Council of the
European Union

Brussels, 9 March 2023
(OR. en)

7054/1/23
REV 1

ENV 195
AGRI 100

NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Regulation of plants obtained by new genomic techniques – need for further discussions respecting environmental aspects - Information from the Austrian delegation, supported by the Cyprus and Hungarian delegations

Delegations will find in the Annex an information note from the Austrian delegation, supported by the Cyprus and Hungarian delegations, on the above subject, to be dealt with under 'Any other business' at the Council (Environment) meeting on 16 March 2023.

ANNEX

Regulation of plants obtained by new genomic techniques – need for further discussions respecting environmental aspects

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

On 24 September 2021, the European Commission published an inception impact assessment containing the option to change the rules regarding plants obtained by mutagenesis and cis-genesis, currently covered by the legislation on genetically modified organisms (GMOs). Following a public consultation, the European Commission started the impact assessment by carrying out public consultations and involving stakeholders and Member States' authorities. It is expected that the European Commission will table the result of this impact assessment together with a legislative proposal in early June 2023. Further discussions at Council level are envisaged to take place in a Working Group (WG) in the AGRI/FISH configuration.

The impact assessment was mainly done by using a questionnaire, which was to a large extent based on expectations, assumptions and suggestive scenarios, rather than on data and scientifically sound methods. Therefore, a number of Member States was unable to answer the questions or declined to do so. We firmly believe that the results of this survey cannot and should not be the basis for any future policy actions on plants using new genomic techniques in the European Union.

In October 2022, the European Food Safety Authority (EFSA), following a request by the European Commission, published a statement on the criteria for the risk assessment of plants obtained by mutagenesis or cis-genesis. The core of these criteria is the concept of 'history of safe use', which was originally developed for food risk assessment and has always been heavily debated regarding its use in environmental risk assessment. The EFSA itself stated in the document, that before the proposed risk assessment criteria could be applied, many aspects required further development and definition, including the concept of 'history of safe use'. In particular with regard to the environmental risk assessment, many questions remain open, as the EFSA considers them to be overly vague. As many products obtained by targeted mutagenesis might carry environmentally relevant traits, this should be given adequate attention.

We therefore urge the European Commission to foresee a comprehensive environmental and health risk assessment, like that in place for GMOs, and not to base its legal proposal on a vague and yet insufficiently elaborated concept. Once again, we ask the Commission to invest in research in the areas of biosafety, the impacts on biodiversity and the detection of products of new genomic techniques. Traceability is necessary to detect potential harm to species and ecosystems, in particular regarding possible threats to biodiversity. We ask the European Commission to conduct a comprehensive impact assessment based on solid data rather than assumptions, also reflecting data obtained in other parts of the world.

Finally, we would like to ask the Presidency to consider establishing an ad hoc WG for the upcoming discussions at Council level, in order to facilitate discussion involving all concerned areas (environment, health and agriculture), following the scope of the current GMO legislation and taking into account the responsibilities of the different competent authorities in the Member States.