

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 / 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 .

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

[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

EUROPEAN FLOUR MILLERS asbl is the association representing the European flour milling industry. We are registered at the Transparency Register under 81318861355-20

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

The European Flour Millers' association is representing the European wheat, rye and oat milling industry both at EU & international levels. Members are the representative national associations from 28 European countries. In representing over 90% of the milling capacity in Europe, it is able to reflect credibly and authoritatively the interests of the industry.

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

All members have contributed to this questionnaire

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

Answers refer to the use of NGTs in plants

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

If NGTs for wheat were to become available - with seed varieties being tested according to the European registration, certification and inspection rules and protected by the Community plant variety rights as it is already the case for current seeds - European flour millers would potentially source them, as long as they improve sustainability along the flour supply chain and bring practical advantages for the European consumers to enjoy public acceptance. For example by providing breeders with innovative solutions such as:

- Disease resistance, thus reducing the need for pesticides;
- Resistance to increased heat stress events;
- Improve drought tolerance;
- Adapt other negative stresses impacting cereals under climate change;
- Improved nutritional quality;
- Reduced allergenicity (the potential to cause an allergic reaction)

* 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

European flour millers source conventional crops – mostly bread-making wheat. To our knowledge, there are no authorised NGT wheat or NGT wheat products on the market. Moreover, as established by the Joint Research Centre (JRC), there are no analytical tools available that distinguish NGT crops from conventional crops.

* 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

As food operators, we do not develop NGTs and mill agricultural raw commodities – and mostly bread-making common wheat – all of which are assured in our European countries.

Typically, we are made aware that international researches are going on regarding common wheat. For ex. we were recently reported - in the AAAS Science review - about a new tool discovered by the Agricultural Research Service (ARS) of the US Department of Agriculture (USDA) to fight Fusarium Head Blight (FHB) in wheat and published in the journal Science. This is research that identifies a potential source of genetic resistance to FHB - the report made by the press seemed a little confused between whether it is resistance to mycotoxin formation or FHB presence. The technique by which this is introduced or switched on in commercial cultivars may or may not be a NGT process, although that would be a matter for the breeding companies.

* **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

* **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

Millers source wheat and there are no authorized NGT wheat. If it was the case - as the question seems to imply it – we should be therefore asking how producers of NGT crops and those intentionally cultivating them intend to convey relevant information to millers downstream in the food chain.

* What best practices can you share?

None

* 5 bis. What challenges have you encountered?

None

* **6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?**

- Yes
- No
- Not applicable

* **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

* **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

As food business operators, flour millers use traceability as risk-management tool which allows them or authorities to withdraw or recall products which have been identified as unsafe.
Today, the flour miller source and blend different qualities of traced wheat. There has been no commercialisation of non-conventional or GM wheat anywhere in the world. Hence, all wheat flour milled in Europe is of conventional origin.

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

* 8 bis. What challenges have you encountered?

None

*** 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 European flour milling industry is not directly involved in wheat research.

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

- Yes
- No
- Not applicable

*** 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

If NGTs for wheat were to become available and registered/certified, European flour millers would potentially source them, as long as they improve sustainability along the flour supply chain and bring practical advantages for the European consumers to enjoy public acceptance.

For example by providing breeders with innovative solutions such as:

- Disease resistance, thus reducing the need for pesticides;
- Resistance to increased heat stress events;
- Improve drought tolerance;
- Adapt other negative stresses impacting cereals under climate change;
- Improved nutritional quality;
- Reduced allergenicity (the potential to cause an allergic reaction)

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

- Yes
 No
 Not applicable

* Please provide concrete examples/data

European flour millers would have to be convinced of their public acceptability and practical potential for the European citizens and consumers before using them. If NGTs and NGT products are officially assimilated to GMOs, they will de facto enjoy distrust from the public and will not .

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

- Yes
 No
 Not applicable

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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 ambitions set out in the European Green Deal and the forthcoming Farm-to-Fork strategy on sustainable and more resilient food systems demonstrate the need to reduce the environmental impact of the agricultural supply chain. As food business operators we also wish to play a key role in this transition.

For example by providing breeders with innovative solutions such as:

- Disease resistance, thus reducing the need for pesticides;
- Resistance to increased heat stress events;
- Improve drought tolerance;
- Adapt other negative stresses impacting cereals under climate change;
- Improved nutritional quality;
- Reduced allergenicity (the potential to cause an allergic reaction)

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

- Yes
 No

* Please explain

We guess so, as these innovations are expected and not yet available

* **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

For example by providing breeders with innovative solutions such as:

- Disease resistance, thus reducing the need for pesticides;
- Resistance to increased heat stress events;
- Improve drought tolerance;
- Adapt other negative stresses impacting cereals under climate change;
- Improved nutritional quality;
- Reduced allergenicity (the potential to cause an allergic reaction)

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

If there is a transparent certification process and therefore public acceptance

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

- Yes
 No

* Please explain

Again, we guess so as these innovations are expected and not yet available

*** 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 European flour millers are small and medium-sized companies. We see the access to be relatively inexpensive, once they are made available to European farmers through certified seeds that further become crop varieties available on the market.

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

- Yes
 No

* Please describe and provide concrete examples/data

We do represent the flour milling sector and not seed manufacturers

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 explain why not

As for products from traditional breeding, NGTs/NGT products will have to go through extensive analyses by the breeders, before being released and will have to follow the regulatory process applying to current existing varieties. This will have to be explained publicly in order to be accepted by the public. NGT wheat as such does not necessarily raise concerns for the milling sector. The EU regulatory framework, however, should not create additional challenges for the millers, as EU flour millers are already today currently facing severe competition from countries in the neighbourhood such as Turkey due to low flour prices.

*** 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

This is a question to relevant public institutions

*** 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

This is a question to breeding companies

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

Yes

No

* Please explain why not

Today, we are told that most patents on NGTs and NGT products are filed by entities located in China and the United States. If this situation were to persist in the future, due to continued severe regulatory restrictions on the use of NGTs in the EU, it will put the European flour milling sector at a long-term competitive disadvantage.

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**

Our view is that they must be safe. But it is not up to the flour milling sector to answer this question.

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

Yes

No

* Please explain why not

Again, it is not up to the flour milling sector to answer this question.

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 flour milling sector 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 flour milling sector does not have a collective view on ethical aspects related to NGTs.

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**

As mentioned previously, the Joint Research Center (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. Maintaining the existing regulatory framework could create a legally untenable situation for operators and would be of questionable value to consumers.

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

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Contact

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