NUTRITION & FOOD INNOVATION UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 151st MEETING

Held on 20-21 June 2022, Square – Convention Centre Brussels and online

(Agreed on 4 July 2022)

Participants

- Panel Members:

Jean Louis Bresson[1], Tamas Dalmay[1], Ian Dewhurst, Michelle Epstein, Leslie George Firbank[1], Philippe Guerche, Jan Hejatko[1], Francisco Javier Moreno[1], Ewen Mullins (chair), Hanspeter Naegeli[1], Fabien Nogué, Nils Rostoks[1], Jose Juan Sanchez Serrano[1], Giovanni Savoini[1], Eve Veromann[1] and Fabio Veronesi

- European Commission:

DG SANTE : Ilaria Ciabatti[2], Alexandre Huchelmann[3], Carina Lalyer[3], Juliette-Marie Margueritte[2] and Olga Orlova[3]

- EFSA NIF Unit:

Ana Afonso[4], Michele Ardizzone[5], Giacomo De Sanctis[1], Silvia Federici[1], Antonio Fernández Dumont, Andrea Gennaro, Tilemachos Goumperis[1], Paschalina Grammatikou[4], Dafni Maria Kagkli[1], Paolo Lenzi[1], Aleksandra Lewandowska[1], Ana Martín Camargo[1], Franco Maria Neri[1], Nikoletta Papadopoulou, Pietro Piffanelli[1], Tommaso Raffaello, Reinhilde Schoonjans[1] and Franz Streissl[1]

1. Welcome and apologies for absence

The Chair welcomed the participants.

[1] Attended the meeting online
[2] Attended the second day only
[3] Attended the first day only
[4] Attended online the first day
[5] Attended online the first day only

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[6] and the Decision of the Executive Director on Competing Interest Management[7] 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 procedures since the 150th GMO Plenary meeting

Since the 150th Plenary meeting, one output has been adopted by written procedure:

4.1. The minutes of the 150th Plenary meeting

The minutes of the 150th Plenary meeting were adopted by written procedure and published on 16 May 2022.

5. Scientific topics for discussion and possible adoption

5.1. Application for authorisation of genetically modified oilseed rape MON 94100, for food and feed uses, import and processing in accordance with Regulation EC 1829/2003 by Bayer CropScience LP (EFSA-GMO-NL-2020-169)[8]

Oilseed rape MON 94100 was produced by *Agrobacterium*-mediated transformation and expresses two variants of the dicamba monooxygenase (DMO) protein conferring resistance to dicamba containing herbicides. The scope of the application EFSA-GMO-NL-2020-169 is for food and feed uses, import and processing and does not include cultivation in the EU.

The draft text of the opinion was discussed on the 150th plenary meeting.[9] Since then, additional data were submitted by the applicant. 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. Renewal of the authorisation for the placing on the market of food and feed products containing, consisting of or produced from GM maize MIR162 and products other than food and feed containing or consisting of it with the exception of cultivation, authorised under Regulation 1829/2003 (Commission Implementing Decision 2012/651/EU) (EFSA-GMO-RX-025)[10]

[6] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[7] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[8] https://open.efsa.europa.eu/questions/EFSA-Q-2020-00749
[9] https://www.efsa.europa.eu/en/events/150th-plenary-meeting-gmo-panel
[10] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00122

Maize MIR162 was developed to confer resistance to certain lepidopteran pests. Following a thorough risk assessment by EFSA, the placing on the market of maize MIR162 for products containing, consisting of, or produced from this GM maize, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2012/651/EU and Commission Implementing Decision (EU) 2019/60 amending Decision 2009/866/EC, Decision 2010/419/EU, Implementing Decision 2012/651/EU and Implementing Decision (EU) 2016/1685. In 2021 the applicant asked the European Commission to renew the authorisation for the placing on the market of maize MIR162 and submitted application EFSA-GMO-RX-025 in support of their request. The GMO Panel assessed application EFSA-GMO-RX-025 in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines. Additional data requested on bioinformatic analysis update is still to be submitted by the applicant.

The GMO Panel revised the current text, where appropriate and questions were raised and addressed throughout the different sections of the draft opinion. It was agreed that the GMO Panel will assess the missing information once it is provided (updated bioinformatic analyses). If no other questions are identified during the assessment, the opinion will be proposed for possible adoption by written procedure or during one of the next GMO Plenary meetings.

