Beantwoording publieke consultatie nieuwe genomische technieken

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 authorization, 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 organizations. 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
X	**They are not adequate**
	No opinion / I don't know

1.2 This is because

X	**gmo-legislation is not suffiently clear for these plant products**
X	**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
X	**The GMO legislation does not take into account whether products have the potential to contribute to sustainability**
X	**Of other reasons**

Please specify:

- The present regulatory framework is not proportionate in cost, duration and predictability of market authorisation procedures (which is especially difficult for small and mediumsized enterprises).
- The regulatory framework is not future proof and does not keep pace with technological developments (as it does not contain some sort of review or flexibility mechanism.

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?

X	**Yes**
	No
	Not applicable
	No opinion / I do not know

Please specify positive / negative consequences:

New genomic techniques have the potential to contribute to societal challenges, such as food scarcity, climate change and the transition to a sustainable and resilient agri-food system. This can be achieved by accelerating the breeding of crops for example to be more resilient to biotic and abiotic stress.

Currently the EU cannot make the optimal use of these innovations as the new genomic techniques are legislated by a legislation that is not-fit-for-purpose.

If NGTs (cisgenesis and targeted mutagenesis) continue to be regulated under the current GMO framework, the negative consequences are:

- NGT's cannot easily contribute to more sustainable agricultural practices, feed and food supply, product & crop diversity and the transition towards a circular (biobased) economy.

- NGTs are a very useful tool for sustainable and resilient agriculture systems, as crops can be more easily bred to have certain resistance against biotic and abiotic stress. Without such a tool, it will be more difficult to reduce the use of pesticides in agriculture.
- According to our experts, breeding could be accelerated significantly using these techniques (depending on the crop). This can make plant breeding much more flexible to react to changes like emerging pests and climate change. Under the current legislation, the possibilities of plant breeding and the flexibility thereof are very limited, if not impossible.
- There is a number of niche crops that have great potential to contribute to crop diversity and several societal goals. However, they are currently not economically attractive, because the breeding of these crops has lagged behind over the past years. Examples of such crops are Fabaceae crops[1], like field beans and lupine, and fiber crops, like flax, fibre hemp and miscanthus. Such crops can increase the cultivation of plant proteins. With a future proof and proportionate legislation for NGTs, this backlog of breeding can be fixed much faster as the breeding process can be increased.
- Several other countries, like the United States, Canada, Argentina, and Japan, have already legislation in place to make use of NGTs. Other countries, like the UK, are making quick progress to put legislation in place[2]. If the EU chooses not to put new legislation for NGTs into place, there is a good possibility that the EU will lag on innovation and progress in these areas. The EU breeding sector will have a disadvantage compared to their global competitors and R&D of European breeding companies may therefore leave the EU.
- EFSA has reported[3] that NGTs, such as targeted mutagenesis and cisgenesis, are equally safe as conventional breeding techniques. However, they still require lengthy procedures and (in this case) disproportional burdens.
- If such disproportionate burdens on the admission of NGT crops will continue to exist, this will ensure that only large multinationals will be able to put these crops on the market. SME's will therefore be even more at a disadvantage.
- In the areas of safety, labeling and traceability, (new/adapted) requirements should be set in line with the new techniques.
- The current legislation leaves room for legal uncertainties. In the Commission study on NGTs[4], it was stated that the GMO-legislation is not fit for purpose. NGTs do not fit within the definitions of the GMO-legislation.
  In the Commission study it was also suggested that organisms altered by epigenetic techniques would fall under the scope of the GMO legislation. In our view, this statement warrants further discussion.
  As the current policy initiative will not completely address the legal uncertainties, it would be advisable to continue to work on more clarity regarding the scope of the GMO legislation.

[1] These crops have also the added benefit that they perform biological nitrogen fixation and thus improve soil quality.

[2] Legislation on gene editing (the Genetic Technology (Precision Breeding) Bill) has been introduced to the House of Lords per 25.05.2022

[3] https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en

[4] Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16

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 legislative requirements
	Plants produced by targeted mutagenesis and cisgenesis need to be risk assessed using requirements adapted to their characteristics and risk profile
X	**Plants produced by targeted mutagenesis and cisgenesis do not need to be risk assessed when produced through conventional plant breeding or classical mutagenesis**
	Plants produced by targeted mutagenesis and 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 clear answer to this question is hard to give, as of course a plant product that has been produced by targeted mutagenesis or cisgenesis is hard to distinguish from a plant product produced by conventional breeding techniques.

- However, in case a large amount of base pairs have been altered within the DNA (e.g. through a series of point mutations), that would probably be traceable and the use of NGTs could thus be demonstrated (although not be proven inconclusively)
- Another possibility could be a more statistic approach, to see what the likelihood is of a spontaneous mutation (especially in case some conserved gene has acquired specific advantages)
  This is e.g. by analogy of the work of the Dutch forensic institute, where, after sequencing a perpetrator's DNA-profile, this unicity of this profile is statistically supported by comparing with other profiles.

