Council of the
European Union

Brussels, 24 February 2020
(OR. en)

6302/20

LIMITE

AGRI 64
AGRILEG 23
ENV 102

COVER NOTE

From:	General Secretariat of the Council
date of receipt:	21 February 2020
To:	Delegations
No. prev. doc.:	12781/19
Subject:	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, and a proposal, if appropriate in view of the outcomes of the study - Commission's response

Delegations will find attached the Commission's response to the Council's request under Article 241 TFEU, by way of Council Decision (EU) 2019/1904 of 8 November 2019.

Ref. Ares(2020)1117880 - 21/02/2020

European Commission

MAROŠ ŠEFČOVIC
Vice-President of the European Commission

Brussels, 21/02/2020

Dear Mr Grlić Radman,

Please find enclosed the Commission's response to the Council's request under Article 241 TFEU, by way of 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, or otherwise to inform the Council on other measures required as a follow up to the study.

Yours sincerely,

Cc: Stella Kyriakides, Commissioner for Health and Food Safety

Mr Gordan Grlić Radman
Minister of Foreign and European Affairs of the Republic of Croatia

Commission's response to the Council's request under Article 241 TFEU, by way of 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, or otherwise to inform the Council on other measures required as a follow up to the study.

The Commission agrees that it is important to clarify further the status of new genomic techniques under Union law in light of the Court of Justice's judgment in Case C-528/16. The Council states that the Court of Justice ruling has raised practical questions with consequences for the national competent authorities, EU industry, in particular in the plant-breeding sector, research and beyond. These questions concern, *inter alia*, difficulties to comply with EU legal framework and to ensure equal treatment for EU products vis-à-vis imported ones, when products obtained with new genomic techniques are not distinguishable from those resulting from natural mutations.

The Commission recalls that it has held several discussions with national competent authorities on the implementation of the EU legislation on genetically modified organisms (GMOs), as the Court has interpreted it, in the context of regulatory committee meetings. The Commission has reminded Member States of their responsibility to implement GMO legislation in accordance with the Court judgement. To help Member States and operators, the European Commission has mandated the European Union Reference Laboratory for Genetically Modified Food and Feed, together with the European Network of GMO Laboratories, to elaborate a series of reports on the detection of products obtained by new mutagenesis techniques. The Commission has also mandated the European Food Safety Authority (EFSA) to assess the hazards and the adequacy of existing risk assessment guidance for plants developed through certain new mutagenesis techniques.

The requested study will focus on the state-of-play on implementation of the legislation as interpreted by the Court, based on substantiated contributions from the Member States and relevant stakeholders. A dedicated working group of the Member States experts has been set up to this end and the first meeting took place in January 2020. Targeted stakeholder consultations will be launched in February 2020.

The study will also describe and analyse the status and use of new genomic techniques in plants, animals and micro-organisms for agri-food, industrial and pharmaceutical applications. In order to have as complete picture as possible of new techniques in view of continuous scientific developments, an overview of current and future scientific and technological developments in new genomic techniques as well for new products that are, or are expected to be, marketed in third countries, will be provided by the Joint Research Centre. To address the safety of new techniques, EFSA will be mandated to produce an overview on the risk assessment of plants developed through new genomic techniques, based on its own previous and on-going work and on work carried out at national level.

Based on the outcomes of the study, the Commission will consider what action, if any, needs to be taken.