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EUSurvey

Public consultation on plants produced by certain new genomic techniques

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Introduction

In the last decades, advances in biotechnology have led to the development of new genomic techniques (NGTs), i.e. techniques capable of altering the genetic material of an organism that have emerged or have been developed since 2001, when Directive 2001/18/EC (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32001L0018>) on the deliberate release of genetically modified organisms (GMOs) into the environment was adopted. The Court of Justice of the EU in 2018 clarified that organisms produced by targeted mutagenesis are GMOs subject to the requirements of the EU GMO legislation (https://ec.europa.eu/food/plants/genetically-modified-organisms/gmo-legislation_en). Targeted mutagenesis techniques are new genomic techniques, as opposed to random mutagenesis techniques. Based on the reasoning followed by the Court, the GMO legislation also applies to organisms produced by other NGTs, including cisgenesis techniques.

In November 2019, the Council requested (<https://eur-lex.europa.eu/eli/dec/2019/1904/oj>) the Commission to prepare a study on the status of NGTs under EU law, and submit, if appropriate in view of the outcomes of the study, a proposal accompanied by an impact assessment, or otherwise inform of other measures required.

The study (https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en), published in April 2021, confirmed that NGTs have developed rapidly in many parts of the world and are expected to continue to do so. There is significant interest both in the EU and globally for plant applications of NGTs, and some of their applications are already on the market outside the EU; this trend is likely to continue.

The study also concluded that plants obtained by 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. The study also reported concerns, e.g. on potential safety and environmental impacts, including on biodiversity, coexistence with organic and GM-free agriculture and on consumers' right to information and freedom of choice.

Concerning safety, the European Food Safety Authority (EFSA) has concluded 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 study concluded that the GMO legislation has clear implementation challenges and requires contentious legal

interpretation to address new techniques and applications, and that there are strong indications that it is not fit for purpose for some NGTs and their products, needing adaptation to scientific and technological progress.

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Instructions and glossary

The questionnaire features three sections: section A focuses on the current situation and the definition of the problem, while section B and C are forward-looking and focus on possible solutions and other relevant aspects.

For the purposes of this questionnaire, references to plants obtained by targeted mutagenesis or cisgenesis include their food and feed products.

This questionnaire is available in all EU languages and you can reply in any EU language. You can pause at any time and continue later. You can download your contribution once you have submitted your answers. Whenever possible, please substantiate your replies with explanations, data and sources of information, practical examples etc.

A short glossary of terminology relevant to this questionnaire follows below:

- **New Genomic Techniques (NGTs):** An umbrella term used to describe a variety of techniques that can alter the genetic material of an organism and that have emerged or have developed since 2001, when the existing GMO legislation was adopted.
- **Mutagenesis:** Creation of mutation(s) in an organism without insertion of foreign genetic material.
- **Classical (or random) Mutagenesis:** An umbrella term used to describe older techniques of mutagenesis that have been used since the 1950s; they involve irradiation or treatment with chemicals in order to produce random mutations, without insertion of foreign genetic material. Organisms obtained with such techniques are GMOs that are exempted from the scope of the EU GMO legislation.
- **Targeted Mutagenesis:** An umbrella term used to describe newer techniques of mutagenesis that induce mutation(s) in selected target locations of the genome without insertion of foreign genetic material.
- **Cisgenesis:** Insertion of foreign genetic material into a recipient organism from a donor that is sexually compatible (crossable).
- **Transgenesis:** Insertion of foreign genetic material into a recipient organism from a donor organism that is sexually incompatible.
- **Trait:** For the purposes of this document, a trait is a specific characteristic resulting from the modification of a plant by targeted mutagenesis and cisgenesis.

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A. Regulating plant produced by targeted mutagenesis and cisgenesis - current situation

The EU [GMO legislation](#) applicable to plants includes Directive 2001/18/EC on the deliberate release into the environment of GMOs, Regulation (EC) No 1829/2003 on GM food and feed and Regulation (EC) No 1830/2003 concerning the traceability and labelling of GMOs and their food and feed products. The 2010-2011 [evaluations](#) of the GMO legislation and the 2021 Commission [study](#) on NGTs have indicated that, as regards plants obtained by some NGTs and their products, the current legislation is no longer fit for purpose and needs adaptation to scientific and technological progress. On the basis of these evaluations and the study, the [inception impact assessment](#) has identified the following problems associated with the application of the current legislation to plants produced by targeted mutagenesis and cisgenesis:

- Legal uncertainties in Directive 2001/18/EC (and other legislation based on it) have been intensified by developments in biotechnology, with unclear or undefined terms and notions;
- Current regulatory oversight and requirements are not adapted to the resulting diverse risk profiles, and in some cases can be disproportionate or inadequate;
- The GMO legislation includes authorisation, traceability and labelling requirements that raise implementation and enforcement challenges;
- The current legislative framework does not take into account whether products have the potential to contribute to sustainability.

