Scientific Panel on GMO

Minutes of the 102nd Plenary meeting of the Scientific Panel on GMO

28-29 October 2015, Parma

(Agreed on 9 December 2015)

Participants

- **Panel members**:

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

- **EFSA:**

GMO Unit: Fernando Alvarez, Michele Ardizzone, Herman Broll, Yann Devos, Zoltán Divéki, Antonio Fernández Dumont, Andrea Gennaro, Viola Ghio, Ana Gomes, Anna Lanzoni, Sylvie Mestdagh, Franco Neri, Irina Olaru, Claudia Paoletti, Konstantinos Paraskevopoulos, Matthew Ramon and Elisabeth Waigmann.

Other EFSA Units/Directorates: Yi Liu (FIP Unit / REPRO Directorate) for item 5.4.

- **European Commission observer:** Maria Mirazchiyska (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 for absence were received from Fabien Nogué and Elsa Ebbesen Nielsen for 28 and 29 October.

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) 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 101st Plenary meeting held on 16-17 September 2015, Parma

The minutes of the 101st GMO Plenary meeting (16-17 September 2015) were adopted and will be published on the EFSA website at: EFSA Event: 101st plenary meeting of the GMO Panel

5 Scientific outputs submitted for discussion and/or possible adoption

5.1 Request to assess the revised maize MON 810 PMEM report for the 2013 cultivation season provided by Monsanto (EFSA-Q-2015-00432)

Following a request from the European Commission, the Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) assessed the results of the general surveillance activities contained in the revised annual post-market environmental monitoring (PMEM) report for the 2013 growing season of maize MON 810 provided by Monsanto Europe S.A. The supplied data 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 2013. Similar methodological shortcomings to those observed in previous annual PMEM reports were identified in the analysis of farmer questionnaires and the conduct of the literature review. The EFSA GMO Panel therefore strongly reiterates its previous recommendations to improve the methodology of future annual PMEM reports on maize MON 810. The EFSA GMO Panel urges the applicant to consider how to make best use of the information recorded in national registers in order to optimise sampling for farmer questionnaires, reiterates its previous recommendations on insect resistance monitoring and continued screening, and requests to continue reviewing and discussing relevant scientific publications on possible adverse effects of maize MON 810 on rove beetles. Also, the EFSA 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 GMO Panel publications.

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

5.2 New sequencing information of event GA21 maize (EFSA-Q-2015-00475)

In 2007, 2010 and 2011, the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO Panel) concluded the assessment of genetically modified (GM) maize GA21, Bt11 × GA21, MIR604 × GA21, and Bt11 × MIR604 × GA21. These were found to be as safe as their conventional counterparts and other appropriate comparators with respect to potential effects on human and animal health and the environment. On 23 July 2015, the European Commission (EC) received from Syngenta new nucleic acid sequencing data on maize event GA21 and updated bioinformatic analyses using the new sequencing data. The EC tasked EFSA to analyse these data and to indicate whether the previous conclusions of the EFSA GMO Panel on the above-listed GM maizes remain valid. The EFSA GMO Panel used the appropriate principles described in its guidelines for the risk assessment of GM plants to analyse the received data. Compared with the sequencing data originally provided, the new sequencing data indicated a one-base pair addition in a non-coding region of the insert, a three-base pair deletion in the 3' flanking region of the insert, and a difference in the number of functional copies of the mepsps expression cassette. These differences were only recently identified, but it was confirmed that they had been present in the original plant material used for the risk assessment. Thus, with the exception of bioinformatics analyses, the studies performed for the risk assessment remain valid. The bioinformatic analyses performed on the new sequence did not give rise to safety issues. Therefore, the GMO Panel concludes that the original risk assessment of event GA21 as a single event, and as a part of stacked events, remains valid.

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

5.3 Application for authorisation of genetically modified soybean 305423 x 40-3-2 and derived food and feed submitted under Regulation (EC) No 1829/2003 by Pioneer (EFSA-GMO-NL-2007-47) (EFSA-Q-2007-175)

The Panel discussed the application, focusing on the field trials performed for the comparative assessment. Further discussion is needed.

