

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

CEMA - Agricultural Machinery Industry EU transparency register: 489575310490-58

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

agriculture

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

All companies active in our decision body for technical matters

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)

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

- Yes
 No
 Not applicable

* Please explain why not

the question, even the use relates not really to the growing process in the commercial phase.

* 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

Currently there is no commercial available NGT in 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

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

- Yes
- No

*** 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

not applicable

* 5 bis. What challenges have you encountered?

none

*** 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

*** 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

not their core business

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

- Yes
- No
- Not applicable

* 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

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

- Yes
- No
- Not applicable

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

- Yes
- No
- Not applicable

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

- Yes
- No
- Not applicable

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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 describe and provide concrete examples/data

with more stringent environmental rules on pesticide, fertiliser, water use and on water, soil, air contamination, combined with more severe weather and climate conditions like droughts, we identify that there is a limit to what our technology can contribute. We focus on smart farming and digital services, gaining knowledge and acting on individual plant level with sensor technology, robotics, AI... to optimise output while minimising input. But with less favourable growing conditions that output while drop in any case. Therefore there is a strong need for:
Varieties that are high-yielding and thus area-efficient while being able to survive with less fertilisation, spraying or ploughing (e.g. de novo domesticated tomato) or store more CO₂ in the roots (e.g. perennial grains) (climate mitigation),
Varieties that can adapt to the climate changes, e.g. by being drought resistant or salt tolerant (climate adaptation).

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

- Yes
 No

* Please explain

the alternative to drought resistant plants is irrigation. In water scarce areas sitting the drought out is preferred and more cost efficient. Herbicides can be replaced by mechanical weeding, pests can only be eradicated by pesticides or resistant species.

* **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

Some crops can only stay in Europe and be offered on local markets if they can be produced while achieving the new targets set in the farm to food strategy. The reality is that a 50 % reduction of pesticides in 10 years is impossible unless we use NGTs.
Farmers with a good income due to an increased competitiveness, will be more prepared to implement further soil and environment conservation measures.

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

only if these NGTs can be brought on the market quickly and under reasonable costs, it can be applied also to less common species.

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

- Yes
 No

* Please explain

there are no alternatives

* **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

the low cost of NGTs when not treated as GMOs, makes it suitable to offer

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

- Yes
 No

* Please explain why not

no expertise

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 explain why not

no expert

*

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

no expert

*** 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

no expert but our own machinery industry is consisting of mainly SMEs. Main issues for SMEs is often lack of harmonised rules, cost related to certification, national regional deviations to be followed.

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

- Yes
 No

* Please explain why not

no expert

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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**

IF focus is on those applications of NGTs that lead to plants that could also have been the result of earlier breeding methods, or might have been obtained from natural processes without human intervention, there is no need for further safety assessments.

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

- Yes
 No

* Please explain why not

the current EU legislation for on-GMO is sufficient

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

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

again if focus is on those applications of NGTs that lead to plants that could also have been the result of earlier breeding methods, or might have been obtained from natural processes without human intervention, it is using a techniques to accelerate what is happening since men have settled down.
If it is that acceleration that is the ethical concern, so is the speed at which our biodiversity is decreasing, our climate is changing.

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

- Yes
 No

*** Please explain why not**

see above

Please upload any supporting documentation for this section here

The maximum file size is 1 MB

G - Consumers' right for information/freedom of choice

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

no expertise

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

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

- Yes
 No

Please provide your comments here

As the DNA alterations in NGT are not unique, as traceability is very difficult, and if European farmers are not allowed to use it, the whole sector will lose competitiveness.
Keeping it in scope of the current outdated GMO legislation is a huge bottleneck, where proportionality is lost and Member States can make further ruling. Agricultural products are traded on world markets. European harmonised rules are a must. We follow the opinion of several experts we heard on several occasions that the GMO legislation itself is best revised to accommodate and have an expert discussion in depth on this new reality.

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

Contact

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