

Scientific Panel on GMO

Minutes of the 114th Plenary meeting

Held on 5 – 7 April, 2017, Parma (Italy)

(Agreed on 7 April 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: Tomas Novotny, Jan Paces and Petr Svoboda for item 8.2.²

■ European Commission representatives: Pablo Pindado-Carrion for item 5.1, Anastasia Pagida for item 5.2, Ilaria Ciabatti and Almudena Rodriguez for item 5.5, and Lisa Haller and Beatrice Marquez-Garrido for the entire meeting.

■ EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Herman Broll, Giacomo De Sanctis, Yann Devos, Andrea Gennaro, Mildred Hauck, Anna Lanzoni, Sylvie Mestdagh, Irina Olaru, Franco Neri, Claudia Paoletti, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Matthew Ramon, José Ángel Ruiz and Elisabeth Waigmann.
Other EFSA Units/Directorates: Jaime Aguilera, FEED Unit.

■ Observers (in application of the guidelines for observers³): none.

■ Others: none.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Nicholas Birch, Antoine Messéan, Elsa Nielsen and Nils Rostoks for 7 April.

2. Adoption of agenda

The agenda was adopted with one change: the addition of point 9.3.

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 The three hearing experts invited for item 8.2 are the contractors of EFSA's procurement contract OC/EFSA/GMO/2015/01 (EFSA-Q-2015-00258)

³ <http://www.efsa.europa.eu/en/stakeholders/observers.html>

3. Declarations of Interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 113th 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. 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 was first discussed in the September 2016 GMO Panel plenary meeting. Since then, it had gone through a targeted consultation with Member States (28 October - 9 December 2016) and the received comments had been incorporated by the dedicated WG in the updated 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, focusing on the molecular characterisation and comparative assessment sections.

The draft guidance was endorsed by the GMO Panel and will be published on the EFSA website for a public consultation.

5.2. Request to assess maize MON 810 PMEM report for the 2015 cultivation season provided by Monsanto ([EFSA-Q-2016-00690](#))

The GMO Panel discussed the scientific opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2015, focusing on the methodology and the results of the case-specific monitoring and general surveillance activities performed by the consent holder. Comments from the GMO Panel were addressed and the text was amended as needed.

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

5.3. Application for authorisation of genetically modified maize Bt11 x MIR162 x 1507 x GA21 for food and feed uses, import and processing and sub-combinations

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

⁵ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

independently of their origin submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2010-86) ([EFSA-Q-2010-01087](#))

The GMO Panel worked on the section on sub-combinations of the draft opinion. Further discussion may be needed, pending the arrival of additional information.

5.4. Application for authorisation of genetically modified maize MON 87427 x MON 89034 x NK603 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-BE-2013-117) ([EFSA-Q-2013-00765](#))

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

Maize MON 87427 x MON 89034 x NK603 was obtained by conventional crossing of genetically modified maize lines MON 87427, MON 89034 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. The single events are maintained in the maize stack MON 87427 x MON 89034 x NK603.

The GMO Panel revised the draft opinion, focusing on the following sections of the risk assessment of the three-event stack: molecular characterisation, comparative assessment, food and feed safety assessment, and environmental risk assessment. Further discussion on specific points of the three-event stack is needed in the standing WGs. The discussion of the section on sub-combinations is scheduled for the next plenary meeting (17-18 May).

5.5. Guidance on the characterisation of microorganisms used as feed additives or as production organisms

A member of the EFSA FEED Unit presented the draft guidance on microbial characterisation, focusing on sections 4.1 and 4.2, which were up for discussion and possible endorsement by the GMO Panel. The draft text was amended to take into account comments and suggestions from the GMO Panel.

The GMO Panel endorsed sections 4.1 and 4.2 of the draft guidance. This document will be published for public consultation on the EFSA website.

6. New Mandates

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

One new application was received:

- EFSA-GMO-NL-2017-140

Further information on these applications can be found at [EFSA Register of Questions](#).

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

None.

6.3. Other Requests and Mandates

None.

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

7.1.1. Feedback on Biological relevance WG

A GMO Panel member presented the concepts listed by the Scientific Committee's Biological relevance draft guidance and the outcome of an exercise that was undertaken to check how these concepts are applied in a scientific opinion of the GMO Panel.

The Panel discussed how these concepts are used in the risk assessment of GMOs.

7.2. EFSA including its Working Groups /Task Forces

None.

7.3. European Commission

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

8. Other scientific topics for information and/or discussion

8.1. Risk assessment of subcombinations

The GMO Panel discussed the document illustrating the general strategy for the risk assessment of sub-combinations in segregating stacks, taking into account the experience gained during the risk assessment of two applications (applications EFSA-GMO-NL-2013-119 and EFSA-GMO-DE-2010-86). The strategy document will be tabled for discussion and possible adoption at the next plenary meeting of 17-18 May.

8.2. RNAi procurement presentation

The contractor presented the outcome of the EFSA procurement on a systematic literature search of baseline information to support the risk assessment of RNAi-based GM plans – Lot 1. The GMO Panel and Unit welcomed the presentation and discussed the contractor's findings.

9. Any other business

9.1. Information on the EFSA MB decision revising the establishment and operations of scientific panels

The Head of the GMO Unit presented the updated Management Board Decision revising the establishment and operations of the Scientific Committee, Scientific Panels and their Working Groups.⁶

9.2. GMO Network meeting

A member of the GMO Unit presented the topics proposed for discussion at the 2017 meeting of the EFSA Scientific Network for Risk Assessment of GMOs meeting. The meeting will take place on 23-24 May.

⁶ <https://www.efsa.europa.eu/sites/default/files/mb170322-a4.pdf>

9.3. Public consultation on Scientific Committee draft guidance documents

A member of the GMO Unit informed the Panel that the Scientific Committee's draft guidance document on biological relevance and the one on weight of evidence have been published on the EFSA website for public consultation and encouraged the Panel members to read them and to submit their comments, should they have any.

10. Adoption of the minutes of the current meeting

The minutes of the current meeting were adopted at the end of the meeting.