

Scientific Panel on GMO

Minutes of the 106th Plenary meeting of the Scientific Panel on GMO

**13-14 April 2016, Parma
(Agreed on 18 May 2016)**

Participants

- **Panel members:**

Andrew Nicholas Birch, Josep Casacuberta, Achim Gathmann, Mikolaj Antoni Gralak, Philippe Guerche, Barbara Manachini, Antoine Messéan, Elsa Nielsen, Hanspeter Naegeli, Fabien Nogue, Christophe Robaglia, 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, Elisabeth Waigmann and Claudine Ziegelmeier.

Other EFSA Units/Directorates: Jose Tarazona (PRAS Unit / REPRO Directorate) for item 8.2.

- **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 Adinda De Schrijver and Huw Jones for 13-14 April.

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 Processes¹ and the Decision of the Executive Director implementing this Policy regarding

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

Declarations of Interests², 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 105th Plenary meeting held on 9-10 March 2016, Parma

The minutes of the 105th Plenary meeting held on (9-10 March 2016) were adopted and will be published on the EFSA website at: [Event: 105th plenary meeting of GMO Panel](#)

5 Scientific outputs submitted for discussion and/or possible adoption

5.1 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 EFSA Panel on Genetically Modified Organisms (GMO) previously assessed the three single events that are combined to produce the three-event stack oilseed rape (OSR) MS8 x RF3 x GT73. In this Scientific Opinion, the GMO Panel assessed the three-event stack OSR and subcombinations that have not been authorised previously (i.e. MS8 x GT73 and RF3 x GT73), independently of their origin, for food and feed uses, import and processing, with the exception of isolated seed protein for food. The combination of OSR events, MS8, RF3 and GT73, in the three-event stack OSR does not raise issues relating to molecular, agronomic/phenotypic or compositional characteristics requiring further investigations. In line with previous assessments and considering the scope of this application, the GMO Panel did not find indications of safety concern for food and feed with trace levels of glyphosate oxidoreductase (GOX)v247 protein derived from the three-event stack OSR; whereas, the GMO Panel cannot assess the safety of three-event stack OSR products rich in protein, such as rapeseed protein isolates in feed. As the risk assessment of the three-event stack OSR could not be completed for products rich in protein, such as rapeseed protein isolates, the GMO Panel is not in a position to complete the food and feed safety assessment of subcombinations within the scope of this application (i.e. MS8 x GT73 and RF3 x GT73). The two-event stack OSR MS8 x RF3 is outside the scope of this application. Considering the scope of this application, the mode of action of the introduced traits and the data available for the three-event and two-event stack OSR MS8 x RF3, the GMO Panel considered that different combinations of the events, MS8, RF3 and GT73, would not raise environmental concerns.

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

6 New mandates

6.1 Applications under Regulation (EC) No 1829/2003

None.

6.2 Annual PMEM reports

² <http://www.efsa.europa.eu/sites/default/files/assets/independencerules2014.pdf>

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

None.

7.2 EFSA including its Working Groups/Task Forces

7.2.1 Feedback from ERA WG on AP125 (EFSA-Q-2015-00430)

A scientific officer of the GMO Unit gave an update on the status of the risk assessment of the application EFSA-GMO-BE-2015-125, and briefly presented the additional information on the suitability of test materials and representativeness of trial sites supplied by the applicant on 7 March 2016 in the frame of the agronomic/phenotypic and compositional characterisation of maize MON87403.

GMO Panel members were also informed that the applicant accepted EFSA's invitation to attend the Working Group on GMO applications – Environment of 17 May 2016 to provide further clarifications on the suitability of test materials and representativeness of trial sites used for the agronomic/phenotypic and compositional characterisation of maize MON87403.

7.2.2 Feedback from LLP WG

A scientific officer of the GMO Unit gave an update on the status of the Guidance document on LLP and on the timeline for the next steps in the development on this guidance.

7.2.3 Feedback from Allergenicity WG

A scientific officer of the GMO Unit gave an update on the progress of the working group. Comments from the Focus group were received and are being assessed by the Working group. A first draft of the Guidance document is expected to be presented to the GMO Panel at its May Plenary meeting.

7.3 European Commission

The European Commission (EC) representative informed that the GMO Panel opinions on GM Carnation SHD-27531-4 and FLO-40685-2 will be discussed at the next Regulatory Committee on Directive 2001/18/EC.

8 Other scientific topics for information and/or discussion

8.1 Sub-combinations

The GMO Unit gave a presentation on sub-combinations obtained via natural segregation (in case of segregating stacks) and via targeted breeding. The RA of the sub-combinations obtained independently of their origin was discussed by the EFSA GMO Panel.

8.2 GM crops and glyphosate and other herbicides

The Head of the PRAS unit gave a presentation on the risk assessment of pesticide substances in EFSA, with particular focus on glyphosate.

9 Any other business

9.1 GMO Scientific Network on the Risk Assessment of GMOs

A scientific officer of the GMO Unit presented the items that would be discussed at the 7th meeting of the EFSA Scientific Network on Risk Assessment of GMOs (the GMO Network), on 31 May - 1 June 2016, in Parma.

9.2 Follow-up on the clock mechanism discussion

As a follow-up to the discussion held in the previous plenary meeting, the Head of the GMO Unit discussed possible measures to further streamline the risk assessment process of applications.

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 5.1 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 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 Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, 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 item 5.1.