EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
The Director

Brussels
SANTE.DDG2.E.3/IC/nn (2020)5349163

Dear Petitioner,

In Case C-528/16[1] on mutagenesis, the Court of Justice of the EU stated that Directive 2001/18/EC[2] on the deliberate release of genetically modified organisms (GMOs) is applicable to organisms obtained by those mutagenesis techniques that have emerged since its adoption. These techniques include the CRISPR techniques referred to in the petition.

The judgement by the Court of Justice of the European Union on mutagenesis clarified that organisms obtained by new mutagenesis techniques are subject to the provisions of the GMO legislation. These include the requirement for authorisation before GMOs are released into the environment, and for traceability and labelling of GMOs and GM food and feed when they are placed on the market.

Soon after the judgement, the Commission has been cooperating with the Member States to ensure that the legislation on GMOs is implemented as interpreted by the Court.

Furthermore, based on Article 241 of the Treaty on the Functioning of the European Union[3], the Council has requested the Commission[4] to submit a study, by 30 April 2021, regarding the status of novel genomic techniques (NGTs) under Union law in light of the Court of Justice's judgment in Case C-528/16.

The Council has also requested 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.

In the study, the Commission intends to provide a state-of-play on the implementation and enforcement of the GMO legislation, as regards NGTs (including CRISPR), based inter alia on contributions from targeted consultations of Member States and stakeholders.

---

[1] http://curia.europa.eu/juris/document/document.jsf?text=&docid=204387&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=1512838
[2] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, p. 1-39.
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN
[4] OJ L 293, 14.11.2019, p. 103–104

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: [redacted] - Tel. direct line [redacted]

Sante-consult-e3@ec.europa.eu

The above mentioned study will also take into account past and ongoing work of the European Union Reference Laboratory and the European Network of GMO Laboratories, on the detection of products obtained by certain NGTs.

As regards safety aspects, the Commission has requested the European Food Safety Authority (EFSA) to provide an overview on the risk assessment of plants developed through NGTs, based on EFSA's work and on work carried out at national level. The Commission has also asked EFSA for a scientific opinion on gene drive modified organisms: the goal is to identify potential risks on human and animal health and on the environment that gene drive modified organisms could pose, and then importantly to determine whether existing guidelines for risk assessment are adequate. The output of this work is expected before the end of this year.

To conclude, the Commission is currently carrying out the study on NGTs requested by the Council. Since the study is not completed yet, the Commission is not in a position to anticipate its outcome and, as a result, cannot prejudge possible measures that might be required as a follow-up to the study.

Yours faithfully,

Sabine Jülicher