



Council of the
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NOTE

From:	Presidency
To:	Permanent Representatives Committee/Council
Subject:	Study on the status of new genomic techniques - <i>Exchange of views</i>

Delegations will find in annex a Presidency background note for the exchange of views on the above-mentioned subject at the Council ("Agriculture and Fisheries") meeting on 26 and 27 May 2021.

BACKGROUND NOTE ON**The Status of New Genomic Techniques – Follow-up to the Commission's study**

1. There has been substantial progress in the development of new genomic techniques, leading to uncertainty on whether those new techniques come under the definition of a genetically modified organism (GMO) and whether products obtained by new genomic techniques are subject to Union legislation on GMOs.
2. The Court of Justice's judgment in Case C-528/16 clarified that Union legislation on GMOs, notably Directive 2001/18/EC, does apply to new mutagenesis techniques. However, practical questions arose regarding products that are indistinguishable, whether they have been produced through new mutagenesis techniques or through natural mutation.
3. The Council requested the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law. The Commission submitted that study on 29 April 2021.
4. The study concludes that the current legislation on genetically modified organisms has clear implementation challenges and requires contentious legal interpretation to address new techniques and applications. There are strong indications that it is not fit for purpose for some new genomic techniques and their products, and that it needs to be adapted to scientific and technological progress.
5. Based on the conclusions of the study, the Commission considers that action is necessary, not only to address the practical questions leading to the Council's request, but also to reap the benefits from innovation to contribute to the sustainability and resilience of the EU agri-food system as well as to the objectives of the European Green Deal and in particular the 'farm to fork' and biodiversity strategies.

6. The Commission informed the Council that it intends to initiate a policy action on plants derived from targeted mutagenesis and cisgenesis, which will entail carrying out an impact assessment. For other organisms (animals and microorganisms) and other new genomic techniques, the Commission intends to continue to build up the required scientific knowledge, in view of possible further policy actions.
7. The envisaged policy action on plants derived from targeted mutagenesis and cisgenesis will aim at a proportionate regulatory oversight for the relevant plant products, combining high levels of safety with clear added value to farmers, society and the environment.
8. New genomic techniques are a complex technical issue. They are also a topic on which polarised and often sceptical views exist among stakeholders and in society at large, especially when related to food production. The political debate needs to take into account all the different perspectives and the key issues at stake.
9. We invite ministers at the Agriculture and Fisheries Council meeting on 26-27 May 2021 to take part in an exchange of views on the basis of the following questions:
 - a) *What is your reaction to, and how far do you agree with the conclusions of the Commission's study in general, and in particular the need to initiate policy action*
 - b) *What is your view on the envisaged focus on plants (as opposed to animals and microorganisms), and on targeted mutagenesis and cisgenesis (as opposed to other new genomic techniques)?*
 - c) *To what extent should science-based decision-making take account of (i) not only risks but also benefits for sustainability of products of new genomic techniques, and (ii) other legitimate factors, such as consumer expectations and viewpoints of society?*
 - d) *How can we ensure open and participatory debate on the design of new regulation, and its implementation?*