Contribution ID: 4e7e6124-bd4a-4e95-b39e-934247994b4b
Date: 15/05/2020 19:06:32

# 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

**Background**

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/EC).

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 after 2001.

**Instructions**

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

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

***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

Union Fleurs - International Flower Trade Association 14864192565-82

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

Floriculture and ornamental horticulture (cut flowers, live plants, foliage)

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

All the replies refer to crop breeding sector and particularly to ornamental plants obtained by breeding techniques obtained after 2001. We know that new breeding techniques (NBTs) or NewGenomic Techniques (NGTs) as defined for the purpose of this study can be used to insert genetic material from sexually non-compatible species into a plant genome (i.e. transgenics) as well as to induce targeted and small changes within the organism's genome (mutations) or within the genepool of (crossable) species. We focus on the latter applications, which 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.

## 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

The ornamental sector has a number of challenges for which breeding is regarded to provide a significant contribution. Selection has mainly concentrated on consumer values such as number and size of flowers, plant architecture and vase life. Also, productivity, and the main producer value has been bred for. Currently, important additional demands on the producers introduce disease resistance as an important breeding goal – and society, notably in Europe, wants to have solutions soon. Breeding is indeed powerful, but very slow and it is unclear how the ornamental sectors can meet the policy objectives of the Green Deal by 2030 without tools to speed up breeding processes. NGTs are therefore looked upon by various breeders as an opportunity.

* **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 the chain it starts with the breeders. To the extent possible, breeders try to be informed about the breeding origin of parent materials that they obtain from elsewhere, including from countries where NGTs are not regulated.

* 2 bis. Have you encountered any challenges?

- (•) Yes
- ( ) No

* Please provide details

Because tests are not available to identify whether the plant was developed by conventional breeding methods, it is not possible for ornamental breeders to protect themselves against the unintentional use of such NGT-products.

* **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 expert knowledge of all research performed by all our members, but we do know that they are either involved in or closely following the various public and public/private research programmes in the various EU member states, such as:

- PlantED COST Action: CA18111 - Genome editing in plants - a technology with transformative potential (Q3Ref1)
- Biotechnologies for Agriculture (BIOTECH): funded by the Ministry of Agriculture (MiPAF, Italy) and run by the Consiglio per la Ricerca in Agricoltura e l'Economia Agraria (CREA), which started in 2018, including agriculture and horticulture species.
- The Swedish Foundation for Strategic Research, SSF, Agenda 2030 Strategic Research Centre on plant biotechnology.
- Topsector Horticulture and Planting Materials of the Netherlands, including the use of NGTs including in ornamentals.

We are aware of various initiatives to use NGT in breeding research, such as gene function analysis by companies for which they do not provide details to prevent disclosure to competitors.

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

- (•) Yes
- ( ) No
- ( ) Not applicable

* Please provide details

In the chain it starts with the breeders. To the extent possible, breeders try to be informed about the breeding origin of parent materials that they obtain from elsewhere, including from countries where NGTs are not regulated

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

- (•) Yes
- ( ) No

* Please provide details

Because tests are not available to identify whether the plant was developed by conventional breeding methods, it is not possible for ornamental breeders to protect themselves against the unintentional use of such NGT-products.

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

Yes with respect to breeding companies in the chain. Those companies that use NGTs as a research tool do consider this research to fall in Europe under the GMO legislation, and they comply with the rules (commonly the rules relevant to contained use). Several do such research in public laboratories that are used to comply with GMO-rules, either in public-private partnerships or (through service providers) using direct contracts.

* What best practices can you share?

-

* 5 bis. What challenges have you encountered?

-

* **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?

Notably during the period before the ECJ verdict, the situation was very unclear in different EU member states. It was impossible to make strategic choices and those that were made, especially after the publication of the views of the Advocate General, had to be reversed. This lack of clarity was not helpful.

