

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

Hybrid meeting in Brussels, 25 May 2022

Chair: Commission (DG SANTE unit E3)

Member States present: BE, BG, CZ, DK, DE, EE, IE, EL, ES, FR, HR, IT, LV, LT, LU, HU, MT,

NL, AT, PL, PT, RO, SK, SI, FI, SE

Others: NO, DG JRC/EURL, DG SANTE units D1, G1 and F3 (partially)

The Commission welcomed the participants of the Joint Working Group of competent authorities in the area of genetically modified organisms (GMOs) and explained that the objective of the meeting was to provide an update on the ongoing initiative on possible legislation for plants produced by certain new genomic techniques (NGTs) and to exchange views with the Member State experts on the key policy elements of the initiative.

The Commission informed the Joint Working Group on the feedback it had received on the inception impact assessment¹ and on the progress on the impact assessment, including the launch of the public consultation and planning of further targeted consultations. It provided an overview of technical contributions that will be received from the Commission's Joint Research Centre (JRC) and the European Food Safety Authority (EFSA). The public consultation² is open until 22 July 2022 and the Commission invited Member States to respond to the consultation.

The Commission gave also an update on two on-going related policy initiatives: on the revision of the plant reproductive material legislation and on a legislative framework for a sustainable food system. The Commission outlined the different scopes of the initiatives, and emphasised that the Commission is working to ensure coherence between them, in particular regarding the sustainability aspects, an objective shared by many participants.

² https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en/public-consultation_en

The European Reference Laboratory on GM Food and Feed (EURL) gave an update on the activities of the European Network of GM Laboratories (ENGL) on the detection of plants produced by targeted mutagenesis.

The Commission presented an overview of the two NGT fact-finding studies in the Netherlands and Germany, carried out in February and March 2022, respectively, in order to gather information on the implementation of controls on organisms and products obtained through NGTs. The reports from the fact-finding studies are not yet finalised.

A representative from the German Federal Office of Consumer Protection and Food Safety (BVL) gave an update on the EUginius database, which BVL co-hosts with Wageningen Food Safety Research (WFSR, the Netherlands). EUginius is meant to support competent authorities and private users who seek information on GMOs. It provides detailed information regarding the presence, detection and identification of GMOs, focusing on the situation in the European Union as well as providing worldwide coverage. EUginius provides information about commercialised genome-edited organisms when available as well as about published information about such organisms.

The Joint Working Group exchanged views on the key policy elements regarding the policy initiative on a possible legislation for plants produced by certain NGTs.

Regarding the approach to risk assessment, the Commission informed the Joint Working Group about the mandate recently submitted to EFSA³ on possible criteria to establish differentiated data requirements based on risk; the mandate was welcome by several participants. Some participants raised the need for proportionality given that some NGT plants are equivalent to conventionally bred or naturally occurring plants. One participant suggested putting in place a preliminary evaluation mechanism to determine the degree of risk assessment necessary for each product. Other participants emphasised the need to consider possible risks and to base the criteria on science. The case-by-case approach and how much flexibility the current legislation can accommodate were also discussed. The need to focus more on the product than on the process, and to ensure a future-proof legislation, was raised by some participants. Two participants expressed disagreement with the Commission's finding that plants obtained by targeted mutagenesis and cisgenesis generally pose lower risks than plants obtained with transgenesis. The Commission recalled that these techniques and their outcomes are very diverse with different risk profiles, which may require differentiated data, while maintaining the requirement that safety must always be ensured.

Regarding sustainability, participants who intervened generally agreed to the Commission's approach to focus on traits and their impacts to sustainability. Several participants recognised the potential contribution of NGTs to the objectives of the Green Deal/Farm to Fork Strategy. They stressed the need for innovation and cautioned against creating excessive burden through sustainability provisions. Some participants raised whether horizontal frameworks would be the best place to address sustainability. Two participants questioned that NGT products would bring benefits in the short term and could contribute to the objectives of the Green Deal and related strategies, given that there are only very few products in an advanced development stage. Others raised the question if further research and development would be necessary to develop traits of interest. The need to consider the three dimensions of sustainability and equal treatment of domestic and imported products was raised by some

³ https://open.efsa.europa.eu/questions/EFSA-Q-2022-00309

participants, and some stressed that the relevance of some sustainability impacts can be highly divergent at regional or local scale. Several participants noted that the new generation of products should not focus on the delivery of herbicide-tolerant traits.

Participants generally agreed on the need to provide information to ensure coexistence and freedom of choice for operators and consumers, presenting different views on how to achieve this. Some participants called for maintaining GM labelling at all stages and others to ensure transparency about the breeding techniques through the common catalogues of varieties. Some participants expressed the view that labelling of final products was not necessary. The need for uniform application of controls within the EU was also raised.

Several participants commented on possible measures to allow coexistence of NGT and non-NGT crops (e.g. linked to information and traceability), to lower entry barriers for SMEs (such as support to navigate the regulatory procedures) and to ensure a future-proof framework (e.g. monitoring scientific and technological developments, focus on the product rather than the process).

The Commission indicated that these discussions will feed into the on-going work on the impact assessment and informed the Joint Working Group of its intention to convene a follow-up meeting after the summer break in order to continue the discussion.

Finally, some participants informed about on-going activities in their countries. Norway informed on the forthcoming report by the Public Committee on Gene Technology, which will inform and give advice to decision-makers and society at large on questions of gene technology. Austria informed on the "Expert Event on New Genomic Techniques – Regulation, Risk assessment, Sustainability and Challenges for the Food Chain" organised by Environment Agency Austria together with the Austrian Agency for Health and Food Safety, taking place on 21 June 2022 in Vienna. France announced a research programme for 30 million euros lasting 8 years that will look into gene editing for new traits adapted to climate change and the agro-ecological transition. Spain informed on a workshop that the Spanish authorities will hold on 29 June 2022 with stakeholders in the framework of the Commission's public consultation on NGTs. The Czech Republic informed about an international scientific conference on sustainable agriculture and food that will be held in Prague on 28-29 November 2022.