Public consultation on plants produced by certain new genomic techniques

Fields marked with * are mandatory.

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 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. 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 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, 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.

About you

* Language of my contribution

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* I am giving my contribution as

- ○ Academic/research institution
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- ○ Company/business organisation

- ( ) Consumer organisation
- ( ) EU citizen
- ( ) Environmental organisation
- ( ) Non-EU citizen
- (•) Non-governmental organisation (NGO)
- ( ) Public authority
- ( ) Trade union
- ( ) Other

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* Organisation name

255 character(s) maximum

GMO Network Norway

* Organisation size

- (•) Micro (1 to 9 employees)
- ( ) Small (10 to 49 employees)
- ( ) Medium (50 to 249 employees)
- ( ) Large (250 or more)

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Please add your country of origin, or that of your organisation.

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- Uganda
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- United Kingdom
- United States

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- Colombia
- Comoros
- Congo
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- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
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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.

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

* ***1.1 This is because***

multiple answers possible

- [x] the GMO legislation is sufficiently flexible and capable of keeping pace with technological progress
- [ ] the GMO legislation is sufficiently clear
- [ ] risk assessment rules of the GMO legislation are appropriate for these plant products
- [ ] authorisation, traceability and labelling requirements are appropriate for these plant products
- [ ] sustainability can be taken into account under the existing GMO legislation
- [x] of other reasons

* Please specify

500 character(s) maximum

GMO Network Norway supports the ruling in case C-528/16 by The Court of Justice of the EU which clarified that the GMO legislation applies to organisms modified by new genomic techniques. The ruling should be upheld because it excludes from the scope of the directive only organisms obtained by means of techniques/methods which have conventionally been used in a number of applications and have a long safety record. It is also flexible and capable of keeping pace with technological progress.

* ***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

Please specify potential positive consequences

800 character(s) maximum

GMO Network Norway believes that the authorisation requirement is necessary, especially because a minor edit in a genome does not always entail a minor edit in the phenotype. Hazards and risk profiles from plants obtained by targeted mutagenesis and cisgenesis may vary, for instance whether the plant in question has greater fitness than wild relatives. The risk of accidentally spreading such a genetically modified plant may be of greater importance than whether it is transgenic or cisgenic.

GMO Network Norway also believes that labelling and traceability is important. Traceability is essential for

organic and conventional farmers in order to avoid contamination by GMOs. In order to secure freedom of choice, retailers and consumers are dependent on GMOs being traceable and labelled.

Please specify potential negative consequences

800 character(s) maximum

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

GMO Network Norway believes that the objective of current legislation (Directive 2001/18 article 1), which is to protect human health and the environment, is even more important than when the directive was adopted, due, in part, to rapid technological development. The deliberate release or placing on the market of plants produced by targeted mutagenesis and cisgenesis, with vastly different traits, a broad range of applications and produced by numerous techniques, needs to be assessed case by case and step by step, in order to avoid risks of adverse effects to human health and the environment.

GMO Network Norway also believes that risk assessment related to the GM-plant at hand (case by case) is a scientifically sound and flexible way of identifying hazards and estimating risks. In addition, a step by step approach is also required, in order to avoid irreversible adverse effects. The avoidance of such effects is in accordance with the precautionary principle, a principle enshrined in the directive.

GMO Network Norway will emphasise the importance of transparency and consultation of third parties in order to strengthen the legitimacy of risk assessment, cf. Regulation (EU) 2019/1381. Providing shortcuts by changing the risk assessment requirements will not further this end.

S U S T A I N A B I L I T Y

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

* ***5.1. In your view, how should any future legislation concerning plant products of targeted mutagenesis or cisgenesis take sustainability into account ?***

multiple answers possible

- [ ] By providing regulatory incentives for plant products with traits that contribute to sustainability objectives
- [ ] By requiring that the traits of plant products contribute to sustainability objectives and not authorising the placing on the market of plant products with traits that are detrimental to sustainability
- [x] By other means

* Please specify

500 character(s) maximum

GMO Network Norway underlines that on deliberate release section 10 second paragraph second sentence of The Norwegian Gene Technology Act reads “The deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on health or the environment. In deciding whether or not to grant an application, considerable weight shall also be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development”.

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)	( )	( )	(●)	( )	( )
* Tolerance/resistance to abiotic stresses (e.g. to climate change or environmental conditions in general, such as drought, heat, cold, salt)	( )	( )	(●)	( )	( )
* Better use of resources (such as water, nitrogen)	( )	( )	(●)	( )	( )

* Tolerance/resistance to plant protection products such as herbicides or insecticides	○	○	◉	○	○
* 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)	○	○	◉	○	○
* Better storage performance (e.g. under harvest, transport or storage conditions, longer shelf-life, non-browning and fewer black spots)	○	○	◉	○	○
* Better composition (e.g. higher or better content of nutrients such as fats, proteins, vitamins, fibres, lower content of toxic substances and allergens)	○	○	◉	○	○
* Other quality-related characteristics (e.g. better colour, flavour)	○	○	◉	○	○
* Production of substances of interest for the food and non-food industry	○	○	◉	○	○

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	○	○	◉	○	○
* Measures to facilitate the approval process (waiving of fees, faster procedures)	○	○	◉	○	○
* Allowing sustainability-related claims to appear on the final product	○	○	◉	○	○

Please specify any other incentives you would like to propose

500 character(s) maximum

GMO Network Norway's response is no opinion because GMO-legislation in Norway differs from EU-legislation.

