



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, 24 October 2022

Chair: Commission (DG SANTE unit E3)

Member States attending: BE, BG, CZ, DK, DE, EE, IE, EL, ES, FR, HR, IT, LV, LT, LU, HU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE

Others: NO, EFSA

The Commission welcomed the participants of the Joint Working Group (JWG) of competent authorities in the area of genetically modified organisms (GMOs). The agenda was approved without any request for any other business.

The Commission presented the outcome of the public consultation on the policy initiative on plants produced by certain new genomic techniques¹ (NGTs) and thanked the Member States for the participation in the targeted survey, which gathered expert opinions on impacts of the policy options.

Several participants mentioned some difficulties with the targeted survey, indicating that the questions were not clearly formulated and that the format did not lend itself for easy distribution. Two Member States noted that it was difficult to answer questions due to limited data on the future developments. One Member State questioned whether the outcome of the targeted survey would be of much use. The Commission acknowledged that various questions had been raised by Member States and stakeholders and that for this reason clarifications had been provided during the process and the time-period for Member States to answer was also prolonged. It also explained that the targeted survey was one of various consultation activities and opportunities for Member States to comment, which also included the meetings of the Joint Working Group.

¹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

The CZ delegation communicated about an upcoming event under their Presidency: the European Agri-Food and Sustainability Innovation conference² to be held in Prague on 28-29th November. EFSA informed of the EFSA NGT risk assessment event on the 12th of December³.

EFSA provided an overview of their new opinion on cisgenesis and intragenesis⁴ requested by the Commission to update the previous opinion from 2012. EFSA confirmed the conclusions of the 2012 opinion. In assessing different contributions to potential hazards in cisgenic/intragenic plants, EFSA concluded that no new risks are identified in cisgenic and intragenic plants compared with plants obtained with conventional breeding or established genomic techniques. EFSA also confirmed that on a case-by-case basis lesser amounts of data may be needed for the risk assessment of cisgenic and intragenic plants developed by established or new genomic techniques.

EFSA presented its statement on the criteria for the risk assessment of plants produced by targeted mutagenesis, cisgenesis, and intragenesis⁵ that had been requested by the Commission. It was emphasised that data requirements were not part of the mandate and therefore not included in the statement.

The Commission explained the context for EFSA's statement on the criteria for the risk assessment. It confirmed that three risk assessment options are being considered in the context of the impact assessment: the current risk assessment approach contained in the GMO legislation, a risk assessment adapted to NGT plants, and an approach where products derived from NGTs that are similar to products derived from conventional breeding are subject to a notification regime without further risk assessment. A risk assessment adapted to the variety of risk profiles associated to NGT plants, if pursued, would need to be based on a set of criteria allowing to establish differentiated requirements and ensuring safety, adaptability and predictability. The work of EFSA is a contribution to the establishment of such criteria.

Member States' experts raised a number of questions for clarification to EFSA and noted that both EFSA publications became only available on short notice prior to the meeting. The discussion mostly centred around the concepts and definitions of "history of safe use" (HoSU) and "breeders' gene pool", in particular on the need to provide clarity on their definition and on how to make these concepts operational. The Commission mentioned that HoSU and breeders' gene pool are not new concepts, but would need to be clearly defined if used in the context of a possible new regulatory framework. Other contributions to the discussion questioned the possibility to decide on the criteria without knowing the data requirements.

Questions were raised on the need for risk assessment for products similar to conventional breeding techniques. The Commission referred to the policy option being considered in relation to such products, explained that the EFSA statement did not include a comparison between products from NGTs and conventional breeding techniques, and indicated that a discussion on the approach to such products could take place at a next meeting of the JWG.

The Commission thanked the participants for their comments and invited further written comments till the end of November, especially whether EFSA's criteria would form a suitable basis for the development of a risk assessment approach in the legislative proposal, which would ensure a high level of safety,

² <https://czech-presidency.consilium.europa.eu/en/events/international-scientific-conference-european-agri-food-sustainability-innovation/>

³ <https://www.efsa.europa.eu/en/events/stakeholder-event-safety-plants-derived-new-genomic-techniques-looking-future-risk>

⁴ <https://www.efsa.europa.eu/en/efsajournal/pub/7621>

⁵ <https://www.efsa.europa.eu/en/efsajournal/pub/7618>

flexibility and predictability. It also concluded that further work on clarifying some concepts (HoSU, breeders' gene pool) is needed.

The Commission gave a timeline on further activities. The impact assessment will be finalised in early 2023 with a view to the possible legislative proposal (Q2 2023). Another JWG meeting for further discussion will be planned in the first weeks of 2023.

The Commission thanked EFSA and the Member States for the fruitful discussion.