5.4 Application for authorisation of genetically modified maize Bt11 x MIR162 x MIR604 x GA21 for food and feed uses, import and processing, submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2009-66) (EFSA-Q-2009-00444)

The EFSA GMO Panel previously assessed the four single events combined to produce a four-event stack maize Bt11 × MIR162 × MIR604 × GA21 and did not identify safety concerns. In this opinion, the EFSA GMO Panel assesses the four-event stack maize and all its subcombinations independently of their origin. No new data on the single events, leading to modification of the original conclusions on their safety, were identified. The molecular, agronomic, phenotypic and compositional data on the four-event stack maize did not give rise to safety concerns and there is no reason to expect interactions between the single events impacting on the food and feed safety of the four-event stack maize. Considering

the routes of exposure and limited exposure levels, the Panel concludes that this four-event stack maize would not raise safety concerns in the event of accidental release of viable grains into the environment. The EFSA GMO Panel concludes that the four-event stack maize is as safe and as nutritious as its conventional counterpart in the context of its scope. Among the 10 subcombinations, four have been assessed previously and no safety concerns were identified. For the remaining six subcombinations, the EFSA GMO Panel followed a weight-of-evidence approach, and concluded they are expected to be as safe as the four-event stack maize. For some subcombinations that could be produced by conventional crossing through targeted breeding approaches, little or no specific data were submitted, giving rise to uncertainties due to data gaps. To reduce these uncertainties and to confirm assumptions made for the assessment of these subcombinations, the EFSA GMO Panel recommends that the applicant collate relevant information, if these subcombinations were to be created via targeted breeding approaches and commercialised in the future. In this case, this information should focus on expression levels of the newly expressed proteins.

The EFSA GMO Panel voted in favour of adopting this scientific opinion, except for two members who abstained from voting. The scientific opinion will be published on the EFSA website at: EFSA GMO Panel publications.

5.5 Application for authorisation of genetically modified maize Bt11 x MIR162 x 1507 x GA21 for food and feed uses, import and processing and all sub-combinations independently of their origin submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-DE-2010-86) (EFSA-Q-2010-01087)

The Panel did not discuss this application due to lack of time.

6 New mandates

6.1 Applications under Regulation (EC) No 1829/2003

A new application was received as follows: Application for authorization of genetically modified soybean MON 87705 x MON87708 x MON 89788 for food and feed uses submitted by Monsanto under Regulation (EC) No 1829/2003 (EFSA-GMO-NL-2015-126).

6.2 Annual PMEM reports

A new request was received as follows: Request to assess maize MON 810 PMEM report for the 2014 cultivation season provided by Monsanto.

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

None.

7.2 EFSA including its Working Groups/Task Forces

Dose-selection in 28-day toxicity studies on newly expressed proteins

A senior scientific officer of the GMO Unit presented an overview of toxicological studies submitted to EFSA as part of applications for authorisation of GM plants for food and feed uses. These studies were conducted using the test substance in low doses. This was highlighted as a recurrent issue of lack of adherence to OECD technical guidance.

7.3 European Commission

The European Commission (EC) representative updated the Panel on applications that are undergoing authorisation procedures and on generic mandates.

8 Other scientific topics for information and/or discussion

Missing values

This item was not discussed due to lack of time.

9 Any other business

9.1 EuropaBio letter

The GMO Panel and Unit discussed briefly a letter received by EFSA from EuropaBio, related to timelines for risk assessment of GMOs.

9.2 NPBT definition

The Head of the GMO Unit informed the GMO Panel that the European Commission had asked EFSA to provide technical assistance on issues related to the legal analysis of new plant breeding techniques.

9.3 Communication guidelines

The Head of the GMO Unit reminded the GMO Panel that the EFSA Communications Team is available to support panel members in any communication activity, conducted whether in their capacity of GMO Panel members or as individuals.

9.4 Additional Plenary meeting 2016

The GMO Panel discussed the possibility of having an additional plenary meeting organised in April 2016.

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 the following interest: Mr Gathmann commented on the MON810 PMEM report in his quality of senior scientist of the BVL, the leading competent authority in Germany. 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.

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