GENETICALLY MODIFIED ORGANISMS UNIT

SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS

MINUTES OF THE 131st MEETING

Held on 22 & 23 May 2019, Parma

(Agreed on 7 June 2019)

Participants

- Panel Members:

  Jean-Louis Bresson, Tamas Dalmay, Ian Dewhurst[1], Michelle Epstein[2], Leslie George Firbank, Philippe Guerche, Jan Hejatko[3], Francisco Javier Moreno, Ewen Mullins, Hanspeter Naegeli, Fabien Nogué, Nils Rostoks, Jose Juan Sanchez Serrano, Giovanni Savoini[4], Eve Veromann and Fabio Veronesi[5].

- Hearing expert:

- European Commission and/or Member States representatives:

  Alexandre Huchelmann, Béatrice Marquez-Garrido, Hans Moons (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 and Tommaso Raffaello.

  Legal and Assurance Services Unit: Simone Gabbi.

1. Welcome and apologies for absence

The Chair welcomed the participants.

[1] Participated via web conference on 22 and 23 May.
[2] Participated on 22 May only.
[3] Participated via web conference on 22 and 23 May.
[4] Participated via web conference on 22 May and 23 May pm.
[5] Participated physically on 22 May and via web conference on 23 May.
[6] 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

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[7] and the Decision of the Executive Director on Competing Interest Management[8,] 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 130th GMO Plenary meeting

Not applicable.

5. Scientific topic(s) for discussion

5.1. Application for authorization of genetically modified soybean MON 87708 x MON 89788 x A5547-127 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-2016-135) (EFSA-Q-2016-00688)

The three-event stack soybean MON 87708 x MON 89788 x A5547-127 was obtained by conventional crossing of three single transformation events MON 87708, MON 89788 and A5547-127. The three single events produce newly expressed proteins which confer tolerance to herbicides: tolerance to dicamba (from MON 87708), glyphosate (from MON 89788) and glufosinate (from A5547-127).

Application EFSA-GMO-NL-2016-135 was submitted by Monsanto for the placing of soybean MON 87708 x MON 89788 x A5547-127 on the EU market for food/feed uses, import and processing. Application EFSA-GMO-NL-2016-135 was received by EFSA after the entry into force of Regulation (EU) No 503/2013. In this respect application EFSA-GMO-NL-2016-135 was fully compliant with the legal requirements laid down in that Regulation: e.g. search for scientific literature, 90-day rodent feeding studies with single events, estimated intake and dietary exposure assessment.

In addition to the core information package, the applicant submitted new studies on the three-event stack soybean that were conducted within the period of 10 years prior to the date of submission of application EFSA-GMO-NL-2016-135 in order to comply with Regulation (EU) No 503/2013. The GMO Panel considered these additional studies in its risk assessment of soybean MON 87708 x MON 89788 x A5547-127 and reported the outcome of its evaluation in the scientific opinion.

At its last meeting on 3rd April, the GMO Panel already scrutinized and revised most of the text of the draft opinion. The GMO Panel did not discuss the sections dedicated to the assessment of the 90-day rodent feeding studies with single events pending clarifications from the applicant.

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

Following receipt and evaluation of the additional information, the GMO Panel revised the draft text on the 90-day rodent feeding studies, where appropriate, and subsequently adopted the opinion, which will be published on the EFSA website and in the EFSA Journal.

5.2. Application for authorization of genetically modified maize MON 87427 x MON 89034 x MIR162 x NK603 and all its sub-combinations 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-2016-131) (EFSA-Q-2016-00148)

The four-event stack maize MON 87427 x MON 89034 x MIR162 x NK603 was obtained by conventional crossing of GM maize lines MON 87427, 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.

The scope of application EFSA-GMO-NL-2016-131 includes the four-event stack MON 87427 x MON 89034 x MIR162 x NK603 and all its sub-combinations, independently of their origin, for food/feed uses, import and processing. In case of an application on a stack event of a segregating crop (e.g. maize, rapeseed), some sub-combinations falling within the scope might not be supported by a specific dataset. The risk assessment strategy of such sub-combinations was discussed and endorsed by the GMO Panel at its 115th plenary meeting. The risk assessment of these sub-combinations is conducted following a weight of evidence approach that takes as a starting point results of the assessments of the single events, the comprehensive dataset produced for the six-event stack maize, and all the data available for sub-combinations previously assessed by the EFSA GMO Panel as stand-alone dossiers. This strategy was implemented in several GMO Panel scientific opinions.

A scientific officer of the GMO Unit led the GMO Panel through the text of the draft opinion on application EFSA-GMO-NL-2016-131. Questions were raised and addressed throughout the reading of 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.

5.3. Application for authorization of genetically modified maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603 and all its sub-combinations 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 neomycin phosphotransferase II (NPTII) and the cold shock protein B (CspB) (i.e. RNA) aiming to reduce yield loss caused by drought stress. 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.

