SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

164th Plenary meeting

19th – 20th June 2024
9:00-16:30 / 9:00-12:30
MINUTES - Agreed on 1 July 2024

Location: EFSA premises, Parma

Attendees:

- Panel Members:
Ewen Mullins (chair), Jean-Louis Bresson (by tele), Tamas Dalmay, Ian Dewhurst, Michelle Epstein, Leslie George Firbank, Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Hanspeter Naegeli (by tele), Fabien Nogué, Nils Rostoks, Jose Juan Sanchez Serrano, Giovanni Savoini, Eve Veromann and Fabio Veronesi

- Hearing Experts[1]:
Petr Svoboda (for item 6.1)

- European Commission:
DG SANTE: Alexandre Huchelmann (by tele for item 5.2), Kathleen Lehmann (by tele for item 5.4), Olga Orlova and Mara Sgroi (by tele).

- EFSA:
NIF Unit:

Ana Afonso, Michele Ardizzone, Giacomo De Sanctis, Antonio Fernández Dumont, Arianna Ferrari, Andrea Gennaro, Aina Belen Gil Gonzalez, Tilemachos Goumperis, Sara Jacchia, Dafni Maria Kagkli, Paolo Lenzi, Ana Martin Camargo, Franco Maria Neri, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, Marta Rodrigues and Reinhilde Schoonjans.

FDP Unit:

Claudia Parisi and Elena Lannocca (both by tele and only 19th June)

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

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 Working Group 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 163rd Plenary

4.1 Agreement of the minutes of the 163rd Plenary meeting held on 15th May 2024

[1] As defined in Article 17 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

The minutes of the 163rd plenary meeting were agreed by written procedure on 24th May 2024.

5. Scientific outputs submitted for discussion

5.1 Application for authorisation of genetically modified maize MON 95275 in accordance with Regulation (EC) No. 1829/2003 (AP173)
GMFF-2022-5890
EFSA-Q-2022-00330

Maize MON 95275 expresses two insecticidal proteins Mpp75Aa1.1 and Vpb4Da2 which are members of the pore-forming ETX_MTX2 β-PFPs protein family and of the Bacterial_exotoxin_B protein family, respectively, and the DvSnf7.1 double-stranded ribonucleic acid (dsRNA). The insecticidal proteins and the dsRNA provide control for coleopteran pests including the northern corn rootworm (*Diabrotica barberi*) and the western corn rootworm (*Diabrotica virgifera virgifera*). The scope of application GMFF-2022-5890 is for food and feed uses, import and processing and does not include cultivation in the 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.

5.2 European Parliament's request for a scientific opinion on recent studies on the proposal for a regulation of the European Parliament and the Council on plants obtained by certain NGT and their food and feed and amending regulation (EU) 2017/625
EFSA-Q-2024-00178

The European Parliament on 22 February 2024 requested EFSA in accordance with Article 29 of Regulation 178/2002, to deliver a scientific opinion on the analysis by ANSES on Annex 1[4] of the EC proposal for a regulation on plants obtained by certain NGTs and their food and feed and amending Reg (EU) 2017/625.

The GMO Panel was informed that the cross cutting WG [5] finalised the opinion that was presented to the Panel for discussion and possible adoption.
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.

5.3 Scientific opinion on new developments in biotechnology applied to microorganisms
EFSA-Q-2023-00050

At the 161st Plenary meeting of the GMO Panel, the draft opinion on new developments in biotechnology applied to microorganisms was endorsed and a public consultation launched.[6] The consultation was closed 8/4/24 and about four hundred comments were received. The assessment of the comments took place in the GMM-NGT WG[7]. The GMO Panel revised the updated draft opinion.
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.

[4] https://eur-lex.europa.eu/resource.html?uri=cellar:c88fe9ac-1c06-11ee-806b-01aa75ed71a1.0001.02/DOC_2&format=PDF
[5] https://www.efsa.europa.eu/sites/default/files/2024-04/applications-cross-cutting.pdf
[6] The public consultation was accessible at: https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0lTk000000C3VB/pc0848
[7] https://www.efsa.europa.eu/sites/default/files/2023-01/gmm-ngt-minutes.pdf

5.4 Application for authorisation of genetically modified maize DP910521 in accordance with Regulation (EC) No. 1829/2003 (AP174) GMFF-2021-2473 EFSA-Q-2022-00120

Maize DP910521 expresses the Cry1B.34 protein for control of certain lepidopteran insect 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-2022-5890 is for food and feed uses, import and processing and does not include cultivation in the 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.

6. Other scientific topics for information/discussion

6.1 Presentation of the procurement on the development of risk assessment methodology for RNAi-based GM plants

To keep EFSA's guidance and RA methodologies up to date with the scientific knowledge, EFSA has procured an update of past literature reviews on the mechanism and mode of action of non-coding RNAs in plants, related to the risk assessment of RNAi-based GM plants and their safety in food and feed. The progress of this procurement that has been launched through the MESE framework contract[8] OC/EFSA/MESE/2022/03 for Methodological Support for the Performance of Literature Reviews within Evidence-based Scientific Assessments, was presented to the GMO panel by the tenderer. This includes: i) an update on aspects of molecular characterisation of RNAi-based plants; ii) a review of the *in silico* tools for RNAi off-target predictions; and iii) updated literature review on the food and feed safety of RNAi-based plants including dietary exposure and measurement of silencing RNAs in humans and animals. Based on the outcome of the updated literature review EFSA will propose potential updates to the Panel's strategy Note (2017[9]) for the RA of RNAi based GM plants.

6.2 Update on recent activities on the improvement of PMEM plans for import and processing applications

EFSA presented the activity on the potential improvement of the Post-Market Environmental Monitoring (PMEM) plans required under Directive 2001/18/EC. The GMO Panel's CompERA Working Group (WG), which assesses the adequacy of PMEM plans in January 2024 annexed to its meeting minutes [10] a set of recommendations for the preparation of PMEM plans for applications for import, processing and all food and feed purposes. EFSA is currently engaged with the different stakeholders to define how applicants should provide additional details in PMEM plans and the amount of detail required, considering factors like crop specificity and the balance between prescriptiveness and flexibility.

7. Update on new Mandates

7.1 Applications

None

7.2 Mandates

None

[8] https://etendering.ted.europa.eu/cft/cft-display.html?cftId=10566
[9] http://www.efsa.europa.eu/sites/default/files/event/171025-m.pdf
[10] https://www.efsa.europa.eu/sites/default/files/2024-03/Compiled%20minutes%20CompERA%20WG.pdf

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

8.1 Scientific Committee

Tamas Dalmay, the Vice-Chair of the GMO Panel reported on discussions at the last Scientific Committee meeting and ongoing EFSA activities.[11]

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

The GMO Panel was updated on discussions of transversal relevance that took place in the last working groups.[12]

9. Any other business

9.1 Overview of the outputs produced by the current Panel

The NIF Unit gave an overview of the scientific outputs produced by the current GMO Panel (2018-2024). The NIF Unit and the GMO Panel mutually acknowledged the fruitful collaboration and the reciprocal trust that characterised the mandate of this Panel.

10. Next meeting

The next meeting will be held on 2nd – 3rd July 2024 in Parma.

[11] https://www.efsa.europa.eu/en/events/119th-plenary-meeting-scientific-committee
[12] https://www.efsa.europa.eu/en/science/scientific-committee-and-panels/gmo#working-groups