Scientific Panel on GMO

Minutes of the 109th Plenary meeting of the Scientific Panel on GMO

21-22 September 2016, Parma

(Agreed on 26 October 2016)

Participants

- **Panel members**:

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

- **EFSA:**

GMO Unit: Fernando Alvarez, Michele Ardizzone, Herman Broll, Chiara Belvederi, Fabrizio Chiaramonte, Yann Devos, Antonio Fernández Dumont, Niccolò Franceschi, Andrea Gennaro, Anna Lanzoni, Franco Neri, Claudia Paoletti, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Matthew Ramon, Regina Selb, Elisabeth Waigmann.

Other EFSA Units/Directorates:

- **European Commission observers:** Kaja Kantorska (DG SANTE).
- **Observers (in application of the guidelines for observers)**: none.
- **Others:** none.

1 Welcome and apologies for absence

The Chair of the EFSA GMO Panel welcomed the participants. Apologies were received from Elsa Nielsen for both days and from Jeremy Sweet for 22 September.

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 Processes[1] and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests[2], EFSA screened the Annual Declarations of Interest (ADoIs)

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[2] http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf

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 108th Plenary meeting held on 13-14 and 15 July 2016, Parma

The minutes of the 108th Plenary meeting held on 13-14 and 15 July 2016 were adopted by written procedure on 16 August and published on the EFSA website at: Event: 108th plenary meeting of GMO Panel.

5 Scientific outputs submitted for discussion and/or possible adoption

5.1 Application for authorisation of genetically modified cotton GHB119 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer (EFSA-GMO-NL-2011-96) (EFSA-Q-2011-00311)

The draft opinion was discussed in the EFSA GMO Panel Standing Working Group meetings and was presented to the EFSA GMO Panel for discussion and possible adoption.

The EFSA GMO Panel voted unanimously in favour of adopting this scientific opinion, which will be published on the EFSA website at EFSA Journal.

5.2 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)

Not discussed due to lack of time.

5.3 Application for authorisation of genetically modified soybean DAS-81419-2 for food and feed uses, import and processing in accordance with Regulation (EC) No 1829/2003 submitted by Dow AgroSciences (EFSA-GMO-NL-2013-116) (EFSA-Q-2013-00527)

The draft opinion was discussed in the EFSA GMO Panel Standing Working Group meetings and was presented to the EFSA GMO Panel for a first reading. Further refinement of the text is needed.

5.4 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)

Not discussed due to lack of time.

5.5 Mandate on possible derogation of existing requirements for applications of GM food and feed at low levels submitted under Regulation (EC) No 1829/2003 on GM food and feed (EFSA-Q-2015-00629)

The draft guidance was discussed in the specific GMO Working Group and presented to the GMO Panel at its 108th Plenary meeting.

The EFSA GMO Panel endorsed the draft Guidance on low level presence of GM food and feed.

In a first round of consultation, Member States will be consulted on this draft guidance for a period of 6 weeks.

6 New mandates

6.1 Applications under Regulation (EC) No 1829/2003

Two applications were received as follows:

EFSA-GMO-RX-003 (EFSA-Q-2016-00526)

EFSA-GMO-RX-002 (EFSA-Q-2016-00478)

6.2 Annual PMEM reports

None.

6.3 Other Requests and Mandates

A new mandate was received as follows:

New sequencing information for DAS-59122-7 maize (EFSA-Q-2016-00506)

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

7.1 Scientific Committee and other Scientific Panels

The Chair of the GMO Panel provided feedback on the 80th plenary meeting of the EFSA Scientific Committee, which took place on 14-15 September. At the Scientific committee meeting, he gave a presentation of activities of the GMO Panel with particular focus on the activities of the Working Groups on "*Supplementary guidelines for the allergenicity assessment of GM plants*" and "*Guidelines on possible derogation of existing requirements for applications of GM food and feed at low levels submitted under Regulation (EC) No 1829/2003*".

Feedback on the GMO Panel discussion on sub-combination was also provided to the Scientific Committee.

Finally, the Chair of the GMO Panel reported a discussion on Prometheus and informed that a presentation will be given to the GMO panel on this subject by the end of the year.

7.2 EFSA including its Working Groups/Task Forces

7.2.1 Feedback from the Allergenicity public consultation

The GMO scientific officer in charge provided an update on the public consultation of the draft Guidance Document on allergenicity assessment of genetically modified plants and informed that as of date 78 comments had been received. The consultation period will run until 25 September.

7.2.2 Integration on DNA vaccine

The GMO scientific officer in charge informed that the kick-off meeting of the new EFSA Working Group on integration/non-integration of a DNA plasmid vaccine will take place on 27 September. It was underlined that the working group will focus only on data linked

to the integration/non-integration of the DNA plasmid vaccine but not perform a risk assessment. The working group is expected to complete its mandate by the end of 2016.

7.3 European Commission

The representative from the European Commission provided feedback on applications:

No opinions were given by the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) on a draft Commission Implementing Decision authorising GM cotton 281-24-236 × 3006-210- 23 × MON 88913 (EFSA-GMO-NL-2009-68) and a on a draft Commission Implementing Decision renewing the authorisation for the placing on the market of GM maize MON 810 as food and feed.

Commission Implementing Decision on maize Bt11 x MIR162 x MIR604 x GA21 and all sub-combinations (EFSA-GMO-DE-2009-66) will be published in the Official Journal.

EFSA will be asked to present the recently adopted applications on GM soybean 305423 x 40-3-2 EFSA-GMO-NL-2007-47 and GM maize Bt11 x 59122 x MIR604 x 1507 x GA21 (EFSA-GMO-DE-2011-99) to the PAFF Committee at its November meeting.

A mandate on the 2015 PMEM report on MON 810 will be sent to EFSA after the MS comment period that will end on 7 October 2016.

8 Other scientific topics for information and/or discussion

8.1 Sub-combinations

Following discussion on the risk assessment of sub-combinations obtained by targeted breeding approaches at its April and May Plenary meetings, the EFSA GMO Panel further discussed its approach. Further discussion is needed.

9 Any other business

9.1 Review of authorship principle

The Head of the GMO unit gave a presentation on EFSA guidance on Review of authorship principles.

9.2 Potential Conflicts of Interest for EFSA experts receiving prizes/awards

The Head of the GMO unit shared some considerations prepared by the EFSA legal department regarding the acceptance of prizes.

9.3 GMO Open Plenary, 26-27 October, Brussels

The Head of the GMO shared information with the panel regarding the forthcoming Open Plenary including communication aspect and logistics.

In line with EFSA guidance, the draft agenda was published on 13 September and registration will be opened until 4 October. Over 20 registrations have already been received.

The Guidelines for Observers will be presented at the beginning of the meeting. In line with the procedure, at the end of the meeting the questions received in written are addressed.

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 5.2 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 (EFSA-GMO-NL-2011-91) submitted to EFSA under Regulation (EC) No 1829/2003 by Dow AgroSciences, 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 Processes[3] and the Decision of the Executive Director on Declarations of Interest[4], 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 5.2.

[3] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf
[4] http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014