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

Videoconference, 18 September 2020

Chair: Commission (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
Others: DG JRC/EURL (partly), DG RTD (partly), EFSA (partly), Mission of NO

The Commission welcomed the participants of the Joint Working Group of GMO competent authorities and explained that the objective of the meeting was 1) to receive feedback from Member States on the implementation of the GMO legislation as interpreted by the Court of Justice of the European Union (CJEU) and 2) to inform Member States on the progress made by the Commission regarding the study on the status of new genomic techniques (NGTs) requested by the Council.

As mentioned in the previous Joint Working Groups held in 2019 and 2020, the Commission recalled that Member States need to continue to ensure that the GMO legislation is implemented at national level as interpreted by the CJEU. In view of the rapid developments in this field, the Commission invited the Member States to provide feedback to COM and other MS, or to add to the information already given in the past, on any issue related to the implementation and enforcement of the GMO legislation.

- One Member State informed of the national measures on *in vitro* mutagenesis that were notified to the Commission in accordance with the rules of Directive (EU) 2015/1535. The Member State will now examine the detailed opinions/responses received from the Commission and some Member States and will soon decide on the follow up.

- One Member State reported on a forthcoming hearing and confirmed that no new varieties have been added to the seed catalogues and that they rely solely on trust that the information provided is correct.
- Regarding the application of the CJEU ruling to Directive 2009/41/EC, one Member State noted that legislative changes as well as more resources for control purposes may be needed.
- No other update on the implementation and enforcement was provided by the participants.

The Commission referred to the work of the European Union Reference Laboratory for GM food and feed (EURL GMFF), together with the European Network of GMO Laboratories (ENGL), concerning a series of reports on the detection of products obtained by new mutagenesis techniques. The EURL GMFF gave an update on the ongoing work regarding GM microorganisms (GMM). In this respect, the Commission encouraged Member States to provide expertise to support the important work on GMM detection.

- A number of Member States agreed to increase their efforts to provide such expertise to the EURL GMFF.

Further to the intervention of two Member States on a recently published article[1], the EURL GMFF noted that, from a preliminary evaluation, the method as described in the article is largely in line with the applicable EU method performance requirements, although some aspects need further clarification. The method is limited to pure seed samples and to a known mutation. The method is not designed to differentiate between techniques used. EURL GMFF informed that the article and the method described therein will be discussed with ENGL in the ENGL Plenary meeting on 30 September. The outcome of the discussion will be included in the minutes of the meeting, which will be available on the EURL GMFF website[2].

- Member States who intervened agreed with these preliminary views of the EURL GMFF.
- One Member States noted that the problem with the method for gene editing products (ODM-mutation) is the identification, and not the detection. The EURL GMFF noted that this is a technical/analytical aspect, which will be part of the discussion in the EURL GMFF/ENGL.
- One Member State stated that it welcomes diverse approaches on detection, and that it has commissioned their own national laboratory to assess if the published detection method on the mutated oilseed variety meets the specificity and other requirements needed. The study by the national laboratory will also be published.
- One Member State asked the Commission to clarify the regulatory status of the mutated oilseed rape subject to the scientific article. The Commission invited Member States to provide any available information on the said product. The Commission will

[1] Chhalliyil et al. (2020) (https://www.mdpi.com/2304-8158/9/9/1245/htm)
[2] https://gmo-crl.jrc.ec.europa.eu/ENGL/ENGL.html

discuss the follow up with the Member States after the outcome of EURL/ENGL discussion.

In the second part of the meeting, the Commission presented the state of play of the on-going work on the study on NGTs, as requested by the Council. In particular, the Commission gave a brief presentation on the on-going work of the Joint Research Centre (JRC) on the scientific state-of-the-art in NGTs as well as on the current applications that are marketed, or are in a near-market development stage. The European Food Safety Authority (EFSA) informed of the on-going work to prepare an overview on risk assessment of plants developed through NGTs, based on EFSA's previous and on-going work and on the work carried out by national risk assessment bodies. The Commission provided a state of play on the on-going work of the European Group on Ethics in Science and New Technologies (EGE) on gene editing, expected to be finalised by mid-December.

- One Member State asked what is to be considered a new technique. The Commission clarified for the purposes of this study it considers only new genomic techniques as techniques which are capable to alter the since 2001.

- One Member States noted that therapeutic applications both for early stages of cancer but also for later therapeutic use, such as precision oncology, should be considered as well. The Commission took note and confirmed that those applications are in the scope of the study.

- One Member State inquired if the market study of the JRC examined also patent databases or other patent-related information sources, which could be helpful for finding new products. The Commission replied that patent databases were not systematically examined, however the potential information was compensated by other means.

On the targeted consultation, the Commission explained that it received replies from 26 Member States and 58 stakeholders and that the analysis of the replies was still on-going. A preliminary assessment so far indicates that Member States and stakeholders' views are polarised, especially on benefits, concerns, safety and ethical aspects related to NGTs. From the feedback received, there appears to be considerable interest in NGT-related research, attested by the research activities reported by both stakeholders and Member States. Member States reported on past and ongoing public dialogues, organised by various institutions and mostly focused on agriculture. While most stakeholders agree that the safety of products is of major importance for their placing on the market, views concerning the safety of NGT products are divided. Views on ethical aspects are also polarised, with only few Member States reporting opinions on ethical aspects issued by national bodies or expert groups. All stakeholders in principle support transparent consumer information; their views diverge when it comes to NGT product labelling. The Commission concluded that a more detailed and thorough analysis is needed in particular to include the outcome of the ongoing work by the Joint Research Centre, EFSA and EGE.

- One Member States asked if the study considered legal options for a possible change in the GMO legislation regarding NGTs. The Commission noted that the Council requested the Commission to submit a proposal, if appropriate in view of the outcomes

of the study, or otherwise to inform the Council on other measures required as a follow-up to the study. Consequently, since the study is not finished, it is too early at this stage to conclude on any follow-up action.

One Member State asked to discuss public access to the Member States replies to the targeted consultation. The Commission clarified that a Member State reply is to be considered a document pertaining to that particular Member State and confirmed that all replies to the consultation as well as all the accompanying reports will be published on the Commission's website once the study is finalised.

The minutes were agreed by the participants at the end of the meeting.