Scientific Panel on GMO

Minutes of the 103rd Plenary meeting of the Scientific Panel on GMO

9-10 December 2015, Parma

(Agreed on 27 January 2016)

Participants

- **Panel members**:

Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Achim Gathmann, Mikolaj Antoni Gralak, Philippe Guerche, Huw Jones, 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, 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: Elisa Aiassa (AMU Unit / RASA Directorate) for item 7.2.

- **European Commission observers:** Kaja Kantorska (DG SANTE).
- **Observers (in application of the guidelines for observers)**: none.
- **Others:** Michael Meissle and Judith Riedel, Agroscope Reckenholz Switzerland for item 8.1.

1 Welcome and apologies for absence

The Chair of the GMO Panel welcomed the participants. Apologies for absence were received from Barbara Manachini for both days and from Jean Michel Wal for 9 December.

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

[1] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

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. No conflicts of interests relating to the issues discussed in this meeting were identified during the screening process or in the Oral Declaration of Interest (ODoI) at the beginning of this meeting.

4 Agreement of the minutes of the 102nd Plenary meeting held on 28-29 October 2015, Parma

The minutes of the 102nd GMO Plenary meeting (28-29 October 2015) were adopted and will be published on the EFSA website at: 103rd plenary meeting of GMO Panel.

5 Scientific outputs submitted for discussion and/or possible adoption

5.1 Part C notification (reference C/NL/13/01) from Suntory Holdings Limited for the import, distribution and retailing of carnation SHD-27531-4 cut flowers with modified petal colour for ornamental use (EFSA-Q-2015-00126)

The Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority (EFSA GMO Panel) has evaluated the overall safety of genetically modified (GM) carnation SHD-27531-4 cut flowers to be imported into the European Union (EU) for ornamental use. The genetic modification results in the flowers having purple petals. The stability of the new colour trait was observed over multiple vegetative generations. The purple colour of the petals comes from the altered expression levels of anthocyanins, common pigments found in edible fruits and vegetables. Considering the intended use of the GM carnation and the possible routes of exposure, the EFSA GMO Panel did not find indications that the genetic modification will increase the risk of allergy among those coming into contact with carnations. Overall there are no reasons for safety concerns of carnation SHD-27351-4 for humans. The EFSA GMO Panel also considered whether viable seed or pollen from GM carnation cut flowers could be dispersed into the environment and whether GM carnation can be propagated by rooting. Owing to the limited environmental exposure and the biology of the plant, the EFSA GMO Panel did not identify any environmental safety concerns and agrees with the scope of the post-market environmental monitoring plan. The EFSA GMO Panel concludes that the import, distribution and retailing of the GM carnation will not cause adverse effects on human health or the environment.

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

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

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

6 New mandates

6.1 Applications under Regulation (EC) No 1829/2003

None.

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

A vice-Chair of the GMO Panel provided feedback on the 76th plenary meeting of the Scientific Committee, which took place on 11-12 November 2015. Documents discussed at this meeting included the draft opinions on environment risk assessment and the draft revised guidance document on the use of benchmark dose in risk assessment. This meeting was open to observers.

7.2 EFSA including its Working Groups/Task Forces

EFSA PROMETHEUS Project

A scientific officer of the AMU Unit presented an overview of the "PROmoting METHods for Evidence Use in Scientific assessments" (PROMETHEUS) project. She explained which the objectives and deliverables of the project are and how the GMO Panel members could contribute to the project.

LLP Working Group

A senior scientific officer of the GMO Unit presented an overview of the Working group on the low level presence of GM plants in food and feed (LLP WG) and provided feedback on the outcome of the 1st meeting that took place on 25 November 2015.

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

EFSA's Fauna database

Michael Meissle and Judith Riedel, from Agroscope Reckenholz, Switzerland, presented the outcome of the project "Establishing a database of bio-ecological information on non-target arthropod species to support the environmental risk assessment of GM crops in the EU".

9 Any other business

9.1 Feedback from the Applicants Meeting

The Head of the GMO Unit gave feedback on the 'Info session on applications – GMO – Technical meeting with applicants', which took place in Parma, on 26 November 2015.

9.2 Improvements for GM stacks opinion

The GMO Panel discussed how to enhance clarity of the scientific opinions on stacked GM events. Further discussion is needed.

9.3 Studies performed in other countries

The GMO Unit and Panel discussed the provision of studies performed or commissioned by applicants for non-EU jurisdictions. According to the Implementing Regulation (EU) No 503/2013, applicants should provide full study reports for applications submitted under IR 503/2013.

9.4 Systematic review

Systematic reviews are required by the Implementing Regulation (EU) No 503/2013 for applications for authorisation of GM plants. The systematic review should be done on scientific literature published within a period of 10 years prior to the date of submission of the dossier on the potential effects on human and animal health of the GM food and feed covered by the application. The GMO Unit and Panel discussed how applicants should meet this requirement when there are only few papers available on the respective GM food and feed.

9.5 2016 Plenary meeting dates

The GMO Panel agreed that a Plenary meeting would be held on 13-14 April 2016 and the July plenary meeting would be postponed by one week, therefore taking place on 13-14 July 2016.