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Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council

Fields marked with * are mandatory.

Questionnaire on new genomic techniques to contribute to the study requested by the Council

Discussed and finalised in the Ad-hoc Stakeholder meeting on 10 February 2020

Background

The Council has requested [1] the Commission to submit, by 30 April 2021, "a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law" (*i.e.* Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41/EC).

To respond to this Council's request, the Commission is collecting contributions from the stakeholders through the questionnaire below. The study covers all new genomic techniques that have been developed after 2001.

Instructions

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001 [2].

Unless specified otherwise, the term "NGT-products" used in the questionnaire covers plants, animals, micro-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research.

Please substantiate your replies with explanations, data and source of information as well as with practical examples, whenever possible. If a reply to a specific question only applies to specific NGTs/organisms, please indicate this in the reply.

Please indicate which information should be treated as confidential in order to protect the commercial

interests of a natural or legal person. Personal data, if any, will be protected pursuant to Regulation (EU) 2018/1725 [3].

[1] Council Decision (EU) 2019/1904, OJ L 293 14.11.2019, p. 103-104, https://eur-lex.europa.eu/eli/dec/2019/1904/oj
[2] Examples of techniques include: 1) Genome editing techniques such as CRISPR, TALEN, Zinc-finger nucleases, mega nucleases techniques, prime editing etc. These techniques can lead to mutagenesis and some of them also to cisgenesis, intragenesis or transgenesis. 2) Mutagenesis techniques such as oligonucleotide directed mutagenesis (ODM). 3) Epigenetic techniques such RdDM. Conversely, techniques already in use prior to 2001, such as Agrobacterium mediated techniques or gene gun, are not considered NGTs.
[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

Guidelines

Please note that the survey accepts a maximum of 5000 characters (with spaces) per reply field. You might be able to type more than 5000 characters, but then the text will not be accepted when you submit the questionnaire. You will also receive a warning message in red colour below the affected field.

You have the option to upload supporting documentation in the end of each section. You can upload multiple files, up to the size of 1 MB. However, note that any uploaded document cannot substitute your replies, which must still be given in a complete manner within the reply fields allocated for each question.

You can share the link from the invitation email with another colleague if you want to split the filling-out process or contribute from different locations; however, remember that all contributions feed into the same single questionnaire.

You can save the draft questionnaire and edit it before the final submission.

You can find additional information and help here: https://ec.europa.eu/eusurvey/home/helpparticipants

Participants have until 15 May 2020 (close of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

Please provide the full name and acronym of the EU-level association that you are representing, as well as your Transparency Registry number (if you are registered)

If the name of the association is not in English, please provide an English translation in a parenthesis

Friends of the Earth Europe 9825553393-31

Please mention the sectors of activity/fields of interest of your association

environment, climate, food

If applicable, please indicate which member associations (national or EU-level), or individual companies /other entities have contributed to this questionnaire

national member groups from FoEE from DE, Bul, Hun, DK, At, Cy, HR

If applicable, indicate if all the replies refer to a specific technique or a specific organism

to all NGT

A - Implementation and enforcement of the GMO legislation with regard to new genomic techniques (NGTs)

* **1. Are your members developing, using, or planning to use NGTs/NGT-products?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

The sustainability of NGT has not been assessed yet, thus using products or organisms that haven't been assessed at all in regards of environmental, economic or social impacts is not supported by Friends of the Earth Europe.
The claims that NGT could contribute to reduce pesticide is not based on plant breeding experience and research. Plants selected for their resistance to a certain pathogen that are derived from these techniques and cultivated on big scale will quickly cause these pathogens adapt and break the resistance and long term experience from Americas give evidence that pesticides use is increasing.

* **2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

With the ruling of the European Court of Justice, NGT/NGT products are defined as GMO and fall under all rules for GMO like safety checks, authorisation, traceability, labelling as well as only authorised GMO shall be imported to the EU.

Yes, we raised concerns that national authorities and the EU Commission have not developed testing methods to ensure that imports to the EU are not contaminated with non-authorised NGT/NGT products (http://foeeurope.org/eu-public-exposed-illegal-gm-imports-lack-tests-190719). Therefore, the ruling is not fully implemented and puts additional burden on the food chain to avoid using non-authorised NGT, see also http://foeeurope.org/sites/default/files/gmos/2018/new_gm_techniques_state_of_play.pdf
The question does also not include how the lack of implementation by EU Commission and national authorities may have impacts environment protection as demanded by EU GMO law (directive 2001/18). The lack of import control for non-authorised NGT can result they are accidentally disseminated in the environment, such as Swiss authorities reported about GM rapeseed. https://www.bafu.admin.ch/bafu/en/home/themen/thema-biotechnologie/biotechnologie--daten--indikatoren-und-karten/biotechnologie--indikatoren/indikator-biotechnologie.pt.html/aHR0cHM6Ly93d3cuaW5kaWthdG9yZW4uYWRtaW4uY2gvUHVibGljL0FlbURldGFpbD9pbmQ9QlQwNDAmbG5nPWVuJlN1Ymo9Tg%3D%3D.html

FoEE and its member do not use NGT/NGT products and therefore are not taking measure to comply with the GMO legislation. The sustainability of NGT has not been assessed yet, thus using products or organisms that haven't been assessed at all in regards of environmental, economic or social impacts is not supported by Friends of the Earth Europe.

