SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

169th Panel Plenary meeting

5-6 February 2025
09:00-16:00 / 9:00 – 13:00
MINUTES - Agreed on 17 February 2025

EUROPEAN FOOD SAFETY AUTHORITY

Location: Teleconference

Attendees:

- Panel Members:
Josep Casacuberta (Chair), Francisco Barro, Albert Braeuning, Pilar Cubas, 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.
- Hearing Experts[1]:
- European Commission:
Mara Sgroi, Olga Orlova (DG-SANTE)
- EFSA:
NIF Unit:

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

MESE Unit:

Jose Angel Gomez Ruiz (item 6.5)

FDP Unit:

Claudia Parisi (Item 7.1)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Pilar Cubas and Antoine Messéan for the second day of the meeting.

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[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 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.

[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

4. Report on written procedure since the 168th Plenary meeting held on 11 December 2024, online

4.1. Minutes of the 168th GMO Plenary

The minutes of the 168th GMO Open Plenary meeting were agreed by written procedure on 19 December 2024.

4.2. Scientific opinion 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 for public consultation. The Panel was informed that the public consultation has been launched on the 22 January 2025.[4] The mandate deadline for the adoption by the GMO Panel is 30th June 2025. The Panel was also informed that on the 18 February a webinar to introduce the draft scientific opinion has been organised.[5]

5. Scientific outputs submitted for discussion/possible endorsement

5.1. Application for authorisation of genetically modified maize DAS1131 submitted under Regulation (EC) No 1829/2003 by Corteva Agriscience GMFF-2021-1530 (AP175) (EFSA-Q-2022-00410)

Maize DAS1131 was produced by Agrobacterium-mediated transformation using a single transformation vector to introduce genes encoding the Cry1Da2 and DGT-28 EPSPS proteins to confer resistance to certain susceptible lepidopteran pests, as well as tolerance to glyphosate-based herbicides, respectively.

The scope of application GMFF-2021-1530 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.

6. Scientific outputs for discussion

6.1. Application for renewal of genetically modified soybean MON 87708 submitted under Regulation (EC) No. 1829/2003 GMFF-2024-21237 (RX038) (EFSA-Q-2024-00154)

Soybean MON 87708 contains the DMO gene conferring tolerance to dicamba-based herbicides. Following the submission of application EFSA-GMO-NL-2011-93 and the publication of the EFSA scientific opinion[6], the placing on the market of soybean MON 87708 for products containing, consisting of, or produced from this GM soybean, excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/700. In 2024, the applicant asked the European Commission to renew the authorisation for the placing on the market of soybean MON 87708 and submitted dossier GMFF-2024-21237 in support of

[4] https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000003Wxsr/pc1293
[5] https://www.efsa.europa.eu/en/events/webinar-new-developments-biotechnology-including-synbio-and-ngts-applied-animals-food-feed
[6] https://doi.org/10.2903/j.efsa.2013.3355

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. It was agreed that the GMO Panel will assess the missing information in the relevant working groups once it is 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.

6.2. Application for renewal of genetically modified maize T25 submitted under Regulation (EC) No. 1829/2003 GMFF-2024-22651 (RX042) (EFSA-Q-2024-00185)

Maize T25 contains the PAT gene conferring tolerance to glufosinate ammonium-based herbicides. Following the submission of applications EFSA-GMO-RX-T25 and EFSA-GMO-NL-2007-46 and the publication of the EFSA scientific opinion[7], the placing on the market of maize T25 for products containing, consisting of, or produced from this GM maize, excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/697. In 2024 the applicants asked the European Commission to renew the authorisation for the placing on the market of maize T25 and submitted dossier GMFF-2024-22651 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. It was agreed that the GMO Panel will assess the missing information in the relevant working groups once it is 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.

6.3. Application for renewal of genetically modified cotton GHB614 x LLCotton25 submitted under Regulation (EC) No. 1829/2003 GMFF-2024-21890 (RX043) (EFSA-Q-2024-00186)

Cotton GHB614 x LLCotton25 contains the 2mEPSPS and PAT genes conferring tolerance to glufosinate-ammonium- and glyphosate-based herbicides. Following the submission of applications EFSA-GMO-CZ-2008-62 and the publication of the EFSA scientific opinion[8], the placing on the market of cotton GHB614 x LLCotton25 for products containing, consisting of, or produced from this GM cotton, excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/690 and 2019/1195. In 2024, the applicants asked the European Commission to renew the authorisation for the placing on the market of cotton GHB614 x LLCotton25 and submitted dossier GMFF-2024-21890 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. It was agreed that the GMO Panel will assess the missing information in the relevant working groups once it is 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.