* **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

There is some experience with tracking and tracing strategies in environmental sustainability labels, including NMP and Global GAP. These actions lead to a specific label that the consumer can trust, but which contain a wide range of criteria that would be too complex for the consumer to grasp.
Using the same tracking and tracing systems to produce a specific information system for breeding strategies does not fit into the concept of these sustainability labels.

* **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 specify including subject, type of research, resources allocated, research location

•The Topsector Horticulture and Planting Materials of the Netherlands, (not a member but the triple helix organisation for horticulture and starting materials in NL) is including the use of NGTs in ornamentals, notably a project on improving the efficiency of polyploid breeding with various Chrysanthemum and other crop breeders in The Netherlands

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

- ◉ Yes

- ○ No
- ○ Not applicable

* Please specify

There is a great deal of research underway around the world into NGTs. Many ornamental breeders follow this to see which technologies would be applicable for their breeding goals. Seed for example:
https://www.oecd.org/environment/genome-editing-agriculture/
SLU (Sweden): https://www.slu.se/en/Collaborative-Centres-and-Projects/grogrund/
https://www.frontiersin.org/articles/10.3389/fpls.2019.00114/full
https://doi.org/10.1016/j.tplants.2019.09.006
https://doi.org/10.3389/fpls.2018.01607
BVL, JKI and FLI (Germany): https://www.bvl.bund.de/DE/ Arbeitsbereiche/06_Gentechnik/02_Verbraucher/09_Monitoring_Molekulare_Techniken/gentechnik_molekulare_techniken_node.html

* **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 scientific community considers that the decision is hampering its work and putting up barriers and costs that do not have a commensurate benefit for society or the environment. See http://www.vib.be/en/news/Pages/Open%20Statement%20for%20the%20use%20of%20genome%20editing%20for%20sustainable%20agriculture%20and%20food%20production%20in%20the%20EU.aspx
We understand that research projects using NGT have been be put on hold or delayed due to the ECJ ruling, which made it clear that perspectives for product development from this research would not happen in Europe. A particular example is a large Dutch potato breeding company that recently announced to move its research NGT potatoes with multiple resistance against phytophthora to Canada, as far as it concerns field trials. https://www.boerderij.nl/Akkerbouw/Nieuws/2020/2/HZPC-verplaatstaardappelonderzoek-naar-Canada-544771E
It is obvious that the current regulatory frame is a strong deterrent to any research that our members may have undertaken, or wished to undertake.

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

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide concrete examples/data

We foresee benefits of NGT related research. Examples,
a) The use of NGTs in research can greatly accelerate the speed at which the genome of a crop is understood, e.g. in relation to susceptibility or resistance against a particular disease, or greenhouse production at a lower temperature in cool seasons, thus reducing greenhouse gas emissions. This knowledge can then be used to develop a more targeted/efficient traditional breeding program.
b) Using NGTs in actual breeding, the use of NGTs can significantly reduce the time needed to develop good new varieties, notably for polyploid species and ornamental trees for which conventional breeding takes a very long time.
c) NGT can be used to speed up the domestication process in improving agronomic
traits as well as quality. Domestication of wild plants occurs quite regularly in ornamentals, and increases the diversity of crops and products.

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

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide concrete examples/data

The first challenge is that the technology is not applicable to ornamental crops for which genomic knowledge is still insufficient. This is true for a rapidly reducing number of species.
Secondly, the European Court of Justice's ruling on 25th July 2018 makes it practically and commercially impossible to apply the techniques in small crops like ornamentals as the cost of deregulating a new product outweighs many times the value in the market. GMOs are almost exclusively commercialized in globally important crops like maize, cotton and soybean. The same will happen with NGTs as long as they are considered regulated GMOs.

