July 2022

Public consultation on plants produced by certain new genomic techniques

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
English

I am giving my contribution as
- ~~Academic/research institution~~
- **Business association – Biotechnology/bio-based industry**
- ~~Company/business organization~~
- ~~Consumer organization~~

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- ~~Trade Union~~
- ~~Other~~

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The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published. Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected.
[indicate if you agree with personal data protection provisions] I agree

In**structions 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?**
   ~~**a.** They are adequate~~
   b. They are not adequate
   ~~**c.** No opinion/I do not know~~

1.2 This is because

~~- The GMO legislation is not sufficiently clear for these products~~

- The GMO legislation includes authorization, traceability and labelling requirements that are not appropriate for these plant products.
- The risk assessment approach of the GMO legislation cannot factor in the diverse risk profiles of plants obtained by targeted mutagenesis or cisgenesis

- ~~The GMO legislation does not take into account whether products have the potential to contribute to sustainability~~
- Other reasons [if so please specify, 500 characters maximum]

Instead of discriminating against the specific technique with which a product is made, balanced and future-proof legislation should rather focus on the characteristics of the final product, its application as well as sensible practices on the usage of products. For a cohesive approach, microorganisms should be considered in parallel to the ongoing policy action for plants. Especially since the Commission stated in its 2021 study that microorganism-based applications have been in use for decades.

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?**
   a. Yes
   ~~**b.** No~~
   ~~**c.** Not applicable~~
   ~~**d.** No opinion/I do not know~~

Please specify positive consequences [800 characters maximum]

None

Please specify negative consequences [800 characters maximum]

- Sustainability: negative impact on realizing ambitions set out in EU Green Deal, Farm to Fork and UN Sustainable Development Goals.
- Innovation: inability to apply NGTs elongates innovation timelines, increases costs and R&D failure rates.
- Political: member states remain split and GMO deadlock will prevail.
- Level playing field: EU competitiveness declines as other regions do move forward (examples provided at question 18).
- Economic/SMEs: NGTs remain out of reach for startups, scaleups and SMEs to commercialise both plants and application via microorganisms.
- Trade: Increased complexity due to global regulatory differences as well as detection issues.

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.

<u>RISK ASSESSMENT</u>

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.

3. **Currently, plants produced by targeted mutagenesis and cisgenesis are risk assessed as any other GMOs. What is your view on their risk assessment?**
   a. ~~Plants produced by targeted mutagenesis and cisgenesis need to be risk assessed using the current GMO legislation requirements.~~
   b. ~~Plants produced by targeted mutagenesis and cisgenesis need to be assessed using requirements adapted tot heir characteristics and risk profile.~~
   c. ~~Plants produced by targeted mutagenesis and cisgenesis do not need to be risk assessed when they could have been produced through conventional breeding or classical mutagenesis.~~
   d. Plants produced by targeted mutagenesis or cisgenesis do not need to be risk assessed.
   e. ~~No opinion/I do not know.~~
   f. ~~Other~~

3.2 **In your view, which criteria should be used to determine whether a plant produced by targeted mutagenesis or cisgenesis could have been produced via conventional breeding or classical mutagenesis?** [500 characters maximum]

The same criteria should apply for the assessment of all products, regardless of the underlying technology (e.g. NGTs, classical mutagenesis, conventional breeding, transgenesis). Instead of discriminating against the specific technique with which a product is made, legislation should focus on the characteristics of the final product, its application as well as sensible practices on the usage of products to be balanced and future-proof. This is in line with EC advisor group statement **(**REF 1**)**

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?**
   [Insert response, 1500 characters maximum]

Competitiveness: The EU is home to leading agricultural universities such as WUR in the Netherlands, and excels in crop knowledge & biotech. We fail to capitalize on this position because legislation hampers application of scientific progress. Knowledge leaks away to other parts of the world that do take steps to modernize legislation to unlock the potential of NGTs. (see Q18 for examples)
Speeding up innovation: breeding using NGTs takes 4-6 years and 8-10 years with conventional methods (REF 2) and diminishes costs & failure rates.
Counteract monopolies: NGTs must be equally available to research institutes, SMEs and multinationals. Now, NGT product market access is insecure and only unaffordable for multinationals.
Greater biodiversity: legislation must stimulate application of technology, innovation, R&D, and new or local varieties. As a result of the current, outdated GMO legislation, use of NGTs is limited to multinationals, commercially viable for limited number of characteristics in the biggest, most profitable crops.
Environmental: varieties can be developed more easily based on environmental demands: robustness, climate chance resilience, using less fertilizer/protection products.
Food supply & security: Higher yields, nutrients & optimized for local climates.
Customisation: bigger choice of seeds & crops for big & small farmers.

