

Scientific Panel on GMO

Minutes of the 120th Plenary meeting

Held on 24 – 25 January, 2018, Parma (Italy)

(Agreed on 8 February 2018)

Participants

■ Panel Members:

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

■ Hearing Experts¹:

Thomas Frenzel, member of the standing Working Group Applications Food and Feed (24 January pm)

■ European Commission representatives:

Béatrice Marquez-Garrido and Hans Moons (DG SANTE)

■ EFSA:

GMO Unit: Fernando Álvarez, Michele Ardizzone, Herman Broll, Giacomo De Sanctis, Yann Devos, Antonio Fernández Dumont, Silvia Federici, Andrea Gennaro, José Ángel Gomez Ruiz, Anna Lanzoni, Sylvie Mestdagh, Franco Maria Neri, Claudia Paoletti, Nikoletta Papadopoulou, Konstantinos Paraskevopoulos, Matthew Ramon and Elisabeth Waigmann

Other EFSA Units/Directorates: Jaime Aguilera (FEED Unit/REPRO Directorate) and Simone Gabbi (LA Unit/BUS Directorate)

■ Observers (in application of the guidelines for observers²):

None

■ Others:

None

¹ As defined in Article 11 of the Decision of the Executive Director on Declarations of Interest: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>.

² <http://www.efsa.europa.eu/en/stakeholders/observers.html>

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Barbara Manachini (for both days) and Elsa Nielsen (for 24 January am).

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 Processes³ and the Decision of the Executive Director on Declarations of Interest⁴, EFSA screened the Annual Declarations of Interest and the Specific Declarations of Interest filled in by the experts invited for the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of Interest at the beginning of this meeting.

4. Report on written adoption procedure since 119th Plenary meeting

The minutes of the 119th Plenary meeting held on 29-30 November 2017 were adopted by written procedure on 14 December and were published on 15 December on the [EFSA website](#).

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

5.1. Assessment of genetically modified maize NK603 x MON 810 for renewal of authorisation under Regulation (EC) 1829/2003 (application EFSA-GMO-RX-007) ([EFSA-Q-2017-00028](#))

The GMO Panel had discussed this application in its previous meeting.⁵ In this meeting, the GMO Panel discussed the sections that had been updated since then and, where appropriate, revised the draft opinion.

The GMO Panel finalised and subsequently adopted the draft opinion, which will be published on the EFSA website and on the [EFSA Journal](#).

³ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

⁴ <http://www.efsa.europa.eu/en/keydocs/docs/independencerules2014.pdf>

⁵ <http://www.efsa.europa.eu/sites/default/files/event/171129-m.pdf>

5.2. Assessment of genetically modified maize 4114 for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-123) ([EFSA-Q-2014-00850](#))

Genetically modified maize 4114 was developed through *Agrobacterium tumefaciens*-mediated transformation to provide protection against certain lepidopteran and coleopteran pests by the expression of the Cry1F, Cry2Ab2 and Cry1A.105 proteins derived from *Bacillus thuringiensis*, and tolerance to the herbicidal active ingredient glufosinate-ammonium by expression of the PAT protein derived from *Streptomyces viridochromogenes*.

Since the draft opinion was brought to the attention of the Panel for the first time, a representative from each standing Working Group reported the main findings of their risk assessment. Subsequently the GMO Panel reviewed and, when needed, revised the draft opinion. Further discussion is needed.

5.3. Assessment of genetically modified maize MON 87403 for food and feed uses submitted under Regulation (EC) No 1829/2003 (application EFSA-GMO-BE-2015-125) ([EFSA-Q-2015-00430](#))

The GMO Panel had discussed the safety evaluation of maize MON87403 in its previous meeting and had concluded that further discussion within the standing Working Groups was needed.⁶

The GMO Panel was therefore informed of the latest views and remaining open points of the standing Working Groups. Detailed discussion took place on the specificities of the intended trait and the implications on the ongoing risk assessment. The GMO Panel mandated its Working Groups to finalise the draft opinion for possible adoption in due time.

