

# 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

### B a c k g r o u n d

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 / E C ) .

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 a f t e r 2 0 0 1 .

### I n s t r u c t i o n s

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

[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 as 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

CEPM (European Confederation of Maize Production); 583664013504-15

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

Farmer association

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

EU Level

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

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

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

- Yes
- No
- Not applicable

\* Please provide details

European maize producers hope that these techniques will be fully accessible to the breeding sector, as they would allow them to envisage a selection adapted to various problems and to respond to several challenges such as the consequences of climate change (tolerance to abiotic stress: extreme temperatures, drought, excess water, etc.), the appearance of new pests, or the maintenance of high technological and sanitary quality. NGTs allow for a rapid selection of a set of traits that can be specifically integrated into the same variety. Maintaining access to innovative varieties is essential for European maize production. Throughout this questionnaire, we consider as NGTs, in accordance with the decision of the European Court of Justice, all techniques developed after the publication of Directive 2001/18/EC.

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

- Yes
- No
- Not applicable

\* Please provide details

In view of the current European Court of Justice decision, NBTs being considered as GMOs, all existing regulations at the European level and at the level of each Member State must be respected to avoid unintentional uses and to regulate the use of NGTs. All of the planned measures cover assessment, traceability and labelling, which are relatively cumbersome and costly to implement. CEPM members will implement the ad hoc regulations decided by the Member States, as is currently the case for GMOs. Coexistence measures, based on spatial or temporal isolation, have proven to be effective and can be considered also for NGT crops.

Every year, maize seed producers implement a production plan that enables Europe to be the world's leading exporter of maize seed. This program makes it possible to develop a large number of varieties while respecting very precise isolation specifications. This know-how, framed by the regulations ensuring seed certification, can be put to good use in any initiative aimed at specific traceability and labelling, including, where appropriate, NGTs.

\* 2 bis. Have you encountered any challenges?

- Yes  
 No

\* Please provide details

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

- Yes  
 No  
 Not applicable

\* Please provide details

We have no knowledge of NGT maize varieties present on the European market.

In the United States, varieties derived from NGTs are marketed:

- Waxy maize, whose starch is particularly well suited to certain industrial uses.
- Maize with low phytic acid content, allowing better digestibility.
- Maize resistant to a pathogenic fungus (cercosporiosis)
- Maize with optimisation of the photosynthesis process and therefore improved yield.

Research is also underway on areas of major interest to European maize producers:

- disease resistance (reduction of the impact on yield, better food safety)
- food safety (control of mycotoxin contaminations)
- tolerance to hydric stress through the initial vigour, the vigour of implantation, the desiccation at the end of the cycle, characteristics that allow the adaptation of the species to more stressful conditions, with security of production and economy in drying.
- In the longer term applications on the best tolerance to insects.

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

- Yes  
 No  
 Not applicable

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

- Yes  
 No

\* Please provide details

As NBT products are considered to be GMOs according to the decision of the European Court of Justice, there are no different initiatives to combat unintended effects

\* **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

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

- Yes  
 No  
 Not applicable

\* Please describe what type of support and what best practices you can share

In view of the practice that maize producers may have had with regard to GMO regulations, the coherence between European and national regulations is cumbersome, distorting between Member States and with third countries, since the import of many transgenic maize species is authorised even though they cannot be grown in the European Union. In fact, it discourages companies and research institutes from developing varieties in this way. This is why CEPM is in favour of the deployment of an appropriate regulatory framework for NGTs, science-based, that is disconnected from the GMOs regulatory framework and that does not create new distortions of competition.

\* **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

At present, the only traceability requirements that exist for producers are within the Hygiene Package/CAP regulations, as producers are obliged to keep a record of certain practices (quantity of phytosanitary products, detection of harmful organisms that may affect sanitary quality, etc.). In the context of the application of the GMO regulation in France for example, producers had rather heavy obligations towards the services of the Ministry of Agriculture ,including transmission of various pieces of information such as the coordinates of the plot, the plant species cultivated, the surface area covered or the expected duration of the crop and the expected end dates of the crop. Romania has experience with GM traceability rules, because of its past experience with GM crop cultivation.

CEPM is opposed to the introduction of an additional and specific traceability system, which would risk creating new administrative complexities. Moreover, it would require that, upstream, farmers would have the means of knowing whether or not the seed was from NBT.

**\* 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 describe the measures and their effectiveness including details on the required financial, human resources and technical expertise

⋮

\* What best practices can you share?

⋮

\* 8 bis. What challenges have you encountered?

