EUROPEAN COMMISSION

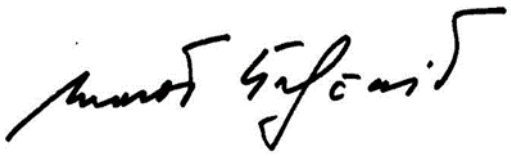
Maroš Šefčovič
Vice-President

Brussels, 29/04/2021

Dear Minister,

Please find enclosed the Commission's response to the Council's request under Article 241 TFEU, by way of the Council Decision (EU) 2019/1904 of 8 November 2019, that the Commission submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study, or otherwise inform the Council on other measures required as a follow up to the study.

Yours sincerely,



Maroš Šefčovič

Mr. Augusto Santos Silva
Minister of Foreign Affairs of Portugal

The Commission's response to the Council's request under Article 241 TFEU, by way of Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and any 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.

The Council, in its Decision (EU) 2019/1904 of 8 November 2019, requested the Commission to submit, by 30 April 2021, a study in light of the Court of Justice of the European Union's judgment in Case C-528/16 regarding the status of certain new innovative breeding techniques ("novel/new genomic techniques") under Union law. Please find herewith the requested study in the form of a Commission Staff Working Document.

The scope of the study covered the use of new genomic techniques (NGTs) in plants, animals and micro-organisms, and in agri-food, industrial and medicinal applications. For the purposes of this study, NGTs are defined as techniques that are capable of changing the genetic material of an organism and that have emerged or been developed since 2001.

The study has examined the status of NGTs under EU law, including, among others, the implementation and enforcement of the EU legislation, research and innovation, as well as safety aspects. In addition, the study has investigated potential benefits and concerns associated with NGT products and their applications, including their potential contribution to achieving the objectives of the European Green Deal and the Farm to Fork Strategy.

The study is based on a broad targeted consultation that includes the views of Member States and relevant EU-level stakeholders as well as expert opinions (e.g. European Food Safety Authority, the Commission's Joint research Centre, national risk assessment bodies). Consulted stakeholders[1] were selected with a view to involving all EU-level organisations and associations that could be impacted, or have shown interest on NGTs.

The key elements of the study are summarised as follows:

- NGTs and their products have been rapidly developing in the last two decades in many parts of the world, with some applications already on the market of some EU trade partners. More applications in various sectors are expected in the years to come; the large majority are being developed outside the EU.
- Under the current EU regulatory system, there are implementation and enforcement challenges, in particular related to the detection and differentiation of NGT products that do not contain any foreign genetic material. This is a problem for enforcement authorities, operators and applicants.

[1] These included professional associations and non-governmental organisations (NGOs) in the agri-food sector (including organic and GM-free sectors), as well as associations and NGOs from other fields of interest, e.g. academia and research, biotechnology, environment, biodiversity, cosmetics and pharmaceuticals.

- In light of the different regulatory oversight for NGTs in other countries, the above difficulties could lead to trade limitations and disruptions, and create a competitive disadvantage to EU operators with further negative consequences. This could also lead to the creation of technical barriers to trade, potentially leading to disputes between the EU and its trade partners.

- There is considerable interest for NGT-related research in the EU. For many Member States and stakeholders, the current regulatory framework has a negative impact on EU public and private research and innovation in NGTs.

- There are indications about both benefits and concerns associated to NGT products and their current and future applications. NGT products 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, as the study has demonstrated (examples include plants more resistant to diseases and environmental conditions or climate change effects in general, improved agronomic or nutritional traits and reduced use of agricultural inputs such as plant protection products). In the pharmaceutical sector, these techniques would allow faster, more affordable development of medicinal products and would have the potential to tackle currently unmet medical needs. The main concerns are related to their possible safety and environmental impact including on biodiversity, to the coexistence with organic and GM-free agriculture, as well as concerning labelling and consumers' right to information and freedom of choice. Stakeholders have different and often opposing views on these aspects.

