

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

ENA - European Nurserystock Association - 248993414712-40

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

live plants production

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

AVBS (Belgium), Nursery Association Czech Republic, Hungarian Interbranch Organization for Ornamental Horticulture

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

We give the opinion about NGT on plants only, mainly on plants for urban and ornamental uses.

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 provide details

In some countries only. There is no interest in other countries.

* 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

Control led by the authorities.

* 2 bis. Have you encountered any challenges?

- Yes
 No

* Please provide details

GMO orange petunia in 2017

* 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

Breeding companies are currently looking to collaborate with research institutes to start some projects using Crispr technology. Initiatives know for annuals, perennials, shrubs (plants).

* **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

We do not know the consequences of free pollination in nature.

* **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 very few GMO varieties in the market.

* 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

* What challenges have you encountered?

Authorities have not given support and just some general information.

*

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

Very simple traceability measures, registering the plants from the entrance to the nursery and along all the production process.

*** 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

Because our members don't produce food nor GM plants for food.

*** 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

Lack of funding

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

- Yes
- No
- Not applicable

* Please specify

There is some research work done by research institutes in different countries.

*** 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

It has a significant effect on the introduction to the market of the products resulting from previous research, and on the possibilities of further research. Start-up company that just started with Crispr technology stopped her business. Also, R&D in private breeding companies towards the use of NGT was stopped.

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

- Yes
- No
- Not applicable

* Please provide concrete examples/data

Technology offers opportunities to develop plants with improved biotic or abiotic stress resistance. It might be a tool to help in the reduction of the use of chemical pesticides and can lead to a more durable culture of ornamental plants. Also improved shelf life is a valuable trait of interest. Novel growth habits, other morphological characteristics.

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

- Yes
- No
- Not applicable

* Please provide concrete examples/data

Due to the current uncertainty it is very hard to invest in the technology and our position compared to outside the EU is weakened.

*** 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

Long-term research is absolutely necessary. Financial and legal gaps.

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 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

Improved tolerance or resistance to different pests and disease, tolerance to abiotic stress ... Breeding cycles can be much faster for certain traits. Not food, therefore low risk. If the resistance is increased by breeding, therefore lower amounts of chemicals are needed for pest control, by plant sterility in case of invasive species the risk is eliminated, in case of toxic plants the elimination of toxins.

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

- Yes
- No

- * Please explain

This mainly depends on the specific trait and crop. In some cases, traditional breeding methods can result in the same outcome but it will be less efficient and more time-consuming.

- * **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

Increased plant health might lead to social benefits.

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

Increased resistance to pests and diseases will reduce the use of pesticides.

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

- Yes
 No

* Please explain why not

other breeding techniques can also be used

* **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

SME can offer the technology as provider to other breeding companies. If new ornamentals with specific traits are developed, this can open new markets for growers (the vast majority of which are SME)

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

- Yes
 No

* Please explain why not

Plant Breeders Rights are adequate to protect novel varieties that are developed. This is independent of the technology that is used.

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

The regulations need to be sorted out and made unambiguous.
We do not know the consequences of free pollination in nature.

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

- Yes
 No

* Please explain

There is no perceived risk with new varieties of plants obtained by hybridization or natural selection.

* **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

Possible negative impact on the environment, human, animal, and plants health.

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

Mostly on food or feed.

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

- Yes
 No

* Please explain why not

Chemical treatments also raise concerns to the society.

* **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

The biggest challenge is the legislation.
Information on the possible risks must be disclosed to customers

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

- Yes
 No

* Please describe and provide concrete examples/data

risk of a monopoly, that plant genetics will be left in the hands of a few companies.

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 - Safety of NGTs/NGT-products

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

Everything depends on the specific trait, but this is independent of the technology. We deal with ornamental plants (not food), and if we take into consideration the rules and regulations the risk is low. However, care must be taken to avoid misuses.

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

- Yes
 No

*** Please explain why not**

We should not look to the technology but to the end-product. It is the end product that has to be safe. But this is independent of the technology used.

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

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

Ethical aspects should not go about the technology but about what is done, made with the technology. It is a very sensitive topic.

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

- Yes
 No

*** Please explain why not**

NO, if proper information is provided to customers.

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**

Labelling is necessary to guarantee the consumers right to choice. However, labelling has only sense as you can identify the products. The technology is so diverse, and evolution is going so fast that it is impossible to discriminate between i.e. mutations obtained by NGT's and natural mutations. Here again the EU should move to legislation on the safety of the product and not on legislation which technology is used to obtain a certain product.

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

Human beings are more important than money.

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

SANTE-NGT-STUDY@ec.europa.eu