Draft responses for EU Consultation on new genomic Techniques

Deadline 22 July

* 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?***

Answer They are adequate	x
Answer They are not adequate	
Answer 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?***

Answer Yes	
Answer No	x
Answer Not applicable	
Answer No opinion/I do not know	

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.	x
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	

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?***
Box 1500 character(s) maximum
By understanding how random mutagenesis methods has never - since 2001 - been risk assessed, traced or labelled on food and products, you will understand the most probable process of how the new GMO's (Crispr Cas, TALEN, ODM, ZInc fingers etc.) will not be risk assessed, traced or/and labelled in future, if it gets deregulated! This should not be allowed in the EU, because "modern technology" has impact far beyond anything that could be achieved with conventional breeding e.g. override natural genome organisation by altering whole gene families, block the restoration of gene functions and separate genes which are naturally inherited together: Thus, it need other ethical, technological and political considerations than random mutagenesis, which besides that had a record of safe history.

With the ruling of the European Court of Justice from July 2018, the legal status of all kind of new generations of GMO were clarified. The best option is to keep them under the framework of directive 2001/18, Regulations 1829/2003 and 1830/2003.

The application of the current GMO regulatory framework has proven its worth and ensures risk assessment, authorization, traceability and labelling. It thus guarantees the application of the precautionary principle and safeguards freedom of choice.
Any exemptions for new genomic techniques will result in negative economic and social impacts for the whole conventional, organic and GMO-free food sector.

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	X
Specific regulatory provisions for sustainability should be included in this initiative	
No opinion/I do not know	

Explain why?
GMO-agriculture is not a sustainable agriculture. And new GMO-methods has never been assessed for neither the social, the environmental or the economic leg - in the concept sustainable.

Question *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 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		

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

Question
Please specify any other incentives you would like to propose
Box 500 character(s) maximum

Questions 6 and 7 are designed to generate argumentative support for deregulation based on hypothetical potential for sustainability. However, freedom of choice, safety and the precautionary principle are non-negotiable and must not be weakened in favor of hypothetical benefits. Expressing this view is not made possible in the answers, so we are forced to select the answer "I do not know".

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* Question ***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	x
No opinion/I do not know	

Question
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?

Box 1500 character(s) maximum

We are questioning why the survey puts forward the idea that the new GMO-methods are sustainable. Why are the survey not relying and emphasizing on scientific data that points out the risks connected with deregulating the new GMO-methods? What is the pulling factors in going biotech-way in agriculture today?

Instead, the EU needs to strengthen a real sustainable agriculture eg. organic farming. Sustainability goals and risk assessment must not be allowed to play off each other. Even sustainable products only can be marketed if they have been subjected to a comprehensive risk assessment, and consequential damage is excluded as far as possible in accordance with

the precautionary principle. Non-irreversible risk technologies must not be approved, in order not to penetrate into the environment and food systems. The limitation of the approval of risk products to e.g. 10 years (as in the case of GMO technology) must also be maintained and current scientific studies analyzed with a view to a reassessment before new approvals are granted.

According to the UN, we only have 60 years of fertile land left if we continue to use the conventional farming methods that dominate industrial agriculture today. The UN points out that it is necessary to make a transition to agricultural methods that can regenerate the soil's organic matter - i.e. stop using conventional agricultural methods. It is scientifically documented that small-scale farming improves the environment and secures many jobs.

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INFORMATION FOR OPERATORS AND CONSUMERS

* Question ***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

x	Answer documentation transmitted through the chain of operators
x	Answer public databases/registries
x	Answer digital solutions, e.g. block chain
	Answer other means
	Answer No opinion/I do not know
	Answer only via procedure that requires full traceability as one of the criterium for approval - the burden is on the producer/manufacturer or no approval

* 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:***

	Answer not be asked at all to provide an analytical method that can both detect and differentiate their product

	Answer 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
	Answer be asked to provide a detection method, but without the need to differentiate, if they can justify that the latter would be impossible
x	Answer not be allowed to place the product in question on the market
	Answer No opinion/I do not know

