



EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

SUMMARY REPORT

Ad hoc Stakeholder meeting on new genomic techniques

Brussels, 10 February 2020

Chair: DG SANTE/E3

COM: JRC (partly), TRADE (partly), GROW (partly)

Stakeholders present: AAC, AMFEP, ARGE/VLOG, AVEC, BEUC, CEEV, CEFIC/EFG, CEFS, CEMA, CEO, CEPM, CIBE, COCERAL COCEGA, COPA, EASAC, ECA, ECVC, EFB, EFFAB, EFM, EFPIA, ENSSER, EPSO, EU SAGE, Eurocommerce, Eurocoop, Eurogroup for Animals, Europabio, EUROPATAT, Euroseeds, FDE, FEDIOL, FEFAC, FEFANA, FERM, FIAN International, FoEE, FVE, Greenpeace Europe, IBMA, IFOAM, NATURE, Plant ETP, Starch Europe, Testbiotech, UECEBV, UF, UNISTOCK Europe

The Commission welcomed the participants of the ad hoc stakeholder meeting and introduced the request of the Council to the Commission to submit a study on the status of new genomic techniques (NGT) under Union law (Council Decision (EU) 2019/1904).

The Commission informed the meeting of the intended follow-up to the Council Decision as follows:

- For the purpose of the Commission study, NGTs are defined as techniques that are capable of altering the genetic material of an organism and that have emerged or have been developed since 2001. The study will cover all new genomic techniques and their applications in plants, animals, micro-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and research.
- The study will address the implementation and enforcement of the GMO legislation with regard to NGTs in light of the European Court of Justice ruling.
- The study will take into account the work of the European Union Reference Laboratory, together with the European Network of GMO Laboratories, on the detection of products obtained by new mutagenesis techniques. It will include an overview of the risk assessment of plants developed through NGTs, which is to be provided by the European Food Safety Authority, and an overview on market applications and state of art on new techniques to be provided by the Joint Research Centre. The Commission also mentioned that the on-going work of the European Group on Ethics on gene-editing will be taken into account.

- Information on the study and its progress can be found on a dedicated webpage (https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en).

The Commission further clarified that:

- The Commission organises two stakeholder consultations: one for the Member States competent authorities and one for the targeted EU-level stakeholders. Information obtained by these consultations will feed into the study. The EU-level organisations interested or likely to be impacted by NGTs were invited to participate.
- Some stakeholders were not able to be present in the meeting, but they will participate to the consultation.
- EU-level organisations interested in providing contributions are welcome to join the consultation process and should contact the Commission (via SANTE-NGT-STUDY@ec.europa.eu) before the end of February.
- Stakeholders participating to the consultation can submit only one reply to the questionnaire per organisation.
- The replies to the questionnaire must be received by 30 April 2020.
- All stakeholder contributions will be made available when the study is published.

The draft questionnaire was discussed in detail and amended during the meeting to address the comments raised by stakeholders. The finalised questionnaire (as pdf-document) will be sent by email to the stakeholders.

The minutes of this meeting and the questionnaire will be published on the Commission's website to inform the general public.

**Stakeholder consultation on new genomic techniques to contribute to a
Commission study requested by the Council**

Questionnaire

*Discussed and finalised
In the Ad-hoc Stakeholder meeting
on 10 February 2020*

Background

The Council has requested¹ 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/EC).

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 after 2001.

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 2001².

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 interests of a natural or legal person. Personal data, if any, will be protected pursuant to Regulation (EU) 2018/1725³.

Stakeholders will be invited to reply to the questionnaire via EUsurvey by 15 May 2020 (close of business).

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

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).
- Please mention the sectors of activity/fields of interest of your association.
- 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.

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
 - If yes, please provide details.
 - If no, please explain why not.
2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products? *Yes/no/not applicable*
 - If yes, please provide details.
 - If no, please explain why not.
 - If yes or no, have you encountered any challenges?
 - If yes, please provide details
3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products? *Yes/no/not applicable*
 - If yes, please provide details.
4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products? *Yes/no/not applicable*
 - If yes, please provide details.
 - If yes or no, are you aware of any challenges encountered?
 - If yes, please provide details
5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs? *Yes/no/not applicable*
 - If yes, please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise.
 - If yes, what best practices can you share?
 - If no, please explain why not.
 - If yes or no, what challenges have you encountered?