- As concluded by the European Food Safety Authority (EFSA), plant products with similar risk profiles can be obtained with conventional breeding techniques, targeted mutagenesis and cisgenesis. Thus, a different regulatory oversight for similar products with similar levels of risk would not be justified in these cases. In addition, the current risk assessment procedures, embedded in the existing legislation, are rigid and limit a case-by-case evaluation, preventing risk assessment requirements to adapt to scientific progress.

- For other NGTs or for applications in animals and microorganisms, the necessary scientific knowledge is still limited or lacking, especially on safety aspects.

Issues related to the adequacy of the GMO legislation to deal with technological and scientific developments in biotechnology were already acknowledged in the evaluations held in 2010 and 2011. These evaluations identified the burdensome risk assessment, the difficulties to detect certain NGT products and to reap possible benefits from new developments. The study confirmed that those findings are still relevant.

The study concludes that the GMO legislation has clear implementation challenges and that there are legal uncertainties as regards new techniques and new applications. There are strong indications that it is not fit for purpose for some NGTs and their products, and that it needs adaptation to scientific and technological progress. The study noted that follow-up actions should consider if, how and by which policy instruments this adaptation should be provided, in order for the legislation to be resilient, future-proof and uniformly applied, as well as contribute to sustainability objectives.

The Council also requested the Commission to submit 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 Commission considers that action needs to be taken in the field of NGTs, to address the current challenges that were at the origin of the Council request, and are further confirmed by the study. Action in this field can also contribute to the objectives of the Green Deal and Farm to Fork strategy and to a more competitive economy, which are at the centre of current priorities of the EU.

Based on the information available and the outcome of the study, the Commission has concluded that there is sufficient evidence and scientific basis to initiate a targeted policy action on plants derived from certain new genomic techniques (targeted mutagenesis and cisgenesis).

The Commission therefore intends to initiate a policy action on plants derived from targeted mutagenesis and cisgenesis, which will entail carrying out an impact assessment. For other organisms (animals and microorganisms) and other new genomic techniques, the Commission intends to continue to build up the required scientific knowledge, in view of possible further policy actions. These other organisms will remain, at this stage, subject to the current GMO legal framework. Considerations related to the use of NGTs in medicinal products will be addressed separately, in the context of the Commission's Pharmaceutical Strategy[2].

The envisaged policy action on plants derived from targeted mutagenesis and cisgenesis will aim at a proportionate regulatory oversight for the relevant plant products by adapting, as warranted by the future impact assessment, the risk assessment and authorisation procedures and the labelling/traceability requirements. It would maintain the objectives of the current legislation as regards a high level of protection of human and animal health and the environment. In addition, it should be fully aligned with the objectives of the European Green Deal and the Farm to Fork Strategy, including the development of a proposal for a legislative framework for sustainable food systems. It should allow reaping benefits from innovation by enabling safe NGT products to contribute to the sustainability and resilience of the EU agri-food system. Therefore, the impact assessment will look into the design of a proposal that combines high levels of safety with clear added value to society and the environment.

As regards the next steps, the study, together with the supporting studies and replies to the consultation, will be published on 29 April 2021 on the dedicated Commission website https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en. I would like to inform you that we also intend to publish this letter, as a way to communicate the Commission's intentions also to stakeholders and the public.

After the publication of the study, the Commission will engage in a wide-ranging communication effort to share its results and to discuss its outcome with the Council, the European Parliament and stakeholders in dedicated meetings, as it is important for the Commission to gather views on the proposed follow-up.

[2] COM(2020) 761 final.

As regards the future policy action, it will be prepared in full respect of proportionality, subsidiarity and better law-making principles. We expect to publish an inception impact assessment in the third quarter of 2021, building on the study and the exchanges with the co-legislators and stakeholders once the study is published. The impact assessment will follow, and will include further consultation of all interested parties.

I take this opportunity to thank the Member States for their contributions to the study, which have allowed the Commission to gather a comprehensive overview on the current status of NGTs across the EU. We look forward to further discussions on this important topic in the Council, the European Parliament and with stakeholders.

I would like to ask for your support on the next steps to ensure a comprehensive and balanced debate paving the way for the development of a legal framework suited to this rapidly evolving field, while taking into account the various issues at stake, from the protection of health and the environment to the opportunities for innovation and sustainability.