*** 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

The main gap is that researchers and breeders need access to the technology, not only access from a technical and IP point of view, but also from the view of economic perspective, which is not there in Europe due to the ECJ decision.
For some ornamental species, genomic knowledge and cell- and tissue culture to be able to develop plants after the use of NGT are insufficiently developed. However, even for tulip, the genome – which is extremely large – has recently been sequenced in preparation for NGT use.
More knowledge about off-target effects of the technology would be useful, even though it is generally understood that NGTs have far less off targets than random mutagenesis or cross breeding.

*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

Gaps in terms of breeding goals:
Many conventional breeding goals could be pursued, and accomplished more efficiently with NGTs. More particularly, ornamental breeders look upon NGTs as a chance to effectively breed for disease restitance and possibly also pest resistance, where the ornamental sector has a need to catch up with vegetable and field crop breeders who have a longer experience in this.

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

- (●) Yes
- ( ) No

* Please explain

-

* **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

Society will greatly benefit from more disease resistant varieties becoming available soon. Pesticide use is high in certain crops, such as lily and can very likely be reduced when NGTs can effectively be used.
The number of authorized crop protection chemicals is reducing at a significant pace. For ornamentals that would mean that it may not be possible to cultivate good quality flowers and plants of several species in Europe anymore.
For crops NGTs can be essential to breed for tolerance to abiotic stresses, may reduce the use for irrigation water, for heat tolerance (currently a challenge in crops like Cyclamen, and tolerance to lower temperatures (less energy use in greenhouses – for example in Chrysanthemum, roses etc.)

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

-

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

- (●) Yes
- ( ) No

* Please explain

-

* **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

Most ornamental crops are mainly bred by SMEs. They look upon NGTs as a (technically) relatively cheap set of technologies. It requires laboratories though which several of these SMEs don't have. Some are however in touch with service providers like Hudson River Biotechnologies that can advise these SME's on the use of NGTs and they can apply the NGTs in their own or in public laboratories after which the further breeding will be done by the SME-breeder.
NGTs are particularly also suited for use by SME's in this manner, unlike conventional transgenesis which is very expensive to work with.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Yes and No
Yes because patenting in principle creates benefits and opportunities for the patent holder that they may re-invest in innovation and/or pay for the regulatory costs. Patents disclose information on the patented technology which can also provide innovation benefits to others.
No because patents create exclusive rights and thus tend to reduce the necessary access to technology or the products thereof (plant material) by others and can have an overall negative effect for the plant sector as you always need existing breeding material to develop new plant products. You can't start from scratch At some point there can be many patents on one specie, resulting in extra costs in the chain and market disturbances. So over all we oppose patents on products of NGT's.

*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

Ornamental breeders are concerned about how to handle breeding materials and plant genetic resources coming from all over the world, where some of those genetic resources might be regulated as GMOs in the EU, but are indistinguishable from conventional plants. This would actually mean that breeders will not be able to access materials from outside the EU for further breeding anymore. Such restrictions on access and use of genetic resources will have severe negative impact on EU-based breeding companies. Furthermore, such restrictions will negatively impact European farmers and consumers, reduce biodiversity (genetic diversity within crops), and will challenge steps towards increasing environmental sustainability. The current situation therefore does not support the purposes of the Green Deal.

In parallel, when NGT-products remain regulated as GMOs in the EU, it may not even be possible anymore to import any planting materials from outside the EU, since screening to make sure that such imports do not contain NGT products is impossible. As the ornamental sector is global web of businesses this would severely damage the European market and chain of breeders, propagators, growers, importers, wholesalers, distributors and retailers.
So we are very much concerned that the current rules will not be implementable.

It should also be acknowledged that the current regulation will severely slow down research and innovation in the EU, compared to countries where the use of NGTs is less restricted. This will put all EU stakeholders at a competitive disadvantage.

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

- (●) Yes
- ( ) No

* Please explain

The challenges immediately relate to the NGTs leading to regulated GMOs in Europe.

* **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.
We don’t see any risks that are different from the risks for man and environment of regular breeding with methods that do not lead to regulated GMOs such as cross and (random) mutation breeding. We see benefits, not risks, for plant health.

