SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS
Minutes of the 156th Plenary meeting

15-16 March 2023
MINUTES - Agreed on 29 March 2023

Location: EFSA, Parma

Attendees:

- **Panel Members:**

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

- **Hearing Experts**[1]**:**

  Ivan Dimitrov (for item 6.3)

- **European Commission:**

  DG SANTE:

  Alexandre Huchelmann (for items 5.2, via tele), Juliette-Marie Margueritte (for items 5.2, 5.5, 6.1, 7, 8 and 9, via tele) and Olga Orlova

- **EFSA**:

  NIF Unit:

  Ana Afonso, Michele Ardizzone, Giacomo De Sanctis, Silvia Federici, Antonio Fernández Dumont, Andrea Gennaro, Tilemachos Goumperis, Paschalina Grammatikou, Dafni Maria Kagkli, Aleksandra Lewandowska, Ana Martin Camargo, Franco Maria Neri, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, Reinhilde Schoonjans and Kyriaki Xiftou

  MESE Unit:

  Jose Ángel Gómez Ruiz (for item 5.4)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Ian Dewhurst who was unable to attend most of the 1st day 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 Working Group members invited to the present meeting. No Conflicts of Interest related to the

[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

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 procedures since the 155th Plenary meeting

4.1 Minutes of the 155th Plenary meeting

The minutes of the 155th Plenary meeting were agreed by written procedure on the 15 February 2023. [4]

5. Scientific topics for discussion and possible adoption

5.1 Application for the renewal of the authorisation for the placing on the market of food and feed products containing or consisting of genetically modified oilseed rapes MS8, RF3 and MS8 x RF3, authorised under regulation (EC) No 1829/2003 (Commission Implementing decision 2013/327/EU and (EU) 2019/1301) submitted by BASF Agriculture Solutions (EFSA-GMO-RX-024)[5]

Oilseed rape MS8×RF3 was developed through conventional crossing of events MS8 (male sterile) and RF3 (fertility restorer) to contain *bar*, *barstar* and *barnase* genes, and confer tolerance to glufosinate ammonium containing herbicides. Following a thorough risk assessment by EFSA, the placing on the market of oilseed rapes MS8, RF3 and MS8 x RF3 for products containing, consisting of, or produced from these oilseed rapes, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2013/327/EU and (EU) 2019/1301. In 2021 the applicant asked the European Commission to renew the authorisation for the placing on the market of oilseed rapes MS8, RF3 and MS8 x RF3 and submitted application EFSA-GMO-RX-024 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.

5.2 EC mandate requesting EFSA to assess the additional information on maize MIR162[6]

On 28 November 2022, the European Commission mandated EFSA to consider whether, on the basis of the new information submitted via public consultation [7][8] of two recently published opinions, the conclusions for the adopted opinions[9] on events containing MIR162 remain valid. The GMO Panel discussed the additional information provided by the applicant. The text of the draft Panel statement was revised, and where appropriate, questions were raised and addressed throughout the different sections. The EFSA GMO Panel concluded that the new information would have no impact on the previous conclusions on maize MIR162 and stacked events containing MIR162. The GMO Panel adopted the statement, which will be published on the EFSA website and in the EFSA Journal.

[4]
[5] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00121
[6] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00853
[7] https://food.ec.europa.eu/system/files/2022-09/gmo_pub-cons_comments_2022-7451.pdf
[8] https://food.ec.europa.eu/system/files/2022-11/gmo_pub-cons_comments_mir162.pdf
[9] Maize Bt11 × MIR162 × MIR604 × GA21 (EFSA-GMO-DE-2009-66), Bt11 × MIR162 × 1507 × GA21 (EFSA-GMO-DE-2010-86), Bt11 × MIR162 × MIR604 × 1507 × 5307 × GA21 (EFSA-GMO-DE-2011-103), MON 87427 × MON 89034 × MIR162 × MON 87411 (EFSA-GMO-NL-2017-144), MON 87427 × MON 89034 × MIR162 × NK603 (EFSA-GMO-NL-2016-131), MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 (EFSA-GMO-NL-2016-134) and 1507 × MIR162 × MON810 × NK603 (EFSA-GMO-NL-2015-127)

5.3 Request for placing on the market of soy leghemoglobin produced from genetically modified *Pichia pastoris*. (EFSA-GMO-NL-2019-162)[10]

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 (P. pastoris)* 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 GMO Panel was informed about the status of these applications and discussed the scientific content of the dossier submitted under its remit. The GMO Panel discussed how the risk assessment work is being organised in collaboration with the FAF Panel. Further discussion is needed.