5.3. Assessment of adequacy of existing EFSA Guidance to cover food and feed risk assessment aspects plants developed through synthetic biology[11]

At the 147th GMO Plenary meeting the draft opinion on the assessment of adequacy of existing EFSA Guidance to cover food and feed risk assessment aspects of plants developed through synthetic biology (SynBio) was endorsed for public consultation.[12]

The revised draft text was presented, and further minor changes were introduced. The GMO Panel adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

5.4. EC request for an "EFSA statement on the criteria for risk assessment for plants produced by targeted mutagenesis and cisgenesis"[13]

On 28 April 2022, the EC mandated EFSA to deliver a statement under Article 31 of Regulation (EC) No 178/2002, as advice for consideration by the EC, on possible criteria for the risk assessment of plants produced by targeted mutagenesis and cisgenesis. The mandate foresees two outcomes, the 1st to be completed by 31 August and the 2nd by 30 September 2022.

The mandate was discussed in the frame of the cross-cutting working group of the GMO Panel[14] and the preliminary outcome of the discussion was presented. The GMO Panel discussed possible criteria for the risk assessment of plants produced by targeted mutagenesis and cisgenesis.

5.5. Additional bioinformatic studies on soybean 40-3-2[15]

Genetically modified soybean 40-3-2 expresses a 5-enolpyruvylshikimate-3-phosphate synthase protein from *Agrobacterium* sp. strain CP4 (CP4 EPSPS), which confers tolerance to glyphosate. This event was previously assessed by the GMO Panel as a single event and as part of a two-event stack and was found to be as safe as its conventional counterparts and other appropriate comparators with respect to potential effects on human and animal health and the environment. On September 2021, the European Commission (EC) requested EFSA to evaluate a new bioinformatics study which revealed predicted genomic deletions at the insertion sites using the available soybean reference genome.

[11] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00052
[12] https://www.efsa.europa.eu/en/events/event/147th-plenary-meeting-gmo-panel-open-observers
[13] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00309
[14] https://www.efsa.europa.eu/sites/default/files/2022-06/applications-cross-cutting.pdf
[15] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00556

Questions were raised and addressed throughout the different sections of the draft GMO Panel scientific opinion. The GMO Panel revised the draft text, where appropriate, and adopted the output, which will be published on the EFSA website and in the EFSA Journal.

5.6. Application for the modification of the terms of the authorisation regarding the placing on the market of isolated seed protein from genetically modified oilseed rape GT73 for food pursuant Regulation 1829/2003[16]

On 22 March 2021 EFSA received an application (EFSA-GMO-RX-026) for (1) renewal of the authorisation for the placing on the market of food containing or consisting of GM oilseed rape GT73, or food and feed produced from that GMO (Commission Implementing Decision (EU) 2015/701 of 24 April 20151) and (2) for the expansion of authorisation to cover isolated seed protein for food pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed. In accordance with Regulation 1829/2003 it is not possible to (1) renew and (2) expand the scope of an application at the same time. For this reason, the original application was split in EFSA-GMO-RX026/1 and EFSA-GMO-RX026/2 to cover the renewal and the expansion of the scope respectively. The current status of the risk assessment for two applications was presented. Further discussion is needed.

6. New Mandates

6.1. Applications under Regulation (EC) No 1829/2003

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

- **EFSA-GMO-NL-2022-173** Application for authorisation to place on the market of maize MON 95275 in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed[17]

Since the last meeting of the GMO Panel, the following application was made valid:

- **EFSA-GMO-NL-2019-160** Request for placing on the market of genetically modified oilseed rape NS-B50027-4 submitted under Regulation (EC) No 1829/2003 by Nufarm B.V.[18]

6.2. Upcoming mandates

None

6.3. Other Requests and Mandates

None

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

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

None

[16] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00283
[17] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00330
[18] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00572

7.2. EFSA including its Working Groups/Task Forces

The EFSA staff reported on the discussions on the GMO Network meeting[19] and on the meeting with applicants.[20]

7.3. European Commission

The representatives of the EC informed the GMO Panel on their on-going activities, including approval procedures for applications for which the GMO Panel has delivered a scientific opinion.

8. Other scientific topics for information and/or discussion

None

9. Any other business

9.1. Preparedness for future risk assessment – EFSA outsourcing

The Head of the NIF Unit introduced the ongoing grants and procurements that were recently launched in the area of GMO risk assessment. The main goals and timelines were summarised.

10. Adoption of the minutes and 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/151st-plenary-meeting-gmo-panel

The 152nd GMO Plenary meeting will be held on 4 July 2022 online.

[19] https://www.efsa.europa.eu/en/events/13th-meeting-gmo-network
[20] https://www.efsa.europa.eu/en/events/gmo-ad-hoc-meeting-industry-representatives-0