NETWORK ON RISK ASSESSMENT OF GMO
Minutes of the 16th meeting

13 December 2023
14:00-18:00
Minutes agreed on 18 January 2024

Location: Webconference

Chair: Head of the Nutrition and Food Innovation (NIF) Unit

Attendees:

- **Competent authorities of the Member States:**

Country	Competent Authority
Austria	- Austrian Agency for Health and Food Safety GmbH (AGES) - Environment Agency Austria (Umweltbundesamt)
Belgium	- Sciensano
Bulgaria	- Agrobioinstitute - Risk Assessment Center on Food Chain, Ministry of Agriculture - National Centre of Public Health and Analysis
Croatia	- Croatian Agency for Agriculture and Food - University of Zagreb, Faculty of Science
Czech Republic	- Ministry of Agriculture
Denmark	- National Food Institute, Technical University of Denmark (DTU - Food)
Estonia	- Ministry of Environment
Finland	- Ministry of Social Affairs and Health - Finnish Food Safety Authority Evira
France	- French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
Germany	- German Federal Agency for Nature Conservation (BfN) - Federal Office of Consumer Protection and Food Safety (BVL)
Greece	- Independent Authority for Public Revenue; Directorate General of General Chemical State Laboratory
Hungary	- Ministry of Agriculture
Ireland	- Food Safety Authority of Ireland - Environmental Protection Agency (EPA)
Italy	- Istituto Superiore di Sanità - INAIL-Settore Ricerca Dipartimento Innovazioni Tecnologiche e Sicurezza degli Impianti, Prodotti ed Insediamenti Antropici

Latvia	- Ministry of Agriculture - Food and Veterinary Service (FVS) - Scientific Expert Committee on GMO RA - Ministry of Agriculture of Latvia
Lithuania	- National Food and Veterinary Risk Assessment Institute
Luxembourg	- Luxembourg Veterinary and Food Administration - ALVA
Netherlands	- Institute for Public Health and Environment (RIVM) - Wageningen Food Safety Research
Norway	- Norwegian Scientific Committee for Food and Environment
Poland	- Plant Breeding and Acclimatisation Institute
Romania	- National Sanitary Veterinary and Food Safety Authority
Slovak Republic	- Faculty of Chemical and Food Technologu STU in Bratislava - Ministry of Agriculture and Rural Development of the Slovak Republic
Spain	- Ministry for the Ecological Transition and the Demographic Challenge, General Directorate of Quality and Environmental Assessment, National Biosafety Commission - Spanish National Research Council (CSIC) - Center for Biological Research (CIB), Ministry of Science, Innovation and Universities - Spanish National Research Council (CSIC) - National Institute for Agricultural and Food Research and Technology (INIA), Ministry of Science, Innovation and Universities
Sweden	- Swedish National Food Agency

- **Observers:**
  - **Switzerland**: Federal Food Safety and Veterinary Office (FSVO);
  - **Serbia**: Institute for Biological Research "Siniša Stanković";
  - **Montenegro**: Administration for Food safety, Veterinary and Phytosanitary Affairs;
  - **Türkiye**: Ministry of Food, Agriculture and Livestock General Directorate of Agricultural Research and Policies;
- **Hearing Experts:**
  Chair of the GMO Panel
- **European Commission/Other EU Agencies representatives:**
  Representative of the European Commission
- **Nutrition and Food Innovation (NIF) Unit:**
  Chair of the NIF Unit; 7 staff members of the NIF Unit

Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from the representative of the Ministry of Environment of the Czech Republic.

Adoption of agenda

The agenda was adopted without changes.

Agreement of the minutes of the 15th Network meeting held on 08-09 June 2023, in Prague

The minutes of the 15th GMO Network meeting had been previously agreed by written procedure on 3rd July 2023 and published on the EFSA website[1].

Federal Food Safety and Veterinary Office (FSVO) (Switzerland) requested to include their apologies in the minutes.

Item 4: Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625

Abstract presentation from European Commission

The European Commission (EC) presented the proposal (hereafter, EC proposal) for a new Regulation on plants produced by certain new genomic techniques (link). The proposal, adopted on 5 July 2023, is part of a package of legislative proposals to support the EU's Farm to Fork and Biodiversity strategies.
The proposal creates two distinct pathways for New Genomic Techniques (NGT) plants to be placed on the market:

1. NGT plants that could also occur naturally or by conventional breeding ('Category 1 NGT plants') would be subject to a verification procedure, based on criteria set in the proposal. NGT plants that meet these criteria would be treated like conventional plants and exempted from the requirements of the GMO legislation. Criteria for verification of equivalence to naturally occurring or conventionally bred plants are specified in Annex I to the proposal. Intragenesis is excluded from this category.
2. For all other NGT plants ('Category 2 NGT plants'), the requirements of the current GMO legislation would apply. They would be subject to risk assessment and authorisation before placing on the market. The risk assessment, detection method and monitoring requirements would be adapted to different risk profiles, and regulatory incentives (Annex III) are foreseen for NGT plants featuring traits that can contribute to sustainability goals. General principle of risk assessment of plants falling under Category 2 are presented in Annex II.

