

Dear allies,

The threat to organic and sustainable food and farming systems raised by new genomic techniques (NGTs) is huge. The speed and potential lack of precaution pose a level of genetic disruption like we have never seen before. In most countries the lack of regulation of NGTs that poses a truly existential risk.

Until now, the European Union has ruled that NGTs are to be regulated and labeled like other GMOs, but that position is being questioned through a current consultation conducted by the European Commission. The consultation questions are, quite frankly, biased towards leading respondents to support the deregulation of NGTs – but it is possible to answer in a way that avoids falling into that trap. It is highly important that a strong voice for strict regulation of GMOs and NGTs continues, so please have your say through this survey. If our position is not heard here then we shall lose influence in the debate. **The deadline to respond to the survey is 22 July 2022.**

There are also several organizations rallying stakeholders via a petition, which you may sign through the organization/format of your choice:

- Friends of the Earth: <https://friendsoftheearth.eu/news/sign-the-petition-to-say-ichoosgmofree/>
- Via Campesina: <https://www.eurovia.org/european-petition-against-new-gmos/>
- Biodynamic Federation: <https://demeter.net/keep-new-gm-food-strictly-regulated-and-labelled/>
- BOLW: <https://organic-market.info/news/online-petition-demands-no-free-pass-for-genetic-engineering.html>

This is a watershed moment in human evolution. Rise!

If you have questions or need assistance, please be in contact.

## **Input – EU Commission consultation on NGT legislation 2022**

### **Instructions:**

1. Register on the EU “Have your say” website. Go to **[https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en)** and use an existing account, or create one and set a password.
2. Suggested answers to the survey are given below. **Blue bold font indicates suggested responses.** Please feel free adjust the language to make it “your own,” but you’ll need to pay attention to the strict character limits.

### **GENERAL**

***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*

**Triggers question 1.1:**

- *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*
- *other reasons*
- *They are not adequate*
- *No opinion/I do not know*

**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?**

**(Depending on how one interprets the question both “Yes” and “No” are feasible answers, but an explanation can only be added if the answer is “Yes” so choose that.)**

- **Yes**

*Please specify potential positive consequences. 800 character(s) maximum*

Significant environmental, economic, and societal benefits accrue from the expansion of certified organic production systems, which prohibit the use or inadvertent (unavoidable) presence of organisms regulated by current regulations above very low thresholds. These benefits have been recognized by the Commission as evidenced by its plans to promote and expand organic production and markets. Protecting producers against potential income loss from trespass by users of these new organisms is critical to safeguarding organic systems. Transparency and traceability regarding the creation, origination, and chain of custody must therefore be implemented more rigorously to assure the integrity of the organic sector. Consumers expect to make informed choices based on credible assurance mechanisms. 799/800

*Please specify potential negative consequences. 800 character(s) maximum  
<You can leave this section blank.>*

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

**RISK ASSESSMENT**

**Question3. 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

**Triggers question 3.1. Check the first 4 boxes, ie:**

- ✓ the novelty (or not) of the trait
- ✓ the technique used to introduce the modification
- ✓ the extent of the genetic modification
- ✓ the resulting (phenotypic) changes in the plant

**note:**

The first answer (Plants produced by targeted mutagenesis and cisgenesis need to be risk assessed using the current GMO legislation requirements.) could also be chosen, with the idea that risk assessment guidelines, not legislation, will have to be updated to take into account the properties of the capabilities of the tools which are inter alia alteration of multiple, identical DNA sequences, Multiplexing (alteration of multiple, different DNA-sequences) and the alteration of protected parts of the genome (normally protected by DNA Mismatch Repair).

**Question 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:

A comprehensive, enforceable risk assessment protocol that takes precautions against inadequately informed environmental release is absolutely necessary. The "precision" of certain NGTs does not yet adequately take into consideration off-target changes within the genome or epigenetic effects, including but not limited to: 1) the introduction of unintended molecular changes that lead to unintended effects on physiology, development or composition with implications for food, feed and environmental safety, (2) introduction of changes that modify the expression of endogenous genes and impact the organisms metabolism, (3) introduction of transgenic constructs that are present during intermediate steps that might not be fully removed and absent from the final product. A thorough, socially responsible and scientifically sound risk-assessment must show clear value in preventing potentially harmful impacts on the environment, biodiversity and human health. Genomes developed through NGTs should have their DNA sequences compared to the reference/original

genome to really assess the "precision" of the changes at the genetic level, as well as a corresponding study (under protected conditions) of their phenotypic expression, in order to more reasonably assess safety, utility, and stability. This entails the absolute necessity of requiring that reference genome material be made available. Such studies should occur under protected conditions and be for a duration of multiple generations. (1497/1500)

## **SUSTAINABILITY**

**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 (500 chr.)*

*Inclusion for sustainability would imply that beneficial traits can only be inserted by using a certain NGTs. However, organic and other traditional breeders have already developed varieties that are adapted to low-input conditions. If risk assessment protocols are truly robust, then these will take into account enough considerations that would also encompass sustainability. (377/500)*

- *Specific regulatory provisions for sustainability should be included in this initiative*

*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*
- *By other means (500chr.)*
- *No opinion/I do not know*

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

- *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

**Answer: Choose “No opinion” for all lines.** (Explanation: The survey requires an answer, but with this list of plant traits, the EU Commission apparently wants to narrow down what a sustainable plant trait is, which could then qualify for a sustainability label. However, a list of plant traits and characteristics that may or may not find its way into commercialized crops is not appropriate to define their contribution to sustainable food systems.)