* 2 bis. Have you encountered any challenges?

- Yes
- No

*** 3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?**

- Yes
- No
- Not applicable

*** 4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?**

- Yes
- No
- Not applicable

* Please provide details

With the ruling of the European Court of Justice, NGT/NGT products are defined as GMO and fall under all rules for GMO like safety checks, authorisation, traceability, labelling as well as only authorised GMO shall be imported to the EU, even tiny traces of non-authorised GMO are not allowed.

Yes, we raised concerns that national authorities and the EU Commission have not developed testing methods to ensure that imports to the EU are not contaminated with non-authorised NGT/NGT products. Therefore, the ruling is not fully implemented and puts additional burden on the food chain to avoid using non-authorised NGT. (http://foeeurope.org/eu-public-exposed-illegal-gm-imports-lack-tests-190719 and http://www.foeeurope.org/sites/default/files/gmos/2019/gmo_implementation_letter.pdf)

FoEE is emphasising that transparency and traceability are key requirements in the implementation of EU's GMO laws (directive 2001/18, regulations 1829/2003 and 1830/2003) as well as the strict application of the implementing regulation 611/2011.
The implementation of these laws ensures transparency - and thus ensure free choice for breeders, farmers, food processors and consumers.

The polluter pays principle and a liability regime must be established in order to ensure that those who contaminate food, seeds and feed with GMOs are held responsible and pay compensation for the economic damage caused by such contamination.

* 4 bis. Are you aware of any challenges encountered?

- (●) Yes
- ( ) No

* Please provide details

The polluter pays principle and a liability regime must be established in order to ensure that those who contaminate food, seeds and feed with GMOs are held responsible and pay compensation for the economic damage caused by such contamination.
Yes, we raised concerns that national authorities and the EU Commission have not developed testing methods to ensure that imports to the EU are not contaminated with non-authorised NGT/NGT products. Therefore, the ruling is not fully implemented and puts additional burden on the food chain to avoid using non-authorised NGT. (http://foeeurope.org/eu-public-exposed-illegal-gm-imports-lack-tests-190719 and http://www.foeeurope.org/sites/default/files/gmos/2019/gmo_implementation_letter.pdf)

* **5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs?**

Please also see question 8 specifically on labelling

- ( ) Yes
- (●) No
- ( ) Not applicable

* Please explain why not

FoEE and its member do not use NGT and therefore are not taking measure to comply with the GMO legislation. The sustainability of NGT has not been assessed yet, thus using products or organisms that haven't been assessed at all in regards of environmental, economic or social impacts is not supported by Friends of the Earth Europe.

This question does not include how authorities, governments and the EU Commission should have taken measures to allow all stakeholders to comply with GMO legislation and fully implement the ECJ ruling from 2018. The question also does not include how the lack of implementation by EU Commission and national authorities may have impacted environment protection as demanded by EU GMO law (directive 2001/18). The lack of full implementation puts additional burden on stakeholders in the food chain and the gaps on implementation of environmental protection are concerning.

* 5 bis. What challenges have you encountered?

see response above

* **6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?**

- ○ Yes
- ◉ No
- ○ Not applicable

* What challenges have you encountered?

EU GMO legislations state - this clarified through ECJ ruling from July 2018 - that organisms derived from new genomic techniques are GMO and have to be labelled and approved according to the legislation.

The delay to develop testing methods by the EU Commission in 2017 (https://gmo-crl.jrc.ec.europa.eu/ENGL/docs/ENGL-Plenary-27th.pdf) and the limited resources that EU commission and national authorities have dedicated for developing testing methods and to ensure that imports do not contain non-authorised NGT/NGT products is worrying and can be defined as a lack of support for the food chain. It would be illegal to market any product contaminated with non-authorised NGT, therefore the food sector is left alone in ensuring that their products fulfill all EU rules.

* **7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products?**

- ◉ Yes
- ○ No
- ○ Not applicable

* Please describe the traceability strategy, including details on the required financial, human resources and technical expertise

EU GMO law defines that applicant for GMO authorisation must deliver testing methods and national authorities are responsible to ensure via regular tests that economic stakeholders fulfil the traceability requirements. As for 1st generation of GMO the main tasks are to ensure via paper control and tests that imports do not contain non-authorised GMO, this includes NGT/NGT products. See directive 2001/18, regulations 1829/2003 and 1830/2003 as well as regulation 611/2011.
The European Commission has previously successfully coordinated joint actions to avoid imports of non-authorised GM rice in 2006 from the US and GM linseed in 2009 from Canada (http://europa.eu/rapid/press-release_MEMO-06-310_en.htm). These kind of measures should be now applied to avoid any non-authorised NGT/NGT products (such as Cayxgen and Cibus) are entering the EU food chain illegally and unlabelled. An EU wide coordination approach would limit costs for developing testing protocols of each national laboratory and authority.
Researchers from the EU's Joint Research Centre clarified in 2017 that checking authorisations, patent applications and other information to apply a targeted approach for testing on imports delivers the best results (https://gmo-crl.jrc.ec.europa.eu/ENGL/docs/WG-DIR-Final-Report.pdf).
Experiences from both conventional, organic as well as GMO-free value chains show that a combination of labelling, paper documentation, traceability tools and testing methods secure best against fraud and contamination with GMO. Main parts of the traceability strategies are strict labelling and well-done paper documentation, which are legally required.
In addition a European data bank with comparison material is urgently needed as suggested in regulation 1830/2003, article 9, para 3.