A scientific officer of the GMO Unit led the GMO Panel through the text of the draft opinion, except the sections dedicated to the assessment of allergenicity and in particular to the assessment of 'novel' proteins with regard to their potential to cause celiac disease. This area of the risk assessment is to be supported by specific information in accordance with the 2017 guidance of the GMO Panel on the allergenicity assessment of GM plants.

Following the *ad hoc* meeting with industry representatives on 5th April 2019 (for more information, see https://www.efsa.europa.eu/en/events/event/190405), EFSA received further data on celiac assessment of this application. The GMO Panel will therefore evaluate all available data packages in its risk assessment of maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603. Further clarifications may be required during the assessment of this additional information.

In this meeting, the GMO Panel scrutinized and, where appropriate, revised the text of the draft opinion, except on the assessment of allergenicity. 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 application EFSA-GMO-NL-2019-156 submitted by Bayer Agriculture for the placing on the market of maize MON 87427 x MON 89034 x MIR 162 x MON 87419 x NK 603 for food/feed uses, import and processing.

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

Not applicable.

6.3. Other Requests and Mandates

Since the last meeting of the GMO Panel, EFSA received from the European Commission:

- the request for a scientific opinion on plants developed using type 1 and type 2 Site-Directed Nucleases and Oligonucleotide Directed Mutagenesis (Register of Questions); and
- the request to complement its original scientific opinion on soybean MON 87769 x MON 89788 taking into account additional information provided by the applicant (Register of Questions).

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). All relevant materials presented at the workshop (15 May 2019, Brussels) are now available to all online at: https://www.efsa.europa.eu/en/events/event/190515; and
- The EFSA task force on animal dietary exposure (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 and informed the GMO Panel that next PAFF meeting will take place on 11 June 2019.

8. Other scientific topics for information and/or discussion

8.1. Evaluation of additional unpublished studies received in GMO applications

The GMO Panel discussed the studies generated by applicants within the period of 10 years prior to the date of submission of GMO applications and submitted to EFSA in addition to the core information package required under Regulation (EC) No 503/2013. These additional unpublished studies are considered by the GMO Panel during its safety evaluation of GMOs applications. The GMO Panel discussed and agreed on a standardised way to report on these additional studies in a consistent manner throughout the scientific opinions on GMOs applications.

8.2. Appropriateness of the GM test material

The production of GM stacked events subject to applications received by EFSA involved the segregation of event(s) that was/were not present in the final stack. Null segregant progeny from already assessed events were used to develop the final stack. Similarly, applicants used 'not defined/unknown' events (i.e. that were not subject to a risk assessment by the GMO Panel). In addition, the breeding process is not always informative regarding the presence or absence of these events in the final stack under assessment.

This issue was initially introduced to the GMO Panel at its 128th meeting of 23 January 2019. A discussion took place on the possible need for information on the events used throughout the breeding process (e.g. events known vs unknown to the GMO Panel, known events already assessed by the GMO Panel with a conclusive vs inconclusive risk assessment).

At the present meeting, the GMO Unit identified the need to further discuss the specific case of stacked events generated from unknown event(s). The GMO Panel acknowledged that additional information was needed. Further discussion is needed.

8.3. Risk assessment of GM oilseed rape

Application EFSA-GMO-BE-2016-138 was submitted by Bayer CropScience for the placing on the market of *Brassica napus* Ms11 for food and feed uses, import and processing under Regulation (EC) No 1829/2003.

To continue the discussion initiated at the last meeting of the GMO Panel (130th meeting on 3 April 2019), two scientific officers of the GMO Unit re-introduced the peculiarities of this male sterile rapeseed event and the subsequent technical limitations (e.g. suitable test material, herbicide

treatment, comparator) encountered by the applicant to perform field trials in line with the applicable guidelines. In addition, the GMO Panel discussed the 'inconsistency' between the scope of this application for food/feed uses of the male sterile event Ms11 and the intended use of this event (i.e. for breeding purpose only). The Ms11 event is of commercial of interest in combination with the restorer line Rf3. The GMO Panel was informed that some EU Member States already raised comments on the intended use of Ms11 event.

The GMO Panel considered different scenarios for completing the risk assessment of Ms11 event in the light of the considerations listed above. The Working Groups were tasked to supplement the draft opinion accordingly. Further discussion is needed.

9. Any other business

9.1. Pilot project WP3 digital collaboration

A scientific officer of the GMO Unit informed the Panel about EFSA campaign to use new digital tools (for instance, in the preparation of scientific opinions).

9.2. Info session for Panel plenaries on independence progress in 2018

A colleague of the Legal and Assurance Services Unit joined the meeting to update the GMO Panel on the revised EFSA independence policy.

9.3. Forthcoming meetings with stakeholders

Scientific officers of the GMO Unit informed the GMO Panel about forthcoming meetings with stakeholders:

- Ad hoc meeting with industry representatives on 13 June (pm), and
- Annual meeting with the Network of EU Member States on GMO Risk Assessment on 18 and 19 June.

10. Adoption of the minutes and next meeting

The minutes of the current meeting will be adopted by written procedure and published at http://www.efsa.europa.eu/en/events/event/190522-0.

The 132nd GMO Plenary meeting will be held on 3 July (am) in Parma.