

# 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

Euro Coop - European Community of Consumer Co-operatives. Transparency register number: 3819438251-87.

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

Retail, in particular food retail.

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

Coop Italy and Coop Norway.

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)

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

- Yes
- No
- Not applicable

\* Please explain why not

Coop Italy has for example decided not to use GMOs in the production of its own brand products as well as in the feed for animals bound to become fresh beef, poultry and pig meat. Similar guarantees are present in the supply chains of fresh and microfiltered milk, eggs and many of the COOP brand cured meats.

\* 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

Coop Italy has for example implemented measures to keep processing structures separate in order to prevent contamination as well as carries out supply chain controls to check that raw materials are not contaminated. All this is coupled with third party audits and annual laboratory checks on products and feed.

\* 2 bis. Have you encountered any challenges?

- Yes
- No

\* Please provide details

A higher level of attention from stakeholders in the own-brand supply chain.

\* 3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?

- Yes
- No
- Not applicable

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

- Yes
- No
- Not applicable

\* 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

For Coop Italy, supply chain control and traceability using internal and external technical staff. The commitment to guarantee these results has an overall estimated cost of around an average of 10 million euros per year.

\* What best practices can you share?

For Coop Italy, the experience and knowledge of supply chain controls.

\* 5 bis. What challenges have you encountered?

A higher level of attention from stakeholders in the own-brand supply chain.

\* 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

\* Please describe the traceability strategy, including details on the required financial, human resources and technical expertise

For Coop Italy, documental traceability with mass-balance, block-chain, deeper cost analysis, specific human resourcing and technical requirements for the different supply chains.

**\* 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**

For Coop Italy, documental traceability with mass-balance, block-chain, deeper cost analysis, specific human resourcing and technical requirements for the different supply chains.

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

For Coop Italy, the experience and knowledge of supply chain controls.

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

A higher level of attention from stakeholders in the own-brand supply chain.

**\* 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**

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**\* 10. Are your members carrying out NGT-related research in your sector?**

- Yes
- No
- Not applicable

**\* 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

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

- Yes  
 No  
 Not applicable

\* Please explain why not

At the moment there is not a sufficient level of knowledge about possible misapplications of NGTs and related effects.

**\* 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**

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**\* 16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?**

- Yes  
 No

\* Please explain why not

At the moment there is not a sufficient level of knowledge about possible misapplications and related effects.

\*

**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

We are not opposed to NGTs/NGT-products in principle but it is extremely important to abide to the precautionary principle and count on scientifically sound answers when it comes to their safety both from a consumer and environment protection standpoint. For example, their application shall not imply an increased use in chemicals/pesticides.

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

We are not opposed to NGTs/NGT-products in principle but it is extremely important to abide to the precautionary principle and count on scientifically sound answers when it comes to their safety both from a consumer and environment protection standpoint. For example, their application shall not imply an increased use in chemicals/pesticides.

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

- Yes
- No

\* Please explain why not

The same applies to biotech in general.

**\* 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

At the moment there is not a sufficient level of knowledge about possible misapplications and related effects.

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

- Yes
- No

\* Please explain why not

The use of patenting in this particular field could be risky from the point of view of potential negative ethical repercussions. For example, patents/property rights to NGTs must not be obtained at the expense of smallholders'/indigenous people's rights to own/local seeds/plants.

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

Main concerns relate to safety problems for consumers and negative implications for the environment.

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

- Yes  
 No

\* Please explain why not

The same applies to biotech in general.

**\* 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

Agricultural-derived NGT products could pose serious economic challenges to conventional and organic agricultural products.

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

We are not opposed to NGTs/NGT-products in principle but it is extremely important to abide to the precautionary principle and count on scientifically sound answers when it comes to their safety both from a consumer and environment protection standpoint. For example, their application shall not imply an increased use in chemicals/pesticides.

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

- Yes  
 No

\* Please explain why not

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The same applies to biotech in general.

**\* 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

Consumer distrusts, as showed by many surveys.

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

- Yes  
 No

\* Please describe and provide concrete examples/data

The use of patenting in this particular field could be risky from the point of view of potential negative ethical repercussions. For example, patents/property rights to NGTs must not be obtained at the expense of smallholders'/indigenous people's rights to own/local seeds/plants.

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The maximum file size is 1 MB

## 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**

The controls on safety at the moment are not adequate to understand the risk level.

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

- Yes  
 No

\* Please explain

Not enough long-term safety checks are carried out and the controls (on products, people and environment) must be performed by independent bodies. Besides, the "burden of proof"/documentation requirement reg. safety (herein health, environment, ethics, etc) must be born by the NGTs operators and not by the other stakeholders of the agri-food supply chain.

*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

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**\* 26. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply**

The ethical aspects associated with NGTs are complex and range from the monopoly of big biotechnology companies on seeds, to the threat to biodiversity. For example, patents/property rights to NGTs must not be obtained at the expenses of smallholders'/indigenous people's rights to own/local seeds/plants.

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

- Yes  
 No

**\* Please explain**

The ethical aspects associated with NGTs are complex and range from the monopoly of big biotechnology companies on seeds, to the threat to biodiversity. For example, patents/property rights to NGTs must not be obtained at the expenses of smallholders'/indigenous people's rights to own/local seeds/plants.

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## 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**

Consumer's right to know is critical and a complete/correct labelling and traceability is essential. Euro Coop members have always called for transparency coupled with scientifically-based information and education campaigns. Consumers have the right to receive clear and correct information as well as to count on a fact-based scientific labelling.

*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

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

- Yes  
 No

*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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