EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

SUMMARY REPORT

JOINT WORKING GROUP

of the Standing Committee on Plants, Animals, Food and Feed
Section Genetically Modified Food and Feed,
Regulatory Committee under Directive 2001/18/EC and
Regulatory Committee under Directive 2009/41/EC

on new genomic techniques

Brussels, 15 January 2020

Chair: DG SANTE/E3
MS present: BE, BG, CZ, DK, DE, EE, IE, EL, ES, FR, HR, IT, LV, LT, LU, HU, NL, AT, PL, PT, RO, SK, SI, FI, SE, UK
Others: Mission of NO, EFSA (partly, via videolink), DG RTD (partly)

The Commission welcomed the participants of the joint working group of GMO competent authorities and introduced the request of the Council to submit a study on the status of new genomic techniques (NGT) under Union law, and, if appropriate, a proposal or other measures required as a follow-up to the study (Council Decision (EU) 2019/1904).

Two Member States (MS) presented national initiatives regarding communication with stakeholders on NGTs. The presentations are attached. MS will keep the Commission updated regarding similar on-going and future national initiatives.

The European Food Safety Authority (EFSA) updated the MS on their ongoing work to prepare scientific opinions on synthetic biology, gene drive engineered organisms and plants developed through type 1 and 2 site-directed nucleases (SDN1 and 2) and oligonucleotide directed mutagenesis (ODM). EFSA explained that the relevant EFSA panels had recently carried out a first reading of the draft opinions. Public consultation will be launched in spring 2020 and lasts 6-8 weeks. Publication of final outputs will be by end of 2020 for the synthetic biology and gene drive opinions, and by end of October 2020 for the SDN1 and 2/ODM opinion.

The Commission updated the MS on the work of the European Union Reference Laboratory for GM Food and Feed and of the European Network of GMO Laboratories (ENGL) on detection possibilities. The annual ENGL Plenary Meeting (October 2019) supported the conclusions of the ENGL report on the detection of food and feed plant products obtained by new mutagenesis techniques. Follow-up work includes the verification of the applicability of

the current “Method Performance Criteria” for detection and quantification methods for genome-edited products. In addition, The ENGL launched work on the detection of genetically modified microorganisms, including those obtained by new mutagenesis techniques.

The Commission updated the MS on the work of the European Group on Ethics in Science and New Technologies (EGE) on gene editing. Report expected by April/May 2020.

The follow-up of the Council Decision was discussed as follows:

- The Commission recalled that the Council Decision refers to NGTs, which include new mutagenesis techniques. The Commission also clarified that the study includes genome editing techniques, leading to mutagenesis, cisgenesis, intragenesis or transgenesis. It also includes epigenetic techniques such as RNA directed DNA methylation. The study also concerns plants, animals, microorganisms and derived products obtained by NGTs for agri-food, medicinal and industrial applications.
- The study will notably address the implementation and enforcement of the GMO legislation with regard to NGTs in light of the European Court of Justice ruling [i.e. Directive 2001/18/EC, Regulation (EC) 1829/2003 and Directive 2009/41/EC]. The study will also address practical questions, which have consequences for the national competent authorities, the Union’s industry, research and beyond. To this effect, the Commission clarified that organisms from new mutagenesis techniques under contained uses are subject to the requirements of Directive 2009/41/EC.

The Commission informed the MS of the targeted consultation of MS via a dedicated EUSurvey questionnaire and clarified the following:

- Every MS should submit only one reply to the questionnaire.
- Every MS should inform the Commission who is the contact point for the questionnaire by end of January (via SANTE-NGT-STUDY@ec.europa.eu)
- The EUSurvey will be open from February 3rd; MS committed to reply to the questionnaire by April 15th.

MS and the Commission discussed and endorsed the attached finalised questionnaire.

The Commission informed the MS that, it is carrying out in parallel a targeted consultation of selected EU-level stakeholder organisations.

The Commission informed the MS that, to support the Commission study, EFSA would provide an overview on risk assessment of plants developed through NGTs, based on its previous scientific opinions as well as risk assessment and opinions published by competent authorities and national institutions. MS were invited to provide to the Commission any information regarding plants and other organisms without delay.

The Commission informed the MS that it has requested the Joint Research Centre to provide an overview on the state of the art, market applications, as well as future scientific and technological developments of NGTs.

The discussions at technical level will be pursued at the next joint working group planned for the first half of June 2020.

The Commission informed the MS that a webpage on the study was created, where all relevant information is available (https://ec.europa.eu/food/plant/gmo/modern_biotech_en).

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.