Discussion

The Netherlands asked whether EFSA will develop guidance documents following the adoption of the Commission proposal. The Commission clarified that the EFSA will be

[1] https://www.efsa.europa.eu/sites/default/files/2023-07/minutes-15th-gmo-network-meeting.pdf

mandated to develop guidance for risk assessment in case the proposal is adopted by the Council and the Parliament. Moreover, guidance for verification procedure and for the detection methods by EURL will also be needed to be developed.

Item 5: Overview discussion on NGT at the GMO network in past years

Abstract
EFSA provided a summary of the discussion on topics related to NGTs which took place in the past years at the GMO Network meetings. EFSA briefly recalled the GMO Network terms for reference (ToRs). The overall objectives of the GMO Network were also briefly recalled (link to ToRs here). These objectives include considering the challenges posed by the development of GMOs through novel genomic techniques.
The subject of NGTs has been a recurring topic for discussion within the GMO Network during various meetings. In April 2022, the GMO Network participants explored the distinction between proportionate risk assessment and case-by-case approach, identifying a possible list of criteria. These criteria encompassed factors such as the expressed traits of the plant, the presence or absence of exogenous DNA and novel proteins, the specific techniques employed, and several others. Furthermore, during that meeting, Member States (MS) provided valuable insights into their ongoing activities which were summarized in the Annex to the meeting's web minutes (here).
In November 2022, following the publication of two important EFSA documents, the GMO Network discussed the criteria proposed by EFSA for the risk assessment of NGT plants. The discussion focused on the history of safe use, the presence of exogenous DNA in the final product, the environmental familiarity of the new plant and its traits, the required data for a proper risk assessment, and the potential for unintended effects in the resulting NGT plant.
Finally, in June 2023, as the EFSA's work on NGT plants reached its finalization and the European Commission prepared to release its proposal on July 3rd, the discussion at the GMO Network focused on two new mandates presented by EFSA on NGT techniques applied to microorganisms and animals.

Discussion
See discussion in Item 6.

Item 6: Future work on NGTs/RA challenges/collaboration with MS

Abstract
The Chair of the EFSA GMO Panel informed the GMO Network that the experts of the GMO Panel engaged in a preliminary discussion at the recent GMO Panel meeting on the future of risk assessment of NGT plants (29-30 November 2023, Item 6.1, link to the minutes). The main objective was to identify potential data requirements using hypothetical case studies. This exercise was very useful to identify challenges to be addressed to develop guidances for the risk assessment of NGT plants.

Discussion
Belgium informed that they are also using case studies to assess the applicability of Annex I of the new EC proposal to plants developed by NGT. Belgium clarified that almost all the applications received during the last years under Part B of Directive

