

# 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 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

European Landowners' Organization

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

Agriculture, forestry and others.

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

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

Replies from ELO refer to New Plant Breeding Techniques or NGTs used to develop plant varieties.

## 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

Plants obtained by NGTs are not yet available on the market. However, our members have expressed their intention to use seeds varieties obtained by NGTs. European farmers will adopt such plants if these :

- 1) Meet our members' needs such as crop protection benefits (alternatives to pesticides and/or fertilizers use), productivity gain with minimal use of chemical inputs, climate resilience of crops, increase nutritional value of agricultural products and others.
- 2) Meet European safety standards with regards to human and animal health, as well as environmental sustainability.
- 3) Meet consumers' demand. This of course will depend on the classification and labelling requirements put on products derived from NGTs. As transgenics have been subject to strong aversion from European consumers, our members would be willing to use such seeds only if a clear distinction between products obtained by transgenesis and those obtained by gene-editing (or NGTs) is made.

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

- Yes
- No
- Not applicable

**\* 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

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

- Yes
- No

**\* Please provide details**

As the current GMO regulation requires crops obtained by NGTs to be labelled and traced and as these crops are undistinguishable from plants obtained by conventional breeding techniques, detection poses a great challenge. At the moment, no acceptable detection method has been developed.

**\* 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**

There are no plant varieties obtained by NGTs yet on the European market.

**\* 5 bis. What challenges have you encountered?**

No comment

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

- Yes
- No
- Not applicable

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

- Yes
- No
- Not applicable

**\* 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

No comment

**\* 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

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

- Yes
- No
- Not applicable

\* Please explain why not

No comment

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

- Yes
- No
- Not applicable

\* Please specify

Last year, members visited the John Innes Centre and the Rothamsted Research Institute, prior to that, where they had the opportunity to learn more about different applications of gene editing technologies. See next websites:

<https://www.jic.ac.uk/people/wendy-harwood/>

<https://www.rothamsted.ac.uk/>

For more extensive data, see applications of NGTs for crop improvement in next document: <https://www.researchgate.net/publication>

[/329326632\\_Applications\\_and\\_potential\\_of\\_genome\\_editing\\_in\\_crop\\_improvement](https://www.researchgate.net/publication/329326632_Applications_and_potential_of_genome_editing_in_crop_improvement)

**\* 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

see q14

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

- Yes
- No
- Not applicable

\* Please provide concrete examples/data

NGTs have the potential to make plant varieties resistant to specific pests and bacteria. CRISPR-Cas 19 has been used to develop tomato varieties resistant to bacterial speck for example. If not treated with chemicals, this bacterium can spread very rapidly, leading to the loss of significant amounts of products unsuitable for the market. Other applications of NGTs such as drought stress tolerant maize represent even more benefits as there exist no other methods yet for making crops climate resilient. There exist numerous other benefits of NGTs research for the agricultural sector (see document provided q.11)

Overall, NGTs represent an important crop protection tool for European farmers whose access to effective plant protection products has been limited over the past years because of the phasing out of multiple active substance. Crops obtained through NGTs that are more resistant to pests and diseases are vital for the EU's food safety. As research in NGTs is already advanced and as it will soon be ready for regulation, NGTs have the best potential to reach farmers in due time, i.e. as soon as the sector will be hit by pesticides' reduction targets.

What's more, creating new varieties with NGTs, varieties that can range from being more nutritious to fulfilling specific food processing purposes, can open interesting markets to European farmers and make the EU plant breeding sector competitive on the global scene.

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

- Yes
- No
- Not applicable

\* Please provide concrete examples/data

The challenge for NGT-related research in the EU comes from the decision of the European Court of Justice (case C-528/16) to put NGTs under the same definition than mutagenesis techniques, making NGTs subject to the strict GMO regulation. As this regulation represents a financial and administrative burden for any small to medium-sized company developing NGT-related products, research has been halted or moved outside of the European Union. The ELO warns against the possibility that the future of plant breeding will therefore be shaped by research and political vision from outside the EU, creating new varieties that will most certainly not meet European farmers' nor European citizens' needs.

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

- Yes
- No
- Not applicable

*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

See q. 1 and 13

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

- Yes
- No

\* Please explain

Yes as they are related to the opportunities this particular techniques offer

**\* 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

With regards to the environment the main benefit of NGTs' applications for the agricultural sector is that it can provide alternatives to chemical inputs which could be harmful to biodiversity and/or are very polluting. This in turns provides benefits to human health because of better air, soil and water quality. Importantly, NGTs can pave the way to a more sustainable agriculture and preserve agricultural land from degradation over time.

NGTs have the potential to improve the nutritional traits in crops, by for example enriching certain food groups with vitamins which are lacking in a population's diets. This has already successfully been applied with Vitamin C in rice (<https://www.nature.com/articles/s41467-020-14981-y>). Therefore, NGTs-derived food products could positively impact our daily diets and be effective for tackling obesity and other food-related diseases.

Equally importantly is that NGT-related research can strongly contribute to the EU's competitiveness and relevance in the plant breeding sector. As the techniques are developed in other parts of the world for various application, and as ultimately, NGT-derived products will enter the European market, the EU farmers have to be able to compete with imports by proposing even better-quality products that respond to the EU's consumers' demands.

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

If NGTs are subject to a new legislative framework.

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

- Yes  
 No

- \* Please explain

Yes as they are related to the opportunities this particular techniques offer

- \* **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

Because NGTs are placed under the GMO regulation, the cost of going through the approval of NGT-related products is too high for smaller enterprises to enter the market.

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

- Yes  
 No

- \* Please explain why not

No comment



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

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

- Yes  
 No

\* Please explain why not

No comment

\* 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 explain why not

There is no evidence that NGTs-derived plant varieties will have different societal impacts from the conventionally obtained crop varieties. ELO would argue that it would rather bring additional benefits such as climate resilience of crops, more sustainable crop protection management and better-quality products for consumers.

\* 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

Because NGTs are placed under the GMO regulation, the cost to go through the approval of NGT-related products is too high for smaller enterprises to afford entering the market.

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

- Yes  
 No

\* Please explain why not

No comment

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## 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**

The ELO believes that there is no inherent risk to NGTs. As the resulted crop varieties cannot be distinguished from conventionally obtained plant varieties, the former do not represent a higher risk to the health and the environment than the latter.  
NGT-derived products should however meet the same safety standards as any other food products in the EU.

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

- Yes  
 No

\* Please explain why not

See q24

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

## 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 ELO believes that ethical aspects should be part of the discussion and evaluation of NGTs. However, such discussion can only be driven by verifiable facts and science-based risk assessments. Ethical concerns have to be addressed but cannot overcome the established environmental, economic and social benefits of such technologies.

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

- Yes  
 No

\* Please explain why not

No comment

*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**

No comment

*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

## H - Final question

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

- Yes  
 No

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The maximum file size is 1 MB

### Contact

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