European Food Safety Authority

GMO UNIT

SCIENTIFIC PANEL ON GMO

Minutes of the 82nd Plenary meeting of the Scientific Panel on GMO

Held on 29–30 May 2013, Parma

(Agreed on 3 July 2013)

Participants

- **Panel members**:

Andrew Nicholas Edmund Birch, Andrew Chesson, Patrick du Jardin, Achim Gathmann, Jürgen Gropp, Lieve Herman, Hilde-Gunn Opsahl Hoen-Sorteberg, Huw Jones, Jozsef Kiss, Gijs Kleter, Martinus Løvik, Antoine Messéan, Hanspeter Naegeli,[1] Kaare Nielsen,[2] Jaroslava Ovesná, Joe Perry, Nils Rostoks and Christoph Tebbe.

- **Hearing experts**:

None.

- **EFSA:**

GMO Unit: Herman Broll, Anna Christodoulidou, Yann Devos, Zoltán Divéki, Anders Falk, Antonio Fernández Dumont, Andrea Gennaro, Ana Gomes, Yi Liu, Sylvie Mestdagh, Irina Olaru, Claudia Paoletti, Matthew Ramon and Elisabeth Waigmann.

- **Other EFSA Units/Directorates:** Andrea Germini (SCOM Unit/SCISTRAT Directorate[3]).
- **European Commission observers:** Sabine Pelsser (DG SANCO).
- **Observers (in application of the guidelines for observers[4])**: none.
- **Others:** Hilko van der Voet,[5] Steven Tompkins,[6] Richard Weightman,[7] Nigel Halford[8]

1. Welcome and apologies for absence

The Chair welcomed the participants.

Apologies were received from Salvatore Arpaia.

[1] Attended on 29 May only.
[2] Attended via teleconference.
[3] Scientific Committee (SCOM) Unit of the Science Strategy and Coordination (SCISTRAT) Directorate.
[4] http://www.efsa.europa.eu/en/stakeholders/observers.htm
[5] Attended discussion on item 9.a only.
[6] Attended discussion on item 9.b only
[7] Attended discussion on item 9.b only
[8] Attended discussion on item 9.b only

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 regarding Declarations of Interests (DoIs)[3] and the Decision of the Executive Director implementing this Policy,[4] EFSA screened the Annual Declaration of Interest (ADoI) and the Specific Declaration of Interest (SDoI) 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 81st Plenary meeting held on 17–18 April 2013, Parma

The minutes of the 81st GMO Plenary meeting (17–18 April 2013) were adopted and will be published at: EFSA Event: 81st plenary meeting of GMO Panel

5. Report on written procedures since the 81st Plenary meeting

There have been no written adoptions since the 81st Plenary meeting.

6. Scientific outputs submitted for discussion and possible adoption

6.1 Scientific Opinion on application EFSA-GMO-UK-2006-34 for the placing on the market of genetically modified maize 3272 with a thermotolerant alpha-amylase for production of ethanol and food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop (EFSA-Q-2006-026)

Maize 3272 contains a single insert consisting of the *amy797E* and the *pmi* cassettes, expressing a thermotolerant alpha-amylase (AMY797E) and a phosphamannose isomerase (PMI). Bioinformatic analyses and genetic stability studies did not raise safety issues. The levels of the AMY797E and PMI proteins in maize 3272 have been sufficiently analysed. In the absence of an appropriately performed comparative assessment, the EFSA Panel on Genetically Modified Organisms (GMO) was not in the position to conclude either on the compositional, agronomic and phenotypic characteristics of maize 3272 or on its nutritional assessment, on the basis of the data provided. The safety assessment could therefore not be completed, and has focused mainly on the newly expressed proteins. No indications of safety concern over the toxicity of the AMY797E and PMI proteins and over the allergenicity of the PMI protein were identified. The Panel could not conclude on the potential for *de novo* allergic sensitisation of the AMY797E protein. The Panel has identified a gap in the data on the agronomic and phenotypic characterisation of GM maize 3272 and considers that uncertainty over these characteristics remains. However, considering the scope of this application, a weight of evidence approach from different sources of available data and the poor ability of maize to survive outside cultivated land, the Panel concluded that there is very little likelihood of any adverse environmental impacts due to the accidental release into the environment of viable grains from maize 3272. Considering its intended uses as food and feed, interactions with the biotic and abiotic environment were not considered to be an issue. Risks associated with a theoretically possible horizontal gene transfer from maize 3272 to

prokaryotes have been analysed and did not raise safety concerns. The monitoring plan and reporting intervals were in line with the intended uses of maize 3272.