* **8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

The food sector has avoided the use of GM ingredients for more than a decade and adapted their supply chains and suppliers to avoid contamination with GM products. Whilst more than 80 GM events are authorised in the EU, they are faced with very strong market rejection in the food sector. The costs to minimize risks of GMO contamination have been covered by the food sector and not by the biotech sector. The exclusion of NGTs/NGT products from GMO labelling requirements would increase the costs and measures taken by the food sector. Without strict traceability applied, NGT products could contaminate non-GMO products which could have a severe economic impact for the breeding, farming, food processing and retailing sectors.

There is a regulation in place (1829/2003) setting the rules for labelling of GMO, it is applicable for new AND old GMOs, including NGT/NGT products. So, there is no need for specific measures of labelling new GMO. This means that meat, milk and eggs from NGT animals also fall under the GMO labelling rules in the EU.

* 8 bis. What challenges have you encountered?

The exclusion of NGTs/NGT products from GMO labelling requirements would increase the costs and measures taken by the food sector. Without strict traceability applied, NGT products could contaminate non-GMO products which could have a severe economic impact for the breeding, farming, food processing and retailing sectors.

* **9. Do you have other experience or knowledge that you can share on the application of the GMO legislation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT-products ?**

- Yes
- (•) No
- Not applicable

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

The maximum file size is 1 MB

B - Information on research on NGTs/NGT-products

* **10. Are your members carrying out NGT-related research in your sector?**

- Yes
- (•) No
- Not applicable

* Please explain why not

The European Green Deal, with its ambitions for greener and more climate friendly way of food production, should prioritise non-NGT related breeding concepts that have the potential to deliver a wide range of benefits for agriculture and society.

On the contrary to the hype about NGT, conventional breeding is still more efficient and quicker in delivering desirable traits, such as drought tolerance, higher yields etc.

There are still a lot of non-answered questions related to risks of NGT and in general to GMO-plants.

* **11. Are you aware of other NGT-related research in your sector?**

- (•) Yes
- No
- Not applicable

* Please specify

To our knowledge, there are major gaps in risk-related research for NGT/NGT products.

*

12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling on mutagenesis?

Court of Justice ruling: Case C-528/16 http://curia.europa.eu/juris/documents.jsf?num=C-528/16

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

The ruling has not changed the definition of GMO, just added clarity. See also response to Q 10

* **13. Could NGT-related research bring benefits/opportunities to your sector/field of interest?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

The most urgent need is a research that

· delivers standardised detection methods

· deepens the understanging of unintended modifications that is central for better understanding of side-effects

Research that would provide benefits would for instance explore the potential impacts of a wider application of NGT on issues such as

· assessment of socio-economic, health and environmental impacts of using and importing NGT/NGT products

· on farmers' rights to save and reproduce seeds and to breed animals, given the patents and licensing agreements on these techniques,

· on rights to produce and consume conventional and organic products, not contaminated with NGT

· on concentration in the European seed market, which is currently supplied by a variety of companies including many small and independent local breeders,

· the capacity to effectively monitor potential adverse outcomes through post-market surveillance.

The question is partly biased, who would actually benefit from it besides the few companies that control the patents in the fields of agricultural NGT? Why does the questionnaire puts such a priority on a few stakeholders that would actually use NGT whilst it ignores that with the ECJ ruling GMO law must be applied and should contain specific questions on environmental risk assessment, how the precautionary principle in the environment legislation in general and especially in the directive 2001/18 would be impacted by promoting NGT.

* **14. Is NGT-related research facing challenges in your sector/field of interest?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

Research on possible risks for environment and health caused by NGT/NGT products is severely underfunded. This results in a situation which exaggerates the perceived potential and opportunities of NGTs, as opposed to their risks.
From our view this is coherent with the EU Directive 2001/18, recital 21: “Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted.”

Governments and authorities rely on precaution-oriented, non-interest-based risk research to be able to fulfill their obligations to protect health and environment from possible risks of genetic engineering and biotechnology as defined in directive 2001/18

*** 15. Have you identified any NGT-related research needs/gaps?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please specify which needs/gaps, explain the reasoning and how these needs/gaps could be addressed

Research on the development of sustainable alternatives to NGTs is missing and underfunded. Extreme weather conditions will continue and divers cropping systems with adapted divers varieties are more sustainable than NGT in the research pipelines.
Only few research focuses on NGT risks in regards of environment or health impacts.
Current research has overlooked mistakes that occur during the integration of NGTs. This can lead to unwanted residues of DNA in the final product, which are a potential risk to health and the environment. For example, in the case of genome-edited cattle, unwanted fragments of DNA ended up in the final organism, including an antibiotic resistance gene. (see Lombardi H. et al. (2020): Template plasmid integration in germline genome-edited cattle. Nature Biotechnology 38, 163-164. https://www.nature.com/articles/s41587-019-0394-6)
Although evidence is mounting on numerous unintended ‘off-target’ and ‘on-target’ effects of NGT/ gene-editing techniques, such as CRISPR, the concrete implications of these unexpected changes for human /animal health and environment are still poorly understood and under-researched.
The fact that the new genomic techniques have been only recently developed, and therefore have do not have a long history of safe use, gives substantive reasons to keep them under the general framework of the GMO as well as EU food law (regulation 192/2002).

