Council Decision (EU) 2019/1904 of 8 November 2019 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, and a proposal, if appropriate in view of the outcomes of the study

COUNCIL DECISION (EU) 2019/1904

of 8 November 2019

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THE COUNCIL OF THE EUROPEAN UNION

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

Whereas:

(1) According to the definition set out in Directive 2001/18/EC of the European Parliament and of the Council[(1)], 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. Lists of techniques complete this definition and specify the scope of that Directive. The definition and the lists of techniques have been drafted in the light of those breeding techniques that were available and used at the time of the adoption of Directive 2001/18/EC.

(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 and the scope of Directive 2001/18/EC or not and, as a consequence, whether products obtained by them should be subject to the obligations laid down in that Directive.

(3) By its judgment in Case C-528/16[(2)], 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 mutagenesis techniques, but also raised practical questions which have consequences for the national competent authorities, the Union's industry, in particular in the plant breeding sector, research and beyond. Those questions concern, inter alia, how to ensure compliance with Directive 2001/18/EC when products obtained by means of new mutagenesis techniques cannot be distinguished, using current methods, 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.

Changes to legislation: *There are currently no known outstanding effects for the Council Decision (EU) 2019/1904. (See end of Document for details)*

(5) The Council considers that a study is necessary to clarify the situation, in accordance with the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[(3)], and in particular paragraph 10 thereof on the application of Article 225 and 241 of the Treaty on the Functioning of the European Union,

HAS ADOPTED THIS DECISION:

Article 1

The Council requests the Commission to submit, by 30 April 2021, 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.

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 Brussels, 8 November 2019.

For the Council

The President

L. ANDERSSON