



Council of the
European Union

Brussels, 7 May 2019
(OR. en)

8134/19

AGRILEG 95
ENV 465
DENLEG 58

NOTE

From: General Secretariat of the Council

To: Delegations

Subject: Follow up to the judgment of the Court of Justice in Case C-528/16
– *Information from the Netherlands delegation, supported by the Estonian delegation*

Delegations will find in annex an information note from the Netherlands delegation, supported by the Estonian delegation on the above mentioned subject to be dealt with under "Any other business" at the meeting of the Council (Agriculture and Fisheries) on 14 May 2019.

Information note from the Netherlands delegation, supported by the Estonian delegation

Rapidly progressing technical and scientific developments urgently require addressing the adequacy and sustainability of the existing European regulatory framework for GMOs. The Netherlands is therefore calling on the European institutions to initiate a joint way forward, addressing the legislative and policy consequences stemming from the recent ruling of the Court of Justice in Case C-528/16, both within the framework of ENVI as well as in SANTE/Internal market. In general the Netherlands are of opinion that:

- The recent ruling of the European Court of Justice in Case C-528/16 provides more legal clarity as regards the legal status of food & feed obtained by so called ‘new breeding techniques’ in respect of the existing European legislative framework for GMOs.
- It also triggers questions and challenges in the field of Food Safety, Innovation, Environment and freedom of choice for consumers and professional users.
- Member States would all benefit from a joint and shared approach.
- In view of the recent statements made in public by EU Health Commissioner Vytenis Andriukaitis in favour of new laws to promote the development of so-called new plant breeding techniques¹, the Netherlands therefore call upon the incoming new Commission to include addressing the adequacy of the European legislative framework for GMOs – and as appropriate other related legal and policy instruments – in its Programme of Work.

¹ https://www.euractiv.com/section/agriculture-food/news/andriukaitis-new-plant-breeding-techniques-need-new-regulatory-framework/?utm_source=POLITICO.EU&utm_campaign=2b5a55585d-EMAIL_CAMPAIGN_2019_03_27_11_12&utm_medium=email&utm_term=0_10959edeb5-2b5a55585d-189781449

Justification

During recent decades, inside and outside of Europe, several innovative technological developments have occurred that are relevant to different sectors of use, such as agriculture, horticulture, industrial processes and the development of medicinal and pharmaceutical applications, including gene therapy.

The scale and diversity of potential applications of new technologies increased as developments in biotechnology progressed; the most prominent innovation at the moment being the CRISPR-Cas technology and precise gene editing technologies.

The ruling of July 25th, 2018, by the European Court of Justice in Case C-528/16 provides more legal clarity as regards the legal status of so called ‘new breeding techniques’ and products obtained therewith, in respect of the existing European legislative framework for GMOs. However the ruling also leaves many important questions unanswered. Implicitly, the responsibility to address these questions is therefore placed in the hands of the European legislator and the responsible European Competent Authorities.

In addition the appropriateness of updating existing legislative frameworks in view of technical and scientific progress, as well as evaluating or reviewing the adequacy and consistency of existing legislative frameworks is raised by the Court’s ruling.

By consequence, the Court’s ruling challenges the European legislator and Competent Authorities to address these issues without undue delay. For this reason it is deemed necessary and appropriate for the incoming European Commission to include addressing the adequacy of the European legislative framework for GMOs – and as appropriate, other related legal and policy instruments – in its Programme of Work.