

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

Federation of European Rice Millers (31958409365-30)

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

Rice industry

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

FERM members are not involved in the development of NGTs. As no commercialisation of NGT rice is currently foreseen, no use of NGT rice is planned.

* 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

See answer to question 1.

* 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

A 2017 survey compiled by the German Julius-Kühn-Institut pointed to research involving novel genome techniques (NGTs) related to rice, predominantly in China and the US (with limited research in Korea). As the US is a significant rice supplier to the EU market, FERM has sought clarifications on expectations regarding the potential commercialisation of rice varieties based on novel mutagenesis techniques. The USA Rice Federation indicated (in 2019) that in the United States, no varieties are expected to be released within the next 5 years. The prospects regarding potential timescales for breeding and commercialisation of rice with these techniques in China are less clear. The European rice market is less directly implicated by varietal developments in China, as the EU is not a traditional import of Chinese rice.

*** 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**

There is no authorised NGT rice on the EU market. If these foods are in the EU food supply chain “unintentionally”, it would be due to an illegal placement on the market and, because illegal, hidden to subsequent operators further down the food supply chain. As established by the European Commission Joint Research Centre (JRC), there are most probably no analytical tools available that distinguish NGT crops from conventional crops, and certainly not where there is no prior knowledge of the altered genome sequence.

Question 4 implicitly lays the burden of management of GM events primarily on operators who are poorly placed to influence the intentional actions taken by plant breeders. In 2006, the rice industry suffered significant economic damage due to the inadvertent release of GMO Liberty Link 601 rice into the US rice crop. Analytical methods were eventually made available to identify this rice and has provided the industry with a method (albeit one providing insufficient legal certainty due to the zero threshold in EU legislation) for identifying the presence of LL 601. With NGT varieties, even this option is not available.

It is crucial that any changes to existing legislation do not perpetuate the shortcomings of today's rules that place the immediate costs and economic damage associated with unintentional use on operators who play no role in decisions to develop and/or release GM events. EU legislation must place the burden for unintentional release on those responsible for that release.

*** 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**

See answer to question 4.

* 5 bis. What challenges have you encountered?

See answer to question 4.

* **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?

In the absence of commercialised NGT rice, no particular support from national/European authorities has yet been required. However, as established by the JRC, there are no analytical tools available that distinguish NGT crops from conventional crops. Legislation which requires specific action e.g. labelling for certain defined products, but offers no analytical tools to permit an operator to determine conformity with the legislation is by definition inadequate.

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

- Yes
- No
- Not applicable

* **8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?**

- Yes
- No
- Not applicable

* Please explain why not

In answer to question 7, see answer to question 4.

* 8 bis. What challenges have you encountered?

In the absence of commercialised NGT rice, there are no particular measures that could be taken relevant to the labelling requirements of the GMO legislation.

* **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

The rice industry is not directly involved in rice research, but would clearly indirectly benefit from any production or quality improvements associated with NGTs.

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

- Yes
 No
 Not applicable

* Please specify

It is clear that extensive research is ongoing, particularly in China, and with the current focus of applying CRISPR/Cas9 to rice. Rice is reported to be especially amenable to functional genomic studies “due to its small genome size, availability of genetic resources, high transformation efficiency, and greater genomic synteny with other cereals” (Mishra et al, 2018).

* **12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling on mutagenesis?**

Court of Justice ruling: Case C-528/16 <http://curia.europa.eu/juris/documents.jsf?num=C-528/16>

- Yes
 No
 Not applicable

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

- Yes
 No
 Not applicable

* Please provide concrete examples/data

See answer to question 16

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

- Yes
 No
 Not applicable

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

- Yes
 No
 Not applicable

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

The reported potential benefits of this technology for rice include the following (see e.g. reviews by Fiaz et al., 2019, Mishra et al., 2018, Romero and Gatica-Arias, 2019):

- yield improvement (by increasing the number of panicles per plant, number of grains per panicle and grain weight).
- quality improvement by modifying the enzymes that lead to grain deterioration and removing undesirable qualities such as chalky grains.
- cooking improvement by increasing the amylase content and level of resistant starch with potential implications for reducing the risk of certain diseases.
- reducing contamination by removing metal transporter genes and thereby reducing e.g. levels of cadmium.
- increasing resistance to biotic agents including bacteria, from fungi, viruses, and insects that lead to rice yield loss and poor product quality.
- creating tolerance to abiotic stress, creating herbicide tolerant rice varieties.

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

- Yes
 No

* Please explain

See scientific reviews referred to in question 16

*

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

The benefits noted in answer to question 16, have obvious benefits for society, provided their potential can be fulfilled in practice. In this respect, the literature notes potential challenges in applying genome editing in rice, not least ensuring that the types of improvements reported in confined environments apply to rice when grown in normal environmental conditions (see Mishra et al., 2018). Nevertheless, given the EU's New Green Deal, it would seem to be a crucial moment for the EU to construct a legal framework that permits NGTs producing safe food to fulfil their maximum potential in contributing to current climate and environmental ambitions. Increasing limitations on access to traditional tools used by rice producers, such as plant protection products, necessitates the development of adequate alternative options.

