SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 132nd MEETING

Held on 3 July 2019, Parma

(Agreed on 12 July 2019)

Participants

- Panel Members:

  Jean-Louis Bresson, Tamas Dalmay, Ian Dewhurst, Michelle Epstein[1], Leslie George Firbank[1], Philippe Guerche, Jan Hejatko, Francisco Javier Moreno, Ewen Mullins[1], Hanspeter Naegeli, Fabien Nogué, Nils Rostoks, Jose Juan Sanchez Serrano, Giovanni Savoini, Eve Veromann and Fabio Veronesi.
- Hearing expert:
- European Commission and/or Member States representatives:

  Alexandre Huchelmann, Béatrice Marquez-Garrido (DG SANTE).
- EFSA:

  GMO Unit: Fernando Álvarez, Michele Ardizzone, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Silvia Federici, Andrea Gennaro, José Ángel Gomez Ruiz, Anna Lanzoni, Ana Martin Camargo, Sylvie Mestdagh, Franco Maria Neri, Irina Olaru, Konstantinos Paraskevopoulos, Nikoletta Papadopoulou, Tommaso Raffaello and Elisabeth Waigmann.

1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

[1] Participated via web conference.
[2] 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[3] and the Decision of the Executive Director on Competing Interest Management[4], 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 131st GMO Plenary meeting

The minutes of the 131st Plenary meeting were adopted by written procedure on 7 June and published on the same day at https://www.efsa.europa.eu/en/events/event/190522-0.

5. Scientific topic(s) for discussion

5.1. Application for authorization of genetically modified maize MON87427 x MON87460 x MON89034 x MIR162 x NK603 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V. (EFSA-GMO-NL-2016-134) (EFSA-Q-2016-00686)

The five-event stack maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603 was obtained by conventional crossing of GM maize lines MON 87427, MON 87460, MON 89034, MIR162 and NK603. Maize MON 87427 and NK603 produce CP4EPSPS, which confers tolerance to glyphosate. Maize MON 89034 produces two newly expressed proteins, Cry1A.105 and Cry2Ab2, which confer resistance to specific lepidopteran pests. Maize MIR162 produces Vip3A and PMI proteins, which confer resistance to specific lepidopteran pests and function as a selection marker, respectively. Maize MON 87460 expresses the cold shock protein B (CspB) (i.e. RNA) and the neomycin phosphotransferase II (NPTII) which aim to reduce yield loss caused by drought stress and function as a selection marker, respectively. The scope of application EFSA-GMO-NL-2016-134 includes the five-event stack maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603 and all its sub-combinations, independently of their origin, for food/feed uses, import and processing.

At its last meeting on 22-23 May, the GMO Panel already scrutinized and revised most of the text of the draft opinion. The GMO Panel did not fully discuss the section dedicated to the '*Assessment of newly expressed proteins*'. The assessment of the potential of new peptides to trigger celiac disease was put on hold pending discussion on the way forward with additional bioinformatics data spontaneously provided by the applicant ahead of the full implementation of the 2017 Guidance on allergenicity assessment of genetically modified plants. The Working Group on Food/Feed evaluated all available data packages at its meetings of 20-21 May, 5 June and 1-2 July 2019.

In this meeting, a member of the GMO unit presented the overall strategy for risk assessing the potential of newly expressed proteins to trigger celiac disease as well as text of the section entitled '*Assessment of newly expressed proteins*' of the scientific opinion under discussion.

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

[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

5.2. Mandate for assessment of additional information related to the application for authorisation of food and feed containing, consisting and produced from genetically modified maize 3272 (EFSA-GMO-UK-2006-34) (EFSA-Q-2017-00341)

Maize 3272 was already subject to previous risk assessments by the GMO Panel. The 2013 scientific opinion of the GMO Panel was inconclusive owing to data gaps identified for comparative analysis and safety of the thermostable alpha-amylase AMY797E. Late 2017 EC tasked EFSA and its GMO Panel to assess new datasets on comparative analysis and *de novo* sensitisation to alpha-amylases to supplement its previous risk assessment of maize 3272.

A member of the GMO unit presented the peculiarities of the GM crop, and the discrepancy between the full scope of application EFSA-GMO-UK-2006-34 and the intended use (mainly for ethanol production) of maize 3272 as well as additional information requested from the applicant (e.g. a scoping review on the sensitisation potential of alpha-amylases).

Lately the applicant provided an extensive information package in support to the intended uses of maize 3272 (mainly for ethanol production, but also by-products for feed) and related exposure scenarios (i.e. production under closed-loop system subject to a stewardship program). The additional information was discussed in the Food/feed Working Group of 1-2 July 2019.

The GMO Panel discussed the way forward, including the proposal to highlight and, when possible, to conclude on different exposure scenarios driven by the mismatch between the full scope and the intended use of maize 3272. 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-DE-2019-157 submitted by BASF Agricultural Solutions Belgium NV for the placing on the market of LBFLFK canola for food/feed uses, import and processing; and
- application EFSA-GMO-NL-2019-158 submitted by BASF Agricultural Solutions Belgium NV for the placing on the market of Brassica juncea Rf3 for food/feed uses, import and processing.

6.2. Annual Post-market environmental monitoring reports of GM plants

No new mandate was received.

6.3. Other Requests and Mandates

On 24 May 2019, the European Commission mandated EFSA to evaluate three scientific publications, by Tomaszewski *et al.* (2012), Paula *et al.* (2015) and Paula and Andow (2016), and to indicate whether they contain elements that could lead the GMO Panel to reconsider its previous scientific opinions on the cultivation of GM maize MON 810 (M-2019-0119). The Working Group on Comparative Analysis and Environmental Risk Assessment assessed the three scientific publications at its meeting of 11 June 2019. EFSA concluded that the publications do not contain any scientific elements that would lead EFSA to reconsider GMO Panel's previous opinions on the cultivation of GM maize MON 810.

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 GMO Unit updated the GMO Panel about the progress made by:

- The ad hoc Working Group on Synthetic Biology (link to minutes),
- The ad hoc Working Group on GMOs engineered with Gene Drives (link to minutes)

The Chair of the GMO Panel reported on discussions at the last Scientific Committee meeting, on new mandates and ongoing EFSA activities.

7.2. EFSA including its Working Groups/ Task Forces

Not applicable.

7.3. European Commission

The representative of the European Commission provided feedback on recent meetings held at the European Commission.

8. Other scientific topics for information and/or discussion

Not applicable.

9. Any other business

9.1. Draft note on animal dietary exposure

A scientific officer of the GMO Unit presented the draft technical report developed by the EFSA BIOCONTAM, FEED, GMO and PESTICIDES units and which aims at the compiling available information pertaining to animal dietary exposure. The main objective of the report is to map the current approaches used at EFSA to estimate animal dietary exposure in order to support follow up discussions on the possible need for guidelines. The draft technical report was discussed by the Food/feed Working Group at its meeting of 1-2 July.

9.2. Feedback from meetings with stakeholders

10. Adoption of the minutes and next meeting

The minutes of the current meeting will be adopted by written procedure and published at https://www.efsa.europa.eu/en/events/event/190703.

The 133rd GMO Plenary meeting will be held on 25-26 September in Parma.