SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

170th Panel Plenary meeting



26-27 March 2025 09:00-16:00 / 9:00 - 12:00 MINUTES - Agreed on 8 April 2025

Location: Teleconference

Attendees:

o Panel Members:

Francisco Barro, Josep Casacuberta, Michelle M Epstein (Chair), 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 Experts¹:

Angela Bearth (for item 7.1)

o European Commission:

Mara Sgroi and Olga Orlova (DG-SANTE)

o EFSA:

NIF Unit:

Michele Ardizzone, Martina Bonatti, 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

Communication Unit:

Anthony Smith and Joana Sousa Lourenço (for item 7.1)

1. Welcome and apologies for absence

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

2. Adoption of agenda

The agenda was adopted with changes. Application GMFF-2024-23010 was moved from section 5 (items for discussion and possible adoption) of this agenda to section 6 (items for discussion) because of pending reception of additional information EFSA requested.

3. Declarations of Interest of Panel members

In accordance with EFSA's Policy on Independence² and the Decision of the Executive Director on Competing Interest Management³, 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 document "Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups":

https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf

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

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4. Report on written procedure since the 169th Plenary meeting held on 5-6 February 2025, online

The <u>minutes</u> of the 169th GMO Plenary meeting were agreed by written procedure on 17 February 2025.

5. Scientific outputs submitted for discussion and possible adoption

5.1 Application for authorisation of genetically modified sugar beet KWS20-1 submitted under Regulation (EC) No 1829/2003 by Bayer Agriculture BV and KWS SAAT SE & Co. KGaA GMFF-2023-14732 (AP184) (EFSA-Q-2023-00378)

Sugar beet KWS20-1 was produced by *Agrobacterium* mediated transformation using a single transformation vector to introduce genes encoding the CP4 EPSPS, DMO and PAT proteins to confer tolerance to glyphosate-, dicamba- and glufosinate-based herbicides, respectively.

The scope of application GMFF 2023 14732 is for food produced from genetically modified sugar beet KWS20 1 or containing ingredients produced from sugar beet KWS20 1 and feed produced from sugar beet KWS20 1 for import and processing and does not include the cultivation or the import of viable material in the European Union

The GMO Panel revised the draft opinion and, where appropriate, questions were raised and addressed throughout the different sections. Among other elements, the GMO Panel discussed the zygosity of the KWS20-1 event in the assessed materials. The GMO Panel adopted the opinion, which will be published on the EFSA <u>website</u> and in the EFSA <u>Journal</u>.

5.2 Application for renewal of genetically modified cotton MON 88913 submitted under Regulation (EC) No. 1829/2003 by Bayer CropScience GMFF-2023-21234 (RX030) (EFSA-Q-2024-00131)

Cotton MON 88913 contains the CP4 EPSPS gene conferring tolerance to glyphosate-based herbicides. Following the submission of application EFSA-GMO-UK-2007-41 and the publication of the EFSA scientific opinion⁴, the placing on the market of cotton MON 88913 for products containing, consisting of, or produced from this GM cotton, excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/688. In 2024, the applicant asked the European Commission to renew the authorisation for the placing on the market of cotton MON 88913 and submitted application GMFF-2023-21234 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 <u>website</u> and in the EFSA <u>Journal</u>.

5.3 Application for renewal of genetically modified oilseed rape MON 88302 submitted under Regulation (EC) No. 1829/2003 by Bayer CropScience GMFF-2023-21220 (RX031) (<u>EFSA-Q-2024-00133</u>)

Oilseed rape MON 88302 contains the CP4 EPSPS gene conferring tolerance to glyphosate - based herbicides. Following the submission of application EFSA-GMO-BE-2011-101 and the publication of the EFSA scientific opinion 5 , the placing on the market of oilseed rape

⁴ https://doi.org/10.2903/j.efsa.2013.3311

⁵ https://doi.org/10.2903/j.efsa.2014.3701

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MON 88302 for products containing, consisting of, or produced from this GM oilseed rape, excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/687. In 2024, the applicant asked the European Commission to renew the authorisation for the placing on the market of oilseed rape MON 88302 and submitted application GMFF-2023-21220 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 quidelines.

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 <u>website</u> and in the EFSA <u>Journal</u>.

5.4 Application for renewal of genetically modified soybean MON 87708 submitted under Regulation (EC) No. 1829/2003 by Bayer CropScience 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 opinion⁶, 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 application GMFF-2024-21237 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.