⋮

**\* 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 describe for the:

- Agri-food sector
- Industrial sector
- Medicinal sector

Agri-food sector

In France, the association of maize producers (AGPM) has been involved in a research programme to manage coexistence between GMO/non-GMO crops through the POECB programme and thus avoid contamination. This programme was later supplemented by the “Programme d’Accompagnement des Cultures Biotechnologiques” (PACB). Depending on the legislation in place and the prospects for research on maize varieties derived from NBTs, European maize producers are ready to take such steps if they provide access to varieties adapted to their challenges. As specified above, Romanian farmers in general and the members of the Romanian Maize Growers Association (APPR) particularly have an extensive experience with plantings of GM soybeans and maize. This refers to notifying the neighbors, observing isolation distance, harvesting, ensuring segregation (traceability in terms of storage, channeling, selling, labeling). The members considered the legislation a burden, in fact, despite the benefits of having better yields in the regions with *ostrinia nubilalis* attack (and considerably less mycotoxin challenges), the IR maize cultivation was de facto discontinued for the past 3-4 years, because of the high transaction costs. Every year, maize seed producers implement a production plan that enables Europe to be the world's leading exporter of maize seed. This program makes it possible to develop a large number of varieties while respecting very precise isolation specifications. This know-how, framed by the regulations ensuring seed certification, can be put to good use in any initiative aimed at specific traceability and labelling, including, where appropriate, NGTs.

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

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## B - Information on research on NGTs/NGT-products

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

- Yes
- No
- Not applicable

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

- Yes
- No
- Not applicable

\* Please specify

Research is also underway on areas of major interest to European maize producers:

- disease resistance (reduction of the impact on yield, better food safety)
- food safety (control of mycotoxin contaminations)
- tolerance to hydric stress through the initial vigour, the vigour of implantation, the desiccation at the end of the cycle, characteristics that allow the adaptation of the species to more stressful conditions, with security of production and economy in drying.
- In the longer term applications on the best tolerance to insects

\*

**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 describe

The main risk that we identify is the relocation of research outside the European Union, which will thus be oriented towards the development of varieties that may not be adapted to the pedo-climatic conditions of the European Union or that do not meet the challenges it wishes to meet. More over, there is a big risk of disengagement vis-à-vis of research in the field of precision breeding, because researcher don't see a real perspective of bringing a product to the market.

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

- Yes
- No
- Not applicable

\* Please provide concrete examples/data

NGTs bring 2 major levers:

- Better scientific knowledge of how genes work
- An acceleration of the solutions provided by breeding from the moment the genes are known.

In this way, the work of breeders could better take into account the objectives of the evolution of the agricultural model and identify themes that can help the resilience of the maize species.

To our knowledge, many applications are possible:

- disease resistance (reduction of the impact on yield, better food safety)
- food safety (control of mycotoxin contaminations)
- tolerance to hydric stress through the initial vigour, the vigour of implantation, the desiccation at the end of the cycle, characteristics that allow the adaptation of the species to more stressful conditions, with security of production and economy in drying.
- In the longer term applications on the best tolerance to insects.

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

- Yes
- No
- Not applicable

\* Please provide concrete examples/data

The future varieties developed through the use of NBTs would provide producers with high-performance tools in the medium term to meet the challenges of climate change (drought for example, cold tolerance to delay sowing to optimise summer water consumption, improve water efficiency, etc.), control maize pests, and improve technological and sanitary quality to meet market expectations.



\* **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

Cf answers to 14)

*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

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

- Yes  
 No

\* Please describe and provide concrete examples/data

cf question 13 and 14; In the United States, varieties derived from NGTs are marketed:

- Waxy maize, whose starch is particularly well suited to certain industrial uses.
- Maize with low phytic acid content, allowing better digestibility.
- Maize resistant to a pathogenic fungus (cercosporiosis)
- Maize with optimisation of the photosynthesis process and therefore improved yield.

Research is also underway on areas of major interest to European maize producers:

- disease resistance (reduction of the impact on yield, better food safety)
- food safety (control of mycotoxin contaminations)
- tolerance to hydric stress through the initial vigour, the vigour of implantation, the desiccation at the end of the cycle, characteristics that allow the adaptation of the species to more stressful conditions, with security of production and economy in drying.
- In the longer term applications on the best tolerance to insects.

\* Are these benefits/opportunities specific to NGTs/NGT-products?

- Yes  
 No

\* Please explain

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\*

**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 describe and provide concrete examples/data

Varieties derived from NBTs could offer multiple benefits to society, whether in terms of improved yields to meet a market whose demand will increase with global demographic trends, better protection of the environment by allowing better use of water and nutrients or limiting the use of crop protection products, protecting biodiversity, improving sanitary and technological quality to meet market expectations, as well as improving protein levels.

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

The benefits and opportunities of NGT plants would only be possible if there were an appropriate regulatory framework that would allow their real implementation in Europe, both in terms of research aspects and in the context of varieties derived from NGT plants placed on the market. The application of the GMO Directive does not seem to lead to this result. The regulatory framework governing NGT crops should therefore be geared towards evaluating solutions, and therefore varieties adapted to the needs of farmers, markets and European citizens, rather than to the techniques themselves, which are constantly evolving.

\* Are these benefits/opportunities specific to NGTs/NGT-products?

- Yes
- No

\* Please explain

The expected benefits of NGTs are both technical solutions that can be exploited by European maize growers, but also in terms of saving time and improving security in the selection process of these varieties.

