

# 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

International Association of Horticultural Producers  
AIPH  
Transparency Registry number 873862119851-81

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

AIPH supports national and regional grower associations globally. Twelve of these are located in the EU. The members of the associations are active in propagation and production of ornamentals, including cut flowers, perennials, bedding plants, bulbs, and ornamental trees. Our members also include plant breeders.

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

Not applicable

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 New Genomic 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)

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

- Yes  
 No  
 Not applicable

\* Please provide details

The ornamentals sector has numerous 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, colour variation, plant architecture and vase life. Production aspects of importance for breeding and selection include productivity and vigour. Recently, an important additional demand from the producers is to introduce disease resistance or tolerance as an important goal – and socially and politically this aspect is becoming a priority, particularly in Europe. Breeding is indeed a powerful tool, but very slow, and it is questionable whether the ornamental sector 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 and growers as a vital opportunity. AIPH's industry depends on access to sufficient propagating material of good quality and at reasonable prices. This calls for a worldwide high- functioning and sophisticated breeding industry.

\* 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

Yes From a breeder perspective: 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.

No. From a grower perspective: It is not allowed to grow ornamentals developed by NGT and there are no tools to identify these.

\* 2 bis. Have you encountered any challenges?

- Yes
- No

\* Please provide details

Due to the fact that tests are not available to identify if the plant was developed by conventional breeding methods, it is not possible for ornamental breeders or growers 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

Yes. From a breeder perspective: We have no expert knowledge of all research performed by all our members, but we do know that they are either involved in or are 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.

No. From a grower perspective. We are only aware of various initiatives to use NGT in breeding research.

\* **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 are aware of problems the growers could get into if they use products in which NGT is used unintentional.

**\* 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. From a breeder perspective: Those companies that use NGTs as a research tool do consider how this research is regulated in Europe under the GMO legislation, and they comply with the rules (commonly the rules relevant to contained use).

\* What best practices can you share?

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.

\* 5 bis. What challenges have you encountered?

From a grower perspective: Growers do no research in this field, leaving it to the breeders.

**\* 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 for growers to make strategic choices. 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 are several schemes on sustainability with possibility of tracking and tracing, including NMP and Global Gap, and recently the introduction of plant passport for all plants for planting, that is especially focusing on T&T.

**\* 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

Not applicable as there are to our knowledge no products of NGTs in the market

\* 8 bis. What challenges have you encountered?

Due to the fact that tests are not available to identify if the plant was developed by conventional breeding methods, it is not possible for ornamental breeders or growers to ensure compliance

**\* 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*

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## **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

The lack of clarity regarding differentiation between NGTs and GMOs creates a lack of confidence in investing in NGT-related research.

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

- Yes  
 No  
 Not applicable

\* Please specify

Topsector Horticulture and Planting Materials of the Netherlands, 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. However, breeders and growers are aware that many research initiatives and projects into NGTs have started worldwide. Many ornamental breeders and growers follow this research to see which technologies may be applicable in the ornamental sector.

\* **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

Research projects have been cancelled and it is very hard to get financial support for this type of research. Europe falls behind.  
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.  
Growers strongly depend on the research results of the breeders.

\* **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.  
It needs no arguments that the growers will benefit from these advantages enormously as well.

\* **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, due to the very broad assortment of ornamentals in commercial production. 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 such as ornamentals as the cost of deregulating a new product outweighs many times the value in the market. GMOs are almost exclusively commercialised in globally important crops such as 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

Due to the restrictions in Europe and the ECJ decision European researchers do not have access to the information and technologies available in other parts of the world, not only from a technical and IP point of view, but also from the economic perspective .

For some ornamental species, the use of NGT is insufficiently developed. However, for the tulip, for example, the genome has recently been sequenced in preparation for NGT techniques. 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.

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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



Many conventional breeding goals could be pursued, and more efficiently with NGTs. More particularly, ornamental breeders look upon NGTs as a chance to effectively breed for disease 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.

NGT will help growers to comply with many aspects of the (UN) sustainable goals and reducing production costs.

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

- Yes  
 No

\* Please explain

The speed of NGTs enables breeders to address current issues in a manner not afforded by conventional breeding.

\* **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 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 of several species in Europe in the future.

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

NGTs can be essential to breed for tolerance to abiotic stresses (for example heat tolerance, drought, salinity). NGT can contribute to developing crops with tolerance to lower temperatures so less energy is used in greenhouses (for example in Chrysanthemum, roses etc.). NGTs will contribute to biodiversity and improving ecology.

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

- Yes  
 No

\* Please explain

The speed of NGTs enables breeders to address current issues in a manner not afforded by conventional breeding.

**\* 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. They require laboratories though which several of these SMEs don't have. Several are however in touch with service providers like Hudson River Biotechnologies that can advise them on the use of NGTs and that 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.

Growers will benefit from new varieties developed by SME with those new techniques.

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

- Yes  
 No

\* Please explain why not

No because patents create exclusive rights and thus tend to reduce access to technology or the products thereof (plant material) by others and can have an overall negative effect for the plant sector.

*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 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 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 growers and consumers, reduce biodiversity (genetic diversity within crops), and will challenge steps towards increasing environmental sustainability. The current situation therefore does not support 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.

So we are 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 and the association with GMO regulations in Europe. Screening to make sure that imports do not contain NGT products is impossible.

\* **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

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.

We do see socio-economic risks through parallels with the introduction of conventional GMOs (transgenics), the regulation of NGTs will give benefit to the larger companies that have the legal and financial resources to deal with the complex rules, and will thus put SMEs at a competitive disadvantage.

\* **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, breeders as well as growers, 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 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 (the so called 'breeder's exemption' in plant breeders rights) 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 manage license requirements. So it is not only the license costs that are relevant, but also stewardship requirements that are common in current GMO licenses that make it impossible for SME companies to enter into such a license agreement.

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

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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**

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 less of a concern

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

- Yes  
 No

\* Please explain why not

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 less of a concern

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## 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**

From growers point of view ethical aspects related to NGTs appears not to be significant as these techniques don't create any issues regarding the order of nature (as GMO's do).

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

- Yes  
 No

**\* Please explain why not**

From growers point of view ethical aspects related to NGTs appears not to be significant as these techniques don't create any issues regarding the order of nature (as GMO's do).

*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**

Growers don't see benefits for consumers to know by which (of the approx. 20 breeding methods) a flower has been produced. We also don't know how that would work out 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.

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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

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. AIPH therefore appreciates the invitation to participate in this survey as an important stakeholder in the broader horticultural industry. This is particularly pertinent in view of the general dominance of agriculture over horticulture in many debates, and the dominance of vegetables and fruits over ornamentals within the horticulture sector.

*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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