5.4. Assessment of genetically modified oilseed rape GT73 for renewal of authorisation under Regulation (EC) 1829/2003 (application EFSA-GMO-RX-002) ([EFSA-Q-2016-00478](#))

Genetically modified oilseed rape GT73 was developed to express tolerance to glyphosate based herbicides, conferred by the expression of the CP4 EPSPS and GOXv247 proteins.

Based on a presentation by a staff member of the GMO unit, the GMO Panel discussed the scope of the risk assessment of this GM oilseed rape as defined in application EFSA-GMO-RX-002. As for past assessments of applications on stacked events containing oilseed rape GT73 (e.g. EFSA-GMO-NL-2009-75), the GMO Panel highlighted some limitations owing to

⁶ <http://www.efsa.europa.eu/sites/default/files/event/171129-m.pdf>

lack of relevant data supporting the safety of the GOXv247 protein (i.e. 28-day oral toxicity study). The GMO Panel then considered possible ways forward for concluding the risk assessment of this application. Further discussion is needed.

6. New Mandates

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

Two new applications were received:

EFSA-GMO-RX-010 (cotton LLCotton25)

EFSA-GMO-RX-011 (soybean MON 89788)

6.2. Annual Post-market environmental monitoring reports of GM plants

At its previous meeting⁷, the GMO Panel was informed about a new request from the European Commission to evaluate the annual 2016 PMEM report on GM maize MON810. Against this background, the GMO Panel was reminded that, in common agreement with the requestor, the outcome of this evaluation will be published as a Statement of EFSA in the EFSA Journal.

6.3. Other Requests and Mandates

One mandate was received:

New sequencing information of maize event T25.

7. Feedback from the Scientific Committee/Scientific Panels, EFSA and the European Commission

7.1. Scientific Committee and other Scientific Panel(s) including their Working Groups

FEEDAP [draft guidance](#) on characterisation of microorganisms used as feed additives or as production organisms

Development of the draft guidance was led by the FEEDAP Panel in close collaboration with other relevant scientific Panels such as GMO Panel. These Panels had already endorsed their respective sections of the draft guidance. However, in view of the finalisation of the draft guidance document, a staff member of the FEED unit joined the present meeting to inform the Panel of the outcome of the public consultation that took place between 15 June and 15 September 2017. He also informed the GMO Panel that the EFSA report on the public consultation will be published together with the guidance once adopted by the FEEDAP Panel.

⁷ <http://www.efsa.europa.eu/sites/default/files/event/171129-m.pdf>

7.2. EFSA including its Working Groups /Task Forces

The chair of the GMO Working Group⁸ on 'Sequencing quality'⁹ updated the Panel of the discussion progress. Since the receipt of this mandate, the Working Group already met at three occasions.

7.3. European Commission

The representatives of the European Commission informed the Panel on their on-going activities, including approval procedures for applications for which the GMO Panel had issued a scientific opinion. The GMO Panel was informed of upcoming public comments on application EFSA-GMO-BE-2013-118 to EFSA's attention. The European Commission also indicated that an application for the renewal of the authorisation of GM oilseed rape T45 will be sent to EFSA soon.

8. Other scientific topics for information and/or discussion

8.1. RNAi procurement presentation

The contractor presented the outcome of the EFSA procurement on a systematic literature search of baseline information to support the environmental risk assessment of RNAi-based GM plants. The GMO Panel and Unit welcomed the presentation and discussed the contractor's findings.

9. Any other business

9.1. Information on March plenary

A member of the GMO Unit provided information on the GMO Open Plenary meeting that will take place in Parma on 7-8 March 2018. Further information is available on the following EFSA webpage <http://www.efsa.europa.eu/en/stakeholders/observers>

9.2. Competing interest management

A member of the LA unit gave an overview on the 2017 rules on competing interest management ([Policy on Independence](#)).

9.3. Horizontal topics in the GMO panel

The GMO Panel discussed the procedure for dealing with risk assessment issues that require direct collaboration between its Working Groups.

10. Adoption of the minutes of the current meeting

The minutes of the current meeting were adopted by written procedure.

⁸ <http://www.efsa.europa.eu/en/gmo/working-groups>

⁹ <http://www.efsa.europa.eu/en/events/event/171025>