EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
The Director

Brussels
SANTE.DDG2.E.3/SH/gk (2021)6828954

Dear Petitioner,

Subject: Petition on the upholding of the Court of Justice judgment of 2018: Classification of new genetic engineering techniques

I refer to your petition of 7 September 2021 addressed to President von der Leyen, which relates to the Commission study on new genomic techniques[1], published on 29 April 2021, and in which you call on the Commission to keep new genomic techniques subject to the current EU framework on genetically modified organisms (GMOs).

Let me first recall that Court ruling provided authoritative interpretation of the EU legislation which does, however, not prevent legislators to adapt the legal framework to scientific and technical progress, if needed. In this regard, the Council recognised that the ruling of the Court of Justice of the EU brought legal clarity on the status of new mutagenesis techniques, but also raised practical questions on implementation and enforcement. Therefore, the Council asked the Commission to conduct a study[2] on the status of new genomic techniques under Union law and submit a proposal (accompanied by an impact assessment), if appropriate, in view of the outcome of the study.

The Commission considers that action needs to be taken in the field of new genomic techniques, to address the current challenges that were at the origin of the Council request for the study, and are indeed further confirmed by the study. In this context, I would like to emphasise that the study is based on the available information and contributions from broad range of stakeholders as well as experts opinions including the European Food Safety Authority (EFSA) and the Joint Research Centre (JRC).

One of the key findings of the study is that these techniques have the potential to contribute to sustainable agri-food systems in line with the objectives of the European Green Deal and Farm to Fork Strategy. The EU current regulatory framework does not have specific mechanisms to consider such potential contributions, which is an important aspect to address in any future policy action.

The Commission's study has shown that new genomic techniques are a diverse group of techniques that can achieve very different results, from limited and well-characterised modifications that might also occur naturally, to more extensive and less-known alterations. The study has concluded that this variety of outcomes calls for case-by-case risk assessment and more flexibility in the legal framework.

1 https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en

2 Decision (EU) 2019/1904

The study has also indicated that, in terms of specificity, there is general agreement among, inter alia, Member States, EFSA, JRC and the Group of Chief Scientific Advisors, that targeted mutagenesis represents a substantial improvement over random genetic modifications and that several approaches have been developed to improve method specificity.

Furthermore, EFSA and a significant part of scientific bodies have concluded that some plants obtained by targeted mutagenesis and cisgenesis do not pose new risks compared to conventionally bred plants.

Therefore, based on the available information and the outcome of the study, the Commission has concluded that there is sufficient evidence and scientific basis to initiate an impact assessment aiming at developing new legislation on plants derived from targeted mutagenesis and cisgenesis.

I would like to inform you that the roadmap (inception impact assessment) for such an initiative on plants obtained by targeted mutagenesis and cisgenesis has been published in the 'Have Your Say' webpage and is open for feedback[3] until 22 October 2021. It provides further details of the issues that will be considered in the context of the impact assessment that will be carried out in 2022. These include issues raised in the petition regarding the need to consider how to address concerns regarding coexistence with non-GMO and organic sectors and the provision of information to consumers to ensure freedom of choice.

Let me conclude by emphasising that the inception impact assessment makes it clear that the Commission's intention with the new policy initiative is to maintain the objectives of the current legislation as regards a high level of protection of human and animal health and the environment. In that regard, the Commission will consider the development of risk assessment and approval requirements proportionate to the risk involved.

The Commission is aiming at a proportionate regulatory oversight that combines high levels of safety with clear benefits to society and the environment, in line with the objectives of the Green Deal and Farm to Fork strategy that are at the centre of current EU priorities.

Yours sincerely,

[e-signed]
Sabine Jülicher

[3] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en