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

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C - Information on potential opportunities and benefits of NGTs/NGT-products

*** 16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?**

- ( ) Yes
- (●) No

* Please explain why not

The sustainability of NGT has not been assessed yet, thus using products or organisms that haven't been assessed at all in regards of environmental, economic or social impacts is not supported by Friends of the Earth Europe.
The claims that NGT could contribute to reduce pesticide is not based on plant breeding experience and research. Plants selected for their resistance to a certain pathogen that are derived from these techniques and cultivated on big scale will quickly cause these pathogens adapt and break the resistance and long term experience from Americas give evidence that pesticides use is increasing.

* **17. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits?**

- ○ Yes
- ◉ No

* Please explain why not

The sustainability of NGT has not been assessed yet, thus using products or organisms that haven't been assessed at all in regards of environmental, economic or social impacts is not supported by Friends of the Earth Europe.

Instead of focusing on predictions about widely untested NGT benefits, various solutions with evidence and long history of safe use should be priorities in the food and farming sector. Prioritise agroecology and organic breeding in EU research programmes like Horizon2020.

With a long list of promises about potential benefits of NGT it is suggested that complex societal, political and economic problems can be solved by screwing on the plant genome or with a technical intervention through NGTs, respectively. Such a narrow view bears the danger of seeking a simple technical solution to complex problems, continuing a wrong system of industrial agriculture and preventing real solutions as recommended in the FarmtoFork and European Green Deal strategies as well as by https://ec.europa.eu/info/files/scientific-opinion-sustainable-food-system-march-2020_en.
The debate on NGTs/NGT-products often focuses deregulation of NGT/GMO: This debate attacks precautionary principle as the foundation of the EU environmental legislation,(including the directive 2001/18 and its emphasise on the precautionary principle), as well as the consumers right to know and the freedom of choice as the foundation of EU consumer policy (in order to abolish GMO labelling and make GMOs invisible to consumers and economic operators), not to mention transparency about the origin of a product and how or with which processes it was produced as the foundation of sustainability concepts.

* **18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products?**

- ○ Yes
- ◉ No

* Please explain why not

Experiences with GMO show that patented GM seed increased market concentration in the seed market. There is no evidence that NGT would support SME but instead one could conclude NGT will just as old lead to more concentrations, and destroy SME.

Very few corporations control the key licences and patent family for CRISPR in the plant breeding sector. Thus access to these technologies cause financial and administrative burden to SME.
Torshizi, Mohammad and Clapp, Jennifer, Price Effects of Common Ownership in the Seed Sector (April 22, 2019). Available at SSRN: https://ssrn.com/abstract=3338485 or http://dx.doi.org/10.2139/ssrn.3338485

*** 19. Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products?**

- ○ Yes
- ◉ No

* Please explain why not

Experiences with GMO show that patented GM seed increased market concentration in the seed market. There is no evidence that NGT would support SME but instead one could conclude NGT will just as old lead to more concentrations, and destroy SME.

The patenting of seeds, breeding techniques that could extend the patent scope to the harvest denies access to breeding pools. This poses a major risk for developing divers varieties that can cope with extreme weather conditions and can be adapted to new plant diseases and pests and blocks the necessary innovation in the plant breeding sector. Open access to genetic material is crucial to adapt farming to the climate and biodiversity crisis.
Clapp, J. 2018. Mega-Mergers on the Menu: Corporate Concentration and the Politics of Sustainability in the Global Food System. Global Environmental Politics 18: 12–33. https://doi.org/10.1162/glep_a_00454

Torshizi, Mohammad and Clapp, Jennifer, Price Effects of Common Ownership in the Seed Sector (April 22, 2019). Available at SSRN: https://ssrn.com/abstract=3338485 or http://dx.doi.org/10.2139/ssrn.3338485

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D - Information on potential challenges and concerns on NGTs/NGT-products

*** 20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?**

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

EU general food law (178/2002) ensures that citizens need to have access to safe and wholesome food of highest standards as well as ensures a high level of protection of human life and consumers' interests in relation to food. The EU treaties enforce consumers rights, this includes labelling as a precondition for the right to information for consumers (Art 169 TFEU). Only the strict implementation of GMO law ensures this core right of consumers.
The exclusion of NGTs from GMO labelling requirements would increase the costs and measures taken by the food sector. Without strict traceability applied, NGT products could contaminate non-GMO products which could have a severe economic impact for the breeding, farming, food processing and retailing sectors

as well as for the environment.