Please also see question 8 specifically on labelling

6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation? *Yes/no/not applicable*
 - If yes, please describe what type of support and what best practices you can share?
 - If not, what challenges have you encountered?
7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products? *Yes/no/not applicable*
 - If yes, please describe the traceability strategy, including details on the required financial, human resources and technical expertise.
 - If no, do you have suggestions on possible traceability strategies and/or methods? *Yes/no*
 - If yes, please describe.
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*
 - If yes, please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise.
 - If yes, what best practices can you share?
 - If no, please explain why not.
 - If yes or no, what challenges have you encountered?
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*
 - If yes, please describe for the:
 - Agri-food sector;
 - Industrial sector;
 - Medicinal sector.

Information on research on NGTs/NGT-products:

10. Are your members carrying out NGT-related research in your sector? *Yes/no/not applicable*
 - If yes, please specify including subject, type of research, resources allocated, research location.
 - If no, please explain why not.
11. Are you aware of other NGT-related research in your sector? *Yes/no/not applicable*
 - If yes, please specify.
12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling³ on mutagenesis? *Yes/no/not applicable*

³ Case C-528/16 <http://curia.europa.eu/juris/documents.jsf?num=C-528/16>

- If yes, please describe.
 - If no, please explain why not.
13. Could NGT-related research bring benefits/opportunities to your sector/field of interest? *Yes/no/not applicable*
- If yes, please provide concrete examples/data.
 - If no, please explain why not.
14. Is NGT- related research facing challenges in your sector/field of interest? *Yes/no/not applicable*
- If yes, please provide concrete examples/data.
 - If no, please explain why not.
15. Have you identified any NGT-related research needs/gaps? *Yes/no/not applicable*
- If yes, please specify which needs/gaps, explain the reasoning and how the needs/gaps could be addressed.

Information on potential benefits and opportunities of NGTs/NGT-products:

16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest? *Yes/no*
- If yes, please describe and provide concrete examples/data.
 - If yes, are these benefits/opportunities specific to NGTs/NGT-products?
 - If yes, please explain.
 - If no, please explain why not.
 - If no, please explain why not.
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*
- If yes, please describe and provide concrete examples/data.
 - If yes, under which conditions do you consider this would be the case?
 - If yes, are these benefits/opportunities specific to NGTs/NGT-products?
 - If yes, please explain.
 - If no, please explain why not.
 - If no, please explain why not.
18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products? *Yes/no*
- If yes, please describe and provide concrete examples/data.
 - If no, please explain why not.
19. Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products? *Yes/no*
- If yes, please describe and provide concrete examples/data.
 - If no, please explain why not.

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

- If yes, please describe and provide concrete examples/data.
- If yes, are these challenges/concerns specific to NGTs/NGT-products?
 - If yes, please explain.
 - If no, please explain why not.
- If no, please explain why not.

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*

- If yes, please describe and provide concrete examples/data.
- If yes, under which conditions do you consider this would be the case?
- If yes, are these challenges/concerns specific to NGTs/NGT-products?
 - If yes, please explain.
 - If no, please explain why not.
- If no, please explain why not.

22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs/NGT-products? *Yes/no*

- If yes, please describe and provide concrete examples/data.
- If no, please explain why not.

23. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products? *Yes/no*

- If yes, please describe and provide concrete examples/data.
- If no, please explain why not.

Safety of NGTs/NGT-products:

24. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply.

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

Yes/no

- If yes, please explain.
- If no, please explain why not.

Ethical aspects of NGTs/NGT-products:

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

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

Yes/no

- If yes, please explain.
- If no, please explain why not.

Consumers' right for information/freedom of choice:

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

Final question

29. Do you have other comments you would like to make? *Yes/no*

- If yes, please provide your comments here.