

Scientific Panel on GMO

Minutes of the 117th Plenary meeting

Held on 20 – 21 September, 2017, Parma (Italy)
(Agreed on 27 September 2017)

Participants

■ Panel Members

Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Hanspeter Naegeli, Elsa Nielsen, Fabien Nogué, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli and Jean-Michel Wal.

■ Hearing Experts¹: none

■ European Commission representatives: Lisa Haller, Beatrice Marquez-Garrido and Pablo Pindado.

■ EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Herman Broll, Giacomo De Sanctis, Yann Devos, Andrea Gennaro, José Ángel Gomez Ruiz, Anna Lanzoni, Irina Olaru, Claudia Paoletti, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Matthew Ramon and Elisabeth Waigmann.

Other EFSA Units/Directorates: none.

■ Observers (in application of the guidelines for observers²): none.

■ Others: none.

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

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA

¹ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest:
<http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

² <http://www.efsa.europa.eu/en/stakeholders/observers.html>

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the experts invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Report on written adoption procedure since 116th Plenary meeting

There were no outputs submitted for written adoption since the previous GMO Panel plenary meeting.

5. Scientific outputs submitted for discussion and/or possible adoption

5.1. Assessment of genetically modified maize GA21 for renewal of authorisation under Regulation (EC) 1829/2003 (application EFSA-GMO-RX-005) ([EFSA-Q-2016-00714](#))

This was the first time the GMO Panel discussed the draft opinion.

Maize GA21 produces the CP4 EPSPS protein, conferring tolerance to glyphosate. This single event had been assessed by the GMO Panel in the context of applications EFSA-EFSA-GMO-UK-2005-19 and EFSA-GMO-RX-GA21⁵ and was authorised by Commission Decision 2008/280/EC; application EFSA-GMO-RX-005 was submitted to EFSA in the context of the renewal of the authorisation.

The GMO Panel adopted this scientific opinion, which will be published in the [EFSA Journal](#).

5.2. Mandate to develop guidelines on possible derogation of existing requirements for applications of genetically modified (GM) food and feed at low levels submitted under Regulation (EC) No 1829/2003 on GM food and feed ([EFSA-Q-2015-00433](#))

This draft guidance had been discussed in previous plenary meetings, the last of which was April 2017 GMO Panel plenary meeting.⁶ Since then, it had gone through a public consultation (2 May – 13 June 2017) and the received comments were taken into account by the dedicated WG when updating the draft text. A summary of the received comments and the subsequent changes to the document was presented to the GMO Panel.

The GMO Panel discussed and amended the draft text as needed.

The GMO Panel adopted this scientific opinion, which will be published in the [EFSA Journal](#).

5.3. Assessment of genetically modified maize 1507 x 59122 x MON810 x NK603 and subcombinations for food and

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁵ <https://www.efsa.europa.eu/en/efsajournal/pub/541>

⁶ <http://www.efsa.europa.eu/sites/default/files/event/170405-m.pdf>

feed uses, under Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2011-92) ([EFSA-Q-2011-00116](#))

The GMO Panel had discussed this application in the previous plenary meeting.⁷

The GMO Panel revised the draft opinion, focusing on the following sections: updated information on the events, information on the expression of the events, environmental risk assessment, risk assessment of subcombinations, and overall conclusions and recommendations.

The GMO Panel adopted this scientific opinion, which will be published in the [EFSA Journal](#).

5.4. Assessment of genetically modified maize MON 87427 x MON 89034 x MIR162 x NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2016-131) ([EFSA-Q-2016-00148](#))

This was the first time the GMO Panel discussed the draft opinion.

Maize MON 87427 x MON 89034 x MIR162 x NK603 was obtained by conventional crossing of genetically modified 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 GMO Panel discussed the draft opinion, focusing on the agronomic and phenotypic characteristics and the toxicological assessment of the four-event stack. Further discussion is needed.

5.5. Assessment of genetically modified maize MON 87403 for food and feed uses, under Regulation (EC) No 1829/2003 (EFSA-GMO-BE-2015-125) ([EFSA-Q-2015-00430](#))

A member of the GMO Unit presented an overview of the field trial data submitted in the context of application EFSA-GMO-BE-2015-125, focusing on the representativeness of the test material. Maize MON 87403 produces the ATHB17 transcription factor, which leads to increased ear biomass at the early reproductive phase compared to conventional maize. Further discussion is needed.

The following agenda item were not discussed due to lack of time:

6. New Mandates

- 6.1. Applications under Regulation (EC) No 1829/2003**
- 6.2. Annual Post-market environmental monitoring reports of GM plants**
- 6.3. Other Requests and Mandates**

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

⁷ <http://www.efsa.europa.eu/sites/default/files/event/170628-m.pdf>

7.1. Scientific Committee and/or Scientific Panel(s) including their Working Groups

7.2. EFSA including its Working Groups /Task Forces

7.3. European Commission

8. Other scientific topics for information and/or discussion

9. Any other business

9.1. GMO Open plenary meeting

A member of the GMO Unit informed the Panel members that the following plenary meeting would be open to observers (attending physically or via web streaming). The meeting will be held in Parma, on 25-26 October 2017.⁸

10. Adoption of the minutes of the current meeting

The minutes of the current meeting were adopted by written procedure on 27 September 2017.

⁸ <http://www.efsa.europa.eu/en/events/event/171025>