EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Biotechnology

Brussels,
SANTE/F3/[redacted](2019) 8513686

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

**Subject:** **Invitation to a Joint Working Group of the Standing Committee on Plants, Animals, Food and Feed Section Genetically Modified Food and Feed, Regulatory Committee for Directive 2001/18/EC and Regulatory Committee for Directive 2009/41/EC on new genomic techniques**

I have the pleasure to invite you to a Joint Working Group meeting on new genomic techniques, which will be organised by the European Commission in Brussels on **Wednesday 15 January**.

The discussion will be held in the Albert Borschette building, meeting room **CCAB-2D** Rue Froissart 36, 1040 Brussels, starting at 10:00.

Please find enclosed the draft agenda. Interpretation will be provided in and to FR-DE-EN-IT-ES-PL.

The European Commission will, in accordance with its rules, bear the **travel expenses** of **one expert of each Committee** per Member State. Experts will be reimbursed by submitting their travel documents electronically (**within 30 days** after the meeting) via the AGM system. For further information, please see https://ec.europa.eu/tools/agm/en

The **registration of participants via the AGM system is mandatory**. Correspondents are invited to register the participants by clicking on the link provided in the AGM email. **Deadline** for registration: **10 January 2020**. E-passes will be issued the day before the meeting.

Participants are requested to present this invitation and the e-pass received by email at the reception desk of the building.

[redacted]

Enclosures: Draft agenda
Draft questionnaire on new genomic techniques

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: B232 4/108 - Tel. direct line +32 229-[redacted] - Fax +32 229-[redacted]

EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

# JOINT WORKING GROUP

*of the Standing Committee on Plants, Animals, Food and Feed*
*Section Genetically Modified Food and Feed and Environmental Risk,*
*Regulatory Committee under Directive 2001/18/EC and*
*Regulatory Committee under Directive 2009/41/EC*
**on new genomic techniques**

**WEDNESDAY, 15 JANUARY, 10:00**

## Draft AGENDA

1. Approval of the draft Agenda
2. Updates from Member States on on-going national initiatives
    a. Presentation by DK
    b. Presentation by DE
3. Update from the Commission
    a. on the mandates to the European Food Safety Authority regarding synthetic biology, gene drives, SDN-1, SDN-2 and ODM
    b. on the work of the ENGL-EURL work on detection possibilities
    c. on the work of the European Group on Ethics in Science and New Technologies (EGE) on gene editing
4. Comments from the Member States on the Draft questions on new genomic techniques
    a. Terminology
    b. Working methods
    c. Finalisation of the proposed questions
    d. Additional questions
5. Any Other Business

**Draft questionnaire on new genomic techniques to contribute to the study requested by the Council**

*For discussion and endorsement*
*Joint Working Group of GMO competent authorities on new genomic techniques*
*15 January 2020*

## Introduction

To respond to the Council's request[1] for a study on the status of new genomic techniques, with this questionnaire the Commission is collecting contributions from Member States competent authorities. 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].

The questionnaire concerns plants, animals, micro-organims and derived products obtained by NGTs for agri-food, medicinal and industrial applications. For some questions, GMO competent authorities are invited to seek input from other competent authorites.

Please document your answers with explanations and data as well as with practical examples, whenever possible. Please indicate which information should be treated as confidential in order to protect the commercial interests of a natural or legal person.

Member States will be invited to reply to the questionnaire via EUsurvey after 15 January 2020 and replies will be requested by 15 April 2020.

*Information on national risk assessment:*

In the context of the study, the Commission will mandate EFSA to produce an overview on the risk assessment of NGTs. For this exercise, EFSA will take into account its previous scientific opinions as well as risk assessments and opinions published by competent authorities and national institutions since 2012[3], where available.

[1] Council Decision (EU) 2019/1904

[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 RdDM. Conversely, techniques already in use prior to 2001, such as Agrobacterium mediated techniques or gene gun, are not considered NGTs.

[3] This timeline is proposed to align with the first EFSA scientific opinions on NGTs dating from 2012.

In order for the Commission and Member States to have a good overview of existing national risk assessments of NGTs, please provide to the Commission any scientific opinion on risk assessment on NGTs, issued by your national bodies. The Commission will share the information with EFSA without delay. **All contributions should be sent by 15 January 2020 to: SANTE-NGT-STUDY@ec.europa.eu**

**Draft questionnaire**

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

1. Have you been consulted by companies/organisations for regulatory advice on products obtained by NGTs that they are developing?
    - If yes, please provide details on the request.
2. Have you taken specific measures to ensure the application of the GMO legislation to all organisms, food or feed obtained by NGTs?
    - If yes, please describe the measures and their effectiveness.
    - What best practices can you share?
    - What challenges have you encountered?
3. Have you adapted your inspection practices to cover all organisms, food or feed obtained by NGTs?
    - If yes, please describe these practices (e.g. adaptation of multiannual control plans) and their effectiveness.
    - What best practices can you share?
    - Have the adapted inspection practices created additional requirements/burden for operators and/or public authorities?
        - If yes, please provide concrete examples/data.
    - What challenges or limitations have you encountered?
4. Do youhave experience on traceability strategies, which could be used for tracing products obtained by NGTs?
    - If yes, please describe the traceability strategy, including details on the required financial, human resources and technical expertise required.
5. What other experience can you share on the application of the GMO legislation, including experimental releases, concerning products obtained by NGTs (e.g. food, feed, medicinal products, industrial products)?
6. Have seed varieties obtained by NGTs been registered in national catalogues?
7. Do you require specific information in national catalogue, if the seed is obtained by NGTs?
    - If yes, please specify.

*Information on research:*

8. Have you supported NGT-related research projects (ongoing or finalised in the last 5 years) with national funding programmes?
    - If yes, please provide an overview including title of project, a brief summary with scope and objectives, as well as the amount of national funding received.
9. How do you see NGT-related research evolving?

*Information on public dialogues and national surveys:*

10. Have you organised national dialogues concerning NGTs?
    - If yes, please describe briefly ithe content, methodology and conclusions.
11. Have you organised national surveys, which assessed public opinion on NGTs?
    - If yes, please describe briefly the content, methodology and conclusions.

*Information on ethical aspects:*

12. Have any national bodies or expert groups discussed or issued opinion on the ethical aspects of NGTs?
    - If yes, please describe briefly (the content, methodology and conclusions).

*Information on potential opportunities and benefits of NGT products:*

13. Could NGT-products bring opportunities/benefits to your national agri-food sector or other sectors (e.g. medicinal, industrial )?
    - If yes, please provide concrete examples/data.
14. Could NGT-products bring opportunities/benefits to society in general?
    - If yes, please provide concrete examples/data.
15. Do you see particular opportunities for SMEs on the market access to NGTs?
    - If yes, please explain under which conditions.

*Information on potential challenges and concerns of NGT products:*

16. Could NGT-products raise challenges/concerns for your national agri-food sector or other sectors (e.g. medicinal, industrial)?
    - If yes, please provide concrete examples/data.
17. Could NGT-products raise challenges/concerns for society in general?
    - If yes, please provide concrete examples/data.
18. Do you see particular challenges for SMEs on the market access to NGTs?
    - If yes, please explain under which conditions.