[7] https://doi.org/10.2903/j.efsa.2013.3356
[8] https://doi.org/10.2903/j.efsa.2014.3680

6.4. Application for authorisation of genetically modified soybean MON 94313 submitted under 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-ammonium-, 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 all working groups was presented. It was agreed that the GMO Panel will assess the missing information once it is 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.

6.5. Application for authorisation of canola LBFLFK import in the European Union submitted under Regulation (EC) No 1829/2003 by BASF Agriculture Solutions EFSA-GMO-DE-2019-157 (EFSA-Q-2019-00394)

Oilseed rape LBFLFK was produced by *Agrobacterium*-mediated transformation using a single transformation vector to introduce genes encoding fatty acid desaturase and elongase proteins to allow for the synthesis of omega-3 long-chain polyunsaturated fatty acids (LC PUFAs), including EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid), from oleic acid, as well as an AHAS (acetohydroxyacid synthase) protein to confer tolerance to imidazolinone containing herbicides.

The scope of application EFSA-GMO-DE-2019-157 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 and discussed with the Panel.

6.6. Application for authorisation of genetically modified cotton GHB614 × T304-40 × GHB119 × COT102 submitted under Regulation (EC) No 1829/2003 by Bayer CropScience N.V. and transferred to BASF Agricultural Solutions EFSA-GMO-ES-2017-147 (EFSA-Q-2017-00505)

Cotton GHB614 × T304-40 × GHB119 × COT102 was produced by crossing to combine four single cotton events: expressing the Cry1Ab, Cry2Ae and Vip3Aa19 proteins to confer resistance to certain lepidopteran pests; the 2mEPSPS protein to confer tolerance to glyphosate-containing herbicides; the PAT protein to confer tolerance to glufosinate ammonium containing herbicides; the APH4 protein used as a selectable marker. The scope of 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 and defined the next steps to progress the risk assessment of cotton GHB614 × T304-40 × GHB119 × COT102. Further discussion is needed.

6.7. 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 (EFSA-Q-2018-00809)

Cotton T304-40 × GHB119 × COT102 was produced by crossing to combine three single cotton events: expressing the Cry1Ab, Cry2Ae and Vip3Aa19 proteins to confer resistance to certain lepidopteran pests, the PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides and the APH4 protein used as a selectable marker. The scope of 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 and defined the next steps to progress the risk assessment of cotton T304-40 × GHB119 × COT102. Further discussion is needed.

7. Scientific topics for discussion

7.1. Requirements for stack applications

The GMO Panel continued the discussion held at the working group level[9,10,11] on the data requirements for stack applications. In the last 20 years, the EFSA Panel assessed more than 130 applications, of which about 60 of them were for stacks. The Panel revised the approach followed and the outcomes of the analysis of the stacks and the singles involved. The Panel started a discussion on how to possibly optimise data requirements for scientific excellence in the risk assessment.

8. Update on new Mandates

8.1. Applications

- Soybean 305423 x DAS-44406-6 (AP195) (EFSA-Q-2024-00728)

8.2. Mandates

- Mandate for the assessment of the 2023 PMEM report on MON 810 cultivation. (EFSA-Q-2025-00152)
- Mandate for the assessment of the 2024 post-market monitoring report of GM oilseed rape 73496 (question number not yet available)

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

9.1. Scientific Committee

The Chair of the GMO Panel reported on the discussions planned for the next Scientific Committee meeting and ongoing EFSA activities. [9]

9.2. 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.

9.3. Scientific Panel(s) 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)[10], comparative risk assessment and ERA (CompERA)[11] and food and feed (FF)[12].

[9] https://www.efsa.europa.eu/en/events/123rd-plenary-meeting-scientific-committee
[10] https://www.efsa.europa.eu/sites/default/files/wgs/gmo/wg-applications-molecular-characterisation-2018-2021.pdf
[11] https://www.efsa.europa.eu/sites/default/files/2024-03/Compiled%20minutes%20CompERA%20WG.pdf
[12] https://www.efsa.europa.eu/sites/default/files/2024-11/Minutes.pdf

10. Any other business

10.1. Resignation from the GMO Panel

Pilas Cubas communicated her decision to resign from the GMO Panel. The Chairs of the Panel and of the molecular characterisation working group as well as the experts and the Unit expressed their gratitude for the work done.

10.2. Calendar 2026

The 2026 Calendar was shared and agreed. The dates will be published soon on the EFSA calendar.[13]

Next meeting

The next meeting will be held on the 26th and 27th March 2025 via teleconference.

[13] https://www.efsa.europa.eu/en/events/advanced-search