



COMMISSION EUROPÉENNE
SECRETARIAT GÉNÉRAL

Direction B - Prise de décision & Collégialité
SG.B.3 - Secrétariat du Groupe des Relations Interinstitutionnelles (GRI)

Bruxelles, le 10 octobre 2019

SI(2019) 566

GRI du 11 octobre 2019
point 4.4.

NOTE À L'ATTENTION DES MEMBRES DU GRI

Objet : Application de l'article 241 TFUE

Draft Council Decision requesting the Commission to submit a study on the Union's options for addressing the legal situation of new plant breeding techniques taking into account the existing legal framework provided by Directive 2001/18/EC of the European Parliament and the Council and the Court of Justice's judgment in Case C-528/1

Mmes et MM. les membres du GRI trouveront en annexe une fiche préparée par la DG SANTE sous l'autorité du cabinet de M. ANDRIUKAITIS et en accord avec le cabinet de M. KATAINEN.

Annexe:

GRI MEETING OF 11 OCTOBER 2019

NOTE TO THE MEMBERS OF THE GRI

Subject: **Draft Council Decision requesting 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**

Council: Adoption in Council in November 2019 (tentative)

PURPOSE OF THIS FICHE

The Directive on the deliberate release into the environment of GMOs contains an exemption applicable to “mutagenesis techniques”. In July 2018, the Court of Justice of the European Union gave a preliminary ruling (Case C-528/16) regarding the regulatory status of organisms produced by means of new mutagenesis techniques, and in particular on whether such techniques are exempted from the GMO-legislation. The outcome of the ruling was that only organisms obtained by means of techniques or methods of mutagenesis, which have conventionally been used in a number of applications and have a long safety record, are exempted. Therefore, the GMO legislation is applicable to organisms obtained by new mutagenesis techniques, which have emerged since the adoption of Directive 2001/18/EC. Several stakeholders consider that various opportunities are missed when products from new genomic techniques are regulated as GMOs, as the legal framework is complex, burdensome and not fit for these products. Since the Court of Justice’s ruling, the Commission services have been holding technical meetings with the Member States experts to ensure Member States implement the GMO legislation as the Court has interpreted it.

The Presidency of the Council is tabling a draft Decision, based on Article 241 TFEU, requesting the Commission to submit, by 30 April 2021, a study in light of the Court of Justice’s judgment regarding the status of novel genomic techniques under Union law. Novel genomic techniques encompass new mutagenesis and all other new techniques to which GMO legislation applies. The draft Decision also requests the Commission to submit a proposal (accompanied by an impact assessment), if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study.

The purpose of this fiche is to inform the College on the state of play described above. It is proposed that the Commission takes note of the draft Council Decision. The Commission will have to reply to the Council in line with the Interinstitutional Agreement on Better Law-Making. It will be up to the next Commission to define the exact scope and intended follow-up to the study.

1. BACKGROUND

The EU has authorised genetically modified organisms (GMOs), obtained by insertion of foreign genetic material, for the last 25 years. In the last decades, advances in biotechnology have led to the development of new genomic techniques (new breeding techniques). Among these, the most prominent are targeted mutagenesis techniques,

which alter the genome of a species without the insertion of foreign DNA. These techniques have been rapidly evolving, with broad innovation potential and agri-food applications ready for the market.

In July 2018, the EU Court of Justice concluded that products from new mutagenesis techniques are subject to the GMO legislation.

Several stakeholders (academia, farmers, breeders, industry) consider that various opportunities are missed when products from new genomic techniques are regulated as GMOs, as the legal framework is complex, burdensome and not fit for these products. They consider that products from these techniques could benefit citizens, society and the economy. Examples of benefits include reduced pesticide use, disease resistance, draught tolerance, improved nutritional content, innovation tailored to local needs or for lower profit margin sectors such as horticulture. As a result, new products could contribute to addressing societal and environmental challenges, such as sustainable production, healthier diets, and climate change.

Other stakeholders, especially NGOs, want to maintain organisms produced with new genomic techniques under the GMO legislation, mainly to ensure safety and consumers' right for information.

Most of the EU's trading partners have decided to regulate products of new genomic techniques differently from conventional GMOs or not to regulate them at all.

2. MAIN CONTENT OF THE DRAFT COUNCIL DECISION

Based on Article 241 TFEU, the Council requests the Commission to submit a study, by 30 April 2021, in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law. Furthermore, the Council requests the Commission to submit a proposal, if appropriate in view of the outcomes of the study, or otherwise to inform the Council on other measures required as a follow-up to the study.

3. STATE OF PLAY IN THE COUNCIL WORKING GROUP

The draft Council Decision was discussed at a Council Working Group on 6 September 2019. Following a round of written comments by the Member States (which are largely in favour of the approach in the draft Council Decision), no further discussions are envisaged in Council. The draft Council Decision is planned as an I-item in Coreper (tentative date: Coreper I meeting of 16 October 2019) and later as an A-item adoption in Council in November. Adoption requires simple majority.

4. SUGGESTED COMMISSION POSITION

It is proposed that the Commission takes note of the draft Council Decision, to which a reply will have to be prepared under the next College.

5. RECOMMENDATION TO THE COMMISSION

It is suggested that the GRI recommends to the Commission to endorse the line set out in the present fiche.

5. OFFICIALS RESPONSIBLE

Contact: (SANTE.E.3)

Personal data