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?***

Bottom line is that EFSA has confirmed that targeted mutagenesis and cisgenesis are equally safe as conventional techniques, so, in our view, this means that no risk assessment is required for plants (that have been altered with these NGT's).

However, we feel that skipping the risk assessment would leave a gap, and that there should be some sort of lighter 'approval' assessment instead of a risk assessment - to verify whether the plant has been obtained through the relevant NGT technique (and whether it is free of foreign DNA sequences).

Should it however be decided that new legislation would still contain a risk assessment for NGT's, then we think we should further discuss, both in the Netherlands as on the European level, the process versus product based approach.

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
X	**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?

X	**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

the answer under the 2nd bullet consists of 2 parts. We disagree with the first part (requirement that traits contribute to sustainability). After all, products with neutral traits, which do not contribute to sustainability (immediately) but do not detract from it either, should also be allowed because they may be or become important for other important purposes. Also, it is difficult to predict which traits are going to be sustainable in the future. Therefore it is not advisable to restrict these traits legislation-wise.

Concerning the second part of the question (require that undesirable traits of plants should not be given a place): we would agree on this notion in general, however: we think that it might occur that a trade-off is necessary in exceptional cases.

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

	Strongly agree	**Tend to agree**	**No opinion/ do now know**	**Tend to disagree**	**Strongly disagree**
Tolerance/resistance to biotic stresses (e.g. plant diseases caused by nematodes, fungi,	**X**				

bacteria, viruses, pests)					
Tolerance/resistance to abiotic stresses (e.g. to climate change or environmental conditions in general, such as drought, heat, cold, salt)	**X**				
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. better colour, flavour)		**X**			
Production of substances of interest for the food and non-food industry	**X**				

Please specify

Regarding question 6, it is important to see these traits and NGT crops in general are not the silver bullet themselves. To build resilient and sustainable food production systems we must see NGTs as one of the many tools to build these systems. Other tools can be for example agroecology and strip cropping. It is therefore one dimensional to look at specific traits and conclude whether they are sustainable or not; this really depends on the systems you are building. It would be better to broadly

define missions on where we want to stimulate development of crops that could benefit the systems, these missions should be flexible and adjustable.

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/ do now 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:

If, in the new legislation, some sort of (light) assessment for targeted mutagenesis and cisgenesis would be incorporated, and facilitating exemptions and using faster procedures would, in our opinion, be useful, certainly in the case of sustainable applications.

We do not use fees for risk assessment procedures in the Netherlands, so we refrain from an opinion on that matter.

Concerning sustainability-related claims: it is difficult to judge what kind of claims would be useful and/or should be allowed. We consider enforceability and workability important criteria and would like to prevent from creating a costly and time-consuming process. More in general, if the decision were to be made to include any sustainability-related claims, that it would be in more overarching legislation (related to sustainable food systems initiative and/or taxonomy).

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?

X	**Yes**
	No
	No opinion / I do not know

8.1 How should the information be provided?

	Via a physical label on the final product
	Via a digital label accessible through the final product (e.g. link to a website, QR code)
X	**Via information available elsewhere (e.g. a website, a public database/register)**
	No oninion / 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?

Concerning sustainability in general:

- Biotechnology can contribute to global challenges of our time, such as the very pressing challenge of food scarcity – due to for example wars, plant diseases and pests, as well as extreme weather conditions, which are more frequently due to climate change - and the transition to a sustainable and resilient agri-food system and to soil health. It can also contribute to other transitions such as the protein transition and the transition towards a circular (biobased) economy.
- Hence, we agree with the Commission that sustainability is an important factor to consider when creating new legislation on biotechnology.
- Having said this, it is also clear that there is a number of challenges when it comes to formulating sustainability criteria.
- Although we have filled in question 5 with the second bullet (specific sustainability requirements needed – that seemed the best answer among these possibilities), we feel that a more overarching sustainability framework would be a more logical solution, addressing not only NGTs but also conventional breeding, non-food, fertilizers, and biocides. For example, related to Farm to Fork and the Sustainable Food systems initiative.
- Moreover, sustainability is a very broad concept; to use it well, it should be defined and scoped in order to have a clear framework for consideration.
- Forming sustainability criteria for EU plant products, might also create a difference (also in level playing field) between EU and non-EU products.
- Establishing criteria and especially determining how they are weighed against each other is a challenging process. For example: sometimes the crop in a particular place is not sustainable at all, but e.g., the trait applied by NGT is. And how do you deal with crops that are not sustainable according to these criteria but are important for food security in 3rd countries? To be able to use sustainability criteria well, they should be objective and verifiable.
- As we still do not have a general and overarching EU sustainability framework, the criteria should in our opinion add to and relate closely to already existing EU sustainability criteria, such as in the Renewal Energy directives RED I and II.
  For example: criteria for efficiently grown crops with less pollution and less input contribute to the criteria of RED (and therefore to biobased materials) and are therefore complementary.
- In our opinion sustainability should be stimulated in broadly defined missions by, for example, subsidies and priority in the administrative process. Hard criteria in this specific legislation would make this new legislation rigid and not-futureproof. What we do support is to exclude undesirable non-sustainable traits.
- We also want to draw attention to the importance of sustainability for the non-food industry, such as the floriculture and fibre crops (question 6: production of substances of interest for the food and non-food industry).
- Sustainability criteria should not lead to more time consuming and costly procedures.
- Disproportionate and time-consuming legislation should be prevented.

