NUTRITION AND FOOD INNOVATION UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 150th MEETING

Held on 4-5 May 2022, TELE/WEB

(Agreed on 16 May 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 (day 2), Eve Veromann and Fabio Veronesi

- European Commission:

DG SANTE : Ilaria Ciabatti, Alexandre Huchelmann and Juliette-Marie Margueritte

- EFSA:

NIF Unit: Ana Afonso (item 6.2), 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, Ana Martín Camargo, 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. Apologies for absence were received from Giovanni Savoini (day 1).

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: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/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 149th GMO Plenary meeting

Since the 149th Plenary meeting, one output has been adopted by written procedure:

4.1. The minutes of the 149th Plenary meeting

The minutes of the 149th Plenary meeting were adopted by written procedure and published on 4 April 2022.

5. Scientific topics for discussion and possible adoption

5.1. 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 BASF Plant Science Company GmbH (EFSA-GMO-DE-2019-157)[4]

Oilseed rape event LBFLFK was produced by *Agrobacterium*-mediated transformation of the conventional 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 (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 (EU).

The progress made in the risk assessment by the food and feed working group were reported. The GMO Panel has discussed the challenges that this application is posing for protein safety assessment, toxicology and allergenicity. Various scenarios for the outcome of the assessment were considered. Further discussion is needed.

5.2. 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)[5]

[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-2019-00394
[5] https://open.efsa.europa.eu/questions/EFSA-Q-2020-00749

Oilseed rape MON 94100 was produced by *Agrobacterium*-mediated transformation and expresses two versions of the dicamba monooxygenase (DMO) protein conferring resistance to dicamba-containing herbicides. The scope of the application EFSAGMONL2020169 is for food and feed uses, import and processing and does not include cultivation in the EU.

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 the GMO Panel will assess the missing information once it is provided (updated bioinformatic analyses and literature search). If no other questions are identified during the assessment, the opinion will be proposed for possible adoption at a subsequent GMO plenary meeting.

5.3. Application for authorisation of genetically modified maize DP4114 x MON 89034 x MON 87411 x DAS-40278-9 and subcombinations, for food and feed uses, import and processing in accordance with Regulation EC 1829/2003 by Pioneer Overseas Corporation (EFSA-GMO-NL-2020-171)[6]

Maize DP4114 x MON89034 x MON87411 x DAS-40278-9 was produced by conventional crossing to combine four single maize events: expressing Cry1A.105, Cry1F and Cry2Ab2 to confer resistance to certain lepidopteran pests; Cry34Ab1, Cry35Ab1 and Cry3Bb1 proteins to confer protection against certain coleopteran pests; DvSnf7 dsRNA to confer protection against western corn rootworm; CP4 EPSPS protein providing tolerance to glyphosate-containing herbicides; PAT protein providing tolerance to glufosinate ammonium-containing herbicides; and AAD-1 protein providing tolerance to 2,4-D and the AOPP-containing herbicides. The scope of the application EFSA-GMO-NL-2020-171 is for food and feed uses, import and processing and does not include cultivation in the EU.

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 the GMO Panel will assess the missing information once it is provided (newly expressed proteins, updated bioinformatic analyses). If no other questions are identified during the assessment, the opinion will be proposed for possible adoption at a subsequent GMO plenary meeting.

5.4. Application for renewing the authorisation for the placing on the market of food and feed products containing, consisting of or produced from genetically modified soybean A5547-127 and products other than food and feed containing or consisting of it with the exception of cultivation, authorised under Regulation 1829/2003 (Commission Decision (EFSA-GMO-RX-020)[7]

Soybean A5547-127 was developed to confer tolerance to glufosinate ammonium-containing herbicides. Following a thorough risk assessment by EFSA, the placing on the market of soybean A5547-127 for products containing, consisting of, or produced from this GM soybean, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2012/81/EU and Commission Implementing Decision (EU) 2019/1195 amending Decision 2012/81/EU. In 2020 the applicant asked the European Commission (EC) to renew the authorisation for the placing on the market of soybean A5547-127 and submitted application EFSA-GMO-RX-020 in support of their request. The GMO Panel assessed the renewal application in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines.

[6] https://open.efsa.europa.eu/questions/EFSA-Q-2020-00833
[7] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00003

The draft text of the opinion was discussed on the 147th plenary meeting. Since then, additional data was requested and submitted by the applicant.
The GMO Panel revised the draft opinion, where appropriate and 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. Request for an updated scientific opinion on plants developed through cisgenesis and intragenesis[8]

On 11 June 2021, the EC mandated EFSA to provide an updated scientific opinion on the safety and the risk assessment of plants developed through cisgenesis and intragenesis. EFSA assigned the mandate to the Cisgenesis working group of the GMO Panel in July 2021.[9]

The conclusions of the previous EFSA opinion (2012) were reviewed, taking into consideration the new guidelines and the recent literature. According to the 'Draft framework for protocol development for EFSA's scientific assessments'[10] a protocol was developed to address the four terms of references.

The GMO panel concludes that no new risks are identified in cisgenic and intragenic plants obtained with new genomic techniques, as compared with those already considered for plants obtained with established genomic techniques. Moreover, the GMO panel concludes that the current guidelines are partially applicable and sufficient. On a case-by-case basis, a lesser amount of data might be needed for the risk assessment of cisgenic or intragenic plants obtained through NGTs.

Questions were raised and addressed throughout the different sections of the draft opinion. The GMO Panel reviewed and endorsed the draft opinion. The output will be open to comments through a dedicated public consultation to be launched in the coming weeks.[11]

5.6. Sequencing Cotton DAS-24236-5 x DAS-21023-5[12]

The GMO Panel has previously assessed GM cotton DAS-24236-5 x DAS-21023-5 and concluded that it is as safe as its conventional counterpart and other appropriate comparators with respect to potential effects on human and animal health and the environment in the context of its intended uses. On 17 November 2020, the EC mandated EFSA to assess additional information received from the applicant on 13 July 2018. The GMO Panel considered the information submitted (new DNA sequence information and updated bioinformatics) and concluded that corrected sequence does not give rise to any safety concerns and therefore the original risk assessment of cotton DAS-24236-5 x DAS-21023-5 remains valid.

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

6. New Mandates

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

[8] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00361
[9] https://www.efsa.europa.eu/sites/default/files/2021-07/145th-plenary-meeting-gmo-panel-minutes.pdf
[10] https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2020.EN-1843
[11] https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l7U0000011Zb2/pc0176
[12] https://open.efsa.europa.eu/questions/EFSA-Q-2020-00796

None

6.2. Upcoming mandates

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 received on 29 April 2022.[13]

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

The Chair of the GMO Panel reported on discussions at the last Scientific Committee meeting and ongoing EFSA activities.[14]

The Panel members were also updated on the activities of the WG on Protocol Development[15] which will be relevant for the Panel's work on future generic mandates.

7.2. EFSA including its Working Groups/Task Forces

None

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

None

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/150th-plenary-meeting-gmo-panel

[13] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00309
[14] https://www.efsa.europa.eu/en/events/108th-plenary-meeting-scientific-committee
[15] https://www.efsa.europa.eu/sites/default/files/wgs/cross-cutting-science/wg-protocol-development.pdf

The 151st GMO Plenary meeting will be held on 20-21 June 2022 in Brussels.