Safety: NGTs can be applied as safe as, or safer than, traditional non-regulated techniques.

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?**
    a. There is no need for specific regulatory provisions on sustainability in this initiative.
    ~~b. Specific regulatory provisions for sustainability should be included in this initiative.~~
    ~~c. No opinion/I do not know~~

Please explain why [500 characters maximum]

Sustainability should not create an additional hurdle during the product approval process, nor should it be an additional requirement for NGTs only. Similar to conventional breeding and classical mutagenesis, the usage of NGTs can contribute to sustainability. Allowing the application of NGTs will unlock a bigger potential to develop sustainable products. If any, sustainability criteria should be part of general (market) approval processes, regardless of technique applied or product type.

6. **In your view, which of the following traits are most relevant for contributing to sustainability?** [On a five-point scale from strongly agree to strongly disagree]
    a. Tolerance/resistance to biotic stresses (e.g. plant disease caused by nematodes, fungi, bacteria, viruses, pests)
    b. Tolerance/resistance to abiotic stresses (e.g. to climate change or environmental conditions in general, such as drought, heat, cold, salt)
    c. Better use of resources (such as water, nitrogen)
    d. Tolerance/resistance to plant protection products such as herbicides or insecticides Ai
    e. 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)
    f. Better storage performance (e.g. under harvest, transport or storage conditions, longer shelf-life, non-browning and fewer black spots)
    g. Better composition (e.g. higher or better content of nutrients such as fats, proteins, vitamin, fibres, lower content of toxic substances and allergens)
    h. Other quality-related characteristics (e.g. better colour, flavour)
    i. Production of substances of interest for the food and non-food industry

Strongly agree to all

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?** [on a five-point scale from strongly agree to strongly disagree]
    a. Regulatory and scientific advice before and during the approval procedure strongly agree

b. Measures to facilitate the approval process (waiving of fees, faster procedures) strongly agree
c. Allowing sustainability-related claims to appear on the final product strongly agree

Please specify any other incentives you would like to propose
[500 characters maximum]
Financial support for sustainable innovations ánd termination of subsidies for (established & new) products with a less favourable footprint. Incentives should include cellular agriculture too, e.g. cultured meat, precision fermentation & better usage of waste streams.
Incentives shouldn't be based on the technology used, and must not be part of GMO legislation.
EU must incentivise development, approval & uptake of (more) sustainable & desired products.

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?**
   ~~a. Yes~~
   b. No
   ~~c. No opinion/I do not know~~

   ~~If yes, how should the information be provided?~~
   ~~a. physical label on the final product~~
   ~~b. digital label accessible through the final product (e.g. website, QR code)~~
   ~~c. Via information available elsewhere (e.g. public database/register)~~
   ~~d. No opinion/I don't know~~

9. **Is there any other aspect that 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 characters maximum]

Full transparency via labelling to consumers can only be achieved when including all breeding methods, e.g. traditional as well as modern technology.
A clear, science based definition of sustainability is urgently needed, though it is often overlooked.
All traits mentioned at question 6 have the potential to have a high impact on sustainability. The realized impact depends on other factors too, which makes it hard or impossible to rank the traits. For example, a crop with higher content of vitamin A might be relevant to the Philippines, but less relevant to consumers in the EU.

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:**
    ~~a. Documentation transmitted through the chain of operators~~
    ~~b. Public databases/registries (zelfde als nu wordt gebruikt? Plantenregister)~~
    ~~c. Digital solutions, e.g. block chain~~
    ~~d. Other means~~
    e. 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:**
    a. Not be asked at all to provide an analytical method that can both detect and differentiate their product
    ~~b. 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~~
    ~~c. Be asked to provide a detection method, but without the need to differentiate, if they can justify that the latter would be impossible~~
    ~~d. Not be allowed to place the product in question on the market~~
    ~~e. No opinion/I do not know~~

12. **Transparency of operators and consumers, on plants produced by targeted mutagenesis or cisgenesis:**
    ~~a. Can be achieved via a physical label on the final product~~
    ~~b. Can be achieved via a digital label accessible through the final product (e.g. link to a website, QR code)~~
    ~~c. Can be achieved via information available elsewhere (e.g. a website, public database/register)~~
    ~~d. Is not necessary for plants produced by targeted mutagenesis and cisgenesis, when they could have been produced through conventional plant breeding or classical mutagenesis~~
    e. Is not necessary for any plant produced by targeted mutagenesis and cisgenesis
    ~~f. 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 characters maximum]

