Public consultation on plants produced by certain new genomic techniques

Substantial excerpt from the **UEAA contribution** to the Public consultation for the EU Commission 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 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.

Glossary

- **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.

Reading tips:

Answers to questions: the choice in bold and blue; in black and italic what was not agreed.

Comments:

In blue and framed (the length was limited, 500, 800 or 1500 characters, and some answers are very summarized).

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

- Question ***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*

  - ***1.2 This is because***

- **the GMO legislation is not sufficiently clear for these plant products**
- **the GMO legislation includes authorisation, 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*
- **of other reasons (please specify)**

The current legislation does not consider targeted mutagenesis or cisgenesis as certain categories of plants obtained through these techniques should be excluded and listed in an annex of the 2001/18/CE directive (Annex 1A and 1B)

* Question ***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

If plants continue to be regulated under the current GMO framework, negative consequences can be expected. GMO cultivation in Europe is forbidden in most countries and their uses as feed or food very restricted. Plants obtained through NGT (targeted mutagenesis and cisgenesis) will be under the same restrictions. As a consequence, Europe will not take any advantage of the possibility to develop new plant traits in cultivated plants. Published papers and databases shown that plants, obtained through NGTs are more adapted to climatic changes, new quality markets, and have a lower need of fertilizers and pesticides. Ensuring a reliable production level, year after year, these plants are also part of the answer to societal requests.

Please specify potential negative consequences

The complexity of GMO EU regulation is obvious. Not a single GM product has been authorized via the 2001/18/CE directive! Only one GM plant is cultivated

today in Europe, with excellent production rates, quality levels and no environmental impacts. However, most EU countries have forbidden cultivation and food and feed uses.
Moreover, the EU regulation leads to big uncertainties: cost of the studies and deregulation dossier follow up, delays in the process leading to huge backlogs. Products of the NGTs will follow the same fate: no cultivation, no uses even if they could answer to agricultural and societal needs. Having more restrictive regulation in EU will also lead to high commercial risks during trade with countries were regulation is exempting such products (N and S America, China).

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

Question ***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*

    - ***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?***

A plant with a:
.allele edited (including KO) to copy a functionality associated with a known allele of in its gene pool;
.allele edited (including KO) to copy a functionality associated with a known allele present in a plant species outside the plant's gene pool;
.allele edited (including KO) for a new functionality, the sequence modifications obtained by NGT of the same type as those which can be obtained by mutagenesis;
.gene from its gene pool and inserted into a targeted site.

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?

A negative economic impact will be on the viability of European farms that will not have access to innovation and plants more adapted to climatic changes, with reduced environmental impact during cultivation (less fertilizers, water and pesticide uses). Their competitivity is at risk. The "F2F" strategy success needs an increased production with lower cultivation costs and impacts that will be not achievable with only organic agriculture especially if NGTs will not be included in that cultivation

protocol. The global situation (lower production of cereals due to climatic accidents) and the Eastern Europe conflict (lower availability of cereals and fertilizers) impose to take into account new innovative tools and plants without delay. The potential impact on trade is huge. Several countries have already authorized products from NGTs, exempted of any regulation, without traceability, detection or identification tools. The social impact of the above economic negative impact will be the reduction on employment in agriculture agro-food and feed sector, the increasing of food safety risk and food cost for consumers. The societal request on reduction of cultivation impacts on the environment will not be answered.

Question ***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*

Please explain why

New traits obtained through NGTs are not only addressing sustainability, some of them are addressing quality and/or productivity. There is no need for specific regulatory provisions on sustainability which is assessed during several rounds of cultivation by farmers and technical institutes. The more specific a regulation is, the more products will be rejected as they will not fulfill the criteria.

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)	**X**				
Tolerance/resistance to abiotic stresses (e.g. to climate change or environmental conditions in general, such as	**X**				

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	Strongly agree	**Tend to agree**	**No opinion/I do not know**	**Tend to disagree**	**Strongly disagree**
drought, heat, cold, salt)					
Better use of resources (such as water, nitrogen)	X				
Tolerance/resistance to plant protection products such as herbicides or insecticides		X			
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)	X				
Better storage performance (e.g. under harvest, transport or storage conditions, longer shelf-life, non-browning and fewer black spots)	X				
Better composition (e.g. higher or better content of nutrients such as fats, proteins, vitamins, fibres, lower content of toxic substances and allergens)		X			
Other quality-related characteristics (e.g.		X			

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	Strongly agree	Tend to agree	No opinion/I do not know	Tend to disagree	Strongly disagree
better colour, flavour)					
Production of substances of interest for the food and non-food industry		X			

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

Please specify any other incentives you would like to propose

A rapid implementation of a regulation adapted to NGT products would be the best incentive, allowing creation of products by agronomic institutions in a serene context. There is a need to allow field trials, without a lengthy authorization process and the risk of vandalism. For marketing, the regulation has to be reliable, simple, rapid, predictable, similar to a variety registration process, without specific claim.

