Consultation Strategy for legislation for plants produced by certain new genomic techniques

1) Background information and context

In the last decades, advances in biotechnology have led to the development of new genomic techniques (NGTs). These are techniques capable of altering the genetic material of an organism that have emerged or have been developed since 2001, when the current legislation on genetically modified organisms (GMOs) was adopted. The Court of Justice of the EU (CJEU) in 2018 clarified that organisms produced by targeted mutagenesis[1] are GMOs, therefore subject to the requirements of the EU GMO legislation. Based on the reasoning followed by the Court, the GMO legislation also applies to organisms produced by other NGTs, including cisgenesis.

In November 2019, the Council requested[2] the Commission to prepare a study on the status of NGTs under EU law. The study, published in April 2021, has confirmed that NGTs have developed rapidly in many parts of the world and are expected to continue to do so on a global scale. There is significant interest both in the EU and globally for plant applications of NGTs. Some of their applications are already on the market outside the EU and this trend is likely to continue, across different sectors and countries.

The study has also concluded that plants obtained from NGTs have the potential to contribute to the objectives of the European Green Deal and in particular to the Farm to Fork and Biodiversity Strategies and the United Nations' Sustainable Development Goals (SDGs) for a more resilient and sustainable agri-food system. At the same time, the study reported concerns linked to the use of these technologies, e.g. on their potential safety and environmental impacts, including on biodiversity, the coexistence with organic and GM-free agriculture as well as concerns on labelling and consumers' right to information and freedom of choice.

Among NGTs, targeted mutagenesis and cisgenesis can be used to produce alterations of the genetic material that can also be obtained by natural mutations or conventional breeding techniques. The European Food Safety Authority (EFSA) concluded[3] that plants obtained by targeted mutagenesis and cisgenesis can have the same risk profile as plants produced with conventional breeding. EFSA has not yet assessed the safety of targeted mutagenesis and cisgenesis in microorganisms or animals, nor the safety of other techniques.

The Council also requested[2] the Commission to submit, if appropriate in view of the outcome of the study, a proposal accompanied by an impact assessment, or otherwise to inform the Council of other measures required.

Based on the outcome of the study, **the Commission has launched a policy initiative on plants obtained by targeted mutagenesis and cisgenesis, accompanied/underpinned by an impact**

[1] In targeted mutagenesis, mutation(s) are induced in selected target locations of the genome without insertion of genetic material. In cisgenesis, genetic material (e.g. a gene) is inserted into a recipient organism from a donor organism with which the recipient is sexually compatible (crossable) in nature, e.g. a gene from a wild potato indo a domesticated potato.

[2] https://eur-lex.europa.eu/eli/dec/2019/1904/oj

[3] https://www.efsa.europa.eu/en/efsajournal/pub/2561, https://www.efsa.europa.eu/en/efsajournal/pub/2943, https://www.efsa.europa.eu/en/efsajournal/pub/6299

assessment. The initiative will also cover food and feed derived from such plants[4] (). The envisaged policy action on plants obtained from targeted mutagenesis and cisgenesis will aim at an appropriate regulatory oversight for the concerned plant products, ensuring a high level of protection of human and animal health and the environment, and enabling innovation and the contribution of safe NGTs to the objectives of the European Green Deal and the Farm to Fork Strategy.

The impact assessment will be supported by a study conducted by an external contractor. It will run roughly from Q1 2022 to Q1 2023.

2) Objectives of the consultation

The consultation activities aim at capturing evidence and views from the public and from a broad range of stakeholders active across all levels of the agri-food chain, and beyond, who are interested in or are impacted by the products under the scope of this initiative.

The consultation activities will inform the impact assessment; they will allow all interested parties to provide relevant information on the problems presented, the baseline scenario, and on the potential ways forward. The consultation will assist the Commission in understanding the implications of the possible policy options for the different stakeholders involved. In addition, the consultation activities will also enable to identifying additional policy option elements and ensure that no impacts have been overlooked.