There are many concerns connected to NGT/NGT products and their environmental impacts, and some specific to NGT as well as their products.
1) As it is the case with first generation of GMO, there are common potential risks that NGT can cause to environment and receiving ecosystems.
2) As it is the case with first generation of GMO , once released NGT organism cannot be taken back out of the environment once released (irretrievably), this conflicts with respecting the precautionary principle as key requirement for all Environmental policies in the EU
3) Questioning the legal status of NGT poses a fundamental risk for transparency and free choice of consumers, farmers, breeders food processors as well as food retailers.
4) Specific risk of NGT are for examples gene drives, including gene drive insects with the specific goal of changing whole ecosystems. This is an unprecedented risk to the environment and ecosystems specific to NGT. In addition, they might disseminate in natural populations since they are more likely to reproduce.

* Are these challenges/concerns specific to NGTs/NGT-products?

- (●) Yes
- ( ) No

* Please explain

There are many concerns connected to NGT/NGT products and their environmental impacts, and some specific to NGT as well as their products.
1) As it is the case with first generation of GMO, there are common potential risks that NGT can cause to environment and receiving ecosystems.
2) As it is the case with first generation of GMO , once released NGT organism cannot be taken back out of the environment once released (irretrievably), this conflicts with respecting the precautionary principle as key requirement for all Environmental policies in the EU
3) Questioning the legal status of NGT poses a fundamental risk for transparency and free choice of consumers, farmers, breeders food processors as well as food retailers.
4) Specific risk of NGT are for examples gene drives, including gene drive insects with the specific goal of changing whole ecosystems. This is an unprecedented risk to the environment and ecosystems specific to NGT. In addition, they might disseminate in natural populations since they are more likely to reproduce.

* **21. Could NGTs/NGT-products raise challenges/concerns for society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Environmental concerns
1) As it is the case with first generation of GMO, there are common potential risks that NGT can cause to the environment and receiving ecosystems.
2) As it is the case with first generation of GMO, once released NGT organism cannot be taken back out of the environment once released (irretrievably), this conflicts with respecting the precautionary principle as key requirement for all Environmental policies in the EU.
3) Specific risk of NGT are for examples gene drives, including gene drive insects with the specific goal

of changing whole ecosystems. This is an unprecedented risk to the environment and ecosystems specific to NGT. In addition, they might disseminate in natural populations since they are more likely to reproduce.

Consumer concerns
Questioning the legal status of NGT poses a fundamental risk for transparency and free choice of consumers, farmers, breeders, food processors as well as food retailers.
EU general food law (178/2002) ensures that citizens need to have access to safe and wholesome food of highest standards as well as ensures a high level of protection of human life and consumers' interests in relation to food. The EU treaties enforce consumers rights, this includes labelling as a precondition for the right to information for consumers (Art 169 TFEU). Only the strict implementation of GMO law ensures this core right of consumers.

Environment, human, animal and plant health concerns
The fundamental concern regarding GMOs, including NGT, is that genetic engineering can unintentionally interfere with the gene expression of an organism and/or with complex biochemical pathways within an organism. Consequently, the biological and biochemical characteristics of the organism might be changed in a way that impacts human and animal health and/or the environment.
In addition, the intended trait(s) conferred by genetic engineering, can also be of concern as they can have consequences for agricultural systems, the environment, as well as for food and animal feed safety. GM herbicide resistant crops is the most used trait for the current GM crops, also Cibus, as first NGT plant commercially grown, is herbicide resistant. This led to increase of pesticide use in USA and Brazil. https://link.springer.com/article/10.1186/2190-4715-24-24, (https://www.ncbi.nlm.nih.gov/pubmed/29069188, https://www.scielo.br/scielo.php?script=sci_arttext&pid=S1413-81232017021003333&lng=en&nrm=iso&tlng=en)
In addition to adverse implications for human and animal health that arise from exposure to increasing amounts of pesticides, this practice is also problematic in the context of current biodiversity crisis, with modern agriculture and intense pesticide use identified as one of the main drivers of biodiversity loss by IPBES. https://ipbes.net/sites/default/files/ipbes_7_10_add.1_en_1.pdf

The model of local selections of diverse plants adapted to each local agro-ecosystem can ensure sufficient resilience to the impacts of climate change. The economic model of NGTs is incompatible with local adaptive selections and relocation of the food chain. Political, financial and legal support for the development of NGTs removes all support for sustainable agro-ecological alternatives and hinders their development.

As NGT have been reported to have higher efficiencies in animals than older GM techniques, it is likely that this will lead to increased number of applications to market genome-edited animals, with all the ethical and welfare concerns this raises.
NGT should not be used to address diseases that primarily result from keeping animals in stressful, crowded conditions.

Challenges for society also lies of not yet having developed testing protocols and methods, and thus not being able to guarantee the freedom of choice not to use NGT for breeders, farmers, food processors, food retailers and consumers.

* Under which conditions do you consider this would be the case?