2001/18/EC would fall under Category 1. Belgium is also exploring the risk assessment of NGT plants. Poland considered that, according to the current version of the proposal, the same plant trait developed by NGT could fall in both Category 1 and Category 2. Also, Poland raised the issues about the definition of 'event', and the implication for the detection and the post-market environmental monitoring.
The Netherlands asked whether in case no genetic material is inserted, all data for the risk assessment would be needed, including for example toxicological analysis. These aspects still need to be clarified. EFSA asked the Member States to explain the work that they have been developing regarding the proposal. The Netherlands informed that they are monitoring the developments in the NGT area, what the implications for risk assessment and traceability detection are, and how these technologies are being regulated elsewhere in the world. However, no specific activity on NGTs was organized. Netherland also informed that some activities were carried out for gene therapy (categorization and requirements for risk assessment, and risk management), and similar activities could be done also for NGT plants at national level, but activity is currently on-hold given the discussion at EU level regarding the proposal.
Norway briefly recalled their presentation at the previous meeting in Prague on their activities on sterile salmon. Norway is expecting further activities on guidances' development from EFSA to be taken into consideration at national level.
France informed that they are finalizing two requests currently in progress on NGT. which should be finalized end of 2023 and published soon after. The first request was from the French Ministry of Agriculture with the main objective to determine whether and how the current requirements regarding sanitary and environmental risk assessment should be adapted. For this request, only CRISPR/Cas9 was considered as the most relevant developed targeted mutagenesis technique. However, the opinion on cisgenesis was excluded from the first request and the publication is planned for January 2024. The second request is an ANSES self-task and regards the criteria of equivalence between NGT and conventional plants and the scientific document published by EC in support of the proposal. This task aims to highlighting any questions or limitations of these criteria.
EFSA presented some information on how the Agency engages with external stakeholders, including Member States. The main objective is not only to share knowledge, expertise and promote capacity building, but also to discuss on potential scientific issues at a very early stage. EFSA suggested to engage in a discussion on EFSA's future NGT activities and to establish a dedicated focus group following a call of expression of interest. An ad-hoc technical workshop could be a organized where specific issues can be discussed together.
The Netherlands asked about the possibility to have more frequent meetings. EFSA replied that the size of the present network is quite large, therefore it would be preferable to identify MS experts to conduct discussions on NGTs. Germany supported the idea to have collaborations with targeted consultation and, in particular, with focus groups in which it wants to participate and contribute expertise. The Netherlands and Belgium agreed. EFSA asked the participants to think about these and other ideas that might contribute to the collaboration between EFSA and the Member States. The hearing expert added that the focus groups would represent a positive contribution to the future GMO Panel activities on NGTs. Poland demonstrated their willingness to contribute but they are not sure at what level of engagement will they be able to. EFSA anticipated that follow-up information will be sent regarding the call for expression of interest.

Item 7: Scientific opinion on new developments in biotechnology applied to microorganisms

Abstract
EFSA presented the status of the mandate M-2022-00146 on new developments in biotechnology applied to microorganisms (GMM NGT). EFSA gave an overview of the findings of the horizon scanning report (link) and provided information on the call for data. Overall, the results of the call for data confirmed the horizon scanning conclusions as regards the category and type of microorganisms to be expected on the market in the next 10 years. A summary of the work of the GMM NGT Working Group and the progress of the scientific opinion was provided. EFSA informed the Member States of the ongoing discussions and main conclusions of the WG. The three terms of reference as requested by DG SANTE have been addressed and the scientific opinion is almost finalised. EFSA informed on the foreseen timelines of the public consultation and final adoption by the GMO Panel. Finally, EFSA committed to inform and share with the Network the horizon scanning report once published.

Discussion
Finland requested some clarifications on the date of public consultation and the adoption of the opinion. EFSA informed that the public consultation on the draft opinion will be launched in February 2024. The adoption of the opinion by the GMO Panel is foreseen in June 2024.
Germany asked whether a distinction was made in the horizon scanning report and in selection of case studies on whether the GMM applications were for contained use only or also for environmental release. EFSA clarified that the objective of the horizon scan was to take into consideration cases that could fall under the remit of EFSA, in other words products that could be on the market under the Regulation 1829/2003.
Poland informed that, being part of the European network of GMO laboratories (ENGL), DG SANTE asked them to elaborate on the challenges for the detection and identification of NGT microorganisms and NGT animals. Poland also asked what type of techniques were mainly used to generate the NGT microorganisms identified in the horizon scanning report. EFSA informed that the technique was mainly CRISPR/Cas while the case studies selected were those of interest for the risk assessment (e.g. food products to be placed on the market, bacteria as probiotics, yeast to produce beer with altered aromas, etc).

Item 8: Scientific opinion on new developments in biotechnology applied to animals (including synthetic biology and new genomic techniques)

Abstract
EFSA provided an overview of the mandate on New Developments in Biotechnology applied to animals. The status of the mandate, its progress and the deadlines were presented. The terms of reference were also presented. EFSA presented some representative information of the knowledge gathering report on known cases of animals and their food and feed products obtained by new developments in biotechnology. With the progress of the mandate, EFSA will provide regular updates to the GMO Network.

Discussion
EFSA asked Norway whether, in their opinion, the current EFSA guidance on GM animals is appropriate considering their experience on NGT animal of the past years, specifically on the sterile salmon case discussed at the previous GMO Network meeting. Norway replied that the EFSA guidance are indeed very useful, considering the holistic approach to the risk assessment of GM animals. The guidance is particulary useful for SDN-3 type of modificaiton, but also for SDN-1 and SDN-2 types. Regarding the sterile salmon case, Norway applied the EFSA guidance in all its parts (including section about fish) and lack of proper data from the applicant was properly addressed. Norway emphasized that the trait of the GM animal is a critical aspect to consider in the risk assessment, especially for the environmenral risk assessment.
Poland informed that they are working on the identification challenges for NGTs, including animals. Poland asked whether EFSA has any information regarding the molecular characterisation relevant for developing methods for identification, although this is not in the EFSA remit. EFSA clarified that this type of information is not always included in the Knowledge Gathering Report due to the confidentiality issues.