The consultation activities above will build on and take into account the information received during the comprehensive targeted consultation with Member State competent authorities and EU-level stakeholder associations impacted by or having expressed interest in NGTs, which was carried out in the context of the NGT study. EU-level stakeholder associations encompassed: agri-food business operators (including organic and GM-free sectors), the biotechnology industry, environmental and agri-food non-governmental organisations and academia/research organisations.

3) Stakeholder mapping

The initiative on plants produced by certain new genomic techniques concerns a broad range of stakeholders from the EU and third countries in the fields of agriculture, food and feed, plants, biotechnology in general and application of targeted mutagenesis and cisgenesis in plants, including their food and feed products, in particular, the environment and sustainability.

The main stakeholder categories include:

- The general public;
- Operators active, from farm to fork, in the agri-food and feed system, including sectors such as
    - farmers,
    - seed and plant breeders,
    - traders, processors, manufacturers, retailers and food services,
    - GM-free and organic operators in all of the above sectors.

[4] hereinafter, references to plants obtained by targeted mutagenesis and cisgenesis will refer as well to their food and feed products

- Operators of plant and bio-based industries active in sectors other than the agri-food sector, including ornamental plants, forestry and industrial biotechnology.
- Academic and research stakeholders active in the field of biotechnology in general and agricultural/plant biotechnology in specific.
- Civil society/non-governmental organisations with interest in the topic, including environmental, grass-root farming and consumer organisations.
- EU institutions: the **Council,** which asked[5] for the New Genomic Techniques study; the **European Parliament,** and specifically the Committees on Environment, Public Health and Food Safety (ENVI) and on Agriculture and Rural Development (AGRI).
- European Food Safety Authority (EFSA), Member State and third country food safety agencies playing a key role in GMOs pre- and post-authorisation processes in general and risk-assessment in particular.
- EU Member States' and third country public authorities – Food, agriculture and environment ministries and national competent authorities responsible for agri-food and biotechnology policies and implementation of the GMO legislation.
- Other stakeholders, such as consultancies and think tanks active or with interest on the topic.

The Commission works closely with its institutional partners (national authorities, EFSA, etc.) and its collaboration with these actors will be part of the process supporting the policy initiative. In addition to their contribution to the consultation activities below, exchanges with national authorities will take place in the Joint Working Group of the Standing Committee on Plants, Animals, Food and Feed Section Genetically Modified Food and Feed, Regulatory Committee under Directive 2001/18/EC and Regulatory Committee under Directive 2009/41/EC. The Commission may also conduct fact-finding missions to gather relevant information in selected Member States.

EFSA will support in particular the scientific aspects relevant to the initiative, primarily in the area of risk assessment. Technical contributions will also be provided by other Commission services. In particular, The Joint Research Centre will develop case studies of plants produced by targeted mutagenesis and cisgenesis to assess their potential impacts.

4) Consultation activities

Feedback on the Inception Impact Assessment (IIA) - The IIA was published for feedback from interested individuals and stakeholders for a period of 4 weeks between 24 September 2021 - 22 October 2021, on the on the 'Have Your Say' portal; it was also announced on the New Techniques in biotechnology Commission webpage (https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology_en).

Public Consultation – the Commission launched a 12-week public consultation between 29 April 2022 – 22 July 2022 via the 'Have Your Say' portal. (to consult the general public and other stakeholders on the key elements of the policy initiative; the consultation was also announced on the New Techniques in

[5] https://eur-lex.europa.eu/eli/dec/2019/1904/oj

biotechnology Commission webpage (https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology_en).

Targeted stakeholder consultation activities, including interviews, surveys and focus groups are currently being conducted to provide technical feedback on specific aspects of the policy initiative. These activities target in particular relevant EU Member State appropriate ministries or competent authorities, all types of operators as described in (3) above, academic and research stakeholders, as well as civil society and non-governmental organisations.