Ref. Ares(2019)5889579 - 20/09/2019

European Commission

**Vytenis ANDRIUKAITIS**
Member of the European Commission

Berl 08/369
Rue de la Loi, 200
B-1049 Brussels - Belgium
Tel. 00 32.2.295.41.59
e-mail: vytenis.andriukaitis@ec.europa.eu

**The Greens / European Free Alliance**
in the European Parliament
60 Rue Wiertz,
1047 BRUSSELS

Brussels, 20. 09. 2019
Ares (2019) 4857109

Honourable Members,

Thank you for your letter of 25 July 2019 concerning the ruling of the Court of Justice of the European Union (CJEU) on mutagenesis.

The CJEU judgement of 25 July 2018 clarified the status of organisms obtained by mutagenesis techniques that have emerged since the adoption of Directive 2001/18/EC on the deliberate release of GMOs: these organisms are GMOs and are subject to the requirements of Directive 2001/18/EC.

You mentioned in your letter that once the Court ruling made the legal status of these techniques clear, it was the role of the European Commission to make available the necessary technical tools to implement the ruling effectively. To this end, I would like to reassure you that the Commission has taken a number of initiatives following the ruling.

The Commission has been working with all Member States to ensure that the legislation, as interpreted by the Court, is properly implemented, both by the Member States and by the operators. The operators, in particular, are responsible, within and outside the EU, to ensure that products which are placed on the EU market are safe and comply with the requirements of the GMO legislation. This includes the submission of an application for marketing authorisation, which shall be accompanied by the provision of detection methods and reference material. Detection methods are validated by the European Union Reference Laboratory for GM Food and Feed (EURL-GMFF), which is assisted by the European Network of GMO Laboratories (ENGL).

On 26 July 2018, the Commission has requested the EURL-GMFF and the ENGL to assess possible challenges and solutions related to the development of detection methods for certain products obtained by new mutagenesis techniques. This would help operators in the agri-food chain as well as enforcement authorities in applying the relevant legal requirements. On 26 March 2019, the EURL-GMFF and the ENGL delivered a first report on plant products, which is available on the EURL-GMFF website[1]. This report concludes that developing and implementing event-specific identification and quantitative detection methods might be challenging for certain plant products of new mutagenesis techniques. Further work on this and similar analysis on genetically modified microorganisms and animals is also envisaged in the coming months.

The Commission's services have also been gathering information from the Member States on the implementation of the Court ruling, including its impact at national level. During meetings of the Standing Committees[2], the Commission has reminded the national competent authorities' of their responsibility to enforce the GMO legislation in accordance with the Court's judgement, including control of products to be placed on the EU market and compliance with GMO legislation of ongoing and future field trials. Importantly, during the meeting of the Regulatory Committee for Directive 2001/18/EC on 18 October 2018, all Member States confirmed that field trials of organisms produced with new mutagenesis techniques are carried out in accordance with the GMO legislation.

As regards risks, the Commission has mandated the European Food Safety Authority (EFSA) to work on the safety assessment of plants developed using certain types of new mutagenesis techniques[3]. The output of this work will be a scientific opinion to be published by EFSA in April 2020.

[1] http://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

[2] PAFF Committees on Genetically Modified Food and Feed and Environmental Risk of 11/09/2018, 03/12/2018, of 07/03/2019 (reports available at https://ec.europa.eu/food/plant/standing_committees/sc_modif_genet_en), Regulatory Committee meeting for Directive 2001/18/EC of 18/10/2018, (report available at https://ec.europa.eu/food/plant/standing_committees/rc_2001-18-ec_en) and Ad hoc meeting of Member States' Competent authorities ("Joint Working Group meeting") of 25 April 2019 (report available at https://ec.europa.eu/food/plant/gmo/modern_biotech_en).

[3] http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?2.

Finally, the Commission has asked the European Group on Ethics in Science and New Technologies to provide an opinion on gene editing[4]. The request covers human and non-human applications for different purposes in the agricultural, health and environmental sectors. The output is expected by the end of this year.

The Commission, as the guardian of the Treaties, is and will continue to be committed to ensure that EU legislation is fully and properly implemented. At the same time, I remain convinced that there should be an open, transparent and honest debate on the possible benefits and risks of products resulting from new breeding techniques and on their possible contribution to a more sustainable agriculture, resilient to climate change.

Yours sincerely,

[4] https://ec.europa.eu/info/sites/info/files/research_and_innovation/ege/letter_chair_of_the_ege_group.pdf