Questionnaire on new genomic techniques to contribute to the study requested by the Council

endorsed in the Joint Working Group of GMO competent authorities on new genomic techniques
on 15 January 2020

Introduction

With this questionnaire the Commission is collecting contributions from Member States competent authorities to respond to the Council's request[1] for "*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). The scope of the study goes beyond new mutagenesis techniques, as there are other new techniques, for which the Council seeks clarification. Therefore, the study covers all new genomic techniques, which have been developed after 2001.

For the purpose of the study, the following definition for **new genomic techniques** (NGTs) is used: techniques, which are capable to alter 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-organims and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research. GMO competent authorities are invited to seek input from other competent authorities when appropriate.

The questionnaire is meant to provide information primarily, but not exclusively, at national level. 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 a specific NGT, please indicate this in the reply. With regard to agri-food applications, replies may include considerations on specific sectors, such as the organic sector.

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) 2018/1725[3].

[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.

Member States have until 30 April 2020 (close of business) to submit the questionnaire via EUsurvey.

[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

Implementation and enforcement of the GMO legislation with regard to new genomic techniques:

1. Have you been consulted by companies/organisations/research institutes for regulatory advice or another issue on products developed or to be developed by NGTs ? *Yes/no*
    - If yes, please provide details on the request.
2. Have you taken specific measures (other than inspection) related to the application of the GMO legislation to NGT-products? *Yes/no*
    - If yes, please describe the measures and, if possible, their effectiveness.
    - If yes, what best practices can you share?
    - If no, please explain why not.
    - If yes or no, have you encountered any challenges or limitations, including administrative burden or costs? *Yes/no*
        - If yes, please describe.
        - If yes, how could this challenges or limitations be overcome?
        - If no, please explain why not.
3. Have you adapted your inspection practices to cover all NGT-products and to ensure the enforcement of traceability requirements? *Yes/no*
    - If yes, please describe these practices (e.g. adaptation of multiannual control plans) and, if possible, their effectiveness (including of physical checks).
    - If yes, what best practices can you share?
    - If yes, have the adapted inspection practices created additional requirements/burden for operators and/or public authorities? *Yes/no*
        - If yes, please provide concrete examples/data.
    - If no, please explain why not.
    - If yes or no, have you encountered challenges or limitations, including administrative burden or costs? *Yes/no*
        - If yes, please describe.
        - If yes, how could these challenges or limitations be overcome?
        - If no, please explain why not.
4. Do you have experience or information on traceability strategies, which could be used for tracing NGT-products? *Yes/no*
    - If yes, please describe the traceability strategy, including details on the required financial, human resources and technical expertise required.
    - If yes, what best practices can you share?
    - If yes or no, have you encountered challenges or limitations, including administrative burden or costs? *Yes/no*
        - If yes, please describe.
        - If yes, how could these challenges or limitations be overcome?

- If no, please explain why not.

5. What other experience can you share on the application of the GMO legislation, including experimental releases (such as field trials and clinical trials), concerning NGT-products in
    - agri-food sector;
    - industrial sector;
    - medicinal sector.
6. Have plant varieties obtained by NGTs been registered in national catalogues? *Yes/no*
    - If yes, please specify.
7. Do you require specific information in national catalogue when registering plant varieties obtained by NGTs? *Yes/no*
    - If yes, please specify.

Information on research and innovation:

8. Have you supported with national funding programmes NGT-related research projects/programs (ongoing or finalised in the last 5 years), including on identification or traceability? *Yes/no*
    - If yes, please provide an overview of the project/program including title of project, a brief summary with scope and objectives, the amount of national funding received and possibly specify if the receiving entity is public or private.
    - If yes or no, please highlight the potential challenges encountered when supporting/funding NGT-related research and any consequences from these challenges.
9. How do you see NGT-related research evolving?
10. Have you identified any NGT-related research needs from private or public entities? *Yes/no*
    - If yes, please specify which needs and how they could be addressed.
11. Could NGT-related research bring opportunities/benefits to science, to society and to the agri-food, medicinal or industrial sector? *Yes/no*
    - If yes, please provide concrete examples/data.
    - If no, please explain why not.
12. Could NGT-related research bring challenges/concerns to science, to society and to the agri-food, medicinal or industrial sector? *Yes/no*
    - If yes, please provide concrete examples/data.
    - If no, please explain why not.

Information on public dialogues and national surveys:

13. Have you or other institutions/bodies/entities organised national dialogues concerning NGTs? *Yes/no*

- If yes, please describe briefly the content, methodology and conclusions.

14. Have you or other institutions/bodies/entities organised national surveys, which assessed public opinion on NGTs? *Yes/no*
    - If yes, please describe briefly the content, methodology and conclusions.

Information on ethical aspects:

15. Have any national bodies or expert groups discussed or issued opinion on the ethical aspects of NGTs? *Yes/no*
    - If yes, please describe briefly the content, methodology and conclusions.

Information on potential opportunities and benefits from the use of NGTs and NGT-products:

16. Could the use of NGTs and NGT-products bring opportunities/benefits to the agri-food, medicinal or industrial sector? *Yes/no*
    - If yes, please provide concrete examples/data.
    - If no, please explain why not.
17. Could the use of NGTs and NGT-products bring opportunities/benefits to society in general, such as for the environment, human, animal and plant health, consumers, animal welfare as well as social and economic benefits, in the short, medium and long term? *Yes/no*
    - If yes, please provide concrete examples/data.
    - If yes, under which conditions do you consider this would be the case?
    - If no, please explain why not.
18. Do you see particular opportunities for SMEs on the market access to NGTs? *Yes/no*
    - If yes, please explain under which conditions
    - If no, please explain why not.
19. Do you see benefits/opportunities in patenting or accessing patented NGTs or 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 of NGT products:

20. Could the use of NGTs and NGT-products raise challenges/concerns for the agri-food, medicinal or industrial sector? *Yes/no*
    - If yes, please provide concrete examples/data.
    - If no, please explain why not.
21. Could the use of NGTs and 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, in the short, medium and long term? *Yes/no*
    - If yes, please provide concrete examples/data.
    - If yes, under which conditions do you consider this would be the case?

- If no, please explain why not.

22. Do you see particular challenges for SMEs on market access to NGTs? *Yes/no*
    - If yes, please explain under which conditions.
    - If no, please explain why not.
23. Do you see challenges/concerns in patenting or accessing patented NGTs or NGT-products? *Yes/no*
    - If yes, please describe and provide concrete examples/data.
    - If no, please explain why.

Final question

24. Do you have other comments you would like to make? *Yes/no*
    - If yes, please provide your comments here.