

Scientific Panel on GMO

Minutes of the 119th Plenary meeting

Held on 29 – 30 November, 2017, Parma (Italy)

(Agreed on 14 December 2017)

Participants

■ Panel Members

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

■ Hearing Experts¹: none

■ European Commission representatives: Lisa Haller, Béatrice Marquez-Garrido and Hans Moons.

■ EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Herman Broll, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Silvia Federici, Andrea Gennaro, José Ángel Gomez Ruiz, Anna Lanzoni, Sylvie Mestdagh, Franco Neri, 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. Apologies were received from Antoine Messéan and Elsa Nielsen.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of Interest

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>

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 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 118th Plenary meeting

Since the 118th Plenary meeting, two outputs have been adopted by written procedure:

- Scientific opinion on the assessment of genetically modified maize 1507 × 59122 × MON810 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2011-92). Following the adoption of a scientific opinion on this application in the Plenary meeting held on 20-21 September 2017, the need to update the description of the data assessed was identified. Accordingly, the text of the scientific opinion was updated and re-adopted by written procedure. The scientific opinion was published on the EFSA website and in the [EFSA Journal](#).
- The minutes of the 118th (Open) Plenary meeting that took place in Parma on 25-26 October 2017. The minutes can be found [here](#).

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

5.1. Assessment of genetically modified maize NK603 x MON 810 for renewal of authorisation under Regulation (EC) 1829/2003 (application EFSA-GMO-RX-007) ([EFSA-Q-2017-00028](#))

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

Maize NK603 x MON 810 was obtained by conventional crossing of genetically modified maize lines NK603 and MON 810. Maize NK603 produces CP4EPSPS, which confers tolerance to glyphosate. Maize MON 810 produces Cry1Ab, which confers resistance against certain lepidopteran pests. This two-event stack had been assessed by the GMO Panel in the context of application EFSA-GMO-UK-2004-01 and was authorised by Commission Decision 2007/701/EC; application EFSA-GMO-RX-007 was submitted to EFSA in the context of the renewal of the authorisation.

The GMO Panel discussed the draft opinion, with a particular focus on the data available for the sequence of the events. Further discussion is needed, pending the arrival of additional information.

5.2. Assessment of additional information related to the application for authorisation of food and feed containing, consisting and produced from genetically modified maize Bt11 x 59122 x MIR604 x 1507 x GA21 and genetically modified maize combining two, three or

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

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

four of the events under Regulation 1829/2003 ([EFSA-Q-2017-00669](#))

The GMO Panel discussed the additional information on the adopted application EFSA-GMO-DE-2011-99. This information consisted of protein expression data for maize Bt11 x 1507 x GA21, which is a sub-combination of the five-event maize stack Bt11 x 59122 x MIR604 x 1507 x GA21.

The GMO Panel revised and then adopted the draft opinion, which will be published on the EFSA website and on the [EFSA Journal](#).

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

The GMO Panel had discussed this draft opinion in the previous plenary meeting.⁵ In this meeting, the GMO Panel continued the discussion, with a particular focus on the intended trait and the representativeness of the test material. Further discussion is needed.

5.4. Assessment of genetically modified maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603 and subcombinations for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2016-134) ([EFSA-Q-2016-00686](#))

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

Maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603 was obtained by conventional crossing of genetically modified maize lines MON 87427, MON 87460, MON 89034, MIR162, and NK603. Maize MON 87427 and NK603 produce CP4EPSPS, which confers tolerance to glyphosate. Maize 87460 produces CspB, which contributes to limiting yield loss under drought conditions. Maize MON 89034 produces Cry1A.105 and Cry2Ab2, which confer resistance to specific lepidopteran pests. Maize MIR162 produces Vip3Aa20, which confers resistance to certain lepidopteran pests. The single events are maintained in the maize stack MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603.

The GMO Panel revised the draft opinion, focusing on the molecular characterisation, comparative assessment and environmental risk assessment of the five-event stack. Further discussion is needed.

5.5. Assessment of genetically modified soybean MON 87708 x MON 89788 x A5547-127 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2016-135) ([EFSA-Q-2016-00688](#))

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

Soybean MON 87708 x MON 89788 x A5547-127 was obtained by conventional crossing of the genetically modified soybean lines MON 87708, MON 89788 and A5547-127. Soybean MON 87708 produces DMO, which confers tolerance to dicamba-based herbicides. Soybean MON 89788 produces CP4EPSPS, which confers tolerance to glyphosate. Soybean A5547-127 produces PAT, which confers tolerance to glufosinate

⁵ <http://www.efsa.europa.eu/sites/default/files/event/170517-m.pdf>

ammonium. The single events are maintained in the soybean stack MON 87708 x MON 89788 x A5547-127.

Further discussion is needed.

6. New Mandates

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

One new application was received:

EFSA-GMO-RX-009 (GM soybean A2704-12)

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

A request from the EC to assess the MON810 monitoring report for the 2016 cultivation season provided by Monsanto was received.

6.3. Other Requests and Mandates

Three mandates were received from the EC:

New sequencing information for carnation FLO-40689-6 (C/NL/06/01)

New sequencing information for carnation FLO-40685-2 (C/NL/13/02)

New sequencing information for cotton LLCotton25

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

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

The Vice-Chair of the GMO Panel reported on the 86th Scientific Committee plenary meeting of 15-16 November 2017. The minutes of the meeting will be available at [86th Plenary meeting of the Scientific Committee](#).

7.2. EFSA including its Working Groups /Task Forces

None.

7.3. European Commission

The representatives of the European Commission informed the Panel on their on-going activities, including approval procedures for applications for which the GMO Panel had issued a scientific opinion.

8. Other scientific topics for information and/or discussion

8.1. Horizontal RA issues:

The GMO Panel discussed the procedure for dealing with risk assessment issues that require direct collaboration between its Working Groups.

9. Any other business

9.1. Feedback from the GMO Open plenary meeting

A member of the GMO Unit provided feedback on the GMO Open Plenary meeting that took place in Parma on 25-26 October.

10. Adoption of the minutes of the current meeting

The minutes of the current meeting were adopted by written procedure.