# SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

171st Panel Plenary meeting

21-22 May 2025
09:00-17:00 / 9:00 – 16:00
MINUTES - Agreed on 10 June 2025

**Location**: Parma / Teleconference

**Attendees**:

- Panel Members:
Josep Casacuberta (Chair), Francisco Barro, Albert Braeuning, Michelle M Epstein, Thomas Frenzel, Jean-Luc Gallois, Frits Koning, Ruud de Maagd, Antoine Messéan, F Javier Moreno, Fabien Nogué, Giovanni Savoini, Alan H Schulman, Christoph Tebbe and Eve Veromann (online).
- Hearing Experts[1]: Ian Dewhurst (item 5.2)
- European Commission:
Mara Sgroi (DG-SANTE)
- EFSA:
Bernhard Url (item 10.1)

NIF Unit:

Ana Afonso, Michele Ardizzone, Martina Bonatti, Giacomo De Sanctis, Antonio Fernández Dumont, Arianna Ferrari, Andrea Gennaro, Tilemachos Goumperis, Dafni Maria Kagkli, Sara Jacchia, Silvija Kološevska, Paolo Lenzi, Aleksandra Lewandowska, Ana Martin Camargo, Franco Maria Neri, Nikoletta Papadopoulou, Tommaso Raffaello, Marta Rodrigues, Elena Sánchez Brunete and Reinhilde Schoonjans

Chief Scientist Office:

Yann Devos (item 9.4) and Konstantinos Paraskevopoulos (item 6.2)

IDATA Unit:

Alain Ducheyne (item 10.2)

MESE Unit:

José Ángel Gómez Ruiz (item 8.3)

## 1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

## 2. Adoption of agenda

The agenda was adopted with changes. Items 10.3 and 10.4 were added to the agenda.

## 3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Panel members invited to the present meeting. No Conflicts of Interest related to the issues

[1] As defined in Article 34 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

# 4. Report on written procedure since the 170th Plenary meeting held on 26-27 March 2025, in online

The minutes of the 170th GMO Open Plenary meeting were agreed by written procedure on 8 April 2025.

# 5. Scientific outputs for discussion and possible adoption

## 5.1 Request for placing on the market of genetically modified soybean DBN9004 for food and feed uses, import and processing submitted by Perseus BVBA on behalf of Beijong DaBeiNong Biotechnology (EFSA-GMO-BE-2019-165) (EFSA-Q-2020-00013)

Soybean DBN9004 was produced by *Agrobacterium*-mediated transformation using a single transformation vector to introduce genes encoding the CP4 EPSPS and PAT proteins to confer tolerance to glyphosate- and glufosinate-based herbicides, respectively.
The scope of application EFSA-GMO-BE-2019-165 is for food and feed uses, import and processing and does not include cultivation in the European Union.

The GMO Panel revised the draft opinion and, where appropriate, questions were raised and addressed throughout the different sections. The GMO Panel adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

## 5.2 Application for authorisation of genetically modified soybean MON 94313 in accordance with Regulation (EC) No. 1829/2003, GMFF-2022-6595 (AP176) (EFSA-Q-2022-00575)

Soybean MON 94313 was produced by *Agrobacterium* mediated transformation using a single transformation vector to introduce genes encoding the DMO, PAT, FT_T.1 and TDO proteins to confer tolerance to dicamba-, glufosinate-, 2,4-D- and mesotrione- based herbicides, respectively.

The scope of application GMFF-2022-6595 is for food and feed uses, import and processing and does not include cultivation in the European Union.
The progress made in the risk assessment by the Food and Feed working group was presented.[4] It was agreed that the GMO Panel will request further information that will be assessed once provided. If no other questions are identified during the assessment, the opinion will be proposed for discussion and possible adoption at one of the upcoming GMO Plenary meetings.

