

Scientific Panel on GMO

Minutes of the 112th Plenary meeting of the Scientific Panel on GMO

25 - 26 January 2017, Parma
(Agreed on 21 February 2017¹)

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.

- **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 and Elisabeth Waigmann.

Other EFSA Units/Directorates: none.

- **European Commission observers:** Lisa Haller and Maria Mirazchyska (DG SANTE).
- **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 Elsa Nielsen for 25 January.

2. Adoption of agenda

The agenda was adopted with one change: addition of agenda point 10.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes² and the Decision of the Executive Director implementing this Policy regarding

¹ The minutes previously agreed on 10 February 2017 were updated to reflect, under point 5.1, the abstention of two Panel members during the adoption procedure.

Declarations of Interests³, 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. Agreement of the minutes of the 111th Plenary meeting held on 30 November – 2 December 2016, Parma

The minutes of the 111th Plenary meeting held on 30 November – 2 December 2016 were adopted by the GMO Panel and will be published on the EFSA website at: [Event: 111th plenary meeting of GMO Panel](#).

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

5.1. Application for authorisation of genetically modified soybean DAS-68416-4 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2011-91) ([EFSA-Q-2011-00052](#))

The draft opinion had been first discussed by the GMO Panel at its 111th Plenary meeting (30 November – 1 December 2016).

Soybean DAS-68416-4 was developed to produce two new proteins, AAD-12 and PAT, which confer tolerance to 2,4-D and glufosinate ammonium-based herbicides.

The GMO Panel revised the draft opinion, focusing on the following sections: information on the expression of the insert, toxicological assessment, nutritional assessment, post-market monitoring, food/feed safety conclusions, and overall conclusions.

The GMO Panel adopted this scientific opinion, except for two members, who abstained from voting. The scientific opinion will be published on the EFSA website at [EFSA Journal](#).

5.2. Application for authorisation of genetically modified soybean DAS-44406-6 for all food and feed uses submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2012-106) ([EFSA-Q-2012-00368](#))

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

Soybean DAS-44406-6 is tolerant to glyphosate, 2,4-D and glufosinate ammonium-based herbicides. These traits are achieved by the presence of three newly expressed proteins: 2mEPSPS, AAD-12 and PAT respectively.

The GMO Panel discussed in detail the sections on molecular characterisation, comparative assessment, food/feed safety assessment, environmental risk assessment and monitoring plan.

As all issues were extensively discussed during the plenary meeting and only some adjustments of the text remained needed, the draft opinion will be proposed for adoption by written procedure.

² <http://www.efsa.europa.eu/en/keydocs/docs/independencypolicy.pdf>

³ <http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf>

5.3. Application for authorisation of genetically modified oilseed rape MON 88302 x MS8 x RF3 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto and Bayer CropScience (EFSA-GMO-NL-2013-119) ([EFSA-Q-2013-01002](#))

The draft opinion had been first discussed by the GMO Panel at its 111th Plenary meeting (30 November – 1 December 2016).

Oilseed rape MON 88302 x MS8 x RF3 was obtained by conventional crossing of oilseed rape single events MON 88302, MS8 and RF3. Lines MS8 and RF3 contain the male sterility (barnase) and fertility restoration (barstar) genes respectively; these lines were developed for the production of hybrid seeds MS8 x RF3, resulting in higher yield due to hybrid vigour; MS8 and RF3 also produces PAT, which confers tolerance to glufosinate ammonium-based herbicides. Oilseed rape MON 88302 was developed to express CP4 EPSPS, which confers tolerance to glyphosate. The single oilseed rape events are maintained in the stack.

The GMO Panel discussed at length the risk assessment of sub-combinations for this stack.

The draft opinion will be placed on the agenda of the next plenary meeting for further discussion and possible adoption.

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

This agenda item was not discussed due to lack of time.

6. New mandates

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

Six new applications were received :

- EFSA-GMO-NL-2016-136
- EFSA-GMO-DE-2016-137
- EFSA-GMO-BE-2016-138
- EFSA-GMO-RX-006
- EFSA-GMO-RX-007
- EFSA-GMO-RX-008

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

Two mandates were received:

- Mandate for assessment of new additional information for authorisation of food and feed containing, consisting and produced from genetically modified maize Bt11 x MIR162 x MIR604 x GA21 and all the possible sub-combinations of the single events, independently of their origin, under Regulation No 1829/2003 (adopted application EFSA-GMO-DE-2009-66) ([EFSA-Q-2016-00730](#))
- Mandate for assessment of new additional information related to the application for authorisation of food and feed containing, consisting and produced from genetically modified maize 5307 (adopted application EFSA-GMO-DE-2011-95) ([EFSA-Q-2017-00052](#))

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

7.1. Scientific Committee and other Scientific Panels

None.

7.2. EFSA including its Working Groups/Task Forces

None.

7.3. European Commission

None.

8. Other scientific topics for information and/or discussion

None.

9. Any other business

9.1. Proposed calendar for 2018

The GMO unit shared a proposed calendar of GMO Panel Plenary meetings for 2018.

9.2. Open plenary (date) and webstream

A member of the GMO Unit informed the GMO Panel that, following the 2016 pilot phase in Brussels, all open plenary meetings will be held in Parma in 2017. The GMO Panel 2017 Open Plenary meeting is scheduled for 25-26 October. This meeting will be video streamed, so remote attendance will be possible.

9.3. Fellowship programme

A member of the GMO Unit presented the [EU-FORA](#) fellowship programme.

9.4. Plenary minutes

A member of the GMO Unit informed the GMO Panel that as of January 2017, EFSA Panel Plenary meeting minutes should be published within 15 working days after the meeting. Therefore, minutes of plenary meetings should be adopted at the end of the meeting or right after the meeting, by written procedure.

9.5. Update of Guidance documents

The GMO Panel discussed whether any of its Guidance documents needed an update. It was agreed that one aspect that needs elaboration in the frame of post-market environmental monitoring is the insect resistance monitoring protocol. As for other possible updates, further discussion will take place in each standing WG.

10. Adoption of the minutes of the current meeting

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

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 Items 5.1 and 5.2 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 soybean DAS-68416-4 for food and feed uses, import and processing submitted to EFSA under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2011-91), and Application for authorisation of genetically modified soybean DAS-44406-6 for all food and feed uses submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2012-106), 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 Processes⁴ and the Decision of the Executive Director on Declarations of Interest⁵, 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 items 5.1 and 5.2.

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

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