Substantial excerpt from the UEAA contribution to the Public consultation for the EU Commission on **"plants produced by certain new genomic techniques"**

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?

Sustainability is not new in agriculture; it covers diverse domains: choice of cropping systems, productions, farm management, etc. More recently, the word was focused on environmental impact of production, including the choice of conventional varieties which are rated in some case during the registration process (disease resistance, stress tolerance for example). Varieties obtained through NGTs have not to be specifically evaluated for sustainability even if their new trait affect positively sustainability (abiotic or biotic stress tolerance, product quality, etc). Finally, recommendation should be to address sustainability criteria for all varieties, whatever the techniques used for breeding (conventional, mutagenesis, NGTs, …). Consumer information should follow the same approach and given in a general way in every step (seed bag, transformation and final product).

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:

- *Additional help available*
- *multiple answers possible*
- **documentation transmitted through the chain of operators**
- **public databases/registries**
- *digital solutions, e.g. block chain*
- *other means*
- *No opinion/I do not know*

Question ***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

- *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?

There is a scientific consensus, validated by food safety agencies, that plants derived by biotechnology are not more subjected to pose a higher risk than plant obtained by conventional breeding. The consequence is that excluding certain categories of plants from the GM regulation when they could have been obtained through classical mutagenesis or classical breeding do not pose any threat. These categories of plants will anyway follow the registration and regulation process of any conventional variety.
For operators and consumer information, databases already exist maintained by USDA (https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry) or by EU: (https://www.eu-sage.eu/genome-search) where specific scientific information is available. When registered in EU a new variety is included into a catalogue publicly accessible.

C. Other relevant aspects of a new framework

Question ***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		**X**			
putting in place mechanisms that facilitate	**X**				

Substantial excerpt from the UEAA contribution to the Public consultation for the EU Commission on **"plants produced by certain new genomic techniques"**

	Strongly agree	**Tend to agree**	**No opinion/I do not know**	**Tend to disagree**	**Strongly disagree**
easy adaptation to scientific progress					
risk assessment that takes into account the characteristics and risk profile of a final product	**X**				

Please specify any other measures you would like to propose

Adaptation of regulation to scientific progress, on time, is a need. The example of the very rapid development of NGTs and the delay taken for regulation to follow innovation should be taken into consideration. The question of null segregants (to be excluded from any regulation) and the possibility to cross and create new combinations from plants obtained through NGTs has to be addressed.

Question ***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?***

There is no general need of co-existence measures. This is the case today for conventional/organic production. In some very specific cases, for quality reasons, measures are taken like isolation (high erucic oilseed rape or seed productions) or harvest of the center of the field and not the border rows (waxy maize). These measures, adapted to several crop species are managed by the operators.

Question ***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)*

In Europe, new conventional varieties are protected by the plant variety certificate and their uses in breeding follow specific rules.
Plant genetic resources access is covered by the Nagoya Protocol.
The technologies used for NGTs are very often protected by patents and industrial property rules; their use is only possible after getting a license from the technology owner.
There is no need to include regulatory measures, only adaptation of the current regulation process is to be considered.

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Question ***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?***

Current GM regulation has excluded SMEs from developing any new product. This is due to the costs, delays, unpredictability of the process, etc. There is an urgent need to adapt the regulation and made it more predictable and affordable to SMEs. This can be done through excluding in the Directive Annex plants that could be obtained by classical mutagenesis. In such case, SMEs can enter this innovative market and propose new plant varieties more adapted to climatic changes, social demand and proposing new qualities for industry, food and feed uses.

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

Discussion on adaptation on the regulation to products to new breeding techniques was initiated in April 2007 by Nederland. 15 years later and after the discovery of novel techniques very efficient, simple, rapid and reliable for genome editing, the situation is unchanged and the discussion on regulation adaptation is very lengthy. There is an urgency for Europe, European agriculture and consumer to move forward on the regulation changes making public and private research easier and products reaching the diverse markets.