All of these concerns are relevant, because the knowledge and the understanding of the risks on environment, human, plant and animal health is so limited that the commercial use of any NGT seems

irresponsible. Any attempt to deregulate NGT would multiply the risks and concerns. The fact that this study will lack of transparency by not publishing all contributions from stakeholders before April 2021, increases an corporate driven biased outcome of the study.

* Are these challenges/concerns specific to NGTs/products obtained by NGTs?

- (●) Yes
- ( ) No

* Please explain

All of these concerns are relevant, because the knowledge and the understanding of the risks on environment, human, plant and animal health is so limited that the commercial use of any NGT seems irresponsible. Any attempt to deregulate NGT would multiply the risks and concerns. The fact that this study will lack of transparency by not publishing all contributions from stakeholders before April 2021, increases an corporate driven biased outcome of the study.

A general public that is critical of GMOs would hardly find it acceptable that products previously classified by the highest EU court as genetically modified should suddenly lose this designation merely due to an amendment to the legislation. This would be perceived as legal trickery and “regulating GMOs out of existence” in favour of the GMO industry.
Who are the proponents of deregulation, and what are their motivations?
1. Seed companies producing new GMOs (such as Bayer, Corteva,Syngenta): Without an authorisation procedure, they would get a faster return of investment. And without a GMO labelling, marketing of genetically engineered seeds would be much easier. EU member states could not ban the cultivation of these new GMOs on their national territory.

2. Governments of the USA, Argentina, Brazil and Canada: These are the major countries where genetically engineered crops are grown. Farmers in these countries and multinational traders of agricultural commodities would not have to worry about authorisations of new GMOs for the EU market. They would no longer have to ensure proper segregation of the flow of goods, including separate logistics. GMO exports to the EU would be much easier.

3. Science organisations and universities: Here too, economic interests are often at stake. Scientists as developers and patent holders of new GMOs want to profit financially from their research. A prominent example is Emmanuelle Charpentier, one inventor of the CRISPR/Cas system. CRISPR Therapeutics, the company in which she holds an interest, has granted Bayer exclusive rights to all CRISPR applications in agricultural plant and animal breeding.

* **22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs /NGT-products?**

- (●) Yes
- ( ) No

* Please explain and provide concrete examples and data

SME have already limited access to NGT because most patent families are controlled by very few global agribusiness corporations.
Experience from Canada and US give strong concerns that patents on plants limit availability of seeds for farmers and results in higher seeds costs without delivering increased yields. There are concerns that

patented seeds can also hamper the innovation in the breeding sector as well as the development of seeds and crops that can cope with more and more extreme weather conditions.
Torshizi, Mohammad and Clapp, Jennifer, Price Effects of Common Ownership in the Seed Sector. April 22, 2019. SSRN: http://dx.doi.org/10.2139/ssrn.3338485

No patents on seeds! Overview 2018-2019: No patents on seeds! End the legal chaos at the European Patent Office! Conventional breeding must be free of patent claims. https://www.no-patents-on-seeds.org/sites/default/files/2019-04/No%20patents%20on%20seeds%20-%20Overview%202018-2019_0.pdf

*** 23. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Experience from Canada and US give strong concerns that patents on plants limit availability of seeds for farmers and results in higher seeds costs without delivering increased yields. There are concerns that patented seeds can also hamper the innovation in the breeding sector as well as the development of seeds and crops that can cope with more and more extreme weather conditions.
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E - Safety of NGTs/NGT-products

*** 24. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply**

Although evidence is mounting on numerous unintended 'off-target' and 'on-target' effects of gene-editing techniques, such as CRISPR, the concrete implications of these unexpected changes for human/animal health and environment are still poorly understood and under-researched.
Risks include unexpected toxicity and/or allergenicity of food products and food crops produced with these techniques. Many animal feeding studies with first-generation transgenic GM crops showed unexpected toxicity and/or allergenicity from these NGT.
http://www.enveurope.com/content/27/1/4/abstract ; and http://sth.sagepub.com/content/early/2015/08/05/0162243915598381

Genome editing and NGT can cause unexpected "on-target" effects, where the intended change occurs at the intended location, but has a different outcome than expected. A small insertion or deletion of DNA within a gene, even if on-target, could change the way a gene is read and processed into proteins in problematic ways.

Kosicki, M., Tomberg, K., Bradley, A. (2018) Repair of double-strand breaks induced by CRISPR-Cas9 leads to large deletions and complex rearrangements. Nature Biotechnology 36: 765-771.

One of the principal concerns of genome editing is “off-target” effects — changes to other genes that were not intended. Off-target effects could unintentionally alter important genes, causing changes in chemistry or protein production — both of which are important for food and environmental safety. Most studies on the potential uses of gene editing techniques in agriculture consider off-target effects to be both a major challenge and a major concern.
Jung, C., Capistrano-Gossmann, G., Braatz, J., Sashidhar, N. & Melzer, S. (2017) Recent developments in genome editing and applications in plant breeding. Plant Breeding 137: 1-9; Zhu, C., Bortesi, L., Baysal, C., Twyman, R.M., Fischer, R., Capell, T., Schillberg, S. & Christou, P. (2017) Characteristics of genome editing mutations in cereal crops. Trends in Plant Science 22: 38–52; Wolt, J.D., Wang, K., Sashital, D. & Lawrence-Dill, C.J. (2016) Achieving plant CRISPR targeting that limits off-target effects. The Plant Genome 9: doi: 10.3835/plantgenome2016.05.0047; Yin, K., Gao, C. & Qiu, J-L. (2017) Progress and prospects in plant genome editing. Nature Plants 3: 17107; West, J. & Gill, W.W. (2016) Genome editing in large animals. Journal of Equine Veterinary Science 41: 1–6.