**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?**

- Regulatory and scientific advice before and during the approval procedure (**strongly agree**)
- Measures to facilitate the approval process (waiving of fees, faster procedures) (**strongly disagree**)
- Allowing sustainability-related claims to appear on the final product (**strongly disagree**)
- Other (500chr.)

**Explanation: Incentives should be in the direction of assuring that risks to environmental sustainability, biodiversity, and human health are minimized to the greatest extent possible. If NGTs have been used then these should be clearly and transparently communicated to consumers in line with existing EU Regulations on GMOs. (313/500)**

**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

8.1 How should the information be provided?

multiple answers possible

- 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)
- Via information available elsewhere (e.g. a website, a public database/register)
- No opinion/I do not know
- **No**
- No opinion/I do not know:

This proposal suggests that beneficial traits can only be introduced through targeted mutagenesis or cisgenesis, which is not the case. Furthermore, traits for themselves do not guarantee a product will be

produced in a more sustainable way. Taken together, this would cause unfair competition with sustainable farming systems like organic that go through a certification process.

**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

*This proposal suggests that beneficial traits can only be introduced through targeted mutagenesis or cisgenesis, which is not the case. Traits themselves do not guarantee a product will be produced in a more sustainable way. Sustainability can only be thought from a systems-perspective, considering the types of inputs and agricultural practices applied throughout the whole process. Furthermore, using NGTs to make sustainability claims that have not been well vetted, substantiated, or studied would cause unfair competition with sustainable farming systems like organic that go through a certification process. (614/1500)*

## **INFORMATION FOR OPERATORS AND CONSUMERS**

**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

- **Documentation transmitted through the chain of operators**
- **Public databases/registries**
- **Digital solutions, e.g. block chain**
- Other means
- No opinion/I do not know

Guidance: all of the methods mentioned above could potentially be part of an effective traceability system. Also see reply to question 13.

**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

Guidance: There is already evidence that some developers will state (as in the CIBUS case) that it was a “natural” specimen they “found” rather than have to declare it as a GMO. Furthermore, the approach

implied here is that the NGTs really are “precise” without paying attention to off-target effects in the genome.

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

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

Guidance: see reply to question 13.

**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

**Draft IFOAM Answer:**

*Re question 10: Full traceability across the entire supply chain must be required. Digital certificates make sense as a medium. More "traditional" process-based approaches such as are used in organic certification can also be applied (whether or one can use laboratory methods to determine the origin of a product).*

*Re question 11: As has already been seen (CIBUS case), some developers will state that it was a “natural” specimen they “found” rather than be subject to current regulations. Furthermore, the question here implies that the NGTs really are “precise” without paying attention to off-target effects in the genome. The onus of precaution and responsibility to assure detectability and differentiation should be with the developer/user of the new genome. A responsible policy would also require that the genomic technique, detection method, and reference material/genomes be made available so that researchers, regulators, and labs may compare the new genome to it.*

*Re question 12: Supply chain operators and consumers have different requirements regarding transparency and the means on how information is transmitted. Operators need a gapless traceability system that provides transparency at every stage of the production chain. Consumers need an easy-to-access label on the final product to inform their choice. Furthermore, we are concerned that patents on new varieties pose a high risk that limits on genetic resources would arise. (1454/1500)*

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

- *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*

*Answer: "No opinion" for all rows, then the following:*

*A comprehensive legislation like Directive 2001/18/EC, Regulation (EC) No 1829/2003 and (EC) No 1830/2003, including risk assessment, traceability and labelling provisions. These are complemented by rules on coexistence (Directive (EU) 2015/412). Risk assessment procedures can be adapted to take into account the specificities of different techniques without re-opening the legislation as a whole. (399/500)*

**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*

*The capacity of the organic sector (as well as the conventional non-GMO sector) to stay free of GMOs depends on the EU traceability system. In this context, it must be clear for all actors in the production or consumption chain if a product from NGTs was used in the process. Avoiding contamination is associated with high costs for organic but also non-organic operators. Even with the current generation of GMOs, a contamination event and measures to mitigate it are linked to high costs and other detrimental effects. The costs for avoiding contamination with NGTs are likely to be thus be multiplied and applicable within comparable limits. To protect the organic and conventional sector from economic losses, there would have to be systems in place (e.g. public funds, mandatory insurance for GM-producers) that compensate farmers for their losses. Fair coexistence would have to be regulated in a way that it is not the organic or conventional farmer that has to bear the economic burden caused by others' trespasses, and/or lose business to due to contamination (or needing to avoid it), de-certification, or other consequences not of their own doing. (1158/1500)*

**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*

*The current regulatory system already allows the cultivation and placing on the market of all types of GMOs, provided that the procedures are followed and that Member States don't make use of their opt-out rights. (213/1500)*

**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*

*<No answer recommended>*

**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

*Despite not being included in the scope of this legal initiative, patents on NGT products raise concerns about the accessibility of genetic material for breeding. Patents on genes that have been modified by NGTs can limit access or even block the use of genetic resources required for all kinds of breeding. Currently, breeders are protected by the breeder's exemption, which is part of the European plant variety protection system and which guarantees open access and freedom to operate in Europe. This access to protected varieties and genetic material for further breeding and commercialization is a cornerstone of breeding innovation. However, this access is at risk due to patents on products from NGTs. If NGT products will be patented on a large scale, traditional breeders will no longer be able to use existing varieties or native populations for producing new varieties without risking patent infringement. This is because patents on genetic variants of important genes can lead to small and medium-sized breeders being confronted with a 'patent jungle' that is hard to navigate for SMEs. Consequently, many breeders will either have to stop breeding or become dependent on patent holders by signing license contracts. (1228/1500)*

Final note: The survey allows the inclusion of small attachments. You may do so at your discretion.  
Thank you for participating!