These problems could impact operators across the agri-food system, including in agricultural biotechnology innovation and research, non-food/feed bio-based and biotechnology industries, operators in EU trade partners, organic and GM-free operators, EU and national authorities, and EU citizens and consumer organisations. The issues are of interest to a broad spectrum of stakeholders, including NGOs active in the environmental protection, agri-food system, biotechnology and consumer protection areas.

*** 1. With regard to the problems above, what is your view of the existing provisions of the GMO legislation for plants produced by targeted mutagenesis and cisgenesis?**

- They are adequate
- They are not adequate
- No opinion/I do not know

*** 2. If plants obtained by targeted mutagenesis and cisgenesis continue to be regulated under the current GMO framework, do you expect short, medium or long term consequences for you/your activity/sector?**

- Yes
- No
- Not applicable
- No opinion/I do not know

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B. Regulating plants produced by targeted mutagenesis and cisgenesis - the future

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 plants developed by safe NGTs to the objectives of the European Green Deal and the Farm to Fork Strategy. This section aims at identifying potential impacts and possible ways to address the problems acknowledged in the [inception impact assessment](#) and mentioned in section A above. Your views will assist us in defining whether the current situation should be changed and the possible way forward.

RISK ASSESSMENT

In the current GMO legislation, risk assessment requirements are to a large extent the same for all GMOs. However, EFSA has concluded that plants produced by targeted mutagenesis and cisgenesis generally pose lower risks than plants obtained with transgenesis (1). EFSA has also concluded that, in some cases, plants produced by targeted mutagenesis and cisgenesis do not pose new hazards compared to plants produced with conventional, non-GM breeding techniques, or compared to classical mutagenesis techniques, which are considered as GMOs outside the scope of the legislation, and not subject to risk assessment. Finally, EFSA has concluded that off-target mutations potentially induced by targeted mutagenesis are of the same type as, and fewer than, those mutations in conventional breeding.

(1) <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>

*** 3. Currently, plants produced by targeted mutagenesis and cisgenesis are risk assessed as any other GMOs. What is your view on their risk assessment?**

- Plants produced by targeted mutagenesis and cisgenesis need to be risk assessed using the current GMO legislation requirements.
- Plants produced by targeted mutagenesis or cisgenesis need to be risk assessed using requirements adapted to their characteristics and risk profile.
- Plants produced by targeted mutagenesis or cisgenesis do not need to be risk assessed when they could have been produced through conventional plant breeding or classical mutagenesis.
- Plants produced by targeted mutagenesis or cisgenesis do not need to be risk assessed.
- No opinion/I do not know
- Other

4. Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the above, or would you like to justify/elaborate on your replies?

1500 character(s) maximum

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SUSTAINABILITY

The Commission [NGT study](#) has concluded that plants obtained by 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' SDGs for a more resilient and sustainable agri-food system. Examples of potential benefits include plants more resistant to pests, diseases and the effects of climate change (e.g. notably increasing severity and frequency of extreme heatwaves, droughts and rainstorms) or environmental conditions in general, or requiring less natural resources and fertilisers. NGTs could also improve the nutrient content of plants for healthier diets, or reduce the content of harmful substances such as toxins and allergens.

*** 5. Should the potential contribution to sustainability of the modified trait of a product be taken into account in new legislation on plants produced by targeted mutagenesis or cisgenesis?**

- There is no need for specific regulatory provisions on sustainability in this initiative

- Specific regulatory provisions for sustainability should be included in this initiative
 No opinion/I do not know

6. In your view, which of the following traits are most relevant for contributing to sustainability?

	Strongly agree	Tend to agree	No opinion/I do not know	Tend to disagree	Strongly disagree
*Tolerance/resistance to biotic stresses (e.g. plant diseases caused by nematodes, fungi, bacteria, viruses, pests)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Tolerance/resistance to abiotic stresses (e.g. to climate change or environmental conditions in general, such as drought, heat, cold, salt)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Better use of resources (such as water, nitrogen)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Tolerance/resistance to plant protection products such as herbicides or insecticides	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Better yield or other agronomic characteristics (e.g. yield stability, more or larger seeds or fruits, greater height, better shape or flowering time, better breeding characteristics)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Better storage performance (e.g. under harvest, transport or storage conditions, longer shelf-life, non-browning and fewer black spots)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Better composition (e.g. higher or better content of nutrients such as fats, proteins, vitamins, fibres, lower content of toxic substances and allergens)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Other quality-related characteristics (e.g. better colour, flavour)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Production of substances of interest for the food and non-food industry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

7. In your view, which of the following would be the best incentives to encourage the development of plant products of targeted mutagenesis or cisgenesis with traits contributing to sustainability?