Item 9: Monitoring and assessing the potential impact of the introduction of the invasive weed teosinte on Bt-maize cultivation in the EU

Abstract
The Spanish representative presented the efforts made in Spain for monitoring and assessing the impact of the introduction of the invasive weed teosinte on Bt-maize cultivation in the EU. The presentation covered the following issues: i) a brief introduction on the origin of the teosinte present in France and Spain and the impact of teosinte and teosinte-maize hybrids on maize cultivation, with particular emphasis on their persistence as noxious weeds and their potential effects on the evolution of resistance to corn borers in Bt maize; ii) the current situation in Spain and the control measures implemented to contain teosinte establishment; and iii) the on-going research studies undertaken in Spain to generate empirical data for assessing the potential impact of teosinte introduction in the EU. The results obtained, so far, have shown high hybridization rates under greenhouse conditions between teosinte (*Z. mays* ssp *mexicana* and *Z. mays* ssp *parviglumis*) and Bt-maize. Studies are currently being carried out to assess: 1) the viability and fertility of the hybrids obtained (F1, F2 and backcross F1 x Bt-maize); 2) the expression of Cry1Ab toxin of these F1, F2 and backcross F1 x Bt-maize plants; and 3) the development of the two species of corn borers targeted by maize MON810 in Spain (*Sesamia nonagrioides* and *Ostrinia nubilalis*) on teosinte and teosinte-maize hybrid plants. Remarkably, no cases of Bt-maize x teosinte hybrids, nor teosinte plants expressing Cry1Ab toxin have been found in Bt-maize fields in the Ebro valley, the region with the highest adoption of Bt-maize in the EU. Future actions are still required, for instance assessing the frequency of hybridization under field conditions and the suitability of Bt-maize x teosinte hybrids as hosts for corn borers and non-target lepidopterans, among others. In this sense, the Spanish representative informed about an initiative led by Spain to create a consortium to address future actions at EU level that could be used to further test specific risk hypotheses.

Discussion
EFSA asked the presenter whether i) Bt maize was serving as father or mother plant, or both, in the experiments described, ii) whether the expression level of Cry1Ab in F1, F2 and BC was known, and whether this level was the same as the parental MON810 plant, and iii) whether the teosinte maize hybrids are found on conventional maize plots serving as refuge of MON810 maize plots. Spain clarified that indeed Cry1Ab expression level in F1 is the same as MON810 maize, but for the rest, more data are needed. Spain also clarified that hybrids are found in conventional maize plots, either serving as refuges or not. EFSA welcomed the research carried out by Spain which provides valuable data to complement the gaps highlighted by the EFSA statements on teosinte (EFSA, 2016; 2022). Spain informed that the Spanish Food Safety Authority together with the competenet authorities from other MS countries are working to establish a consortium that will request funding to progress in this research area.

Item 10: Protein safety of present and future GM plants

Abstract
EFSA presented the self-task mandate of the EFSA GMO Panel to produce a scientific opinion on protein safety assessment in GMOs. The EFSA GMO Panel identified the need to publish a scientific opinion reflecting on current practise, challenges and future opportunities of protein safety in GMOs. EFSA introduced the terms of reference of the mandate and the timelines for the completion of the work. The adoption of the opinion is expected by the end of 2024 and a public consultation will run from the end of June till the middle of September 2024. Furthermore, attendees were reminder of an EFSA Webinar taking place on 19th December 2024 (here). The purpose of the Webinar is to introduce an open survey on protein safety assessment and to collect input on the topic from stakeholders on the question to be launched at the survey were also presented.

Discussion
EFSA presented the mandate about protein safety of present and future GM plants and asked if there were any suggestions of questions to be added to the survey. The Netherlands suggested that 'adjuvanticity' could be an aspect to be added to the survey. The survey will be launched on the 19th December 2023 (Survey available at this **link**).

End of the meeting

The Chair thanked the GMO Network members for their active participation and the fruitful discussion.

The chair informed that the next meeting will be held in presence, in Belgium (30th and 31st May 2023). Belgium informed that the meeting will be held in Brussels and that an information sheet will be sent around with details on the venue and some guidance for travelling.

The chair informed that the draft minutes of the 16th GMO Network meeting will be shared with the participants and published on the EFSA website together with the presentations within 15 working days. The meeting was closed at 18:00.