*** 25. Do you have specific safety considerations on NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please explain

Traceability and risk assessment under EU GMO law are also crucial to limit potential environmental harm. Once an organism is released it cannot be withdrawn anymore. Current research has overlooked mistakes that occur during the integration of NGTs. This can lead to unwanted residues of DNA in the final product, which are a potential risk to health and the environment.

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During the genetic engineering process, large numbers of animals are required as “mothers” for implantation of genetically engineered embryos. It is estimated that an average of 24 embryos are needed to produce one gene-edited pig using microinjection instead of cloning.[8]This is five times fewer animals than required by cloning,[9] but still subjects many animals to dangerous procedures[10].

The introduced trait may itself cause, or increase, existing welfare problems in genetically engineered animals. For example, concerns already exist over the welfare of (conventionally bred) “double-muscled” pigs and cattle, which may have problems calving and have high mortality rates.[12]Such problems could also occur in other gene-edited super-muscly farm animals.
In addition to welfare issues arising from the introduced trait, welfare issues can arise from any genetic errors created by the gene-editing process, for example those caused by off-target effects. These genetic errors could cause malfunctioning of one or more parts of the cell machinery and lead to health problems in the genetically engineered animal.[13] Importantly, such genetic errors can occur as an unintended consequence of genetic engineering, even if genes (e.g. from a different species) are not inserted into the animal, as might be the case with gene-edited animals. For example, researchers found that gene editing for super-muscly animals resulted in rabbits, pigs and a goat[14]having enlarged tongues and pigs having an extra spinal vertebra[15], even though no DNA had been inserted.

[8] Tan, W., Proudfoot, C., Lillico, S.G. & Whitelaw, C.B. (2016) Gene targeting, genome editing: from Dolly to editors. Transgenic Research 25: 273-87.
[9] Tan, W., Proudfoot, C., Lillico, S.G. & Whitelaw, C.B. (2016) Gene targeting, genome editing: from Dolly to editors. Transgenic Research 25: 273-87.
[10] Rodriguez, E. (2017) Ethical issues in genome editing for non-human organisms using CRISPR/Cas9 system. Journal of Clinical Research & Bioethics 8: 1000300. Retrieved from https://doi.org/10.4172/2155-9627.1000300

[12] Bruce, A. (2017) Genome edited animals: learning from GM crops? Transgenic Research26: 385–398.
[13] Ishii, T. (2017) Genome-edited livestock: ethics and social acceptance. Animal Frontiers7: 24–32.
[14] Wang, K., Tang, X., Xie, Z., Zou, X., Li, M., Yuan, H., Guo, N., Ouyang, H., Jiao, H. & Pang, D. (2017) CRISPR/Cas9-mediated knockout of myostatin in Chinese indigenous Erhualian pigs. Transgenic Research 26: 799-805; Wang, K., Ouyang, H., Xie, Z., Yao, C., Guo, N., Li, M., Jiao, H. & Pang D. (2015)
[15]Qian, L., Tang, M., Yang, J. et al. (2015) Targeted mutations in myostatin by zinc-finger nucleases result in double-muscled phenotype in Meishan pigs. Scientific Reports 5: 14435. Retrieved from https://doi.org/10.1038/srep14435

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F - Ethical aspects of NGTs/NGT-products

*** 26. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply**

The consequences of the deployment of new NGT for different actors need to be assessed. Who will benefit most, and who will carry the risks? Directive 2001/18 requires regular reports about the socio-economics impacts of GMO but this was conducted only once since 2003.

Society at large, and all living beings and ecosystems, will carry the wider risks for the environment /biodiversity from the release of new GMOs. Damage to ecosystems may be irreversible. Rigorous risk assessment is therefore of paramount importance. Environmental costs include the disappearance of agrobiodiversity, which is of huge importance to food security, food sovereignty, and represents cultural

values.
Multiple genetic modifications in a very short period of time creates organisms no longer adapted in any way to their environment and vice versa. Techniques that interfere directly at DNA level, e.g. new GM techniques, violate the integrity of life and are consequently not allowed in organic agriculture.
Regulation does not replace the not-knowing, but can help to recognize the absence of certainty. The Precautionary Principle is there to help guide action in case of absence of full information (which is always the case when a new GMO is introduced).