## 5.3 Application for renewal of genetically modified NK603 maize in accordance with Regulation (EC) No. 1829/2003 by Bayer Crop Science LP (RX040) (EFSA-Q-2024-00166)

Maize NK603 contains the *CP4 epsps* and the *CP4 epsps l214p* genes conferring tolerance to glyphosate-based herbicides. Following the submission of applications EFSA-GMO-NL-2005-22, EFSA-GMO-RX-NK603 and the publication of the EFSA scientific opinion[5], the placing on the market of maize NK603 for products containing, consisting of, or produced from this GM maize, excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/684. In 2024, the applicant asked the European Commission to renew the

[4] https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo#working-groups
[5] https://doi.org/10.2903/j.efsa.2009.1137

authorisation for the placing on the market of maize NK603 and submitted application GMFF-2023-21250 in support of their request. The GMO Panel assessed the application in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines.

The GMO Panel revised the draft opinion and, where appropriate, questions were raised and addressed throughout the different sections. The GMO Panel adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

# 6. Scientific outputs for discussion

## 6.1 Mandate on "GMA-NGT" (EFSA-Q-2023-00050)

The scientific opinion on "New developments in biotechnology applied to animals: an assessment of the adequacy and sufficiency of current EFSA guidance for animal risk assessment" was endorsed by written procedure on the 20 January and its public consultation was launched on the 22 January 2025 and was closed on the 19 March 2025.[6] More than two hundred comments were received and their assessment is taking place in the GMA-NGT WG.[7] The GMO Panel revised the updated draft opinion. The opinion will be further revised by the GMA-NGT WG and will be presented at the next GMO Plenary for discussion and possible adoption.

## 6.2 Mandate on "Protein safety" (EFSA-Q-2023-00664)

At the 168th Plenary meeting of the GMO Panel, the draft opinion on "Current practice, challenges, and future opportunities in the safety assessment of newly expressed proteins in genetically modified plants" was endorsed and a public consultation launched on the 15 January 2024.[8] The consultation was closed 12 March 2024. More than sixty comments were received. The assessment of the comments is taking place in the food and feed WG.[9] The type of received comments and the impact on the draft opinion was presented and discussed woth the GMO Panel. The opinion will be further revised and presented at the next GMO Plenary for discussion and possible adoption.

# 7. Update on new Mandates

## 7.1 Applications

- Application for authorisation of genetically modified soybean DAS-44406-6 × FG72 in accordance with Regulation (EC) No. 1829/2003, GMFF-2025-34192 (AP197) (EFSA-Q-2025-00294)

## 7.2 Mandates

- None

# 8. Feedback from the Scientific Committee/ Scientific Panels/EFSA/ EC

## 8.1 Scientific Committee

The Chair of the GMO Panel reported the discussions at the last Scientific Committee meeting and ongoing EFSA activities. [10]

## 8.2 European Commission

[6] https://www.efsa.europa.eu/sites/default/files/2025-02/Minutes%20GMO%20169%20Plenary.pdf
[7] https://www.efsa.europa.eu/sites/default/files/2023-07/minutes-gma-ngt.pdf
[8] https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000003SPsz/pc1278
[9] https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo#working-groups
[10] https://www.efsa.europa.eu/en/events/132nd-plenary-meeting-scientific-committee

The representatives of the EC informed the GMO Panel on their ongoing activities, including approval procedures for applications for which the GMO Panel has delivered a scientific opinion.

### 8.3 Scientific Panels including their Working Groups

The GMO Panel was updated on discussions of transversal relevance that took place in the last working groups molecular characterisation (MC)[11], comparative risk assessment and ERA (CompERA)[12] and food and feed (FF)[13].

## 9. Scientific discussion

### 9.1 Requirements for stack applications

The recent discussions held at the FF and CompERA WGs were reported to the GMO Panel. Regarding comparative analysis, possible strategies were presented on how to use the outcome of the agronomic/phenotypic and compositional analyses of single applications to identify potential interactions when combining multiple events in a stack application. Further discussion is needed to set criteria defining data requirements to support Risk assessment.

### 9.2 Traits' expression and their variability in GM crops

The experience of the GMO Panel on assessing the variability of the traits' expression in GM crops and the characteristics of the expression of simple and complex traits in GM events were presented. A preliminary analysis of the main elements that might contribute to the variability of the trait was discussed. The GMO Panel will further discuss the topic in one of the upcoming Plenary meetings.