*

**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

particularly SMEs will have problems – both in terms of legal capacity and financial considerations to bring NGT products to the market.

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

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Patents on plants derived from NGTs can have a significant negative impact on the free access to genetics for further breeding. Regarding NGT-products that may be falling under the scope of patent protection, it is of key importance that access to the genetic material including the NGT traits can still be guaranteed since this is what allows breeders to continuously build on each other's inventions and develop ever new and better varieties.

Also with regard to patents on the technology, challenges are likely to arise both in terms of breeders finding it hard to get a license, and to deal with license requirements and payments. So it is not only the license costs that are relevant but also stewardship requirements that are common in current GMO licenses, make it impossible for SME companies to enter in such a license.
Heavy regulatory obligations for the trait developer to monitor the use of the trait throughout the chain will likely necessitate trait developers to have patents in order to comply, and as a result will be a tremendous disincentive for SMEs to participate.
As far as the extension of patent claims to NGT products is concerned (either by a patent on the NGT or on the NGT product), these should in any case not cover products with the same characteristics developed in parallel through another method and thus without using the patent holder's material.

*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**

Since we defined NGTs as technologies that create plants that could in principle also be created with conventional (not regulated) breeding methods, the products of such NGTs are not substantially different

and thus do not pose any additional risks.
We may expect even that since much more is known about the altered gene compared with random mutagenesis or cross breeding, that safety may even be improved.

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

- ○ Yes
- ◉ No

* Please explain why not

see answer question 24

*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**

The ethical questions are diverse. There have been major ethical concerns in the GMO discussion in the 1980s/90s from church groups and organizations. Since NGTs do not create any issues regarding the order of nature (traits transferred between species and genera), this ethical concern appears not to be significant. There is also a concern by (part of) the organic sector relating to the integrity of the cell (or integrity of the genome), which leads to non-acceptance of many NGTs (and sometimes even older ones like mutation breeding). Since these concerns are linked to a separate value chain, that of the already very well regulated organic sector, it is up to that chain not to use varieties created by NGTs, like other regulated requirements for organic products; that does not require specific government intervention
Another ethical analysis was presented by the Danish Council on Ethics (http://www.etiskraad.dk/~/media /Etisk-Raad/en/Publications/ DCE_Statement_on_GMO_and_ethics_in_a_new_era_2019.pdf?la=da ) that concluded that it was ethically wrong not to use NGTs when their use would support important (ethical) goals such as food security and sustainability, especially in developing countries that often follow EU standards. We strongly support this point of view.

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

- ◉ Yes
- ○ No

* Please explain

Our main ethical concern is the damage done by not allowing the broad use of NGTs (in line with the Danish Ethical Council, referred to in Q26.

*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**

We don't see a benefit for consumers to know by which (of the approx. 20 breeding methods) a flower, plant or tree has been produced. We also foresee practical impossibilities when consumers buy a bouquet with 20 different flowers (with each some 20 breeding methods in their pedigree).
Apart from the usefulness, we are also concerned about the cost of managing such tracking all along the value chains. Breeders are also wary of the fact that the breeder's exemption is very important and that breeders will not be able to know all methods used by other breeders of materials that have been used in crossing programs. They are thus unable to guarantee their declarations.

Therefore it will be much more transparent towards the public if in the organic production or chain it is incorporated that no NGT's are 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

## H - Final question

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

- (●) Yes
- ( ) No

Please provide your comments here

It is important to have this discussion as a decision (not) to unnecessarily regulate NGTs has to be put within the framework of the general policies of the EU such as the Green Deal, and not within too limited policy objectives. We therefore appreciate to be invited to participate in this survey and hopefully in further discussions, also in relation to the general dominance of agriculture over horticulture in many debates and the dominance of vegetables and fruits within the horticulture area over ornamentals.

*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