5.4 Application for authorisation of LBFLFK canola import in the European Union submitted under Regulation (EC) No 1829/2003 by BASF Agriculture Solutions (EFSA-GMO-DE-2019-157)[13]

Oilseed rape event LBFLFK was produced by *Agrobacterium*-mediated transformation of the conventional cv. Kumily 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 the 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 all working groups was presented, focusing on newly expressed protein characterisation, toxicity assessment, comparative and environmental risk assessment. Further discussion is needed.

5.5 Application for authorization of genetically modified maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Syngenta Crop Protection NV/SA (EFSA-GMO-DE-2018-149)[14]

Maize Bt11 x MIR162 x MIR604 x MON 89034 x 5307 x GA21 was produced by crossing to combine six single maize events: expressing Cry1Ab, Cry1A.105, Cry2Ab2 and Vip3Aa20 proteins to confer resistance to certain lepidopteran pests, eCry3.1Ab and mCry3A proteins to confer resistance to certain coleopteran pests, mEPSPS protein to confer tolerance to glyphosate-containing herbicides, PAT protein to confer tolerance to glufosinate-ammonium-containing herbicides and PMI protein used as a selectable marker. The scope of the application EFSA-GMO-DE-2018-149 is for food and feed uses, import and processing and does not include cultivation within the EU.

Following the discussion of the additional information on maize MIR162 (see item 5.2) the GMO Panel revised the draft opinion. Due to time constrains it was not possible to fine-tune some of the sections. A revised draft opinion will be circulated via email to the GMO Panel that will be proposed for adoption by written procedure.

[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
[13] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00394
[14] https://open.efsa.europa.eu/questions/EFSA-Q-2018-00292

6. Other scientific topics for information and/or discussion

6.1 Protein safety – issues and way forward

Some of the recent GM events under assessment by the GMO panel, contain numerous newly expressed proteins that are difficult to characterise and assess. In particular, the GMO Panel discussed the challenges related to the protein allergenicity and toxicity assessment in GMO applications. The discussion focused on the history of safe use, bioinformatic analysis, *in vitro* and *in vivo* safety testing. The panel proposed that emerging tools and methodologies could be used to strengthen protein safety assessment. A way forward in this area is necessary. It was proposed that the relevant WGs start defining a logic flow for the assessment with alternative approaches.

6.2 Update on recent discussions on the use of GM plants in aquafeed

The implications of using GM-plant based proteins as feed in aquaculture have been recently discussed in the working groups (WGs) FF[15] and CompERA[16] of the GMO Panel. NIF conducted a literature scan to understand whether GM material is currently used for this purpose in Europe, if non-target organisms are exposed to aquafeed, and whether the current food and feed safety assessment covers aquatic animals. EFSA staff has liaised with FEEDCO colleagues and identified relevant methodologies that could be used for environmental risk assessment (ERA). The ERA section of the scientific opinion has been modified to consider this new route of exposure. Further discussion in the WGs is needed.

6.3 Software tool for peptide binding prediction in celiac disease

EFSA contractor presented a software tool (preDQ) developed to predict the capacity of peptides to bind to HLA-DQ2 and/or HLA-DQ8 proteins, which is needed to assess the capacity of novel proteins in food and feed to cause celiac disease. [17][18] The tool is available on EFSA's R4EU platform.[19] The aim of the overall project and the approaches used for the development of the tool, as well as the functionalities of the software were explained. The tool has already been presented to the applicants on the dedicated meeting on 27 February 2023 and is currently in the testing phase running till April/May 2023.

