SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

166th Plenary meeting

2nd-3rd October 2024
9:00 – 16:00 / 9:00 – 13:00
MINUTES - Agreed on 14 October 2024

Location: Teleconference

Attendees

- Panel Members:
Francisco Barro, Josep Casacuberta (Chair), Ruud de Maagd, Michelle M Epstein, Thomas Frenzel, Jean-Luc Gallois, Frits Koning, Antoine Messéan, F Javier Moreno, Fabien Nogué, Giovanni Savoini, Alan H Schulman, Christoph Tebbe and Eve Veromann.
- Hearing experts:
Ian Dewhurst (item 6.2), Lieve Herman (item 5.5) and Luciano Pinotti (item 6.2)
- European Commission:
Olga Orlova
- EFSA:
NIF Unit

Ana Afonso, Michele Ardizzone, Giacomo De Sanctis, Antonio Fernández Dumont, Arianna Ferrari, Andrea Gennaro, Tilemachos Goumperis, Sara Jacchia, Dafni Maria Kagkli, Paolo Lenzi, Aleksandra Lewandowska, Ana Martin Camargo, Franco Maria Neri, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello and Elena Sánchez Brunete.

FEEDCO Unit

Rosella Brozzi (item 5.5), Monserrat Anguita Freixa (item 5.5), Gabriele Gagliardi (item 5.7)

MESE Unit

Jose Angel Gomez Ruiz (item 5.6)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Albert Braeuning and Pilar Cubas.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence[1] and the Decision of the Executive Director on Competing Interest Management[2], 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 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 165th Plenary

4.1 Agreement of the minutes of the 165th Plenary meeting held on 2nd-3rd July 2024

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

The minutes of the 165th plenary meeting were agreed by written procedure on 10th July 2024.

5. Scientific outputs for discussion and possible adoption

5.1 Application for authorisation of genetically modified cotton GHB614 × T304-40 × GHB119 × COT102 submitted under Regulation (EC) No 1829/2003 by Bayer CropScience N.V. EFSA-GMO-ES-2017-147[3]

Cotton GHB614 × T304-40 × GHB119 × COT102 was produced by crossing to combine four single cotton events: expressing Cry1Ab, Cry2Ae and Vip3Aa19 proteins to confer resistance to certain lepidopteran pests, 2mEPSPS protein to confer tolerance to glyphosate-containing herbicides, PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides and APH4 protein used as a selectable marker. The scope of the application EFSA-GMO-ES-2017-147 is for food and feed uses, import and processing and does not include cultivation within the EU.

The Panel discussed the information recently provided by the applicant[3] and defined the next steps to progress the risk assessment of cotton GHB614 × T304-40 × GHB119 × COT102. Further discussion is needed.

5.2 Application for authorisation of genetically modified cotton T304-40 × GHB119 × COT102 submitted under Regulation (EC) No 1829/2003 by BASF Agriculture Solutions EFSA-GMO-BE-2018-155[4]

Cotton T304-40 × GHB119 × COT102 was produced by crossing to combine three single cotton events: expressing Cry1Ab, Cry2Ae and Vip3Aa19 proteins to confer resistance to certain lepidopteran pests, PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides and APH4 protein used as a selectable marker. The scope of the application EFSA-GMO-BE-2018-155 is for food and feed uses, import and processing and does not include cultivation within the EU.

The Panel discussed the information recently provided by the applicant[4] and defined the next steps to progress the risk assessment of cotton T304-40 × GHB119 × COT102. Further discussion is needed.

5.3 Application for authorisation of genetically modified maize DP51291 in accordance with Regulation (EC) No. 1829/2003 by Corteva Agriscience GMFF-2021-0071 (AP179)[5]

Maize event DP51291 expresses IPD072Aa protein for control of susceptible corn rootworm pests, phosphinothricin acetyltransferase (PAT) protein that confers tolerance to the glufosinate ammonium-containing herbicides, and the phosphomannose isomerase (PMI) protein that was used as a selectable marker during transformation. The scope of application GMFF-2021-0071 is for food and feed uses, import and processing and does not include cultivation in the European Union (EU).

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.

5.4 Application for authorisation of genetically modified maize DP202216 × NK603 × DAS-40278-9 and its subcombinations in accordance with Regulation (EC) No. 1829/2003 by Corteva Agriscience GMFF-2022-6232 (AP183)[6]

[3] https://open.efsa.europa.eu/questions/EFSA-Q-2017-00505
[4] https://open.efsa.europa.eu/questions/EFSA-Q-2018-00809
[5] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00051
[6] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00197

Maize DP202216 × NK603 × DAS-40278-9 was produced by crossing to combine three single maize events: CP4 EPSPS and CP4 EPSPS L214P proteins to confer tolerance to glyphosate-containing herbicides, PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides and AAD-1 protein to confer tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) herbicides. In addition, maize DP202216 × NK603 × DAS-40278-9 has been developed to extend and increase the expression of the ZMM28 protein, a MADS-box transcription factor, which can provide an opportunity for a potential yield enhancement under field conditions. The scope of the application GMFF-2022-6232 is for food and feed uses, import and processing and does not include cultivation within the EU.