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

- Yes
- No

\* Please describe and provide concrete examples/data

NGTs are cheaper to develop than conventional techniques, which may allow SMEs/small companies to find their place in the market and thus allow competition to establish itself. Moreover, by multiplying the number of players on the market, it can also help to increase the number of varieties deployed and reduce the cost of access to innovation for farmers.

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

- Yes
- No

\* Please describe and provide concrete examples/data

It should be noted that two systems exist in Europe, which combine protection of innovation in plants, and farmer's access to innovation : (1) patents for all inventions which meet the criteria for a patent to be granted (novelty, inventive step and industrial application), and (2) Plant Variety Rights (UPOV Convention) for varieties for which patenting is not allowed in Europe.

These systems apply for NGTs and NGT-products and, as in other domains, such intellectual protection is necessary both to protect innovation and ensure investment in research and development of innovation, and accordingly should be maintained. In addition access to patented NGTs and NGT-products will be critical for their use.

The difficulty today is that due to the uncertainty in the commercial development of products derived from NGTs in the EU, research is limited in the EU, resulting in fewer inventions (and fewer patents and patent variety rights) by European researchers. Most patent activity is occurring in China and the USA. See J. Martin-Laffon et al., Worldwide CRISPR patent landscape shows strong geographical biases, Nature Biotechnology, VOL 37, June 2019, 601–621, <https://doi.org/10.1038/s41587-019-0138-7>. If severe regulatory constraints continue to apply to Europe, the lack of EU innovation in this field will increase the access cost of these technologies for EU players, putting them at a competitive disadvantage versus players from other countries. This is another justification for modifying current EU GMO legislation to exclude certain types of NGT products.

*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

## 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

See question 14. In addition, it should be noted that there is a risk of distortion of competition for European producers if access to NGTs is not ensured through appropriate regulation in Europe, even though these techniques are used on other markets in the world and Europe would remain accessible to these products through imports.

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

- Yes  
 No

\* Please explain

See above : it should be noted that there is a risk of distortion of competition for European producers if access to NGTs is not ensured through appropriate regulation in Europe, even though these techniques are used on other markets in the world and Europe would remain accessible to these products through imports.

**\* 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

See Question 17

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

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

- Yes  
 No

\* Please explain

‘

**\* 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

See Question 18

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

- Yes  
 No

\* Please describe and provide concrete examples/data

See question 19

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

## E - Safety of NGTs/NGT-products

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

In plant breeding, the question of the safety of NBT plants does not arise as in other fields of application. Intrinsically, the techniques do not carry any particular risk, as the selection process makes it possible to isolate any aberrant results or results that do not correspond to the objectives. In terms of safety, products should be assessed case by case. CEPM trusts that all products that receive a positive safety assessment from EFSA are safe.

On the other hand, as with any breeding process, there is a need for a clear framework for the evaluation and marketing of varieties derived from NGTs.

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

- Yes  
 No

**\* Please explain**

We agree with what has been published on the safety of NGTs and NGT Products by the Scientific Advice Mechanism in its 2017 Exploratory note on new techniques in agricultural biotechnology (pages 17-19, 77-80, 95-97), <https://doi.org/10.2777/574498>, and its 2018 statement entitled "A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive", at pages 3 and 4, <https://doi.org/10.2777/407732>. Similarly we agree with EFSA's Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function, at page 18, <https://doi.org/10.2903/j.efsa.2012.2943>, as well as EFSA's Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis, at pages 9 through 16, <https://doi.org/10.2903/j.efsa.2012.2561>. As previously explained, one has to consider the nature of the products derived from NGTs. For those we have proposed to be excluded from the scope of EU GMO legislation, we think that, from a safety standpoint, there is no difference in safety-related risks between plants derived from NGTs or from traditional breeding techniques.

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

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## F - Ethical aspects of NGTs/NGT-products

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

The agricultural sector wishes to fully fulfil its role of feeding the population, ensuring the production of healthy food that meets consumer expectations while remaining competitive. European maize producers are fully in line with this challenge, provided they are given access to innovative means of production such as varieties from NGTs. However, all decisions taken in the field of NGT crops must continue to be subject to a

precise scientific assessment in the light of all available data. Finally, it is important to educate and communicate with all citizens of the European Union to explain these techniques and their interests/benefits and to reassure them about the safety of the products derived from them.

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

- Yes  
 No

\* Please explain why not

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*Please upload any supporting documentation for this section here*

The maximum file size is 1 MB

## G - Consumers' right for information/freedom of choice

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

In the case where NGTs are used to insert a transgene or synthetic gene, these products are subject to EU GMO legislation, including labelling requirements. For products derived from NGTs, which we propose to exclude from EU GMO legislation, there should be no specific labelling requirements compared the labelling requirements applicable to products derived from traditional breeding techniques.

Furthermore, if labelling were to be introduced, this would require that there are proven means of detection, which seems to be problematic if one wishes to distinguish between spontaneous and induced mutation.

Finally, specific labelling for consumers could in fact lead to additional mistrust of products, as has been the case with GMOs.

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

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## H - Final question

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

- Yes  
 No

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**Contact**

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