NUTRITION & FOOD INNOVATION UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 148th MEETING

Held on 26 January 2022, TELE/WEB

(Agreed on 7 February 2022)

Participants

- 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, Fabien Nogué, Nils Rostoks, Jose Juan Sanchez Serrano, Giovanni Savoini, Eve Veromann and Fabio Veronesi

- European Commission:

DG SANTE : Alexandre Huchelmann

- EFSA:

NIF Unit: Ana Afonso, Michele Ardizzone, Giuseppe Condorelli, Giacomo De Sanctis, Silvia Federici, Antonio Fernández Dumont, Andrea Gennaro, Tilemachos Goumperis, Paschalina Grammatikou, Dafni Maria Kagkli, Paolo Lenzi, Aleksandra Lewandowska, Franco Maria Neri, Nikoletta Papadopoulou, Pietro Piffanelli, Tommaso Raffaello, Reinhilde Schoonjans and Franz Streissl

MESE Unit: José Ángel Gómez Ruiz

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

[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

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 procedures since the 147th GMO Plenary meeting

Since the 147th Plenary meeting, one output has been adopted by written procedure:

4.1 The minutes of the 147th Plenary meeting

The minutes of the 147th Plenary meeting were adopted by written procedure and published on 22 December 2021.

5. Update on NIF unit structure

Since 1 January 2022, the former GMO and NUTRI Units were merged into the Nutrition and Food Innovation Unit (NIF). The Head of the NIF Unit explained the new organizational structure, which included the creation of four teams and the appointment of responsible team leaders. The new organisation does not affect the current structure of the GMO Panel Working Groups.

6. Scientific topics for discussion and possible adoption

6.1. Application for authorisation of genetically modified maize DP4114 x MON810 x MIR604 x NK603 and subcombinations, for food and feed uses, import and processing in accordance with Regulation EC 1829/2003 by Pioneer Overseas Corporation (EFSA-GMO-NL-2018-150)[4]

Maize DP4114 x MON810 x MIR604 x NK603 was produced by conventional crossing to combine four single maize events: expressing Cry1F and Cry1Ab to confer resistance to lepidopteran pests; mCry3A, Cry34Ab1 and Cry35Ab1 to confer resistance to coleopteran pests; CP4 EPSPS (including its variant CP4 EPSPS L214P) and PAT providing tolerance to glyphosate- and glufosinate-ammonium-containing herbicides respectively and the PMI as selectable marker. The scope of the application EFSA-GMO-NL-2018-150 is for food and feed uses, import and processing and does not include cultivation in the European Union (EU).

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

[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] https://open.efsa.europa.eu/questions/EFSA-Q-2018-00370

6.2. Application for authorisation of genetically modified oilseed rape LBFLFK, for food and feed uses, import and processing in accordance with Regulation EC 1829/2003 by Pioneer Overseas Corporation (EFSA-GMO-DE-2019-157)[5]

Oilseed rape event LBFLFK was produced by *Agrobacterium*-mediated transformation of the conventional canola variety 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 (acetohydroxy acid synthase) protein 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 (EU).

The progresses made in the different area of the risk assessment were reported The GMO Panel has discussed the challenges this application is posing such as the protein safety assessment, the nutritional assessment, etc. Further discussion is needed.

6.3. Statement complementing the EFSA Scientific Opinion on application EFSA-GMO-BE-2016-138 for authorisation of food and feed containing, consisting of and produced from genetically modified oilseed rape MS11[6]

On 2 April 2020, the GMO Panel adopted a scientific opinion[7] on application EFSA-GMO-BE-2016-138 for the placing on the market of oilseed rape MS11, import and processing under Regulation (EC) No 1829/2003. The MS11 event expresses a male sterility trait to facilitate hybrid seed production and the PAT protein to confer tolerance to glufosinate-ammonium- containing herbicides. The GMO Panel noted that the characteristics of the intended traits of oilseed rape MS11 challenge the comparative analysis to the extent that it is not possible to produce the materials and collect the data for the comparative analysis without deviating from the legal requirements as per Regulation (EU) No 503/2013. For this reason, it was not possible for the GMO Panel to conclude on the compositional analysis of oilseed rape MS11 and on the toxicological, allergenicity and nutritional assessment in line with the intended scope.

On 5 January 2021, the European Commission mandated EFSA to assess additional information received from the applicant on the comparative analysis of oilseed rape MS11. The GMO Panel considered the information submitted (on the composition of the two-event stack MS11 x RF3) and concluded that it could not be used for a risk assessment of MS11 in line with the intended scope and with Regulation (EU) No 503/2013. The GMO Panel is not in the position to conclude on the compositional analysis nor on the toxicological, allergenicity or nutritional assessment of oilseed rape MS11 in line with the intended scope.

The GMO Panel revised the draft text, where appropriate, and subsequently adopted the statement, which will be published on the EFSA website and in the EFSA Journal.

7. New Mandates

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

None

[5] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00394
[6] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00044
[7] https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.6112

7.2. Upcoming mandates

None

7.3. Other Requests and Mandates

On 26 November 2021 EC mandated EFSA to consider the new sequencing information of genetically modified cotton MON 531[8]. EFSA received the full data package on the 8 December 2021.

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

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

None

8.2. EFSA including its Working Groups/ Task Forces

None

8.3. European Commission

The representatives of the European Commission (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.

9. Other scientific topics for information and/or discussion

9.1. Update on the GMO Panel statement on Animal Dietary Exposure

An update on the development on the GMO Panel statement on animal dietary exposure (ADE) was presented to the Panel members. Applications submitted under Regulation (EC) No 1829/2003, as part of the RA of GM feed in accordance with Regulation (EU) No 503/2013, should include an ADE of the new constituents or of the endogenous ones with altered levels. The Food and Feed Working Group highlighted a heterogeneous reporting of ADE across applications, in part due to lack of specific guidance documents and recommendations, either at international level or in the EU regulatory frame for GM feed. The GMO Panel statement will include recommendations for the reporting of ADE assessment for GMO applications.

10. Any other business

10.1. Calendar of Plenary meetings 2023

The calendar of the Plenary meetings 2023 was communicated to the GMO Panel.

10.2. Dates of the 2022 GMO Network

The dates of the GMO Network meetings in 2022 were communicated to the GMO Panel. The first one will be organised online on the 7th of April, and the second is planned for 26-27th October as a physical meeting, if possible.

[8] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00793

10.3. Observers' feedback of the 147th GMO OPEN Plenary

After the GMO Open Plenary,[9] the observers were invited to participate to a survey. The outcome of the survey was reported as well as the suggestions received.

11. 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/event/148th-plenary-meeting-gmo-panel

The 149th GMO Plenary meeting will be held on 16-17 March 2022 online.

[9] https://www.efsa.europa.eu/en/events/event/147th-plenary-meeting-gmo-panel-open-observers