NUTRITION & FOOD INNOVATION UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 152nd MEETING

Held on 4 July 2022, TELE/WEB

(Agreed on 12 July 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: Ilaria Ciabatti and Alexandre Huchelmann

- EFSA NIF Unit:

Ana Afonso, Michele Ardizzone, 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 and Reinhilde Schoonjans

1. Welcome and apologies for absence

The Chair welcomed the participants.

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[1] and the Decision of the Executive Director on Competing Interest Management[2] 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 151st GMO Plenary meeting

Since the 151st Plenary meeting, one output has been adopted by written procedure:

4.1. The minutes of the 151st Plenary meeting

The minutes of the 151st Plenary meeting were adopted by written procedure and published on 7 July 2020.

5. Scientific topics for discussion and possible adoption

5.1. Application for authorisation of genetically modified maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 and subcombinations, for food and feed uses, import and processing in accordance with Regulation EC 1829/2003 by Corteva Agroscience (EFSA-GMO-NL-2018-151)[3]

Maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9 was produced by crossing to combine five single maize events expressing Cry1A.105, Cry1F, Cry2Ab2 and Vip3Aa19 to confer resistance to certain lepidopteran pests; CP4 EPSPS (including its variant CP4 EPSPS L214P) providing tolerance to glyphosate-containing herbicides; PAT providing tolerance to glufosinate-ammonium-containing herbicides; AAD-1 providing tolerance to 2,4-D- and the AOPP-containing-herbicides; and PMI as selectable marker. The scope of the application EFSA-GMO-NL-2018-151 is for food and feed uses, import and processing and does not include cultivation in the European Union.

The draft text of the opinion was discussed on the 149th plenary meeting.[4] 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.

6. Scientific outputs submitted for discussion

6.1. Application for authorisation of genetically modified maize MON 87429 for food and feed uses, import and processing in accordance with Regulation EC 1829/2003 by Bayer Agriculture (EFSA-GMO-NL-2019-161)[5]

Maize MON 87429 was produced by *Agrobacterium*-mediated transformation and expresses DMO, PAT and FT_T proteins conferring resistance to dicamba-, glufosinate-, quizalofop- and 2,4-D-containing herbicides. In addition, maize MON 87429 expresses the CP4 EPSPS protein and utilises an endogenous maize RNAi regulatory element to suppress its expression in pollen. The scope of the

[1] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf
[3] https://open.efsa.europa.eu/questions/EFSA-Q-2018-00457
[4] https://www.efsa.europa.eu/en/events/149th-plenary-meeting-gmo-panel
[5] https://open.efsa.europa.eu/questions/EFSA-Q-2019-00628

application EFSA-GMO-NL-2019-161 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 that once the GMO Panel assesses the recently submitted toxicological data, the opinion will be proposed for possible adoption by written procedure or during one of the next GMO Plenary meetings.

6.2. Application for the renewal of the authorisation for the placing on the market of food products containing or consisting of genetically modified oilseed rape GT73 authorised under Regulation 1829/2003 (Commission Implementing Decision (EU) 2015/701) submitted by Bayer Agriculture BV (EFSA-GMO-RX-026/1)[6]

Oilseed rape GT73 was developed to confer resistance to glyphosate-containing herbicides. Following a thorough risk assessment by EFSA, the placing on the market of foods and food ingredients containing, consisting of, or produced from oilseed rape GT73 with the exception of isolated seed protein, and feed produced from this GM oilseed rape, excluding cultivation in the EU, was authorised by Commission Implementing Decision 2015/701/EU and Commission Implementing Decision (EU) 2019/1579 amending Decision 2015/701/EU. In 2021 the applicant asked the European Commission to renew the authorisation for the placing on the market of oilseed rape GT73 and submitted application EFSA-GMO-RX-026/1 in support of their request. The GMO Panel assessed application EFSA-GMO-RX-026/1 in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines. Additional data requested on literature search 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. 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.

6.3. 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 (EFSA-GMO-RX026/2)[7]

In parallel with application under item 6.2, the applicant asked the European Commission to expand the authorisation to cover isolated seed protein for food pursuant to Regulation (EC) No 1829/2003 on genetically modified food and feed. The GMO Panel is assessing application EFSA-GMO-RX-026/2 in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 and the relevant EFSA guidelines. Additional data requested on literature search 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. 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.

[6] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00164
[7] https://open.efsa.europa.eu/questions/EFSA-Q-2021-00283

6.4. EC request for an "EFSA statement on the criteria for risk assessment for plants produced by targeted mutagenesis and cisgenesis"[8]

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 recently discussed on the 151st GMO Plenary Meeting[9] and the progress made was presented. The GMO Panel discussed the draft text of the statement, focusing on the possible criteria for the risk assessment of plants produced by targeted mutagenesis and cisgenesis. The statement will be further discussed on the next cross-cutting working group meeting.[10]

7. Any other business

None

8. 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/152nd-plenary-meeting-gmo-panel

The 153rd GMO Plenary meeting will be held on 28-29 September 2022 online.

[8] https://open.efsa.europa.eu/questions/EFSA-Q-2022-00309
[9] https://www.efsa.europa.eu/en/events/151st-plenary-meeting-gmo-panel
[10] https://www.efsa.europa.eu/sites/default/files/2022-06/applications-cross-cutting.pdf