6.4 Risk assessment of stacks and subcombinations

The item was not discussed due to lack of time.

7. New Mandates

7.1 Applications under Regulation (EC) No 1829/2003

Since the last meeting of the GMO Panel, EFSA received the following applications:

- **GMFF-2022-6312** Application of L-tryptophan as a GMM in the European Union to be used as feed additive[20]
- **GMFF-2022-10611** Application of L-threonine as a GMM in the European Union to be used as feed additive[21]
- **GMFF-2021-0071** on GM maize DP51291 (DP-Ø51291-2)[22]
- **GMFF-2022-11270** on oilseed rape MON 94100 × MON 88302 × RF3and its sub-combinations [23]

[15] https://www.efsa.europa.eu/sites/default/files/2022-01/wg-applications-foodfeed-2018-2024.pdf
[16] https://www.efsa.europa.eu/sites/default/files/wgs/gmo/gmocompera2019.pdf
[17] https://etendering.ted.europa.eu/cft/cft-display.html?cftId=4505
[18] https://www.efsa.europa.eu/it/events/webinar-software-tool-celiac-disease-risk-assessment-proteins
[19] https://r4eu.efsa.europa.eu/app/predq
[20] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00046
[21] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00047
[22] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00051
[23] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00084

- **GMFF-2022-11530** on soybean DBN8002 (DBN-Ø8ØØ2-3)[24]
- **GMFF-2022-10651** on maize MON 94804[25]
- **GMFF-2022-6232** on maize DP202216 x NK603 x DAS-40278-9 and its sub-combinations[26]

7.2 Mandates

As previously communicated to the GMO Panel,[27] under mandate M-2018-0205, EFSA received a request to issue an opinion on new developments in biotechnology applied to animals (including synthetic biology and new genomic techniques (NGT)). The opinion needs to be delivered by end of June 2025 and will include a knowledge gathering report to identify cases of animals (for food and feed products) obtained by NGT. The GMO Panel was informed that Giovanni Savoini will be the chair of the dedicated working group (genetically modified animals (GMA-NGT)), and Thomas Frenzel and Fabien Nogué will be vice-chairs.

8. Feedback from the Scientific Committee/the Scientific Panels, EFSA, European Commission

8.1 Scientific Committee and other Scientific Panel(s) including their Working Groups

The Chair of the GMO Panel reported on discussions at the last Scientific Committee meeting and ongoing EFSA activities[28].

The Panel members were also updated on the activities of the WG on Protocol Development[29] which is relevant for the Panel's work on generic mandates.

8.2 Upcoming Mandates

None

8.3 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. Any Other Business

9.1 Dissemination of publications in EFSA Journal

The GMO Panel remarked that there is a need for improved visibility of EFSA's outputs published in EFSA Journal. Communication strategies which will ensure that the scientific outputs of EFSA and its Panels reach their target audiences should be considered.

9.2 Request for placing on the market of genetically modified RF3 Canola Quality *Brassica juncea* submitted by BASF Agriculture Solutions in accordance with Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2019-158)[30]

The GMO Panel was updated on the status of the risk assessment of this application and the outcome of the recent communication of the applicant.

[24] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00103
[25] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00106
[26] https://open.efsa.europa.eu/questions/EFSA-Q-2023-00197
[27] https://www.efsa.europa.eu/sites/default/files/2023-03/Minutes%20of%20155th%20GMO%20plenary_January%202023.pdf https://www.efsa.europa.eu/sites/default/files/2023-03/Minutes of 155th GMO plenary_January 2023.pdf
[28] https://www.efsa.europa.eu/en/events/112th-plenary-meeting-scientific-committee
[29] https://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-protocol-development.pdf
[30] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00412

10. Next meeting

The minutes of the current meeting will be adopted by written procedure and will be published at: https://www.efsa.europa.eu/en/events/156th-plenary-meeting-gmo-panel

The next meeting will be held on 10-11 May 2023, online.