The Panel discussed the information recently provided by the applicant[6] and defined the next steps to progress the risk assessment of maize DP202216 x NK603 x DAS-40278-9. Further discussion is needed.

5.5 Guidance on Micro-organisms in support of the risk assessment of products used in the food chain [7]

This question refers to a self-task of the Scientific Committee of EFSA to prepare a guidance on the characterisation of microorganisms used in the food chain.

The draft guidance for public consultation is currently being presented to all the relevant Scientific Panels for endorsement before it will be discussed for endorsement by the Scientific Committee.

The draft guidance for public consultation was presented by Lieve Herman (expert of the Panel on Biological Hazards). The GMO Panel endorsed the draft document and the experts provided comments during the discussion. The comments will be taken into consideration and the updated version of the guidance will be shared with the Panel in advance of the presentation of the guidance to the Scientific Committee for endorsement.

5.6 Assessment of additional information related to the application for authorisation of food and feed containing, consisting of and produced from genetically modified soybean MON 87705 × MON 87708 × MON 89788 (AP126)[8]

The GMO Panel revised the draft statement, 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.

5.7 Application for authorisation of soy leghemoglobin produced from genetically modified *Pichia pastoris* submitted under Regulation (EC) No 1829/2003 by Impossible Foods Inc. EFSA-GMO-NL-2019-162[9]

EFSA received two applications submitted to gain authorization for the use of soy leghemoglobin (the liquid preparation is referred to as "LegH Prep") produced from genetically modified *Pichia pastoris*, reclassified as *Komagataella phaffii* as a food flavoring ("meaty taste") in meat analogue products to be marketed in the European Union. The first application[10] was received under Regulation (EC) No 1829/2003 and validated in December 2021 and is under the remit of the GMO Panel, the second application[11] received under Regulation (EC) No 1331/2008 and validated in June 2022 is under the remit of FAF Panel[12].The FAF Panel adopted their opinion on LegH Prep on 15 May 2024, which was published on the EFSA website and in the EFSA Journal on 28 June 2024.

[7] https://open.efsa.europa.eu/questions/EFSA-Q-2024-00438
[8] https://open.efsa.europa.eu/questions/EFSA-Q-2024-00277
[9] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00651
[10] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00651
[11] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00031
[12] https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/faf

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.

5.8 Application for authorisation of genetically modified oilseed rape NS-B50027-4 submitted under Regulation (EC) No 1829/2003 by Nufarm B.V. EFSA-GMO-NL-2019-160[13]

This agenda item was not discussed due to lack of time.

6. Scientific topics for discussion

6.1 Update on renewal applications (RXs)

EFSA received 17 renewal applications in the first half of 2024, 16 of which have been validated. An overview of the renewal applications, the ongoing assessment and the identified cross-cutting issues were presented and discussed. Further discussion is needed.

6.2 Proposal for the development of a feed consumption database using a standardized feed classification system (OC/EFSA/GMO/2021/05)[14]

In September 2021 EFSA published a call for a three years procurement to carry out a proposal for future implementation of a feed consumption database using a standardized feed classification system, in support of a more accurate estimation of animal dietary exposure. Luciano Pinotti, as representative of the contracted institution, presented the outcome of the activity that is also published as eternal scientific report accessible on the EFSA website and in the EFSA Journal.

7. Update on new Mandates

7.1 Applications

This agenda item was not presented due to lack of time.

7.2 Mandates

None

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

8.1 Scientific Committee

The chair reported on discussions at the last Scientific Committee meeting and ongoing EFSA activities[15].

8.2 European Commission

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 Panel(s) including their Working Groups

None

9. Any other business

9.1 Media and content management (MECO) function at EFSA

[13] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00572
[14] https://open.efsa.europa.eu/questions/EFSA-Q-2024-00243
[15] https://www.efsa.europa.eu/en/events/120th-plenary-meeting-scientific-committee

This agenda item was not discussed due to lack of time.

10. Next meeting

The next meeting will be held on 13th-14th November 2024 in Parma and will be open to observers.

Harry Kuiper memorial

The GMO Panel members and EFSA staff honoured the memory of Dr Harry Kuiper who sadly passed away. Harry Kuiper offered his valuable contributions to EFSA's work from the very beginning, in particular in the field of food and feed safety, statistics and comparative assessment, shaping the risk assessment of GMO. Those who had the privilege to collaborate with him greatly appreciated and respected him. The GMO Panel members and EFSA staff wish to express their deepest condolences to his family and friends for the loss of an outstanding scientist, and a generous and committed man.