Scientific Panel on GMO

Minutes of the 105th Plenary meeting of the Scientific Panel on GMO

9-10 March 2016, Parma

(Agreed on 13 April 2016)

Participants

- **Panel members**:

Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Achim Gathmann, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Antoine Messéan, Elsa Nielsen, Hanspeter Naegeli, Fabien Nogue, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli, Jean-Michel Wal.

- **EFSA:**

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

Other EFSA Units/Directorates: Elisa Aiassa (AMU Unit / RASA Directorate) for item 7.2.4.

- **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 GMO Panel welcomed the participants. Apologies were received from Barbara Manachini and Christophe Robaglia for both days.

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

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

Declarations of Interests[2], 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 104th Plenary meeting held on 27-28 January 2016, Parma

The minutes of the 104th GMO Plenary meeting (27-28 January 2016) were adopted and will be published on the EFSA website at: Event: 104th plenary meeting of GMO Panel

5 Scientific outputs submitted for discussion and/or possible adoption

5.1 Application for authorisation of genetically modified oilseed Request to assess maize MON 810 PMEM report for the 2014 cultivation season provided by Monsanto (EFSA-Q-2015-00650)

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) assessed the annual post-market environmental monitoring (PMEM) report for the 2014 growing season of maize MON 810 provided by Monsanto Europe S.A. The GMO Panel concludes that the insect resistance monitoring data do not indicate a decrease in susceptibility of field Iberian populations of corn borers to the Cry1Ab protein over the 2014 season. However, as the methodology for insect resistance monitoring remained unchanged compared to previous PMEM reports, the GMO Panel reiterates its previous recommendations for improvement of the insect resistance management plan. The GMO Panel considers that the farmer alert system to report complaints regarding product performance could complement the information obtained from the laboratory bioassays, but encourages the consent holder to provide more information in order to be in a position to appraise its usefulness. The data on general surveillance activities do not indicate any unanticipated adverse effects on human and animal health or the environment arising from the cultivation of maize MON 810 cultivation in 2014. The GMO Panel reiterates its previous recommendations to improve the methodology for the analysis of farmer questionnaires and conduct of the literature review in future annual PMEM reports on maize MON 810. The GMO Panel urges the consent holder to consider how to make best use of the information recorded in national registers to optimise sampling for farmer questionnaires, and requests to continue reviewing and discussing relevant scientific publications on possible adverse effects of maize MON 810 on rove beetles. Also, the GMO Panel encourages relevant parties to continue developing a methodological framework to use existing networks in the broader context of environmental monitoring.

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 Notification for the risk assessment of the genetically modified carnation line FLO-40685-2 from Suntory Holdings Limited for the purpose of import, under Part C of Directive 2001/18/EC (C/NL/13/02) (EFSA-Q-2015-00122)

The Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) has evaluated the overall safety of genetically modified (GM) carnation FLO-40685-2 cut flowers to be imported into the EU for ornamental use. The genetic modification results in the flowers having purple petals. The stability of the newly

[2] http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf

introduced trait (purple flower colour) was observed over multiple vegetative generations. The purple colour of the petals comes from the altered expression levels of anthocyanins, common pigments found in edible fruits and vegetables. Considering the intended use of the GM carnation and the possible routes of exposure, the GMO Panel did not find indications that the genetic modification will increase the risk of allergy among those coming into contact with carnations. Overall there are no reasons for safety concerns of carnation FLO-40685-2 for humans. The GMO Panel also considered whether viable seed or pollen from GM carnation cut flowers could be dispersed into the environment and whether GM carnation can be propagated by rooting. Owing to the limited environmental exposure and the biology of the plant, the GMO Panel did not identify any environmental safety concerns and agrees with the scope of the post-market environmental monitoring (PMEM) plan. The GMO Panel concludes that the import, distribution and retailing of the GM carnation will not cause adverse effects on human health or the environment.

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

5.3 Application for authorisation of genetically modified cotton 281-24-236 x 3006-210-23 x MON88913 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No. 1829/2003 by Mycogen Seeds c/o Dow Agroscience LLC (EFSA-GMO-NL-2009-68) (EFSA-Q-2009-00491)

The Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) previously assessed the three single events combined to produce a three-event stack cotton 281-24-236 × 3006-210-23 × MON 88913 and did not identify safety concerns. In this opinion, the GMO Panel assesses only the three-event stack cotton. No new data on the single events, leading to modification of the original conclusions on their safety, were identified. The combination of cotton events 281-24-236, 3006-210-23 and MON 88913 in the three-event stack cotton did not give rise to issues – based on the molecular, agronomic, phenotypic or compositional characteristics – regarding food and feed safety and nutrition. The combination of the newly expressed proteins in the three-event stack cotton did not raise concerns for human and animal health. Considering the introduced traits and the outcome of the comparative analysis, the routes of exposure and limited exposure levels, the GMO Panel concludes that this three-event stack cotton would not raise safety concerns in case of accidental release of viable cottonseeds into the environment. The post-market environmental monitoring plans provided by the applicant are in line with the scope of the three-event stack cotton. No post-market monitoring of food/feed derived from the three-event stack cotton is considered necessary. The GMO Panel concludes that the three-event stack cotton is as safe and as nutritious as its conventional counterpart in the context of its scope.