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

Please refer to the scientific articles cited.

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

- Yes
- No

* Please explain

Please refer to the scientific articles cited.

*** 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

If NGT-products were to provide specific agricultural solutions e.g. facilitating the production of organic rice or particular varieties, this would potentially help SMEs to compete in niche markets.

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

- Yes
- No

* Please explain why not

Not immediately relevant to the rice industry

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

NGT rice as such does not necessarily raise concerns for the sector. The EU regulatory framework, however, could potentially create considerable challenges for members.

FERM members are rice millers and processors who source rice both from EU rice-producing countries and third country suppliers.

An extremely important, but under-discussed, consideration in the legal framework for NGTs is its impact on the competitive relationship between producers within the EU and outside the EU. If rice varieties produced with NGTs meet the expectations of researchers, these developments could have a fundamental impact on the world rice market and the competitive position of EU rice producers within that market. On the one hand, new varieties are being developed to reduce susceptibility to biotic and abiotic stresses, such as drought, salinity, extreme temperatures and flooding. On the other hand, researchers also aim to improve yields and report on the potential of NGTs to increase yields by augmenting the number of panicles per plant, and the number and weight of grains per panicle. It is not yet known what these combined lines of research could have on rice production or how quickly farmers could adopt any emerging varieties. Nor is it known to what extent any gains in rice production will be offset by potentially more difficult rice growing conditions resulting from climate change. Nevertheless, it is worth bearing in mind that only a small portion of the world's rice production (approximately 7%) is traded on international markets and that world rice prices are therefore particularly volatile and susceptible to shifts in production. For example, a 13% rice yield loss would be expected to lead to a rice price increase of 32% to 37% (Romero and Gatica-Arias, 2019). The rice yield gains that some forecast for varieties produced with NGTs could lead to a comparable decrease in world market prices.

EU rice producers are already today currently facing severe competition from developing countries such as Cambodia and Myanmar due to low rice prices. The current competitive position of EU rice producers is therefore particularly vulnerable to further drops in world market prices. Were, for example, Asian rice-producing countries to extensively adopt NGTs and EU producers not able to do so, there would certainly be concerns as to how to maintain the latter's competitive position. In this respect, the current situation established by today's legislative framework as interpreted by the European Court of Justice – probable de facto non-authorisation in the EU of NGT products due to association with GMOs, but no method available to distinguish in NGT varieties in imported produce – creates the worst possible scenario for European rice sector.

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

- Yes

No

* Please explain

The NGT product-related dimension of these concerns are specific to NGT-products

* **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

In the scientific reviews of rice related NGTs, no evidence is given for environmental, plant health concerns associated with NGTs.

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

Yes

No

* Please explain why not

If NGT products are permitted on the European market, there would not appear to be specific challenges for SMEs.

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

Yes

No

* Please explain why not

This question does not appear relevant to the rice industry.

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**

The rice industry is not aware of any evidence of safety concerns associated with these techniques.

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

- Yes
- No

* Please explain why not

See answer to 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 rice industry does not have a collective view on ethical aspects related to NGTs.

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

- Yes
- No

* Please explain why not

The rice industry does not have a collective view on ethical aspects related to NGTs.

Please upload any supporting documentation for this section here

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G - Consumers' right for information/freedom of choice

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

As noted above, the JRC has indicated that no analytical methods are available that can identify NGTs. Current legislation is therefore inadequate for the purposes of reliably labelling NGTs. Analytical issues aside, in the absence of any established difference between NGT-products and traditional rice, it is not clear what information any label would be providing and therefore how this would enhance a consumer's freedom of choice.

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

H - Final question

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

- Yes
 No

Please provide your comments here

Please find below a list of the references cited above:

Fiaz, S.et al., 'Applications of theCRISPR/Cas9 System for Rice Grain Quality Improvement: Perspectives and Opportunities' (2019) 20 International Journal of Molecular Sciences 888.

Kohl C. et al., 'Übersicht über Nutz- und Zierpflanzen, die mittels Gentechnik und neuer molekularbiologischer Techniken für die Bereiche Ernährung, Landwirtschaft, Gartenbau, Arzneimittelherstellung und -forschung entwickelt werden' (Julius Kühn-Institut, 2018)

Mishra R.et al., 'Genome Editing in Rice: Recent Advances, Challenges, and Future Implications' (2018) 9 Frontiers in Plant Science 1.

Romero, F.M. and Gatica-Arias, A., 'CRISPR/Cas9: Development and Application in Rice Breeding' (2019) 26 Rice Science 265.

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Contact

SANTE-NGT-STUDY@ec.europa.eu