	Strongly agree	Tend to agree	No opinion/I do not know	Tend to disagree	Strongly disagree
*Regulatory and scientific advice before and during the approval procedure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Measures to facilitate the approval process (waiving of fees, faster procedures)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*Allowing sustainability-related claims to appear on the final product	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please specify any other incentives you would like to propose

500 character(s) maximum

0 out of 500 characters used.

*** 8. Do you think information about the sustainability contribution of a modified trait of a plant produced by targeted mutagenesis or cisgenesis should be made available to the consumer?**

- Yes
 No
 No opinion/I do not know

9. Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the above, or would you like to justify/elaborate on your replies?

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INFORMATION FOR OPERATORS AND CONSUMERS

Under the GMO legislation, GMOs are traced (documentation with declaration of presence of GMO, GMO unique identifier for all transactions along the food chain, obligation to keep information for each transaction for a number of years) and labelled as such.

The GMO legislation includes an obligation for applicants for a GMO authorisation to provide a quantitative detection

method that is specific to the product, i.e. it can both detect it and differentiate it from other products. In some cases of plants produced by targeted mutagenesis or cisgenesis, analytical methods might be able to detect the product but might not be able to differentiate it from similar plants produced by conventional, non-GM breeding techniques or by classical mutagenesis. This means that in these cases analytical methods might be able to detect the presence of a modified product, without being able to prove that the change was the result of a technique regulated under the GMO legislation.

*

10. When analytical methods are not available or reliable, effective traceability of plants obtained by targeted mutagenesis or cisgenesis, and of their food and feed products, can be ensured via:

- documentation transmitted through the chain of operators
- public databases/registries
- digital solutions, e.g. block chain
- other means
- No opinion/I do not know

* **11. When reliable analytical methods that can both detect and differentiate a product cannot be provided, operators wishing to introduce plants produced by targeted mutagenesis or cisgenesis in the market should:**

- not be asked at all to provide an analytical method that can both detect and differentiate their product
- not be asked to provide an analytical method that can both detect and differentiate their product, if they can justify that this would be impossible
- be asked to provide a detection method, but without the need to differentiate, if they can justify that the latter would be impossible
- not be allowed to place the product in question on the market
- No opinion/I do not know

* **12. Transparency for operators and consumers, on plants produced by targeted mutagenesis or cisgenesis:**

- can be achieved via a physical label on the final product
- can be achieved via a digital label accessible through the final product (e.g. link to a website, QR code)
- can be achieved via information available elsewhere (e.g. a website, a public database/register)
- is not necessary for plants produced by targeted mutagenesis and cisgenesis, when they could have been produced through conventional plant breeding or classical mutagenesis
- is not necessary for any plant produced by targeted mutagenesis and cisgenesis
- No opinion/I do not know

Note that plants produced with conventional, non-GM breeding techniques, or with classical mutagenesis (GMOs exempted from the scope of the legislation), do not need to be traced or labelled as GMOs; other legislation provisions on traceability and labelling apply, e.g. under EU food legislation.

13. Is there any other aspect you would like to mention, for example on the potential economic, social, environmental or other impacts of the above, or would you like to justify/elaborate on your replies?

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C. Other relevant aspects of a new framework

The following questions address other aspects, not covered in the previous sections, that are relevant to a new framework.

14. Which of the following measures do you think would be necessary for future-proof legislation on plants produced by targeted mutagenesis or cisgenesis?

	Strongly agree	Tend to agree	No opinion/I do not know	Tend to disagree	Strongly disagree
*improving legal clarity in the legislation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*putting in place mechanisms that facilitate easy adaptation to scientific progress	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*risk assessment that takes into account the characteristics and risk profile of a final product	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please specify any other measures you would like to propose

500 character(s) maximum

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15. Which of the various measures outlined in section B would be most relevant to co-existence with existing agricultural practices (e.g. conventional, organic)? Are any other measures necessary?

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16. Do you think any regulatory measures should be included in new legislation to facilitate access to targeted mutagenesis or cisgenesis technologies/plant genetic resources? Note that this initiative on plants produced using targeted mutagenesis or cisgenesis does not cover intellectual property rules (e.g. plant variety rights, biotechnology patents)

1500 character(s) maximum

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17. Do you think any regulatory measures should be included in new legislation to facilitate the uptake of these technologies by small and medium-sized enterprises?

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18. You can raise any additional points or provide further information and evidence to support your views using the field below.

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