The introduction of a technology can change economic and social relationships. GM technology has led to an increased concentration of ownership and power in agrifood systems through patents and contracts and license agreements. This is no different for NGTs. These impacts should be taken into account when deciding whether to support their development.
Alongside risk assessment, seed savers, breeders, farmers and consumers should be able to make an informed choice about whether they access NGT-products, which is only possible through rigorous traceability and clear labelling as per the current GMO regulatory regime.
Gene editing has been presented as a solution to increasing human demands for: animal protein, meats of specific qualities and animals resistant or resilient to infectious disease. It has also been suggested to help respond to animal welfare concerns and to global heating (e.g. by creating 'hornless cattle' and heat tolerant animals). However, there are alternative approaches to addressing all of these challenges, including improving animal husbandry and reducing food waste.
Other innovation views get marginalized, like agroecology, agroforestry, regenerative agriculture, etc.

Preston, Christopher J., and Fern Wickson. "Broadening the lens for the governance of emerging technologies: Care ethics and agricultural biotechnology." Technology in Society 45 (2016): 48-57.
Devos, Y., Maeseele, P., Reheul, D., Van Speybroeck, L., & De Waele, D. (2008). Ethics in the societal debate on genetically modified organisms: A (re) quest for sense and sensibility. Journal of Agricultural and Environmental Ethics, 21(1), 29-61. https://biblio.ugent.be/publication/414447/file/6803059.pdf
Van Bueren, Edith T. Lammerts, and Paul C. Struik. "Integrity and rights of plants: ethical notions in organic plant breeding and propagation." Journal of Agricultural and Environmental Ethics 18.5 (2005): 479-493. http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.688.9812&rep=rep1&type=pdf

*** 27. Do you have specific ethical considerations on NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please explain

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G - Consumers' right for information/freedom of choice

*** 28. What is your view on the labelling of NGT-products? Please substantiate your reply**

EU general food law (178/2002) ensures that citizens need to have access to safe and wholesome food of highest standards as well as ensures a high level of protection of human life and consumers' interests in relation to food. The EU treaties enforce consumers rights, this includes labelling as a precondition for the right to information for consumers (Art 169 TFEU). Only the strict implementation of GMO law ensures this core right of consumers.
The exclusion of NGTs from GMO labelling requirements would increase the costs and measures taken by the food sector. Without strict traceability applied, NGT products could contaminate non-GMO products which could have a severe economic impact for the breeding, farming, food processing and retailing sectors as well as for the environment.
The food sector has avoided the use of GM ingredients for more than a decade and adapted their supply chains and suppliers to avoid contamination with GM products. Whilst more than 80 GM events are authorised in the EU, they are faced with very strong market rejection in the food sector. The cost to minimize risks of GMO contamination have been covered by the food sector and not by the biotech sector.
EU GMO law clarified through ECJ ruling from 2018, clearly demand, that new GMO and their products have to be labelled according to the GMO labelling. There is no need to change this.

Most German consumers asked for their opinion on new GMO demand this as well, and are not willing to buy, use or eat neither new or old GMO (-> polls in Germany, BfR 2017: Focus groups genome editing https://www.bfr.bund.de/de/publication /risikowahrnehmung_von_genome_editing__vorbehalte_und_grosses_informationsbeduerfnis_vorhanden-202430.html
BfN 2017 - nature awareness study, https://www.bfn.de/themen/gesellschaft/naturbewusstsein.html,

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H - Final question

*** 29. Do you have other comments you would like to make?**

- (●) Yes
- ( ) No

Please provide your comments here

We welcomed the European Court of Justice ruling. According to the ruling all NGT-products are GMOs and have to be labelled as GMOs. The ruling brought legal certainty for economic operators, the scientific community and consumers. It prevents that feed and food produced with NGTs would be channelled onto the agri-food market in a manner not recognisable for manufacturers, marketers and consumers and could be grown without an environmental risk assessments.

For this study as well as for the political assessment of the legal frame for NGT, it stays important to clearly differentiate between findings of studies and unproven promises. The debate between science and politics often seems driven by promises at the moment - promises neither proven nor likely to come true (Thinking of promises of drought resistance as well as ending world hunger). NGT are tools, in the debate right now it often seems that people forget considering alternative tools.
but the last 30 years of GMO , having started with exactly the same promises, quite clearly showed: you cannot end hunger, you cannot reach a more sustainable agriculture with a tool like GMO.
Fully implementation of ECJ ruling is needed. All NGTs/NGT-products have to remain under the current EU GMO legislation which requires

- comprehensive case-by-case risk assessment according to the precautionary principle;
- methods for detecting, identifying and quantifying the GMO/NGT-product have to be publicly available in an EU database;
- traceability systems: documentation to track NGTs/NGT- products at all stages of the supply chain;
- labelling of all NGT-products;
- post-market monitoring;
- public GMO location registers at national level;
- a global transparency register: it shall cover all GMOs worldwide, bot hold and new.

A deregulation of NGTs/NGT-products would mean

- abolishing of the precautionary principle for NGTs/NGT-products
- elimination of approval procedures, risk assessment and labelling requirements

· health and environmental impacts would no longer be examined by national and EU regulatory authorities
· not intended side effects like on-target effects and off-target effects would not be not examined
· no obligation for biotech companies to provide detection methods
· NGT-products would be channelled into the market untested and unlabelled
· serious problems for organic and conventional non-GMO sector - sooner or later they would loose control over their supply chains (note: organic agriculture uses to at least 90 percent conventional seeds)

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