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

6.2 Scientific Opinion on application EFSA-GMO-NL-2011-97 for the placing on the market of insect-resistant and herbicide-tolerant genetically modified cotton T304-40 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience (EFSA-Q-2011-00312)

Cotton T304-40 contains a single insert consisting of the *cry1Ab* and the *bar* expression cassettes, providing insect resistance and herbicide tolerance, respectively. Bioinformatic analyses and genetic stability studies did not raise safety issues. Levels of the Cry1Ab and PAT proteins in cotton T304-40 have been sufficiently analysed. No biologically relevant differences were identified in the compositional analysis when the seed of T304-40 was compared with its conventional counterpart and non-GM cotton varieties. The safety assessment identified no concerns regarding the potential toxicity and allergenicity of the newly introduced Cry1Ab and PAT proteins. Based on the information available, there is no evidence that the genetic modification might significantly change the overall allergenicity of cotton T304-40. Nutritional equivalence of cotton T304-40 to its conventional counterparts was indicated by compositional data. The EFSA GMO Panel concludes that cotton T304-40 is as safe and nutritious as its conventional counterpart and that it is unlikely that the overall allergenicity of the whole plant is changed. There are no indications of an increased likelihood of establishment and spread of feral cotton plants. Considering its intended uses as food and feed, interactions with the biotic and abiotic environment were not considered to be an issue. Risks associated with an unlikely but theoretically possible horizontal gene transfer from cotton T304-40 to bacteria have not been identified. The monitoring plan and reporting intervals are in line with the intended uses of cotton T304-40. The EFSA GMO Panel considers that the information available for cotton T304-40 addresses the scientific comments raised by the Member States and states that cotton T304-40, as described in the application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses as proposed by the applicant.

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

6.3 Application for authorisation of genetically modified maize T25 and derived food and feed submitted under Regulation (EC) No 1829/2003 by Bayer BioScience (EFSA-GMO-NL-2007-46) (EFSA-Q-2007-134)

The EFSA GMO Panel discussed the draft scientific opinion, with a particular focus on the environmental and food–feed safety-related sections. Further discussion is needed.

7. New mandates

7.1 Applications under Regulation (EC) No 1829/2003

One new mandate was received as follows:

Application for the authorisation of genetically modified soybean DAS-81419-2 in accordance with Regulation (EC) No 1829/2003 submitted by Dow AgroSciences Ltd (EFSA-GMO-NL-2013-116) (EFSA-Q-2013-00527).

7.2 Annual post-market environmental monitoring reports of GM plants

Two new mandates were received as follows:

Request to assess EH92-527-1 potato (Amflora) monitoring report for the 2012 cultivation season provided by BASF (EFSA-Q-2013-00439);

Request to assess maize MON 810 monitoring report for the 2011 cultivation season provided by Monsanto (EFSA-Q-2013-00440).

7.3 Other requests and mandates

None.

8. Feedback from the Scientific Committee/the Scientific Panel, Working Groups, EFSA, the European Commission

8.1 Scientific Committee and other Scientific Panels

None.

8.2 Working Groups

- Risk assessment of stacked events

The GMO Panel discussed various aspects of the risk assessment of GM stacked events, such as: interations among proteins and their impact on the toxicological and allergenicity assessment. Further discussion is needed.

8.3 EFSA

- Internal task force on two-year study protocol

A member of the GMO Unit informed the Panel about the request from the European Commission to provide technical assistance for the development of a protocol for two-year carcinogenicity feeding trials with whole food/feed. An internal task force, led by the Scientific Committee Unit with contributions from several relevant units including the GMO Unit, is preparing a scientific report. The draft scientific report will be circulated to the members of the EFSA Scientific Network for the Risk Assessment of GMOs, and the final report is expected to be published on the EFSA website by the end of July.

8.4 European Commission

A representative of the European Commission updated the Panel on applications that are undergoing authorisation procedures.

9. Other scientific topics for information and/or discussion

a) Presentation on the statistical software

The GMO Panel was given a demonstration of the statistical software that was developed in order to facilitate the analysis of compositional and agronomical data needed for the risk assessment of GM plants.

b) Presentation on per se risk assessment

The GMO Panel was given a presentation on the strategies for the comprehensive food and feed safety and nutritional assessment of GM plants *per se*.

10. Any other business

a) Panel members reporting on meetings and/or conferences they attended on behalf of the EFSA

A Panel member had attended the EFSA Scientific Colloquium on the risk assessment of multiple stressors in bees, on 15–16 May 2013, and reported on the content of the meeting.

b) Feedback from the 81st Plenary meeting

The GMO Panel was given an overview of the feedback provided by observers and Panel members attending the Plenary meeting on 17–18 April 2013.

c) Feedback from Network meeting

The Head of the GMO Unit informed the Panel on the main issues discussed during the fourth meeting of the EFSA scientific network for the risk assessment of GMOs.

11. Questions from and answers to observers (in application of the Guidelines for observers[3])

As there were no observers attending the meeting, other than representatives from DG SANCO, European Commission, this item is not applicable.