Information from the Austrian delegation, supported by the Cyprus, Luxembourg and Hungarian delegations

Delegations will find in the Annex an information note from the Austrian delegation, supported by the Cyprus, Luxembourg and Hungarian delegations, on the above subject, to be dealt with under 'Any other business' at the Council (Environment) meeting on 20 December 2021.

Regulation of plants obtained by new genomic techniques – need for coordinated action

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In the inception impact assessment published by the European Commission on 24 September 2021, a change in the regulation of plants obtained by directed mutagenesis and cis-genesis is one of the possible policy options. The core elements of this new regulation are a "proportionate" risk assessment, a sustainability assessment and traceability and labelling requirements, which should be linked to sustainability. The ECJ ruled in 2018 that new genomic techniques are regulated under the EU gene technology legal framework, especially Directive 2001/18/EC. The reasoning behind this ruling was strongly linked to the precautionary principle, which needs to be taken into account especially with new techniques, where there is little or no experience with possible health or environmental effects. Austria welcomed this ruling and reasoning.

We strongly believe that it is of utmost importance that the level of safety of all GMOs, including plants obtained by directed mutagenesis and cis-genesis for humans and animals as well as for the environment, remains high. In that respect, the freedom of choice for consumers must also be guaranteed, by ensuring a reliable and comprehensive traceability and labelling system. For the foreseen sustainability analysis, we lack information regarding the relevant parameters. In addition, no criteria and methodology exist. Therefore, it remains completely unclear how such an analysis should be performed.

We therefore urge the European Commission to respect the precautionary principle, especially given the relative novelty of the techniques under discussion, and to foresee a comprehensive environmental and health risk assessment, comparable to that in place for GMOs. We also ask the Commission to invest in research in the areas of detection and biosafety of products of new genomic techniques. This is especially important with respect to a functioning traceability and labelling regime and the delivery of independent risk-related data. We also request that the proposed sustainability analysis follows a scientific approach and that outcomes of the related process under the development of “sustainable food systems” are taken into account in a timely manner.

Finally, we encourage the European Commission to engage with the Council, the European Parliament and all stakeholders on the issue of new genomic techniques in a broad and transparent manner.
