

Scientific Panel on GMO

Minutes of the 113th Plenary meeting of the Scientific Panel on GMO

1 – 2 March 2017, Parma

(Agreed on 2 March 2017)

Participants

■ Panel Members

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

■ Hearing experts: Pier Sandro Cocconcelli for item 5.5.

■ European Commission observers: Lisa Haller and Maria Mirazchiyska (DG SANTE).

■ EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Herman Broll, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Andrea Gennaro, Mildred Hauck, Anna Lanzoni, Alessandro Leo, Sylvie Mestdagh, Irina Olaru, Franco Neri, Claudia Paoletti, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Matthew Ramon, Ángel José Ruiz and Elisabeth Waigmann.

Other EFSA Units/Directorates: Jaime Aguilera, FEED Unit.

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

■ Others: none.

1. Welcome and apologies for absence

The Chair of the GMO Panel welcomed the participants. Apologies were received from Barbara Manachini and Christoph Tebbe for both days, and from Antoine Messéan for 2 March 2017.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interests², EFSA screened the Annual Declarations of Interest (ADoIs) and the Specific Declarations of Interest (SDoIs) filled in by the experts invited to the present meeting. For further details on the outcome of the screening of the ADoI and SDoI, please refer to Annex I. Oral Declaration of Interest was asked at the beginning of the meeting and no additional interest was declared.

4. Report on written adoption procedure since 112th Plenary meeting held on 25 – 26 January 2017, Parma

As all issues had been extensively discussed during the 112th Plenary meeting and only some adjustments of the text remained needed, the draft opinion on Application EFSA-GMO-NL-2012-106 had been proposed for adoption by written procedure. The outcome was that the GMO Panel adopted this scientific opinion, except for two members, who abstained from voting. The opinion will be published on the EFSA website at [EFSA Journal](#).

The minutes of the 112th Plenary meeting held on 25 - 26 January 2017 were also adopted by written procedure on 21 February 2017 and are published on the EFSA website at: [Event: 112th plenary meeting of GMO Panel](#).

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

5.1 Application for authorisation of genetically modified oilseed rape MON 88302 × Ms8 × Rf3 and sub-combinations independently of their origin, for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto Company and Bayer CropScience AG. (EFSA-GMO-NL-2013-119) ([EFSA-Q-2013-01002](#))

The GMO Panel discussed and revised the draft opinion, focusing on the section on sub-combinations and the overall conclusions, as the other sections of the opinion had already been discussed in previous meetings.

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

5.2 Mandate for assessment of additional information for authorisation of food and feed containing, consisting and produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21 (adopted application EFSA-GMO-DE-2009-66) ([EFSA-Q-2016-00730](#))

The GMO Panel discussed the additional information related to adopted application EFSA-GMO-DE-2009-66. This information consisted in protein expression data for maize Bt11 × MIR162, which is a sub-combination of the four-event maize stack Bt11 × MIR162 × MIR604 × GA21.

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

² <http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf>

5.3 Application for authorisation of genetically modified cotton MON 88701 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2013-114) ([EFSA-Q-2013-00219](#))

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

Cotton MON 88701 was developed to produce two new proteins, DMO and PAT, which confer tolerance to dicamba and glufosinate ammonium-based herbicides.

The GMO Panel revised the draft opinion, focusing on the following sections: molecular characterisation, comparative assessment, food and feed safety assessment, environmental risk assessment, and overall conclusions. Particular attention was given to aspects related to the compositional analysis and toxicological assessment.

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

5.4 Application for authorisation of genetically modified soybean FG72 × A5547-127 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2013-120) ([EFSA-Q-2013-01032](#))

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

Soybean FG72 × A5547-127 was obtained by conventional crossing of genetically modified soybean lines FG72 and A5547-127. Soybean FG72 produces two newly expressed proteins, HPPD W336 and 2mEPSPS, which confer tolerance to isoxaflutole and glyphosate respectively. Soybean A5547-127 produces one newly expressed protein, PAT, which confers tolerance to glufosinate ammonium-based herbicides. The single soybean events are maintained in the soybean stack FG72 × A5547-127.

The GMO Panel revised the draft opinion, focusing on the following sections: molecular characterisation, comparative assessment, food and feed safety assessment, environmental risk assessment, and overall conclusions.

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

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

The Chair of the FEEDAP Panel's WG on GM Microorganisms, invited as Hearing Expert to this GMO Panel plenary meeting for this agenda item, presented the draft guidance on microbial characterisation, focusing on the section that should be endorsed by the GMO Panel.

Further discussion is needed, therefore the item will be scheduled again for discussion at the next Plenary meeting, on 5-6 April 2017.

6. New mandates

6.1 Applications under Regulation (EC) No 1829/2003

One new application was received:

- EFSA-GMO-NL-2017-139

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

6.2 Annual PMEM reports

None.

6.3 Other Requests and Mandates

None.

7. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA and the European Commission

7.1 Scientific Committee and other Scientific Panels

A Vice-chair of the GMO Panel reported on the Scientific Committee meeting which took place on 13 February 2017. The agenda of this meeting is available on the EFSA [website](#).

A member of the Panel informed on the on-going work of the SC's Genotoxicity WG.

7.2 EFSA including its Working Groups/Task Forces

7.2.1 Feedback from the Allergenicity WG

The Chair of the WG and a scientific officer of the GMO Unit provided feedback on the development of the Allergenicity GD. The comments received during the public consultation and the EFSA Info session of 23 November 2016 will be further discussed by the Allergenicity WG and the draft guidance will be revised accordingly. The positive impact of the "Focus group" during the development of the guidance has been acknowledged, especially on improving the quality, clarity and usability of the document. The document will be scheduled for discussion at the May Plenary.

7.2.2 Feedback from the LLP WG

The Chair of the LLP WG provided feedback on the activities of the WG. The comments received from Member States were analysed and the draft guidance is being updated. The draft guidance is scheduled for discussion and possible endorsement at the next Plenary meeting, before it is published on the EFSA website for public consultation.

7.3 European Commission

The representatives of the European Commission informed the GMO Panel 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

None.

9. Any other business

9.1 Update on MC/FF task force on history of safe use

Two members of the GMO Unit provided an update on the discussions taking place in the Task force on history of safe use. It was agreed that a dedicated discussion on this topic would be scheduled at a future Plenary meeting.

9.2 Possibility to extend April Plenary

The GMO Panel discussed the possibility to extend the April plenary meeting.

9.3 Panel renewal

The Head of the GMO Unit informed the GMO Panel that EFSA has already started preparing for the renewal of several scientific panels, which will take place in the July 2018.

10. Adoption of the minutes of the current meeting

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

Annex I

Interests and actions resulting from the screening of Annual Declarations of Interest (ADoI) or Specific Declarations of Interest (SDoI)

CONFLICT OF INTEREST: In the SDoI filled for the present meeting, Philippe Guerche declared an interest for Item 5.3 in relation to previously declared annual declaration of interest (ADoI): Mr Guerche commented on dossiers submitted to EFSA, including Application for authorisation of genetically modified cotton MON88701 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (EFSA-GMO-NL-114) by Monsanto, in his capacity of member of the French High Council for Biotechnology (FSO), which advises the French government on GMOs. In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, and taking into account the specific matters discussed at the meeting in question, the interests above were deemed to represent a Conflict of Interest.

This results in the exclusion of the expert from any discussion, voting or other processing of the agenda item 5.3.

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

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