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 (NGTs)

Hybrid meeting in Brussels, 9 February 2023

Chair: Commission (DG SANTE unit E3)
Member States attending: BE, BG, CZ, DK, DE, EE, IE, EL, ES, FR, HR, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, RO, SI, SK, FI, SE
Others: NO, EFSA, JRC

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 with the request by one Member State to include information under AOB on a recent application of an NGT vaccine. The Commission also informed that the recent ruling on in vitro mutagenesis of the Court of Justice of the EU and a mandate given to EFSA on new developments in biotechnology applied to animals would be under AOB.

The Commission introduced the meeting indicating that there is no decision on the policy options to be pursued in the proposal. The current JWG discussion is to contribute to the thinking process on the different options. One Member State regretted that the experts of the Standing Committee on seed and plant reproductive material were not invited. The Commission acknowledged that there are points of connection, however the topics in the agenda of this meeting are very specific for the NGT proposal.

The Commission gave a general update on the process of the legislative proposal, which is planned for June 2023. The JRC gave an update on the new report on detection challenges and opportunities under preparation with the ENGL (European Network of GMO Laboratories). This report will update the previous 2019 report. The provisional conclusions align with the previous 2019 report: there might be technical limitations on developing analytical screening methods with the necessary specificity especially for small mutations. Validation of methods for an increasing number of mutations and limitations to apply screening methods may lead to an increased workload for the ENGL. Some mutations will also not be

distinguishable from naturally occurring or mutations from conventional breeding techniques, and individual detection methods may need to be developed for each single mutation.

One Member State commented on several initiatives organised in their country on risk assessment, sustainability (including a list of possible traits of NGT plants for sustainability goals), social/economic, ethical aspects and societal expectations.

Eight Member States had sent in written comments on the EFSA statement on adapted risk assessment[1]. The comments given by the Member States at the last JWG meeting were also considered by the Commission. The Commission gave an overview of the comments received. Among these, technical questions mainly included clearer definitions of some criteria (breeders´ gene pool, history of safe use (HoSU), and safe harbours), while policy questions included comments on a product-based approach, on the overall approach for risk assessment, and on proportionality for conventional-like products. The Commission asked if Member States had any additional comments or wanted to elaborate on some points. Two questions were asked on the scope of the initiative and on off-target effects. Member States also raised questions on how the risk assessment will be performed and if the risk assessment would be proportionate when the same products can be obtained by conventional breeding techniques. Some Member States remarked that a clear understanding of definitions and data requirements are needed to assess proportionality of the approach. One Member State highlighted the need for flexibility to adapt criteria to scientific progress.

Technical questions on the statement were addressed by EFSA. It clarified that the definitions in the adapted risk assessment are the same as from previous EFSA opinions, but these would need to be further clarified to make practical implementation possible. The data requirements were not part of the mandate and were therefore not specified. The concept of HoSU has been used for novel food; further clarification should be provided if used in this context.

The Commission commented that the criteria reflect a combination of product and technique-based approach. Data from the applicant would still be needed in the adapted risk assessment. The scope of the initiative covers cisgenesis and intragenesis, but these would not necessarily be treated in the same way in the assessment. The Commission further stressed that the criteria may be adjusted if needed in view of discussions. The criteria would also need to be adaptable in the future and need to be objective to provide legal certainty and predictability.

The Commission recalled the three options for risk assessment/authorisation considered in the impact assessment: i) status quo; ii) risk assessment adapted to the diversity of products; iii) specific procedures for products that could occur naturally or be produced by conventional breeding methods. While reiterating that a decision on the preferred policy option had not been taken yet, the Commission noted that in case any future regulatory provision were to take similarity to conventional products into account, criteria for this assessment would be needed. Therefore, the Commission presented a scientific literature analysis on mutations derived from conventional breeding techniques and potential criteria to determine whether a product could also occur naturally or be produced by conventional breeding techniques. The analysis was done with the support of the Joint Research Centre and was still work in progress. The Commission underlined that the proposed criteria are product-based and should ensure that conventional-like products do not pose a higher risk than products obtained by conventional breeding methods or naturally. The discussion was then opened for the Member States.

[1] https://www.efsa.europa.eu/en/efsajournal/pub/7618

One Member State asked about the recent ruling of the Court of Justice of the EU on in vitro mutagenesis. The Commission replied that the ruling is currently being analysed and that it will be further discussed at a future meeting.

Several Member States asked technical questions on the proposed criteria for equivalence, while informing that they would still need a thorough discussion with their national experts. Two Member States acknowledged that these criteria are necessary and asked the scientific basis of thresholds. One Member State underlined the need for mechanisms for rapid adaptation of criteria. The Commission replied on the technical questions and stressed that the criteria will be a decision informed by science. The criteria for equivalence are distinct from the criteria for risk assessment in the EFSA statement, but they are compatible with EFSA's findings on NGTs.

The Commission invited Member States to provide written comments on the criteria for equivalence until the 3rd of March, keeping in mind their key objectives (safety, predictability and applicability). The criteria also need to be supported by science and future proof.

Under AOB, a Member State presented a product for which it had received application, and whose regulatory status it was considering, and enquired if other Member States had received applications.

The Commission informed about the recent ruling of the Court of Justice of the EU on in vitro mutagenesis.

The Commission also informed about a mandate given to EFSA on new developments in biotechnology applied to animals (output to be delivered by June 2025).