6 December 2019

DRAFT NOTE FOR DISCUSSION

Subject: **Council Decision (EU) 2019/1904 requesting the Commission to submit a study on the status of new genomic techniques**

The purpose of this document is to lay out the possible content of the study, requested by Council Decision (EU) 2019/1904, regarding the status of new genomic techniques under Union law in light of the Court of Justice's judgment in Case C-528/16.

Summary of the legislation

Directive 2001/18/EC on the deliberate release into the environment of GMOs contains an exemption applicable to "mutagenesis techniques". The Court of Justice's preliminary ruling (Case C-528/16) concluded that only organisms obtained by techniques of mutagenesis, conventionally used in a number of applications and with a long safety record, are exempted. Therefore, the GMO legislation is applicable to organisms obtained by new mutagenesis techniques[1], which have emerged after the adoption of Directive 2001/18/EC.

[redacted]

Request of the Council under Article 241 TFEU

The Council's Decision, based on Article 241 TFEU, requests the Commission to submit

- a study, by 30 April 2021, regarding the status of new genomic techniques under Union law and in light of the Court of Justice's judgment;
- 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 request is justified by practical questions raised by the Court ruling with consequences for the national competent authorities, EU industry, in particular in the plant-breeding sector, research and beyond. These questions concern, among others, 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.

[1] New mutagenesis techniques are a sub-group of new genomic techniques.
[2] Ares(2019)4429992
[3] [redacted]

Interestingly, the Council Decision does not focus the request on new mutagenesis techniques only, but expanded the request to "new genomic techniques". This triggered a statement by six Member States who insist on the need to base the study on a clear and well-defined terminology[4].

According to the Interinstitutional Agreement, the Commission is expected to respond to the Council's request within three months i.e. by 14 February 2020. It is proposed to send a response from Secretary General of the Commission to Secretary General of the Council along the same lines as for the Council's request concerning a study on Aarhus Convention (Ares(2018)4892508).

Proposed content of the study

The Commission has to take a position on what action should be taken as a follow up to the study (a legal proposal or other measures). The study should, therefore, provide the necessary information and assessment to allow the Commission to have a clear understanding of the current situation and take an informed decision.

In view of the polarised views of the stakeholders and the challenges raised in the Council Decision, the study should 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 stakeholders.

The study should 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. To this end, substantiated information related to research, business model, innovation, competitiveness, trade, ethical aspects[5], societal benefits[6] and public acceptance will be collected from the Member States and stakeholders.

To address the safety of new techniques, EFSA will be mandated to produce an overview on the risk assessment of new genomic techniques, based on its own previous work and on work carried out at national level.

In order to have a complete picture 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 (JRC)[7].

The past evaluations[8] of the GMO framework have identified some issues related to the scope of the legislation, in particular its adequacy to rapid technological and scientific developments on biotechnology. These issues are still relevant today. The study's

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4 This statement (by Cyprus, Hungary, Latvia, Luxembourg, Poland and Slovenia) also notes that the term "new mutagenesis techniques" should determine the scope of the study, as the term "novel genomic techniques" is not defined by EU law. The statement by Spain and the Netherlands insists on the urgency of the study and analysis of adequacy of the GMO legislation. Sweden's statement insists on including the costs. Important to note that no Member State voted against the Decision.

5 The forthcoming opinion of the European Group on Ethics in Science and New Technologies (EGE) on gene editing, to be finalised by early 2020, will also be considered.

6 Such as proven decrease of chemical use via improved resistance to pests.

7 Agreed in Interservice Steering Group, confirmation expected at Directors' level between JRC and SANTE.

8 Evaluation of Regulation 1829/2003/EC on GM food and feed in 2010, https://ec.europa.eu/food/sites/food/files/plant/docs/gmo_rep-stud_2010_report_eval-gm.pdf
Evaluation of Directive 2001/18/EC on deliberate release in 2011, https://ec.europa.eu/food/sites/food/files/plant/docs/plant-gmo-cultivation_report_en.pdf

conclusions should notably verify what has changed in the meantime and whether the past evaluations are still valid.

The proposed actions based on the above possible content of the study

The proposed objective and content of the study outlined above would allow the Commission to deliver within the limited time available while having engaged with broad number of stakeholders and collected expert opinions from JRC, EFSA and the European Group on Ethics in Science and New Technologies (EGE).

1) *Working methods.* It is proposed to elaborate the study in-house, possibly with technical support from JRC. This is justified in view of the political sensitivity of the topic and the relatively short time allocated for the study. Based on the Aarhus precedent, the format of the study could be a Staff Working Document. It should be translated into all official languages to reach out an as wide audience as possible.

2) *Stakeholder engagement*
   The views and contributions of Member States experts and stakeholders, will be gathered via targeted consultation. Stakeholders should be represented by those European associations, which are most impacted by GMO legislation[9]. The consultation will be based on written questions, which will be explained in dedicated meetings:
   - Meeting with Member States' GMO competent authorities – 15 January. Contributions requested by 15 April.
   - Meeting with stakeholders – 13 February (tbc). Contributions requested by 30 April.

   If necessary, further bilateral meetings will be organised to clarify the contributions.

   There will be a need to keep the EP informed of the progress on the study. Means to do this need to be defined.

   Relevant third countries will be consulted bilaterally to verify that their legislation is correctly reflected in the study.

3) *Interservice Steering Group (ISSG).* ISSG has been established with the following DGs: SG, AGRI, CLIMA, ENV, GROW, JRC, MARE, RTD and TRADE. The first meeting took place on 3 December, where ISSG approved the approach and the content (minutes enclosed).

4) *Finalisation of the study.* The draft study will need to be endorsed by ISSG by 15 December 2020 to leave time for conclusions, next steps and political validation within the Commission as well as for translation before 30 April 2021.

Annex

Council Decision (EU) 2019/1904
Statements by CY, HU, LV, LU, PL, SI, NL, ES and SE
Minutes of the first ISSG meeting of 3/12/2019 including a draft outline of the study

[9] These will include associations representing primary production, processing, manufacturing and trade industry, retailers, consumers, non-governmental organisations, the pharmaceutical sector and scientific academies.