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

X	**Documentation transmitted through the chain of operators**
X	**public databases/registries**
X	**digital solutions, e.g. block chain**
X	**other means**
	no opinion / do not know

Please specify

Guaranteeing traceability or identifying with *certainty* whether it is an NGT or a conventional crop, is not possible as analytical methods are not available or reliable. Hence, the correct answer cannot really be given under question 10. because there is currently no method that can for sure prevent a plant made with NGT from entering the chain as a conventional crop. Blockchain also does not provide 100% certainty because blockchain is not yet in place at the moment (or the location) when the crop is being developed. All answers 1 up to 4 though are answers that could be used and provide at least the information that is available.

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
X	**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 / do now know

Please specify

Even when NGT and conventional crops cannot be distinguished from each other, a detection method can be useful to know, or at least find out through analysis, which technique has been used. This is useful for enforcement and analysis. In addition: a producer would normally have the method available. In that case, it would not be an additional burden. Therefore, we think the 3rd bullet would come closest: we could ask the producer (full stop).
More generally speaking, we think that transparency within the chain is very important. This can be partly ensured by (making) a difference between biological products and NGTs. A solid documentary system will be crucial.

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

X	Can be achieved via a physical label on the final product
X	can be achieved via a digital label accessible through the final product (e.g. link to a website, QR code)
X	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 / do now know

Please specify

The provision of information to the consumer is a.o. included in the EU food law and in the national Commodities law (through the principle that the consumer should not be misled). This principle also applies to food obtained from NGTs. Therefore, the answer cannot be that no labeling or register (in any form) is necessary. The method of making this information available can still be debated. But strictly speaking, only 1, 2 and 3 can be options. However, option 3 has our strong preference as the other two could bring disproportional burdens.

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?

(See above)

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 don't know**	**Tend to disagree**	**Strongly disagree**
improving legal clarity in the legislation	**X**				
putting in place mechanisms	**X**				

that facilitate 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

In new legislation:

- A review process for the directive (or regulation) for periodical adaptations to technical progress should be designed; and
- An exemption mechanism in order to keep pace with technological developments and innovation (learning system) for applications for which safety to human health and the environment is sufficiently ensured.
- A new mechanism should contain a more product-based approach than currently exists.
- Rather than assessing new techniques or applications thereof on a case-by-case basis, the mechanism must be developed in a manner exempting NGTs based on generally formulated conditions and (science-based) criteria.
- The burden of proof for justifying compliance with the exemption criteria (and also: liability) should be placed on actors that are making use of the exemption.

Criteria can among others be found in British or Australian legislation[5] where exemptions have been defined through general criteria.

In 2018, the Netherlands (based on the existing legislation) proposed to use specific criteria in annex B of the present directive 2001/18[6]. Without knowing what future legislation on NGTs is going to look like, we could imagine a similar system would be useful.

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?

Most relevant proposal:
- in case of co-existence: freedom of choice for professional users must be guaranteed. This should be done by means of a public and transparent system in which it is known which variety has been developed with NGT's.
Other possible measures:
- a limit value for NGT content in organic products, to reduce the risk for organic farmers that their harvest would accidentally be cross-contaminated from a neighboring field.
- In line with this, a minimum distance between plots of organic farmers and regular farmers using NGT crops could be arranged to minimize risk of contamination. This possible measure could be left to the member states themselves.

[5] For Australia: Gene Technology Regulations 2001 (legislation.gov.au) and Overview - status of gene editing and other new technologies (ogtr.gov.au)
For UK: ACRE guidance on genetic technologies that result in 'qualifying higher plants' - GOV.UK (www.gov.uk) and Qualifying higher plant notification (reference: 22/Q01) - GOV.UK (www.gov.uk)
[6] TK 27 428, nr 345

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)*

It is true that in the early days of NGTs the licensing of technologies like CRISPR-Cas were expensive and under strict conditions. However, more and more alternatives are coming onto the market, which make these technologies more accessible. For example, the Wageningen University announced that they would make the use of their CRISPR license free under certain conditions[7]. It is our opinion that for this legislation we should not focus on intellectual property issues.

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?

Above all, we want to ensure human and environmental safety as well as a level playing field. SME's should have equal opportunities as larger companies. More clarity, exemptions in the current legislation for targeted mutagenesis and cisgenesis for the production of plants, as well as (possible) policy instruments to include sustainability criteria (shorter procedures, fiscal incentives) could contribute to this.

[7] https://www.wur.nl/en/newsarticle/wur-gives-away-crispr-intellectual-property-licenses-for-free-in-fight-against-hunger.htm