

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

Comité Européen des Entreprises Vins (CEEV) / EU Transparency Register n°2663914841-28

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

European Union wine companies in the industry and trade (still wines, aromatised wines, sparkling wines, liqueur wines and other vine products).

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

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

Our members believe the principle of precaution is not guaranteed in this issue.

* 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

Some companies enforce the provision by suppliers of legal declarations attesting that no GMOs or GMO-derived products were used in the production of supplied goods. Under the current legal framework, NGT-products are considered GMOs, therefore those legal declarations also attest that no NGT-products were supplied or used in the production of supplied goods.

* 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

* Please provide details

Not in the European Union. We know there are GM-vines and yeasts being developed and used in other parts of the world. Also, a synthetic wine yeast is subject of research for an international consortium.

* **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

Some companies enforce the provision by suppliers of legal declarations attesting that no GMOs or GMO-derived products were used in the production of supplied goods. Under the current legal framework, NGT-products are considered GMOs, therefore those legal declarations also attest that no NGT-products were supplied or used in the production of supplied goods.

* 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

Organisms obtained by NGTs are, under the current EU legal framework considered GMOs. No specific measures needed for NGTs as the same measures as for GMOs apply.

* 5 bis. What challenges have you encountered?

No challenge worth mentioning.

* **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?

No, testing for GMOs is difficult and expensive. The wine sector would have unacceptable costs to include this testing as a routine quality control measure. Risk exists but is estimated to be very low, therefore the legal / administrative approach has been favored.

*** 7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products?**

- Yes
 No
 Not applicable

*** Do you have suggestions on possible traceability strategies and/or methods?**

- Yes
 No

*** Please describe**

It is very hard to trace unregistered NGT-products as they may use the same genetic material as the natural organisms from the same species. Control seems possible only for registered NGT-products. Even in this case, the cost and technical expertise would be out of reach for the average wine producer and even for most collective organizations managing geographical indications.

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

Some companies enforce the provision by suppliers of legal declarations attesting that no GMOs or GMO-derived products were used in the production of supplied goods. Under the current legal framework, NGT-products are considered GMOs, therefore those legal declarations also attest that no NGT-products were supplied or used in the production of supplied goods.

*** What best practices can you share?**

Legal declarations of exemption from GMO and GMO-products requested to all grape and wine suppliers and also all suppliers of additives and processing aids.

*** Please explain why not**

Yes, some companies are taking specific measures for NGT-products (please see above).

*** 8 bis. What challenges have you encountered?**

No challenge worth mentioning.

*** 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 describe for the:

- Agri-food sector
- Industrial sector
- Medicinal sector

Agri-food sector

There is a worrisome lack of research and information on the use of GMO and GMO-products (NGT included) in the grape and wine sector. With time this will increase risk for the 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

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

Generalized public opinion rejection, lack of R&D, principle of precaution not assured.

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

- Yes
- No
- Not applicable

* Please specify

Most R&D on NGT and grape and wine products has been done outside the EU, little is known among the sector who vastly ignores their existence, even though some EU researchers have participated in such projects.

*** 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

Seen from outside the academic world, it seems most of the ongoing research in the EU on these technologies has been suspended, secondarized or altogether stopped.

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

- Yes
- No
- Not applicable

* Please provide concrete examples/data

Yes, but perceived benefits are currently outweighed by perceived risks.
Research would clarify the opportunities and risks of NGT allowing for better, science-based decisions to be made regarding its use. Yet, public knowledge on research being made for grape and wine would have detrimental effects on the public perception of the sector. This is currently a deadlocked situation that needs very careful tiptoeing to disentangle without causing major harms to the business of wine. Consumers would equate the use of NGT on wine as a further step away from the naturalness of the product.

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

- Yes
- No
- Not applicable

* Please provide concrete examples/data

NGT being considered as GMO pushes consumers away from the idea of having them applied to grape growing and winemaking. Therefore, there is not much industrial support to do research on the subject.

*** 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

Main priorities are safety of the technologies towards human health, environment and sustainability of the wine business. Social and psychological research would be needed to understand how consumers react to the notion of using NGT instead of chemicals for crop protection. The effect of releasing NGT organisms in the natural environment also needs to be researched particularly in terms of the effect into the cropping system genetic diversity and in terms of resilience of the cropping system.

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

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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

Yes, but perceived benefits are currently outweighed by perceived risks.

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

- Yes
 No

* Please explain why not

The same applies to all types of GMOs.

*** 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

Yes, but perceived benefits are currently outweighed by perceived risks. The principle of precaution is not guaranteed.

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

Only with a complete assessment of all risks and behavior with a long enough track record of observations.

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

- Yes
 No

* Please explain why not

The same applies to all GMOs.

* **18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products?**

- Yes
 No

* Please explain why not

Not in the current social rejection situation. The wine business would be hurt.

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

- Yes
 No

* Please explain why not

The wine business has an extremely atomized structure. Patenting would create severe imbalances between those that can afford (and understand) the patents and those who cannot. In the long-run those imbalances would destructure the market and shift wine further into an image of a non-natural, technological 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

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 main challenge would be the potential loss of the image of naturalness in wine.

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

- Yes
 No

* Please explain why not

They are shared by all GMOs.

* **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

Environment: possible ecological imbalances, loss of biodiversity
Human health: consumers would be concerned about their health from consuming wine that is produced with what they understand as the ultimate destruction of nature
Animal health: there could be impacts on auxiliary organisms that support ecosystem services in vineyards (pest predators, for example)
Plant health: loss of genetic diversity would make vineyards less resilient and more prone to severe variations of crop output across different years
Consumers: rejection because of perception of artificialization of wine
Economic challenges: polarization of the wine business between the artificial and the natural, something already occurring would worsen.

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

Implementation before general public acceptance.

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

- Yes
 No

* Please explain why not

They are shared with GMOs.

* **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

Major marketing and communication campaigns are required. This is usually out of reach for SMEs.

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

- Yes
 No

* Please explain why not

Being artificial productions, there are no issues with patent protection.

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

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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**

There is no sufficient information available to evaluate their safety. However, perceived benefits are outweighed by perceived risks.

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

- Yes
 No

* Please explain why not

Same as GMOs.

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 biggest ethical challenge is to allow deployment of NGT-products before a complete safety assessment with enough hindsight is possible.

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

- Yes
 No

* Please explain why not

Same as GMOs.

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**

NGT should be labelled as GMOs.

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 essential to preserve natural, ancestral biodiversity by safeguarding the dwindling public reservoir of genetic resources that bear the benefit of having been naturally selected as the fittest. Priority attention should be focused on this preservation and on investments made in this sense, instead of creating artificial genetic diversity without consideration of its adaptability, stability and impact in natural ecosystems.

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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