Tracing and labelling products specifically produced with targeted mutagenesis or cisgenesis is unacceptable, as it seriously impedes the level playing field, is discriminatory and misleading. Even though plants produced with classical mutagenesis legally are GMOs (but exempted from the scope of the legislation), they do not need to be traced nor labelled as GMO. These plants or their products are

even allowed to claim “organic” and/or “non GMO” labels. Any legal requirements regarding transparency should be fair, proportionate, feasible and enforceable – for everyone, including innovative startups, scaleups and SMEs.

B. 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?** [On a five-point scale from strongly agree to strongly disagree]
    a. Improving legal clarity in the legislation (Tend to agree)
    b. Putting in place mechanisms that facilitate easy adaptation to scientific progress (strongly agree)
    c. Risk assessment that takes into account the characteristics and risk profile of a final product (strongly agree)

    Please specify any other measures you would like to propose.
    [500 characters maximum]

To realize the full potential of biotech innovation for health, sustainability and economy, a paradigm shift is needed. Future-proof legislation does not discriminate the technology used, but takes into account the characteristics of the final product. A more thorough modernization of the GMO legislation is urgently needed, not just by extending the modernisation’s scope to all genomic techniques (classical, targeted, cis-, transgenesis, etc) but to any organism, including microorganisms too.

15. **Which of the various measures outlined in section B would be most relevant to co-existence with the existing agricultural practices (e.g. conventional, organic)? Are any other measures necessary?**
    [1500 characters maximum]

It is discriminatory, and it doesn’t make sense to subject plants to mandatory co-existence measures solely based on the technology that was applied to create them. In addition, co-existence measures cannot be enforced, as it may be impossible to distinguish plants produced with NGTs from plants produced with classical GMO or non-GMO techniques.

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 by targeted mutagenesis or cisgenesis does not cover intellectual property rules (e.g. plant variety rights, biotechnology patents)*
    [1500 characters maximum]

Access to technologies and resources should not be part of this specific legislation, but rather of (existing) legislation on access and genetic resources. Removing the current bottlenecks and enabling utilization of modern methods such as targeted mutagenesis and cisgenesis as well as plant genetic resources, will allow academia, startups, scaleups, SMEs as well as multinationals to innovate and develop new products. This will increase the number of crops, varieties and products, contributing to greater biodiversity.

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 characters maximum]

Any regulation or addition to legislation should keep in mind startups, scaleups and SMEs.
Current GMO regulation has created a high boundary, leaving uptake of technology out of reach of startups, scaleups and SMEs as investments are big, the administrative burden too demanding, timelines too long and outcomes and uptake uncertain. Even for bigger companies the investments, timelines and uncertainty are too big to undergo this process for anything other than the biggest and therefore most profitable crops. To illustrate, the current cost and time of the regulatory process for obtaining an EU import authorization is estimated to take 6 years on average and 11-16.7 million euros. The process to obtain GMO cultivation authorization in EU is even longer. (REF 3)

18. **You can raise any additional points or provide further information and evidence to support your views using the field below:**
[1500 characters maximum]

Given the great societal challenges of our time, the EU needs to embrace all solutions available. Unfortunately, Europe's political deadlock regarding GMOs is hampering biotech's contribution to challenges in health, food security, sustainability, competitiveness and welfare. EFSA's science-based safety assessment is followed by a completely politicized member state voting process, stalling authorization for other reasons than safety concerns. By simply changing the legislation or regulatory status of (some) NGTs, without addressing the underlying political or ideological friction, this deadlock will prevail. Thus, in addition to a thorough revision of the GMO framework (including all techniques and organisms), Europe must engage in a societal and political debate about genetic modification and NGTs. That debate should lay the groundwork for a futureproof and fit for purpose system. (REF 4)

Hereby some examples of global steps outside of EU to reduce strict regulation NGT:

- In UK the "Genetic Technology Bill" has recently been submitted (REF 5)
- In Japan gene edited products already are on the market (REF 6)
- New guidelines in China speeds stimulates research and commercialisation of gene edited crops (REF 7)
- In the US no additional regulation on plants that otherwise could have been developed through conventional breeding is imposed via the SECURE biotechnology Regulations (REF 8) plus link to CRISPR crops being developed in the US: REF 9

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

Contact SANTE-NGT-STUDY@ec.europa.eu