Scientific Panel on GMO

Minutes of the 111th Plenary meeting of the Scientific Panel on GMO

30 November – 2 December 2016, Parma

(Agreed on 25 January 2017)

Participants

- **Panel members**:

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

- **EFSA:**

GMO Unit: Fernando Álvarez, Herman Broll, Yann Devos, Antonio Fernández Dumont, Niccolò Franceschi, Andrea Gennaro, Anna Lanzoni, Franco Neri, Claudia Paoletti, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Matthew Ramon, Elisabeth Waigmann.

Other EFSA Units/Directorates:

- **European Commission observers:** Mirazchiyska Maria (DG SANTE).
- **Observers (in application of the guidelines for observers)**: none.
- **Others:** Thomas Frenzel for Item 5.3[1].

1. Welcome and apologies for absence

The Chair of the EFSA GMO Panel welcomed the participants. Apologies were received from Barbara Manachini for 30 November.

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[2] and the Decision of the Executive Director implementing this Policy regarding

[1] Attended by tele-conference on 2 December.
[2] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

Declarations of Interests[3], 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 110th Plenary meeting held on 26-27 October 2016, Brussels

The minutes of the 110th Plenary meeting held on 26-27 October 2016 were adopted unanimously by the GMO Panel and will be published on the EFSA website at: Event: 110th plenary meeting of GMO Panel.

5. Scientific outputs submitted for discussion and/or possible adoption

5.1. Application for renewal of authorisation for continued marketing of maize 1507 and derived food and feed submitted in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences Ltd. (EFSA-GMO-RX-001) (EFSA-Q-2015-00342)

The draft opinion was discussed in the EFSA GMO Panel Standing Working Group meetings and at the GMO Panel 111th Plenary meeting. Following further discussions in the Standing Workings, it 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.

Following the submission of application EFSA-GMO-RX-001 under Regulation (EC) No 1829/2003 from Pioneer Overseas Corporation and Dow Agrosciences LLC, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the frame of a renewal of authorisation application of the insect-resistant and herbicide-tolerant genetically modified (GM) maize 1507. The data package received in the frame of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, an updated bioinformatics analysis and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed this data package for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the frame of the original application. Under the assumption that the DNA sequence of the event in maize 1507 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize 1507 (EFSA, 2005b, 2009).

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

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

by Dow AgroSciences (EFSA-GMO-NL-2011-91) (EFSA-Q-2011-00052)

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.

5.3. 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)

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.

6. New mandates

6.1. Applications under Regulation (EC) No 1829/2003

Two applications were received as follows:

- EFSA-GMO-NL-2016-134 (EFSA-Q-2016-00686)
- EFSA-GMO-NL-2016-135 (EFSA-Q-2016-00688)

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

The Vice-chair of the GMO Panel provided feedback on the 81st plenary meeting of the EFSA Scientific Committee, which took place on 16-17 November 2016. He informed the GMO Panel that EFSA will launch an Online survey on DoI to collect experts feedback.

7.2. EFSA including its Working Groups/Task Forces

7.2.1 Feedback from the Allergenicity public consultation

An update on the status of the draft Guidance Document on allergenicity assessment of genetically modified plants was provided. An EFSA InfoSession was organised by EFSA to discuss the comments received during the public consultation. Additional information can be found at http://www.efsa.europa.eu/en/events/event/161123

7.2.2 Feedback from LLP WG

The GMO scientific officer in charge provided an update on the activities and informed that the consultation with the EU Member States is going to be closed on December 9th 2016. Afterwards the LLP WG will incorporate EU Member States comments and work

out a second draft of the guidance. This is intended to be proposed to the GMO Panel for endorsement before the Public consultation (foreseen in spring 2017).

7.2.3 Integration on DNA vaccine

The GMO scientific officer in charge provided an update on the activities and informed that a EFSA Statement is expected to be sent to the European Commission by the end of the year.

7.3. European Commission

The representative from the European Commission provided feedback on applications and informed the following mandates will be sent the GMO Panel:

- three mandates on renewal applications;
- one new mandate on protein expression level in a sub combination linked to EFSA-GMO-DE-2009-66;
- two mandates on new sequencing information.

8. Other scientific topics for information and/or discussion

8.1. Sub-combinations

Following discussion in recent Plenary meetings on the risk assessment of sub-combinations obtained by targeted breeding approaches, the EFSA GMO Panel endorsed a strategy document on the issue which will be tested in forthcoming meetings.

9. Any other business

9.1. Introduction REPRO HoD

Guilhem de Seze, Head of the REPRO department since 1 September introduced himself to the GMO Panel and followed the discussion of the Panel during the morning of the first day.

9.2. Feedback from meeting with Stakeholders

A member of the GMO Unit provided feedback on the technical meeting with stakeholders that took place on 23 November 2016 and focused on the Allergenicity guidance document.

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[4] and the Decision of the Executive Director on Declarations of Interest[5], 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.

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