5.5 Application for renewal of genetically modified maize MON 87427 in accordance with Regulation (EC) No. 1829/2003 by Bayer CropScience GMFF-2024-21254 (RX041) (EFSA-Q-2024-00182)

Maize MON 87427 contains the CP4 EPSPS gene conferring tolerance to glyphosate-based herbicides. Following the submission of application EFSA-GMO-BE-2012-110 and the publication of the EFSA scientific opinion⁷, the placing on the market of maize MON 87427 for products containing, consisting of, or produced from this GM maize, excluding cultivation in the EU, was authorised by Commission Implementing Decision (EU) 2015/2281. In 2024, the applicant asked the European Commission to renew the authorisation for the placing on the market of maize MON 87427 and submitted application GMFF-2024-21254 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 <u>website</u> and in the EFSA <u>Journal</u>.

6. Scientific outputs for discussion

6.1 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-O-2020-00013)

⁶ https://doi.org/10.2903/j.efsa.2013.3355

⁷ https://doi.org/10.2903/j.efsa.2015.4130

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

6.2 Application for renewal of genetically modified cotton T304-40 in accordance with Regulation (EC) No. 1829/2003 by BASF Agricultural Solutions Seed GMFF-2024-23010 (RX044) (<u>EFSA-O-2024-00196</u>)

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

7. Scientific topics for discussion

7.1 Social Sciences at EFSA: updated 2027 roadmap, cooperation with Scientific committee and Panels

The use of evidence and expertise from social science at EFSA was first formalised in 2018. Social science is now a well-established function, with an in-house team providing research and advice services across the organisation with the support of external expertise, in particular the Working Group on Social Research Methods and Advice.⁸

EFSA's social scientists use primary and secondary social research to inform risk communication and the targeting of audiences for communication on scientific work and for public information campaigns. These research activities also support risk managers on sensitive or emerging topics of interest. Social science approaches and methods are also used at an organisational level to support corporate initiatives.

EFSA's Social Science Roadmap is linked to the EFSA Strategy 2027 and was recently updated following a mid-term review and endorsed for 2025-2027 by EFSA's Management Team. The review took stock of progress on the objectives included in the Roadmap in 2022 and updated subsequent projects and targets for the coming three years.

Social science can also contribute to scientific risk assessment as has been done already at EFSA in a few cases. The invited experts and the GMO Panel experts discussed possible collaboration areas that could benefit from this type of extended interdisciplinary approach.

7.2 Requirements for stack applications

The outcomes of the discussions held at the FF and CompERA WGs were reported to the Panel. Based on the acquired experience gained with stack applications, the Panel continued the analysis on how to optimise data requirements maintaining scientific excellence in the risk assessment. The Panel made hypothesis to differentiate data requirement using different case studies. Further discussion is needed to set criteria to be shared with stakeholders defining which data is needed to support the Panel conclusions.

8. Update on new mandates

- 8.1 Applications
 - Soybean IND-00410-5 (AP196) (EFSA-Q-2025-00226)
- 8.2 Mandates
 - o None

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

9.1 Scientific Committee

⁸ https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/comco

 $^{^9\,\}underline{\text{https://www.efsa.europa.eu/sites/default/files/2025-02/Minutes\%20GMO\%20169\%20Plenary.pdf}\\$

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

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 cross-cutting relevance that took place in the recent meetings of the working groups for molecular characterisation (MC)11, comparative risk assessment and ERA (CompERA)12, and for food and feed (FF)13.

10. Any other business

10.1 Upcoming discussions at the next Plenary meetings

The Panel was informed that the public consultations^{14,15} on the two scientific opinions endorsed by the Panel on protein safety¹⁶ and NGT-GMA¹⁷ were recently closed. The comments received will be presented at the upcoming Plenary meeting.

10.2 Place and length of the Plenary meetings

The Panel also discussed the possibility to increase the number of physical meetings in the future as well as the length of the meetings.

11. Next meeting

The next meeting will be held on the 21-22 May 2025 in Parma.

¹⁰ https://www.efsa.europa.eu/en/events/123rd-plenary-meeting-scientific-committee

¹¹ https://www.efsa.europa.eu/sites/default/files/wqs/gmo/wq-applications-molecular-characterisation-2018-2021.pdf

¹² https://www.efsa.europa.eu/sites/default/files/2024-03/Compiled%20minutes%20CompERA%20WG.pdf

https://www.efsa.europa.eu/sites/default/files/2024-11/Minutes.pdf
 https://open.efsa.europa.eu/consultations/a0cTk00000AwHZ7IAN?status=Closed

https://open.efsa.europa.eu/consultations/a0cTk00000BEWZmIAP?status=Closed

https://www.efsa.europa.eu/sites/default/files/2024-12/Minutes%20GMO%20168%20PL.pdf

https://www.efsa.europa.eu/sites/default/files/2025-02/Minutes%20GMO%20169%20Plenary.pdf