European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 95th Plenary meeting of the Scientific Panel on GMO

Held on 21 January 2015, Parma

(Agreed on 4 March 2015)

Participants

- **Panel members**:

Salvatore Arpaia, Andrew Nicholas Edmund Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Lieve Herman, Hilde-Gunn Opsahl Hoen-Sorteberg, Huw Jones, József Kiss, Gijs Kleter, Martinus Løvik, Antoine Messéan, Hanspeter Naegeli, Jaroslava Ovesná, Joe Perry, Nils Rostoks, Christoph Tebbe.

- **Hearing experts**: Hildegard Przyrembel for Item 5.2
- **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 and Matthew Ramon.

- **Other EFSA Units/Directorates:** Juliane Kleiner (REPRO Department)
- **European Commission observers:** Maria Mirazchiyska (DG SANCO).
- **Observers (in application of the guidelines for observers)**: none.
- **Others:** none.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Kaare Nielsen.

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

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

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 94th Plenary meeting held on 3-4 December 2014, Parma

The minutes of the 94th GMO Plenary meeting (3-4 December) were adopted and will be published on the EFSA website at: EFSA Event: 94th plenary meeting of the GMO Panel

5. Scientific outputs submitted for discussion and possible adoption

5.1 Application for authorisation of genetically modified maize MON 87427 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto (EFSA-GMO-BE-2012-110) (EFSA-Q-2012-00692)

The Panel discussed the draft scientific opinion, focusing on the new template for scientific opinions, as well as various scientific issues of interest. Pending the evaluation of additional bioinformatics analyses, further discussion of the draft opinion by the Panel is needed.

5.2 Explanatory note to the Guidance for risk assessment of food and feed from GM plants on the use of the Comprehensive Database for dietary exposure assessment in industry dossiers of GM foods (EFSA-Q-2014-00674)

Dietary exposure is an essential element of a risk assessment of genetically modified (GM) foods. This is primarily used following the identification and characterisation of a hazard, or for the assessment of the nutritional consequences after consumption of GM foods with altered nutritional profile and then for the full risk characterisations. A crude estimate of dietary exposure may also be used during hazard identification / characterisation to support the choice of dose regimes. Implementing Regulation (EU) No 503/2013 requires that a dietary exposure assessment is carried out on the basis of representative consumption data, and that it should consider also particular consumer groups. The EFSA Comprehensive European Food Consumption Database is currently the only available single source of consumption data in Europe, its use is encouraged for all GM applications. This statement provides technical advice on the use of the EFSA Comprehensive database for the dietary exposure assessment of GM foods.

The explanatory note was endorsed by the Panel and will be published on the EFSA website at: http://www.efsa.europa.eu/en/publications.htm

[2] http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

6 New mandates

6.1 Applications under Regulation (EC) No 1829/2003

None.

6.2 Annual post-market environmental monitoring reports of GM plants

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 REPRO Directorate

The *ad interim* Head of the REPRO Directorate presented herself to the Panel, providing information on her professional background. She also described EFSA's involvement in the World EXPO 2015 exhibition in Milan, which will have food as its central theme, and mentioned the main goals of the REPRO Directorate for 2015.

7.2.2 Working Group to supplement the guidelines for the agronomic and phenotypic characterisation of genetically modified plants

A member of the GMO Unit offered an overview of the 'Info session on applications—Technical meeting with stakeholders on agronomic and phenotypic characterisation of GM plants', held in Parma on 18–19 December 2014.

7.2.3 Working Group on Guidance Document for the risk assessment of the renewal of GM plant products authorised under Regulation (EC) No 1829/2003

A member of the GMO Unit presented a summary of the comments received during the public consultation on the draft Guidance for renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003.

7.2.4 Standing Working Group on Food/Feed

A member of the GMO Unit presented a case-study for 28-day toxicity studies on newly expressed proteins, explaining the doses selected in these studies and how they affect the risk assessment.

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

8.1 Missing values

The GMO Panel discussed aspects of field trial design and the completeness of data packages from trials. The Panel agreed that data must comply with minimal requirements and that the role of the completeness check phase is to ensure the quality of applications entering the risk assessment. Specifically, for

compositional/agronomic/phenotypic field trials, where the number of sites submitted for assessment is eight, the Panel agreed that the number of replicates must be at least four at each and every site. Where the number of sites exceeds eight and the total replication exceeds thirty two over all the trials, if the minimal requirements are not met, the information contained in those sites might be useful for assessment, on a case-by-case basis.

9 Any other business

9.1 Panel Members reporting on meetings / conferences they attended on behalf of EFSA

A member of the Panel reported on proceedings of the Workshop 'Herbicide tolerant crops in the EU – strengthening the economic and environmental impact assessment', held in Paris, on 15-16 December 2014.

9.2 GMO Open plenary 2015

A member of the GMO Unit informed the Panel that the upcoming plenary meeting would be open to observers and held in Brussels.