* Question ***12. Transparency for operators and consumers, on plants produced by targeted mutagenesis or cisgenesis:***
Additional help available
multiple answers possible

x	Answer can be achieved via a physical label on the final product
	Answer can be achieved via a digital label accessible through the final product (e.g. link to a website, QR code)
	Answer can be achieved via information available elsewhere (e.g. a website, a public database/register)
	Answer is not necessary for plants produced by targeted mutagenesis and cisgenesis, when they could have been produced through conventional plant breeding or classical mutagenesis
	Answer is not necessary for any plant produced by targeted mutagenesis and cisgenesis
	Answer 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.

Question ***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?***
Box 1500 character(s) maximum
Information has to appear on a product via a GMO label. As now, it must read "contains genetically modified [ingredient]" and inform both economic operators and consumers.

The information about a GMO must be directly and unambiguously accessible.
The wording in this section suggests that in some cases it is not possible to make NGT plants recognizable and thus traceable. This is incorrect. Scientists reaffirms that they have been possible for a long time.

What is needed is a full assessment of the social and economic impacts for the food and farming sector to segregate NGT from conventional and organic farming. Who want to

benefit from NGT should cover all segregations costs (testing, cleaning, segregation from breeding, cultivation, processing, storage and retail).

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.

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 easy adaptation to scientific progress**					x
*** risk assessment that takes into account the characteristics and risk profile of a final product**					x

Question

Please specify any other measures you would like to propose

Box 500 character(s) maximum

We criticize the three questions: 1. The juristically judgement is already in place - the EU-court ruling 25. July 2018. It is a democratic problem that the EU-courts ruling is being questioned. 2. Scientific progress are already in place and demands no change. 3. This is really problematic: If risk assessment is made only from taking into account the characteristics and risk profile of an end product, you will simply not risk assess the methods used and it will be "invisible" in final products.

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?***

Box 1500 character(s) maximum

The EU doesn't have any European wide coexistence measures. What is needed is a full assessment of the social and economic impacts for the food and farming sector to segregate new GMO's from conventional and organic, GMOfree farming and food chains. Who want to benefit from new GMO's should cover all segregations costs (testing, sampling, cleaning, segregation from breeding, cultivation, processing, storage and retail). Co-existence must encompass the entire chain from seed production to the finished product. And who want to benefit from new GMO's should be subject to the polluter pays principle with legal bindings.

Coexistence with existing agricultural practices, e.g., conventional, organic would require that robust assessment pursuant to the precautionary principle, traceability and labelling are required in order to protect the integrity of those existing agricultural practices.

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)*

Box 1500 character(s) maximum
No, we do not see a need for any new legislation, this will only increase burden for the food sector to segregate new GMOs along the whole food chain from breeding, growing, transport, storage and food retail. It is not the responsibility of the EU Commission to facilitate access to new GMOs. It is the tasks of decision makers to ensure freedom of choice, transparency, liability in the food chain for contaminations and ensure that no food with risks for environment, human and animal health can be marketed or grown.

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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?***

Box 1500 character(s) maximum
No.

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

Box 1500 character(s) maximum
2001/18/EC needs no adjustments, only if it is to make it stronger - to adapts to modern technology.

This consultation is not complying with better regulation tools of the European Commission, it lacks evidence based working thesis, and presents claims made by biotechnology companies as facts.

Capital fonds and biotechnology companies claim today that new GMO's are sustainable, and needed caused by the Ukrainian war, however not even the economic leg in the concept of sustainability is pursued. The issues of seed patents is the elephant in the room.

The EU Commission should have compared the potential of farming systems to contribute to the objectives of Farm to Fork like pesticide or GHG reductions. Then citizens could respond that agroecology and organic farming are best performing systems.

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Question 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
If you have 2 more minutes Please copy one or various of the publication below into a .doc document and then upload it

FoEE & SAG Study on Climate change and New GMO https://friendsoftheearth.eu/wp-content/uploads/2021/10/Editing-the-Truth-Genome-editing-is-not-a-solution-to-climate-change-Report-ENG.pdf

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