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COMMISSION STAFF WORKING DOCUMENT
EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

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Accompanying the document

Legislation for plants produced by certain new genomic techniques

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INTRODUCTION

New genomic techniques (NGTs) provide new opportunities to alter the genetic material of an organism allowing the rapid development of plant varieties with specific traits. The scope of this initiative are plants produced by targeted mutagenesis and cisgenesis and their food and feed products.

The Commission study of April 2021 concluded that the current legislation is in need of adaptation to scientific and technological progress for some NGTs and their products. The study also concluded that NGT plants have the potential to contribute to the objectives of the European Green Deal and its Farm to Fork Strategy.

There is considerable evidence available about the safety of plants obtained by targeted mutagenesis and cisgenesis. The European Food Safety Authority (EFSA) concluded that there are no new hazards specifically linked to these techniques and that, on a case-by-case basis, a lesser amount of data might be needed for their risk assessment compared to transgenesis. Furthermore, targeted mutagenesis and cisgenesis can produce alterations that in some cases can also be obtained naturally or by conventional breeding.

The type of plant applications that feature prominently in the research and development pipeline, coupled with the fairly easy and speedy applicability of these new techniques, could deliver benefits to farmers, consumers and the environment.

PROBLEM DEFINITION

The initiative aims to tackle three problems:

- The authorisation procedure and risk assessment requirements of the current GMO legislation are not adapted to the variety of potential plant products that can be obtained by targeted mutagenesis and cisgenesis, and as a result are disproportionate or inadequate in certain cases.
- The current GMO legislation raises implementation and enforcement challenges for certain plants produced by targeted mutagenesis or cisgenesis, in particular to NGT plants for which a specific detection method cannot be provided.
- The current GMO legislation applied to NGTs is not conducive to developing innovative beneficial products.

The drivers for these problems include the fact that the current framework lags behind scientific developments and is not conducive to developing innovative NGT products and to placing them on the market.

WHY SHOULD THE EU ACT?

EU action is essential to achieve a harmonized, high level of protection of human and animal health and the environment in relation to NGT plants and their food and feed derived so that they may circulate freely within a smooth-functioning internal market. There is also an urgent need to ensure availability of plant varieties that can cope with challenges such as food security, climate change and biodiversity reduction, further aggravated by the present geopolitical and energy crisis in Europe. The Farm to Fork Strategy recognises the role that biotechnology can play in meeting those challenges, which need an EU-wide response.

OBJECTIVES

The general objectives of this initiative are to maintain a high level of protection of human and animal health and of the environment, to enable the development and placing on the market of plants and plant products contributing to the innovation and sustainability objectives of the European Green Deal and of the Farm to Fork and Biodiversity strategies and to ensure the effective functioning of the internal market to enhance the competitiveness of the EU agri-food sector. The specific objectives to meet these general objectives are to:

1. Ensure that the regulatory requirements for plants and plant products obtained by targeted mutagenesis and cisgenesis are proportionate to the risks posed by these plants and products.
2. Design a legislation that enables the development and placing on the market of plants obtained by targeted mutagenesis and cisgenesis and derived food/feed products.
3. Ensure that legislation is conducive to the development and placing on the market of plant products that can contribute to a sustainable agri-food system.
4. Provide a future proof legislation.

WHAT ARE THE AVAILABLE POLICY OPTIONS?

After screening the potential measures, they were grouped into five policy options:

1. Baseline: plants obtained by targeted mutagenesis and cisgenesis would continue to be regulated under the current GMO legislation and its risk assessment, authorisation, traceability and labelling requirements.
2. Option 1: the legislation would be adapted to cater for the diverse risk profiles of plants obtained by targeted mutagenesis and cisgenesis and to address detection challenges, with traceability and labelling as in the baseline.
3. Option 2: the legislation would be adapted to cater for the diverse risk profiles of plants obtained by targeted mutagenesis and cisgenesis, to address detection challenges and to incentivise the development and placing on the market of plant products that can contribute to a sustainable agri-food system through regulatory incentives and two labelling alternatives: a sustainability label or no GMO label if the NGT trait has the potential to contribute to sustainability.
4. Option 3: the legislation would be adapted to cater for the diverse risk profiles of plants obtained by targeted mutagenesis and cisgenesis and to address detection challenges. In addition, applicants for authorisation would be required to show that the introduced trait is not detrimental to sustainability.
5. Option 4: notification procedure for plants obtained by targeted mutagenesis or cisgenesis that could also occur naturally or be produced by conventional breeding, which would be treated similarly to conventional plants. For other plants, options 1, 2 or 3 would apply.

THE PREFERRED POLICY OPTION

The preferred option is a combination of option 4 (for NGT plants that could also occur naturally or be produced by conventional breeding) and of an adapted option 2 (for other NGT plants). The adaptation of option 2 consists in replacing a sustainability label with a mandatory label covering the purpose of the introduced trait, while maintaining the regulatory incentives.

IMPACTS OF THE PREFERRED POLICY OPTION

Making NGT plants that could also occur naturally or be produced by conventional breeding subject to a notification procedure achieves safety while ensuring that requirements are proportionate to risk. It has by far the strongest positive impact on the development and placing on the market of NGT products, as it results in a higher degree of simplification and reduction of administrative burden for applicants and authorities. This option also shows the highest potential to facilitate the contribution of NGTs to sustainability of the agri-food system, in the light of the development pipeline and in synergy with EU policies and regulatory developments. It is by far the most advantageous for SMEs, as administrative and compliance costs will substantially decrease, and it has the strongest impact on competitiveness.

An authorisation with adapted risk assessment for NGT plants not covered by the notification procedure ensures safety, while ensuring proportionality by adapting the data requirements for risk assessment. It would bring an additional, although on certain aspects moderate, improvement concerning attractiveness to develop such NGT plants in the EU. Cost reductions for applicants compared to the baseline range from low to very substantial. Regulatory incentives would bring moderate positive impacts in terms of steering towards traits with sustainability potential and would facilitate access to and navigation of the regulatory framework, especially for SMEs, supporting their competitiveness.

NGT plants subject to authorisation would also remain subject to traceability and labelling. Labelling will be complemented with information on the purpose of the genetic modification to allow operators and consumers to make informed choices and is expected to drive market demand for products with beneficial traits.

For NGT plants subject to authorisation, current tools (traceability labelling, national coexistence measures) would remain available to supply chains that do not use GMOs. Transparency would be ensured about plants subject to notification to allow choice. However, organic farmers could face considerable challenges if any admixture is to be avoided due to legal requirements.

The preferred option creates an enabling framework that meets the demand for new varieties with traits beneficial to the environment, supporting sustainable farming practices and delivering benefits to consumers. It is comparable to the approach followed in an increasing number of third countries and would be the least disruptive of trade. It would ensure close monitoring of the uptake of the NGT products and the accompanying economic, environmental and social impacts.