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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

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To: Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject: COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

Delegations will find attached document SWD(2023) 413 final.

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COMMISSION STAFF WORKING DOCUMENT
EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Executive Summary of the impact assessment report

Accompanying the document

**Proposal for a REGULATION OF THE EUROPEAN PARLIAMNET AND OF THE
COUNCIL**

**on plants obtained by certain new genomic techniques and their food and feed, and
amending Regulation (EU) 2017/625**

{COM(2023) 411 final} - {SEC(2023) 411 final} - {SWD(2023) 411 final} -
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INTRODUCTION

New genomic techniques (NGTs) provide new opportunities to alter the genetic material of an organism allowing the development of plant varieties with specific traits. 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 plants obtained with NGTs have the potential to contribute to the objectives of the European Green Deal and its Farm to Fork Strategy.

The scope of this initiative are plants produced by targeted mutagenesis and cisgenesis and their food and feed. 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 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 designed to developing innovative NGT products and to placing them on the market.

WHY SHOULD THE EU ACT?

EU action is essential to achieve a harmonised, high level of protection of human and animal health and the environment in relation to NGT plants and their food and feed 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 contribute to 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, in accordance with the precautionary principle, 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 and enhance the competitiveness of the EU agri-food sector at the EU and global level, providing a level-playing field for its operators. The specific objectives to meet these general objectives are:

1. Procedures for the deliberate release and placing on the market that ensure that NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden.
2. Deliberate release and placing on the market of NGT plants and derived food/feed products that feature a wide range of plant species and traits by various developers.
3. NGT plants released or placed on the market feature traits that can contribute to a sustainable agri-food system.

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, as labelling alternatives: a GM label accompanied by a sustainability label or a factual statement on the trait introduced, 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 procedure¹ 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; a transparency register would be established for these 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 option 2 (for other NGT plants). In

¹ In the legislative proposal, the term finally used is ‘verification procedure’.

the latter, the labelling would consist in a label identifying the product as obtained by biotechnology and providing a factual statement on the purpose of the introduced trait.

IMPACTS OF THE PREFERRED POLICY OPTION

The combination of option 4 for products that could also occur naturally or be produced by conventional breeding and of option 2 for all other products ensures to the largest possible extent that NGT plants and derived food/feed products are as safe as their conventional counterparts, while not entailing unnecessary regulatory burden, that NGT plants and derived food/feed products featuring a wide range of plant species and traits by various developers are placed on the market and that these plants feature traits that can contribute to a sustainable agri-food system.

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 the risk of such NGT plants. 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, as well as proportionality by adapting the data requirements for risk assessment to the diverse risk profiles of NGT plants that could not occur naturally or be produced by conventional breeding. 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 would 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. For NGT plants subject to notification, transparency measures would allow choice at the beginning of the supply chain for operators to be able to decide to use or avoid NGTs. A public register would inform operators and consumers of NGT plants that have met the criteria of the notification procedure.

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.