*

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?

1500 character(s) maximum

GMO Network Norway's elaboration on our answers to question 6:
Whether genetically modified traits contribute to sustainability must be determined case by case. For example, increased tolerance to biotic or abiotic stresses may contribute to sustainability, but if GM plants with such traits are invasive because of enhanced fitness compared to their wild relatives, they can lead to unsustainable changes in the ecosystem.

GMO Network Norway also believes that some of the phenotypic traits listed may be difficult to achieve by genetic modification, partly due to the genotypic complexity of the trait and partly due to environmental factors. Conventional breeding may in these cases be a better alternative, especially because it is more easily adapted to different ecosystems and economic and social conditions.

Finally, GMO Network Norway emphasises that so far genetically modified plants have not contributed to sustainable food production. On the contrary they have been linked to unsustainable farming practises that have led to increased pesticide resistance. Instead of focusing on single traits, improving a wide range of farming practises is a far better way to make food systems more sustainable, cf. Farm to Fork Strategy.

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:***

multiple answers possible

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

* Please specify

500 character(s) maximum

GMO Network Norway supports research on traceability, including analytical capability to detect and identify GMOs. The Commission study showed that only a small fraction of GMO-research is related to regulatory issues, including detection methods. Developing new analytical detection methods are important, even if document-based traceability is, and will continue to be, a viable alternative.

* ***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:***

multiple answers possible

- [x] 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?

1500 character(s) maximum

GMO Network Norway's elaboration on our answers to question 11:
GMO Network Norway's understanding is that under current EU-legislation, reliable analytical methods for detection is a requirement for giving authorisation to plants produced by targeted mutagenesis or cisgenesis and it is the operator who is responsible for providing these methods. If these requirements are not met, the operator will not be allowed to place the product in question on the market.

GMO Network Norway is concerned about difficulties related to the possibility of detecting some GMOs, cf. our answer to question 10 in this survey. We believe, however, that further research is necessary in order to overcome this difficulty. Merely scrapping the requirement is not a viable solution.

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	○	○	◉	○	○
* putting in place mechanisms that facilitate easy adaptation to scientific progress	○	○	◉	○	○
* risk assessment that takes into account the characteristics and risk profile of a final product	○	○	◉	○	○

Please specify any other measures you would like to propose

500 character(s) maximum

GMO Network Norway's response is no opinion because GMO-legislation in Norway differs from EU-legislation.

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?

1500 character(s) maximum

GMO Network Norway believes that to protect the environment, including the fields of organic and conventional farms, is an essential part of co-existence. Co-existence must be in accordance with the precautionary principle, which means avoidance of irreversible adverse effects. Transparency through traceability and labelling is also important.

Co-existence must encompass the entire chain from seed production to the finished product. Co-existence regulations should also include the polluter pays principle, a key principle underlying environmental policy. It follows from this principle that farmers who use GMOs must bear the cost of co-existence, including any economic damage caused by GMO contamination.

Co-existence regulations ought to be harmonised across the EU. Different rules may result in growing GMOs in member states with weak regulations. It may also increase the risk of GMOs spreading from one member state to another.

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

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?

1500 character(s) maximum

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

1500 character(s) maximum

GMO Network Norway would like to draw attention to the report “Genome editing in food and feed production – implications for risk assessment”. The report, dated 29.10.2021, is an “Opinion of the Steering Committee of the Norwegian Scientific Committee for Food and Environment” (Norwegian name: VKM (Vitenskapskomiteen for mat og miljø))

The main message is that “VKM concludes that the guidance prepared by the European Food Safety Authority (EFSA) on risk assessment of genetically modified organisms provides a functional framework for risk assessment of genome-edited organisms. However, inclusion of specific considerations in the guidance regarding different properties of genome-edited organisms would be beneficial to ensure a common understanding between product developers and risk assessors regarding the type and extent of data needed to perform a risk assessment.”

More information, including the report and an abbreviated version, can be found here (retrieved 29 June 2022):
https://vkm.no/english/riskassessments/allpublications
/crisprandothergenomeeditingtechniquesimplicationsforriskassessment.4.581a91ee16d1a06e872a6bca.html

If you wish to provide additional information which complements your responses, you can upload a document here. The maximum file size is 1 MB. Provision of a document is optional.

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

Useful links

- New Genomic Techniques (https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology_en)

- Factsheet (https://ec.europa.eu/food/document/download/bc1e9b4a-c3fc-45e9-8d0e-72653984ef1f_en?filename=sc_modif-genet_pub-cons-factsheet.pdf)

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