### 9.3 Considerations on the structure of the scientific opinions

In the frame of the discussion initiated at the 124th Scientific Committee meeting,[14] the GMO Panel initiated an analysis for possible improvement of the length and readability of the scientific opinions produced. It was discussed that the main outcomes of this Panel are scientific opinions for applications, which are not extremely lengthy. However, a task force has been established to try to implement some improvements.

### 9.4 Update on gene drive procurement

In 2018, the European Commission (DG SANTE) mandated EFSA to assess whether: (1) the environmental release of gene drive modified insects could pose novel risks to human and animal health and the environment; (2) the scientific considerations given in its previously published guidance for the risk assessment of genetically modified animals are adequate and sufficient for gene drive modified insects; and (3) there is a need for updated guidance in relation to the previous guidance. EFSA focused its activities on disease-transmitting insects, primarily mosquitoes, as they represent the most likely cases of gene drive organisms for environmental release in the near future, but also considered agricultural insect pests and non-native invasive insects.

In 2020, EFSA concluded that its guidelines for genetically modified insects without engineered gene drives provide an appropriate basis for the risk assessment of gene drive modified insects, but that they should be more specific to address the challenges that the environmental release of gene drive modified insects may pose. While the risk assessment of gene drive modified insects can build on the existing framework for genetically modified insects, EFSA identified gaps within the molecular characterisation, environmental risk assessment and post-market environmental monitoring that require additional guidance.

[11] https://www.efsa.europa.eu/sites/default/files/wgs/gmo/wg-applications-molecular-characterisation-2018-2021.pdf
[12] https://www.efsa.europa.eu/sites/default/files/2024-03/Compiled%20minutes%20CompERA%20WG.pdf
[13] https://www.efsa.europa.eu/sites/default/files/2024-11/Minutes.pdf
[14] https://www.efsa.europa.eu/sites/default/files/2025-04/Minutes%20124th%20SC%20Plenary.pdf

In 2023, EFSA commissioned the research project "Preparatory work for the development of risk assessment guidance for gene drive modified insects (OC/EFSA/NIF/2023/01)", which aims to: (1) gather and assess the necessary information to fill the previously identified gaps in existing risk assessment guidelines for genetically modified organisms; and (2) provide recommendations on aspects to consider for the potential development of additional guidance for the risk assessment of gene drive modified insects for environmental release. The project has a duration of two years and kicked off in December 2023. More details about the consortium's composition and the project's progress were presented to the GMO Panel.

# 10. Any other business

### 10.1 EFSA's Executive Director meet the GMO Panel

The acting Executive Director of EFSA, Dr Bernhard Url, extended warm greetings to the members of the GMO Panel, expressing profound gratitude for their dedicated work and commitment. He highlighted the remarkable collaborative spirit among experts from various institutions, emphasizing how this cooperation contributes to achieving common goals. He also identified future challenges for EFSA, emphasizing the necessity of evaluating increasing volumes of evidence in regulatory risk assessments with the current resources available.

### 10.2 Overview of the CORSA Project

The GMO Panel was informed about upcoming changes for the access to the application dossiers. In the coming months the data migration will be completed and access to new visualisation tools will be granted to the Panel experts.

### 10.3 Studies conducted prior to the submission of the dossied to EFSA

The Unit was requested to clarify the procedure to guarantee that the applicants submit all the relevant studies at the time of submission. The GMO Panel was reminded that applicant must notify studies commissioned or carried out as of 27 March 2021 as clarified in the administrative guidance for the preparation of applications on genetically modified plants.[15] It was also clarified that this requirement is not in place for studies carried out before 27 March 2021. The GMO Panel discussed possible actions in case studies conducted prior to that date are not notified.

### 10.4 EFSA in the international context

The Panel discussed possible strategies to increase participation in international context. Possible future actions were examined.

# 11. Next meeting

The next meeting will be held on the 30th of June and 1st of July 2025 via teleconference.

[15] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6473