

Member State 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

endorsed in the Joint Working Group of GMO competent authorities on new genomic techniques on 15 January 2020

I n t r o d u c t i o n

With this questionnaire the Commission is collecting contributions from Member States competent authorities to respond to the Council's request[1] for "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). The scope of the study goes beyond new mutagenesis techniques, as there are other new techniques, for which the Council seeks clarification. Therefore, the study covers all new genomic techniques, which have been developed after 2001.

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques, which are capable to alter 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. GMO competent authorities are invited to seek input from other competent authorities when appropriate.

The questionnaire is meant to provide information primarily, but not exclusively, at national level. 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 a specific NGT, please indicate this in the reply. With regard to agri-food applications, replies may include considerations on specific sectors, such as the organic sector.

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

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

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 30 April 2020 (closure of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

* Which Member State are you representing?

Cyprus

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

* 1. Have you been consulted by companies/organisations/research institutes for regulatory advice or another issue on products developed or to be developed by NGTs ?

- Yes
- No

* 2. Have you taken specific measures (other than inspection) related to the application of the GMO legislation to NGT-products?

- Yes
- No

* Please explain why not

No applications anticipated

* 2 bis. Have you encountered any challenges or limitations, including administrative burden or costs?

- Yes
- No

* Please explain why not

N/A

* 3. Have you adapted your inspection practices to cover all NGT-products and to ensure the enforcement of traceability requirements?

- Yes
- No

* Please explain why not

n

* 3 bis. Have you encountered challenges or limitations, including administrative burden or costs?

- Yes
- No

* Please explain why not

n

* 4. Do you have experience or information on traceability strategies, which could be used for tracing NGT-products?

-

- Yes
- No

* 4 bis. Have you encountered any challenges or limitations, including administrative burden or costs?

- Yes
- No

* Please explain why not

* 5. What other experience can you share on the application of the GMO legislation, including experimental releases (such as field trials and clinical trials), concerning NGT-products in the:

- Agri-food sector?
- Industrial sector?
- Medicinal sector?

Agri-food sector

Industrial sector

Medicinal sector

* 6. Have plant varieties obtained by NGTs been registered in national catalogues?

- Yes
- No

* 7. Do you require specific information in national catalogue when registering plant varieties obtained by NGTs?

- Yes
- No

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 and innovation

*** 8. Have you supported with national funding programmes NGT-related research projects/programs (ongoing or finalised in the last 5 years), including on identification or traceability?**

- Yes
 No

* 8 bis. Please highlight the potential challenges encountered when supporting/funding NGT-related research and any consequences from these challenges.

n

*** 9. How do you see NGT-related research evolving?**

n

*** 10. Have you identified any NGT-related research needs from private or public entities?**

- Yes
 No

*** 11. Could NGT-related research bring opportunities/benefits to science, to society and to the agri-food, medicinal or industrial sector?**

- Yes
 No

* Please explain why not

n

*** 12. Could NGT-related research bring challenges/concerns to science, to society and to the agri-food, medicinal or industrial sector?**

- Yes
 No

* Please provide concrete examples/data

n

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

C - Information on public dialogues and national surveys

*** 13. Have you or other institutions/bodies/entities organised national dialogues concerning NGTs?**

- Yes
 No

* 14. Have you or other institutions/bodies/entities organised national surveys, which assessed public opinion on NGTs?

- Yes
 No

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

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D Information on ethical aspects

* 15. Have any national bodies or expert groups discussed or issued opinion on the ethical aspects of NGTs?

- Yes
 No

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

E - Information on opportunities and benefits from the use of NGTs and NGT-products

* 16. Could the use of NGTs and NGT-products bring opportunities/benefits to the agri-food, medicinal or industrial sector?

- Yes
 No

* Please provide concrete examples/data

n

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

- Yes
 No

* Please provide concrete examples/data

n

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

n

* **18. Do you see particular opportunities for SMEs on the market access to NGTs?**

- Yes
 No

* Please explain why not

n

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

- Yes
 No

* Please explain why not

n

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F - Information on potential challenges and concerns of NGT products

* **20. Could the use of NGTs and NGT-products raise challenges/concerns for the agri-food, medicinal or industrial sector?**

- Yes
 No

* Please provide concrete examples/data

traceability and control

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

- Yes
 No

* Please provide concrete examples/data

acceptance, fear

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

n

* **22. Do you see particular challenges for SMEs on market access to NGTs?**

- Yes
 No

* Please explain why not

n

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

- Yes
 No

* Please explain why not

n

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

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G - Final question

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

- Yes
 No

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Contact

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