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

5.4 Application for authorisation of genetically modified oilseed rape MS8 x RF3 x GT73 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2009-75) (EFSA-Q-2009-00890)

The Panel discussed the application. Further discussion is needed.

6 New mandates

6.1 Applications under Regulation (EC) No 1829/2003

Three new applications were received as follows:

Application for authorization of genetically modified maize VCO-01981-5 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Genective S.A. (EFSA-GMO-DE-2016-130) (EFSA-Q-2016-00077);

Application for authorization of genetically modified maize MON 87427 x MON 89034 x MIR162 x NK603 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto Europe S.A./N.V.(EFSA-GMO-NL-2016-131) (EFSA-Q-2016-00148);

Application for authorization of genetically modified soybean DAS-81419-2 X DAS-44406-6 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences Europe on behalf of Dow AgroSciences LLC (EFSA-GMO-NL-2016-132) (EFSA-Q-2016-00195).

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 provided feedback on the 77th plenary meeting of the Scientific Committee, which took place on 16-18 February 2016. The draft guidance on Uncertainty in EFSA scientific assessment was endorsed for the Panel testing phase. Updates were provided on the Scientific Committee activities, including the WGs on Weight of Evidence and on Biological Relevance.

7.2 EFSA including its Working Groups/Task Forces

7.2.1 Feedback from LLP WG

A scientific officer of the GMO Unit gave an update on the discussions held in the working group.

7.2.2 Feedback from Allergenicity WG

A scientific officer of the GMO Unit gave an update on the proceedings of the working group and explained how the Focus Group would be involved in the development of the draft document.

7.2.3 EFSA-GMO-DE-2011-99 agronomic and phenotypic data

A scientific officer of the GMO Unit gave an overview of certain agronomic and phenotypic data submitted in application EFSA-GMO-DE-2011-99 (EFSA-Q-2011-00894).

7.2.4 Prometheus Project

A scientific officer of the AMU Unit presented to the GMO Panel and Unit the results of the survey launched in January 2016 in the context of the EFSA Prometheus project.

7.3 European Commission

The European Commission (EC) representative reported on the Commission Implementing Decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize MON 810.

8 Other scientific topics for information and/or discussion

8.1 Significant differences in comparative assessment

The GMO Panel discussed the assessment of endpoints for which a significant difference has been detected, independently of the outcome type.

9 Any other business

9.1 Update on the clock mechanism

The Head of the GMO Unit updated the GMO Panel on the new procedures related to the "stop the clock" mechanism used by EFSA during the risk assessment of regulated products.

9.2 GMO Plenary meetings: 2017 dates

A scientific officer of the GMO Unit informed that the 110th GMO Plenary meeting scheduled in Brussels for 26-27 October will be opened to observers. A proposed calendar for the GMO plenary meetings in 2017 was also proposed. The GMO Plenary meetings are provisionally set as follows:

25-26 January;

1-2 March;

5-6 April;

17-18 May;

28-29 June;

20-21 September;

25-26 October;

29-30 November.

9.3 GMO Scientific Network meeting

A scientific officer of the GMO Unit informed that the EFSA Scientific Network on Risk Assessment of GMOs will meet in Parma on 31 May and 1 June. The GMO Panel was invited to propose discussion items.

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, Achim Gathmann declared an interest for Item 5.1 in relation to previously declared annual declaration of interest (ADOI). This item is declared by the expert as an interest based on his employment as senior scientist of the BVL, the leading competent authority in Germany. The expert has commented the 2014 MON 810 PMEM report officially as representative of the German CA as part of his employment. Therefore, the expert declares a conflict of interest for this agenda item. 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 interest above was 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 5.1.

CONFLICT OF INTEREST: In the SDoI filled for the present meeting, Philippe Guerche declared an interest for Item 5.1 and 5.4 in relation to previously declared annual declaration of interest (ADOI): Mr Guerche commented on the PMEM report provided by Monsanto for the 2014 cultivation season of maize MON 810 as well as on Application for authorisation of genetically modified oilseed rape MS8 x RF3 x GT73 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2009-75) as member of the French High Council for Biotechnology, 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 5.1 and 5.4.

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