Scientific Panel on GMO

Minutes of the 101st Plenary meeting of the Scientific Panel on GMO

16-17 September 2015, Parma

(Agreed on 28 October 2015)

Participants

- **Panel members**:

Andrew Nicholas Birch, Adinda De Schrijver, Achim Gathmann, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Hanspeter Naegeli, , Fabien Nogué, Christophe Robaglia (on 17 September), Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli, Jean-Michel Wal.

- **Hearing experts**: Georg Leggewie (Federal Office of Consumer Protection and Food Safety, Germany) for item 6.3.
- **EFSA:**

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

- **Other EFSA Units/Directorates:** Laura Martino (AMU Unit / RASA Directorate) for item 8.1.
- **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 for absence were received from Josep Casacuberta and Elsa Ebbesen Nielsen for 16 and 17 September, and from Christophe Robaglia for 16 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) 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 100th Plenary meeting held on 7-9 July 2015, Parma

The minutes of the 100th GMO Plenary meeting (7-9 July 2015) were adopted and will be published on the EFSA website at: EFSA Event: 100th plenary meeting of the GMO Panel.

5 Report on written adoption procedure since the 100th Plenary meeting

The Panel members were informed that the minutes of the 99th Plenary meeting held on 24-25 June 2015 were adopted by written procedure by the members of the 2012–2015 GMO Panel. The minutes are published at: EFSA Event: 99th plenary meeting of GMO Panel.

6 Scientific outputs submitted for discussion and/or possible adoption

6.1 Scientific statement on updated sequence information for maize MIR604 (EFSA-Q-2015-00473)

In 2009 and 2010, the EFSA GMO Panel concluded the assessment of genetically modified (GM) maizes MIR604, MIR604 × GA21, MIR604 × Bt11 and MIR604 × GA21 × Bt11. These maizes 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 MIR604 and updated bioinformatic analyses using the new sequencing data. 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. The new sequencing data indicated a single base pair difference compared to the sequencing data originally provided, located in a non-coding region of the insert, which had already 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 new sequencing data and 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 MIR604 as a single and as a part of stacked events remains valid.

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

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.

6.2 Application for authorisation of genetically modified soybean MON 87769 x MON 89788 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-NL-2010-85) (EFSA-Q-2010-01086)

The EFSA GMO Panel previously assessed the two single events that are combined to produce soybean MON 87769 × MON 89788 and did not identify safety concerns. No new data on these single events, leading to a modification of the original conclusions on safety, were identified. The molecular, agronomic, phenotypic and compositional data on soybean MON 87769 × MON 89788 did not give rise to safety concerns. The Panel considers that there is no reason to expect interactions between the single events to impact on food and feed safety. There were no concerns regarding the potential toxicity or allergenicity of soybean MON 87769 × MON 89788, and no evidence that the genetic modification significantly changes the overall allergenicity. Because of the lack of data on dietary exposure to refined bleached deodorised oil from soybean MON 87769 × MON 89788, the EFSA GMO Panel could not complete the human health and nutrition assessment. There are no concerns regarding the use of feedingstuffs derived from defatted toasted MON 87769 × MON 89788 soybean meal. There are no indications of an increased likelihood of establishment and spread of feral soybean plants. Potential interactions of soybean MON 87769 × MON 89788 with biotic and abiotic environments were not considered relevant to this application. The unlikely, but theoretically possible, transfer of recombinant genes from soybean MON 87769 × MON 89788 to environmental bacteria is not of safety concern. The post-market environmental monitoring plan and reporting intervals conform with the scope of this application. In conclusion, the Panel could not complete the food and feed safety assessment of soybean MON 87769 × MON 89788 because of the lack of an appropriate nutritional assessment. The Panel concludes that soybean MON 87769 × MON 89788 is unlikely to have adverse effects on the environment in the context of application EFSA-GMO-NL-2010-85.

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

6.3 Application for authorisation of genetically modified maize MIR604 for cultivation submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-UK-2010-83) (EFSA-Q-2010-01084)

A representative from the German Federal Office of Consumer Protection and Food Safety presented the report on the environmental risk assessment of maize MIR604, in the context of application EFSA-GMO-UK-2010-83.

7 New mandates

7.1 Applications under Regulation (EC) No 1829/2003

None.

7.2 Annual PMEM reports

None

7.3 Other Requests and Mandates

None.

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

8.1 Scientific Committee and other Scientific Panels

Uncertainty in risk assessment WG

A scientific officer from the AMU Unit presented the EFSA Scientific Committee's draft guidance document on uncertainty in scientific assessment. The GMO Panel members discussed the potential sources of uncertainty in the risk assessment of GMOs and how to tackle them. They also discussed the feasibility of performing an uncertainty analysis in terms of resources needed. It was agreed that including an uncertainty analysis would enhance transparency of the risk assessment.

8.2 EFSA including its Working Groups/Task Forces

None.

8.3 European Commission

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

9 Other scientific topics for information and/or discussion

None.

10 Any other business

10.1 Appointment of WG Chairs

The Chairs for the standing WGs were appointed by the Chair of the GMO Panel, in consultation with the GMO Unit:

- Josep Casacuberta for the Molecular Characterisation WG
- Hanspeter Naegeli for the Food and Feed WG
- Achim Gathmann for the Environment WG
- Antoine Messéan for the PMEM WG.

The composition of the LLP WG was also discussed and agreed: Josep Casacuberta, Adinda De Schrijver, Achim Gathmann, Mikolaj Antoni Gralak, Elsa Nielsen, Francesco Visioli (Chair) and Jean-Michel Wal.

The composition and the Chair (Jean-Michel Wal) of the Allergenicity WG were also confirmed.

10.2 Nominations for SC WGs

Elsa Nielsen was appointed as a member of the Scientific Committee's Genotoxicity WG. Andrew Nicholas Birch, Adinda De Schrijver and Antoine Messéan were appointed to follow the development of the draft guidance document on uncertainty in risk assessment, and to support the implementation of uncertainty analysis in scientific opinions of the EFSA GMO Panel.

10.3 2016 Meeting dates

The GMO Panel discussed the proposed dates for meetings in 2016.

10.4 Training possibilities for the Panel

The GMO Panel was informed of the opportunities for training on uncertainty in risk assessment, and computational toxicology and modelling tools.

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 was a member of the German Federal Office of Consumer Protection and Food Safety team evaluating the environmental risk assessment for application EFSA-GMO-UK-2010-83 (maize MIR604) 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 6.3.

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