



Brussels, 24 October 2019
(OR. en, sv)

11728/19
ADD 1 REV 1

AGRI 416
AGRILEG 148
ENV 858

'I/A' ITEM NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

Subject: Council Decision regarding the status of novel genomic techniques under
Union law
- *Adoption*
= Statements

Statement by Cyprus, Hungary, Latvia, Luxemburg, Poland and Slovenia

With a view to the objective of protecting the environment and human health, respecting the precautionary principle, we consider that any technique, which alters the genetic material for agricultural purpose in a way that does not occur naturally, requires a special attention.

In this regard, Cyprus, Hungary, Latvia, Luxemburg, Poland and Slovenia recall that the preparation of the Council decision was triggered by the situation resulted from the Court of Justice's judgment in [Case C-528/16](#) which brought legal clarity as to the status of new mutagenesis techniques, but also raised practical questions which have consequences for the national competent authorities (referred to recital (4) of the draft Council decision).

We generally support the idea of the preparation of a study on this important topic. Nevertheless we are of the view that this study should be based on a clear and well-defined terminology. In this respect the term used in the above Court Ruling, "new mutagenesis techniques" should determine the scope of the study, as the term "novel genomic techniques" is not clearly defined by EU law.

The protection of human health and the environment requires that due attention be given to controlling the risks from any technique that alters the genetic material, and the current level of protection should be maintained.

Statement by the Netherlands

The Netherlands recalls the broad support of Member States at the AGRIFISH council of 14/05/2019 for calling upon the Commission to address “the adequacy of the European legislative framework for GMOs” and strongly welcomes the initiative by the Finnish Presidency regarding new breeding techniques to adopt a council decision that provides a follow-up to the judgment of the European Court of Justice (ECJ) in case C-528/16.

The call was explicit regarding *the need for a common EU approach and a review of the current GMO legislation*. The decision requests a study on *the status of novel genomic techniques under Union law*. The Netherlands is of the opinion that an objective review of the legal framework is necessary when evaluating the consequence of the Court ruling. Therefore, the Netherlands expects the study to address the adequacy, efficiency and consistency of the currently existing legal framework, thereby adding value to what the Commission is required to report. In effect, Directive 2001/18/EU already requires the Commission to report on the status of new genomic techniques under Union law and its consequences for the implementation of European GMO legislation.

The Netherlands underlines the urgency of the steps to be undertaken in view of the broad extent of implications of the current situation.

In addition the Netherlands draws attention to several practical and legal implications of the ruling which have been highlighted also by several recent EU led studies¹.

We cannot afford any delay in achieving a comprehensive way forward and a review that takes into account the efficacy of the legislation is therefore urgently needed. The Netherlands expects the Commission to assess as part of the requested study, in view of the ECJ ruling, the existing legal framework, sufficiently taking into account the principles of precaution and proportionality.

Finally, the Netherlands calls on the Commission to inform and consult, as appropriate, the Member States on the progress of the study at regular intervals, so as to ensure an inclusive approach.

1

- The Scientific Advice Mechanism (SAM) report: New techniques in Agricultural Biotechnology, High Level Group of Scientific Advisors Explanatory Note 02, Brussels, 28 April 2017
- NL discussion proposal to amend Annex IB of Directive 2001/18/2018, 7 September 2017
- European Court of Justice decision for genome editing: Consequences on food/feed risk assessment and detection, 25. July 2018
- The SAM statement after the ECJ ruling: A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive, November 2018
- The Norwegian Biotechnology Advisory Board (Bioteknologirådet) (2018). The Gene Technology Act – Invitation to Public Debate.
- Open letter from EU Researchers: Open Statement: European scientists urgently reach out to the newly elected European Parliament and European Commission to enable the potential of genome editing for sustainable agriculture and food production.
- The ENGL report on Detection of food and feed plant products obtained by new mutagenesis techniques, 26 March 2019.
- Danish Council of Ethics (29 April 2019) recommends GMO legislation be changed to help achieve sustainability objectives
- Joint statement French/German AFBV and WGG proposing small changes to the GMO Directive enabling and accelerating smart breeding in European agriculture, 10 September 2019

Statement by Sweden

Sverige välkomnar att den nya kommissionen uppmärksammas på EU-domstolens avgörande om nya gentekniker samt de konsekvenser denna lett till. Sverige är angeläget om att studien omfattar de nya mutagenesteknikerna (riktad mutagenes) för växtförädling som omnämns i domstolsavgörandet och förutsätter att dessa är en integrerad del av studien.

För att studien ska vara komplett anser Sverige att den ska innefatta beräkningar av kostnader och ser särskilt fram emot denna del av studien.

Courtesy translation

Sweden supports the draft Council decision.

Sweden welcomes that the new Commission is made aware of the ruling of the Court of Justice of the European Union concerning new gene techniques and the consequences that this has led to. It is important to Sweden that the study contains the novel mutagenesis techniques (directed mutagenesis) for plant breeding that were mentioned in the court case and we assume that these are an integral part of the study.

Sweden considers that the study should include cost estimates in order to be complete and we are particularly eager to read this section of the study.
