



Council of the
European Union

Brussels, 26 August 2019
(OR. en)

11347/19

LIMITE

AGRI 418
AGRILEG 149
ENV 743

NOTE

From: Presidency

To: Delegations

Subject: 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-528/16

COUNCIL DECISION (EU) 2019/...

of ... 2019

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-528/16

THE COUNCIL OF THE EUROPEAN UNION

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 241 thereof,

Having regard to the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ⁽¹⁾, and in particular paragraph 10 thereof on the application of Article 225 and 241 of the Treaty on the Functioning of the European Union,

Whereas:

- (1) According to the definition set out in Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾, a “genetically modified organism (GMO)” means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination’. The definition was included in a similar form already in the previous Directive, namely Council Directive 90/220/EEC ⁽³⁾, and had been drafted in the light of those breeding techniques that were available and used at the time of its adoption.
- (2) Since then, there has been substantial progress in the development of new breeding techniques, leading to uncertainty on whether those new breeding techniques come under the definition of a GMO or not and, as a consequence, whether products obtained by them should be subject to the obligations laid down in Directive 2001/18/EC.

⁽¹⁾ OJ L 123, 12.5.2016, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ L 117, 8.5.1990, p. 15), repealed by Directive 2001/18/EC.

- (3) By its judgment in Case C-528/16⁴, the Court of Justice, after considering the overall objectives of Directive 2001/18/EC, ruled that new mutagenesis techniques fall within the scope of that Directive and are subject to the obligations laid down therein.
- (4) The ruling brought legal clarity as to the status of new breeding techniques, but also raised practical questions which have consequences for the Union's plant breeding industry, research and beyond. Those questions concern, *inter alia*, how to ensure compliance with Directive 2001/18/EC when products obtained by means of new breeding techniques cannot be distinguished from products resulting from natural mutation, and how to ensure, in such a situation, the equal treatment between imported products and products produced within the Union.
- (5) The Council considers that a study is necessary to clarify the situation,

⁽⁴⁾ Judgement of the Court of Justice of 25 July 2018, *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, C-528/16, ECLI:EU:C:2018:583.

HAS ADOPTED THIS DECISION:

Article 1

The Council requests the Commission to submit, by [2021], a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel plant breeding techniques under Union law.

Article 2

1. 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.
2. In accordance with usual practice, the Council requests the Commission to ensure that the proposal is accompanied by an impact assessment.

Article 3

This Decision shall enter into force on the day of its publication in the Official Journal of the European Union.

Done at ..., ... 2019.

For the Council

The President

...
